EMEA SALES PLAY BOOK
Engage with our personas

Instructions :
How to navigate into the EMEA sales playbook

Buttons :

Engage with the different personas

by clicking on the

Click the ⌂ button to return to the personas page

Next click on the test you want to know more about using the list on the righthand side.

Click the underlined and

BOLD tests only

(Greyed out tests may not be relevant to that persona)

Disclaimer: This document is for Training purposes and Internal Use Only.

Any use of the publications cited in the document for commercial purposes must be supervised by the EMEA Marketing Team.

Please contact the corresponding EMEA Product Manager for further information.

Any customer questions on HemeOnco tests or primary cancer screening, must be sent to MedSci.Oncology@cepheid.com.

Engage with the different personas

By Clicking on the

Laboratory Manager

Infectious Control Specialist Hygienist

Antimicrobial Stewardship Team Pharmacist

Intensive Care Unit Physician

Point of Care Manager

Emergency Clinician

Cytologist

Hepatologist, Gastroenterologist

Infectious Diseases Specialist Pulmonologist

Gynaecologist, Midwife, Paediatrician, Neonatologist

Haematologist

Hospital/Health Care Executive, Hospital Manager, Finance Manager

Meet our Laboratory Manager

Hospital & Reference Laboratory

Goals

- Support clinicians by providing accurate, actionable, accessible and timely results

Challenges

- Staff constraints
- Declining budgets and reimbursement
- Accreditation
- Consolidation (Hospital/labs merge)

What they care about

- Reduce training and staffing burden
- Improve test turnaround time and result accuracy
- Consolidate testing options to reduce footprint and oversight

What is the Cepheid Story?

Improve workflow with consolidation

- Scalable and flexible platform for optimized testing in centralized and decentralized settings
- On-demand and random access with mix-and-match test capabilities for optimal flexibility
- Large menu enables consolidation on a single platform
- Less than 1 minute set-up time* for optimized workflow

* Sample preparation time may vary. See package inserts for specific assays for additional information

They might be interested in :

Click on the GeneXpert® Systems and colored **bold** tests to learn more

GeneXpert® Systems

Respiratory	**Xpress CoV-2/Flu/RSV *plu***
	Xpress CoV-2 *plus*
	Xpress Strep A
	Xpress Flu/RSV
HAI & Other Infectious Diseases	**MRSA NxG**
	SA Nasal Complete
	MRSA/SA Blood Culture
	MRSA/SA SSTI
	Carba-R
	Norovirus
	***C. difficile* BT**
	vanA/vanB
TB & Emerging Infectious Diseases	**MTB/RIF Ultra**
	MTB/XDR
	Ebola
Blood Virology, Women's Health & Sexual Health	**CT/NG**
	HPV v2
	Xpress GBS
	TV
	***ResistancePlus*® MG FleXi**
	HBV Viral Load
	HCV Viral Load
	HCV VL Fingerstick
	HIV-1 Qual XC
	HIV-1 Viral Load XC
Oncology & Human Genetics	Bladder Cancer Detection
	Bladder Cancer Monitor
	Breast Cancer STRAT4
	BCR-ABL Ultra
	BCR-ABL Ultra p190
	NPM1 Mutation (AML)
	Thrombophilia (FII & FV)

CE-IVD. *In Vitro* Diagnostic Medical Device. Not all tests available in all countries

Manufactured by SpeeDx and exclusively distributed by Cepheid under the FleXible for GeneXpert System program

Elevator Pitch- Value Proposition

"Our GeneXpert family of systems sets new standards in molecular workflow flexibility, 24/7 testing, accuracy, and user-friendly design offering a single, standardized solution capable of running multiple tests on one space-saving system. The fully scalable, modular, and consolidated workstation is available in 1 module to 80 modules configuration, enabling to fit a wide range of testing volumes, to adapt to the evolution of your needs through time, and to offer the same quality of testing in every setting. All the systems have our proven GeneXpert module at their analytic heart, and each one uses the same patented cartridge technology for every Xpert® test [1] ".

Customer Objections

I'm running too high number of tests

- Cepheid will ensure that your system is well-suited to handle your testing volume. With the GeneXpert systems the average throughput in an 8-hour shift is up to 15 tests with a single module to more than 800 tests with a GeneXpert Infinity system.
- How many tests/batches per days/ per week do you perform? (use throughput calculator)

I don't want to change my different platforms already validated, and running in routine

- Could we consider the cost savings of this change (training, extra consumables, maintenance, connectivity, and clinical impact costs: LOS*, Isolation and treatment)?
- Moving on to a single platform capable of consolidating multiple assays on the same workstation could help your workflow and staff organization
- Our Wellness Program and application solutions can support your staff with the validation of your GeneXpert platforms.

I don't have enough space in the lab (for a GeneXpert Infinity system)

- Thanks to the GeneXpert Infinity space floor graphic[3] we can easily estimate the space required for a GeneXpert Infinity system and define where it could fit in your laboratory.

*LOS: Length of stay

Probing Questions

- Would you be interested in reducing the number of molecular platforms used in your hospital? How would you estimate the cost savings it could enable in term of maintenance training and staff organization?
- What would be the consequences for your lab if you implemented the same technology across your settings? (centralized and decentralized)
- Do you send out some analysis included in our test menu? [2,3]
- Do you have lack of staff? Do you need to have dedicated staff for each platform in your lab?

References

1. Video: Journey Inside the Cepheid GeneXpert Cartridge - 3D Animation. CepheidNews YouTube Channel. Cepheid Xpert® Test Cartridge, A Look Inside
2. Cepheid-GeneXpert-System-Menu_Flyer-CE-IVD (last update available on Seismic).
3. Cepheid-Menu-Test-Overview-CE-IVD (last update avilable on Seismic).
4. GeneXpert Infinity space floor graphic (To bring with you)

Laboratory Manager

"I'm interested to learn more about

GeneXpert System

today."

CE-IVD. *In Vitro* Diagnostic Medical Device. Not all tests available in all countries

Elevator Pitch- Value Proposition

"Xpert Xpress CoV-2/Flu/RSV plus provides a robust 3-gene design supporting clinicians with broader coverage for SARS-CoV-2 variants whilst still delivering results in 36 minutes and as soon as 25 minutes for SARS-CoV-2 results. Multiple generic targets for SARS-CoV-2 and influenza viruses mitigate against genetic drift, making it the ideal method to ensure accurate detection in urgent cases when faced with overlapping clinical symptomatology for three very common diseases today: That of COVID-19, Influenza and RSV.**".*

Customer Objections

Your assay is more expensive than SARS-CoV-2 assays only

- The diagnosis of SARS-CoV-2, Flu and RSV is difficult due to their similar presentation with symptomatology. A combination assay such as Xpert Xpress SARS-CoV-2/Flu/RSV (plus) avoids sample re-runs and allows fast patient management.
- Consider the consequences and the cost of a prolonged length of stay in the emergency department, while the patient waits for test results or incorrect patient management.

We do not need to test for flu during low prevalence season

- Flu and RSV outbreaks are difficult to predict and can happen unexpectedly. An agile response to outbreaks is key to manage and control new epidemics.

I have faster results with other tests

- Even if you can obtain faster results, could you tell me more about how well they perform?
- The antigenic tests have lower sensitivity and specificity compared to molecular. [2,3]

Probing Questions

- How are you currently testing?
- How will having a test with better coverage for future variants improve your peace of mind? [1] How will it improve clinicians' confidence?
- For your Emergency department clinicians, how would actionable results help them better manage patients?
- What are the consequences of a delay in a result in terms of patient/bed management and reducing isolation costs? [4,5]

Laboratory Manager

"I'm interested to learn more about

Xpress

Cov-2/Flu/RSV ***Plus***

today."

References

1. Jørgensen, R. L. et al. Emergence of circulating influenza A H3N2 viruses with genetic drift in the matrix gene: be alert of false-negative test results. *APMIS* 130, 612–617(2022)
2. Mak GC, Lau SS, Wong KK, Chow NL, Lau CS, Lam ET, Chan RC, Tsang DN. Analytical sensitivity and clinical sensitivity of the three rapid antigen detection kits for detection of SARS-CoV-2 virus. J Clin Virol. 2020 Dec;133:104684 Stockl et al. Use of Antigen and Molecular Testing for the Diagnosis of Coronavirus Disease 2019 (COVID-19) among Patients with Influenze-like Illness (ILI) in the Non-inpatient Setting. Association for Molecular Pathology 2023 Annual Meeting Abstracts. J Mol Diagn 2023, p 53 Abstract 006
3. Mak GC, Lau SS, Wong KK, Chow NL, Lau CS, Lam ET, Chan RC, Tsang DN. Analytical sensitivity and clinical sensitivity of the three rapid antigen detection kits for detection of SARS-CoV-2 virus. J Clin Virol. 2020 Dec;133:104684
4. Stockl et al. Use of Antigen and Molecular Testing for the Diagnosis of Coronavirus Disease 2019 (COVID-19) among Patients with Influenze-like Illness (ILI) in the Non-inpatient Setting. Association for Molecular Pathology 2023 Annual Meeting Abstracts. J Mol Diagn 2023, p 53 Abstract 006
5. University Hospital, Essen, Germany. KILL_2023_CID_Respiratory-Xpert_Xpress_Sars-CoV-2_paper. Economic Study - Point-of-care PCR testing of SARS-CoV-2 in the emergency department

* EAT: with Early Assay Termination for SARS-Cov-2 only

** https://www.cdc.gov/flu/symptoms/flu-vs-covid19.htm

https://www.cdc.gov/rsv/about/symptoms.html

Elevator Pitch- Value Proposition

"The Xpert Xpress CoV-2 plus delivers results in as early as 20 minutes, with 3 gene targets for more confident detection of SARS-CoV-2. [1] Bringing simplified workflow efficiencies to your lab to provide testing for both symptomatic and asymptomatic patients".*

Customer Objections

Your assay is more expensive than other SARS-CoV-2 assays

- The robust assay performance of the assay allows accurate detection within a single run. Avoiding assay underperformance[2,3].
- Less re-runs are important for fast patient discrimination specially among those who need urgent care.
- Consider the consequences and cost of prolonged length of stay in the emergency department, or incorrect patient diagnosis.

We prefer running SARS-CoV-2 samples in batches

- Are there times when a fast on-demand test would be useful - for urgent samples or those that miss the daily batch? You can provide results on demand with less than one-minute hands-on time and have a significant impact on patient health.
- Ensure your system is always ready for an urgent sample without system errors, reagent loading or extensive maintenance.

Your assay is too sensitive, late Cts might not be true positives and are difficult to interpret

- The Xpert Xpress CoV-2 Assays are designed to detect the presence of SARS-CoV-2 nucleic acid in the sample. Test results must be interpreted in conjunction with other clinical and epidemiological observations.
- A sensitive test is needed to have confidence in a negative result.[4]

** For positives only with EAT (Early Assay Termination); reporting of negatives in approximately 30 minutes*
** https://www.cdc.gov/flu/symptoms/flu-vs-covid19.htm https://www.cdc.gov/rsv/about/symptoms.html

Probing Questions

- How are you currently testing?
- How will having a test with better coverage for future variants improve your peace of mind? [2,5] How will it improve clinicians' confidence)
- For your Emergency department clinicians, how would actionable results help them better manage patients?
- What are the consequences of a delay in a result in terms of patient/bed management? To what financial consequences does that lead? [5]

References

1. Xpert Xpress CoV-2 plus package insert
2. Agencia Española de Medicamentos y Productos Sanitarios, Spain (AEMPS): SBN-RDS-Molecular Lab 2021-005
3. Potential for False Results with Roche Molecular Systems, Inc. cobas SARS-CoV-2 & Influenza Test for use on cobas Liat System-Letter to Clinical Laboratory Staff, Point-of-Care Facility Staff, and Health Care Providers. FDA, US Drug and Food Administration
4. Stockl et al. Use of Antigen and Molecular Testing for the Diagnosis of Coronavirus Disease 2019 (COVID-19) among Patients with Influenze-like Illness (ILI) in the Non-inpatient Setting. Association for Molecular Pathology 2023 Annual Meeting Abstracts. J Mol Diagn 2023, p 53 Abstract 006
5. Fistera D, Kikull K, Risse J, Herrmann A, Brachmann M, Kill C (2023) Point-of-care PCR testing of SARS-CoV-2 in the emergency department: Influence on workflow and efficiency. PLoS ONE 18(8): e0288906. https://doi.org/10.1371/journal.pone.0288906.t003

Laboratory Manager

"I'm interested to learn more about

Xpress** CoV-2 **Plus

today."

CE-IVD. *In Vitro* Diagnostic Medical Device. Not all tests available in all countries

Elevator Pitch- Value Proposition

"The scalable GeneXpert system with its large menu and ease of use ensures that results for Xpert Xpress Flu/RSV will always be available, on demand in 30 minutes or less. Bring significant workflow efficiencies to your lab and provide substantial improvements in test availability and turnaround time".*

Customer Objections

Your assay is too expensive!

- May I ask you a few questions to better understand the current testing systems in place and your cost commitments? [1]

We have too many tests to perform during Flu season, we prefer batches

- Are there times when a fast on-demand test would be useful - for urgent samples or those that miss the daily batch?
- You can provide results on demand with less than one-minute hands-on time and have a significant impact on patient health.[2,3]

I prefer to use a panel providing a broader detection of organisms

- Do you need a broad panel for most patients with no other health problems? In many cases, especially during the winter season, it is more useful to have a fast "flu first" or "flu and RSV first" testing strategy, followed by reflexive panel testing where appropriate. Additional studies have shown that unrestricted primary use of large panels is very expensive and of limited value. Recent guidelines do not recommend unrestricted use of large respiratory panels. [4]
- What is the total cost of ownership for multiplex tests? [2,5]

Probing Questions

- How are you currently testing?
- What aspects of your current test system would you consider improving?
- For your Emergency department clinicians, how would definitive information help them better manage patients? [6]

References

1. Xpert Xpress Flu/RSV Performance is key, Flyer (available on Seismic).
2. Green DA, et al. Clinical Utility of On-Demand Multiplex Respiratory Pathogen Testing among Adult Outpatients. J Clin Microbiol. 2016 Dec;54(12):2950-2955.
3. Garvey MI, et al. Impact of PCR point of care test for Influenza A/B on an acute medical unit in large of an observational pre and post intervention study Antimicrob Resist Infect Control. 2019 Jul 16.
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5. Wahrenbrock MG, et al. Comparison of Cepheid Xpert® Flu/RSV XC and BioFire FilmArray® for detection of influenza A, influenza B, and respiratory syncytial virus. J Clin Microbiol. 2016 Jul;54(7):1902-3.
6. Jørgensen, R. L. et al. Emergence of circulating influenza A H3N2 viruses with genetic drift in the matrix gene: be alert of false-negative test results. *APM*IS 130, 612–617 (2022)

Laboratory Manager

"I'm interested to learn more about

Xpress** Flu/RSV **Plus

today."

*EAT: With early assay termination for positive Flu (18min) or for positive RSV (20min) only. Reporting negatives and combined Flu and RSV results in 30 minutes

Elevator Pitch- Value Proposition

"Xpert MRSA NxG delivers standardized, fast, accurate and easy PCR results in 70 minutes, streamlining laboratory workflow and providing on-demand results for clinicians to optimize patient management."

Customer Objections

You are more expensive than culture/batch PCR methodology

- It is important to consider the impact of rapid results on the whole hospital.
- Targeted screening using fast PCR with pre-emptive isolation minimizes transmission opportunities (helping prevent outbreaks and service disruption), while enabling appropriate use of costly isolation facilities.[1]
- Additional consumables associated with traditional culture or batch methodologies, as well as the requirement for higher skilled staff time, should be analyzed.

Our regulations/policies do not specify MRSA surveillance by PCR

- Contemporary literature has cited the performance and value in fast and accurate PCR in helping reduce MRSA rates, and saving overall hospital costs.[1,2]

Probing Questions

- How long is it currently taking you to produce an actionable MRSA result? How many steps are involved?
- How would a fast and simple MRSA test impact your laboratory workflow?
- How are patients currently managed who are awaiting MRSA results?
- What would it mean for your clinicians, patients and even your hospital if you were able to provide actionable MRSA results in 70 minutes?

References

1. Goldsack J, et al. Clinical, patient experience and cost impacts of performing active surveillance on known methicillin-resistant Staphylococcus aureus positive patients admitted to medical-surgical units. American Journal of Infection Control. 2014 Oct;42(10):1039-43
2. Yarbrough M, et al. Multicenter evaluation of the Xpert MRSA NxG assay for detection of methicillin-resistant Staphylococcus aureus in Nasal Swabs. J Clin Microbiol. 2017 Dec;56(1)

Laboratory Manager

"I'm interested to learn more about

MRSA NxG

today."

Elevator Pitch- Value Proposition

"Xpert Carba-R delivers standardized, fast, accurate and easy PCR results in 50 minutes for the "big five" carbapenemase gene families, streamlining laboratory workflow and providing on-demand results for clinicians to optimise patient management. Conventional culture can be difficult to interpret with low sensitivity and are too slow for optimal delivery of patient results.[4]"

Customer Objections

We have very low CPE prevalence

- ECDC data and recent literature are citing near-universally increasing CPE rates.[1,2]
- Certain CPE gene families (e.g., OXA-48-like) are very difficult to detect via culture, potentially resulting in underreporting.[3]

You do not detect all CROs

- CPE specifically are regarded as the biggest threat as plasmid-borne resistance can transmit between unrelated species and are responsible for most outbreaks.[4]
- Xpert Carba-R detects the most commonly circulating carbapenemase genes.[1,3,5]

You are more expensive than our current method culture/batch PCR methodology

- It is important to consider the impact of rapid results on the whole hospital.
- Targeted screening using fast PCR with pre-emptive isolation minimizes transmission opportunities (helping prevent outbreaks and service disruption), while enabling appropriate use of costly isolation facilities.[4,5]

Our regulations/policies do not specify CPE surveillance by PCR

- Contemporary literature has cited the performance and value in fast and accurate PCR in helping reduce CPE rates and saving overall hospital costs.[4,5]

*CPE: carbapenemase-producing Enterobacterales
**CRO: carbapenem-resistant organisms

Probing Questions

- How long is it currently taking you produce an actionable CPE result, including differentiation of the CPE gene family? How many steps are involved?
- How would a fast and simple CPE test impact your laboratory workflow?
- How are patients currently managed who are awaiting CPE results?
- What would it mean for your clinicians, patients and even your hospital if you were able to provide actionable CPE results in 50 minutes?

References

1. ECDC Rapid Risk Assessment. Carbapenem-resistant Enterobacteriaceae - second update 26 September 2019
2. Patel B, et al. Carbapenemase-producing Enterobacterales: a challenge for healthcare now and for the next decade. IPIP. 2020 Sep;2(3):100089
3. Hoyos-Mallecot Y, et al. OXA-244-producing E. coli isolates, a challenge for clinical microbiology laboratories. Antimicrob Agents Chemother. 2017 Aug;61(9):e00818-17
4. Ambretti S, et al. Screening for carriage of carbapenem-resistant Enterobacteriaceae in settings of high endemicity: a position paper from an Italian working group on CRE infections. Antimicrob Resist Infect Control. 2019 Aug;13(8):136
5. Corless C, et al. Impact of different carbapenemase-producing Enterobacterales screening strategies in a hospital setting. IPIP. 2020 May;3(2):100011

Laboratory Manager

"I'm interested to learn more about

Carba-R

today."

Elevator Pitch- Value Proposition

"Xpert C. difficile BT delivers standardized, fast, accurate and easy PCR results in 43 minutes, streamlining laboratory workflow, removing the need for algorithmic or batch testing, and providing on-demand results for clinicians to optimize patient management."

Customer Objections

You are more expensive than algorithmic/batch PCR methodology

- It is important to consider the impact of rapid results on the whole hospital.
- On-demand fast PCR with pre-emptive isolation minimizes transmission opportunities (helping prevent outbreaks and service disruption), while enabling appropriate use of costly isolation facilities.[1]
- Depending on your test volume, a multi-step algorithm can be more expensive than PCR.

PCR risks over diagnosing asymptomatic *C. difficile* carriage

- Testing should be limited to unformed stools, with the clinical context considered.[2]
- Rapid and sensitive commercial PCR as a stand-alone assay together with clear sampling guidance can offer an optimal approach to patient management.[1]

All PCR tests have good performance, and our current test is cheaper

- There are wide variations in molecular *C. difficile* test performance.[3]
- Xpert *C. difficile* BT provides extensive coverage, with multiple targets, including toxin B gene (tcdB), binary toxin gene (cdtA), and the tcdC gene deletion associated with ribotype 027 strains (presumptive 027), a predictor of severe CDI and mortality.[4]
- Not all PCR tests detect the binary toxin gene. Strains such as 033 are positive only for binary toxin and not toxins A and B, yet have caused CDI. [5]

*CDI: Clostridioides difficile infection

Probing Questions

- How long is it currently taking you to produce an actionable CDI result? How many steps are involved?
- How would a single, fast and simple test for CDI impact your laboratory workflow?
- How are patients currently managed who are awaiting CDI results?
- What would it mean for your clinicians, patients and even your hospital if you were able to provide actionable CDI results in 43 minutes?

References

1. Casari E, et al. Reducing rates of C. difficile infection by switching to a stand-alone NAAT with clear sampling criteria. Antimicrob Resist Infect Control. 2018 Mar;7(40)
2. McDonald L, et al. Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA). Clin Infect Dis. 2018 Apr;66(7):e1–e48
3. Carroll K & Mizusawa M. Laboratory tests for the diagnosis of Clostridium difficile. Clin Colon Rectal Surg. 2020 Mar;33(2):73-81
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5. Eckert C, et al. Prevalence and pathogenicity of binary toxin-positive C. difficile strains that do not produce toxins A and B. New Microbes New Infect. 2014 Nov;8(3):12-7

Laboratory Manager

"I'm interested to learn more about

C. difficile BT

today."

Elevator Pitch- Value Proposition

"Cepheid Xpert MTB/RIF Ultra is endorsed by the WHO as a highly accurate molecular PCR test detecting MTB and rifampicin resistance in 77 minutes. It's easy to use, everywhere, on-demand with high sensitivity for your early active case finding."

Customer Objections

PCR is more expensive per result than smear microscopy

Talk me through your current process? What would you improve if you could? What is key for you? (or your Clinicians? or the Hospital?).

- Consumable cost is higher; however, it is vital to consider the total cost of patient management, isolation, treatment and staff time. [1]

There is no INH Resistance detection in your test

- The Xpert MTB/XDR test provides results for INH, Fluoroquinolones and second line injectable drugs used for TB treatment. Used as a reflex test for any MTB positives, this reflex test will provide resistance results for INH and more providing information to support the new 4-month all-oral regimen recommended by WHO which includes Moxifloxacin (FLQ).[1, 2 3,4]
- Xpert MTB/XDR test provides low-INH callout to support the treatment decision with a high dose of INH.

Smear is cheap, and I must do it anyway

- Would you recommend your pulmonologist to treat their patients based on a lab result with less than 65% sensitivity? [1,5,6]
- Smear does not differentiate between MTB and non-tuberculous mycobacteria.
- Are your clinicians initiating treatment empirically? [4,5,6]

*TAT: Turnaround time

Probing Questions

- How is the actual algorithm for rapid active case finding working from your perspective?
- What would it mean for your clinicians, patients and even your hospital if you were able to confirm a negative result in 77 mins?
- How would a fast TAT* impact your decision and patient management?

References

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2. WHO consolidated guidelines on tuberculosis. Module 4: treatment - drug-susceptible tuberculosis treatment. Accessed in Nov 2023 Module 4: Drug-resistant tuberculosis treatment | TB Knowledge Sharing (tbksp.org)
3. Chakravorty S, et al. Improving Detection of Mycobacterium tuberculosis and Resistance to Rifampin in an Assay Suitable for Point-of-Care Testing. mBio 2017 Aug 29;8(4):e00812-17.
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Laboratory Manager

"I'm interested to learn more about

MTB/RIF Ultra

today."

Elevator Pitch- Value Proposition

"Cepheid Xpert MTB/XDR detects genes associated with resistance to 6 antibiotics used for TB treatment directly from patient's specimens in <90 mins. The WHO classes it as the lowest complexity automated NAAT for Drug susceptibility Test (DST)3 and can be performed on-demand to provide clinicians results in a matter of hours to guide treatment decisions."

Customer Objections

Most of our resistance cases are due to RIF and or INH we don't see many XDR cases

- By reflex testing any samples that are positive for MTB onto the Xpert MTB/XDR you will detect both RIF and INH resistances plus resistance for the Fluoroquinolones or second line injectable drug too.
- WHO recommended new 4-month all-oral drug-susceptible TB regimen1 Cepheid's solution provides information to support this new 4-month all-oral regimen which includes Moxifloxacin (FLQ).

We must send any resistant samples to another lab for testing as standard of care anyway

- This is understandable but what the Xpert MTB/XDR test adds is a fast result that accurately detects resistances to 1st and 2nd line treatments[3]. It gives the clinicians the chance to treat patients with the most effective drugs from the start as called for in the treatment guidelines [2,3,4]

Phenotypic DST is still considered as the gold standard and we can test more drugs

- We have good clinical and independent data that the test compares very well with phenotypic and sequencing based DST [4,5,6]. The value of the Xpert MTB/XDR is that it can be done in many more settings, with minimal training and it provides accurate results fast so that clinicians can offer patients the best treatment for them.

*TAT: Turnaround time

Probing Questions

- How is the algorithm for a DST performed now and what would you like to improve?
- What are the challenges you have with the current method for DST testing now?
- What is the impact of having a delay to the results or to the complexity of your current testing to clinicians and your lab routine?
- Do you know that testing for FLQ and INH associated mutations is recommended prior to initiating MDR TB therapy?

References

1. Diel R, WHO consolidated guidelines on tuberculosis. Module 4: treatment - drug-susceptible tuberculosis treatment. Accessed in Nov 2023 Module 4: Drug-resistant tuberculosis treatment | TB Knowledge Sharing (tbksp.org)
2. Nahid P, et al. Treatment of Drug-Resistant Tuberculosis An Official ATS/CDC/ERS/IDSA Clinical Practice Guideline. Am J Respir Crit Care Med Vol 200, Iss 10, pp e93–e142, Nov 15, 2019
3. WHO, December 2019, Rapid Communication: Key changes to the treatment of drug-resistant tuberculoses
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6. Chakravorty S, et al. Detection of Isoniazid-, Fluoroquinolone-, Amikacin-, and KanamycinResistant Tuberculosis in an Automated, Multiplexed 10-Color Assay Suitable for Point-ofCare Use. J Clin Microbiol. 2016 Dec 28;55(1):183- 198.

Laboratory Manager

"I'm interested to learn more about

MTB/XDR

today."

Elevator Pitch- Value Proposition

" Xpert CT/NG Assay technology and design (CT dropout, NG targets, SAC) allow you to get reliable and quick results for informed treatment and to avoid unnecessary costs associated with empiric therapy, confirmatory testing and system set-up & maintenance".

Customer Objections

The price of your test is too high

- There is overall cost savings using Xpert CT/NG on the GeneXpert system. It brings many benefits to your lab, such as high performance, quicker turnaround time and shorter hands-on time.
- NG confirmation is included due to the incorporation of two distinct genetic targets. Your staff has more free time to work in other areas.[4]

Time doesn't matter, and I am happy with batch testing

- Would targeting patient population (asymptomatic versus symptomatic) with a faster test help manage your time better and improve the patient pathway. [2,3]

The CT/NG test we are currently using is good enough for our patient population

- Do you have full confidence in your current results?[3,4]
- Does your current test include a Specimen Adequacy Control?

Probing Questions

- How would it help your lab if you could perform up to 628 tests with our GeneXpert system in an 8-hour shift?
- How does it influence your choice of test, knowing the EU guidelines on NG diagnosis require confirmatory testing for positive samples if the test has only one NG target?[1]
- What is the impact on your choice of test when new EU guidelines on NG diagnosis requires testing for rectal and oropharyngeal specimens in MSM?[1]
- What if you could better manage your resources and consolidate molecular testing on one platform?

References

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2. Jang D, et al. Comparison of Workflow,Maintenance, and Consumables in theGeneXpert Infinity 80 and Panther InstrumentsWhile Testing for Chlamydia trachomatis andNeisseria gonorrhoeae. Sex Transm Dis. 2016Jun;43(6):377-81
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Laboratory Manager

"I'm interested to learn more about

CT/NG

today."

Elevator Pitch- Value Proposition

"Xpert® HPV v2 test can be performed on-demand and used with a Pap specimen **or as a first-line primary screening test,** meeting the WHO recommended "screen-and-treat" approach."

Customer Objections

This is a screening test and there is no need for a quicker result.

- Have you considered the benefit of quick results to get full ownership of combined cytology and HPV results for better patient management?
- HPV results in around 60 minutes for same-visit clinician/ patient consult, minimizes the need for repeat visits, and follows the **WHO screen-and-treat approach**[1].

We are happy with the current HPV technology we use

- Xpert HPV v2 provides partial genotyping, with individual call-outs for high-risk **HPV types 16 and 18/45**, for **primary screening** of women who are at risk of developing cervical cancer.
- Most NAAT can be complicated to use and batch testing can delay results for colposcopy referral. [2,3]

Probing Questions

- What methods are used for your current cervical cancer screening?
- Take me through your process. What is the annual volume and which system do you use to perform HPV testing in your lab?
- What would you like to improve in your process?

References

1. WHO guideline for screening and treatment of cervical pre-cancer lesions for cervical cancer prevention, second edition. Geneva: World Health Organization; 2021
2. Kundrod, K et al. Advances in technologies for cervical cancer detection in low-resource settings. Expert Rev Mol Diagn. 2019 Aug;19(8):695-714.
3. Cox JT, et al. Comparison of cervical cancer screening strategies incorporating different combinations of cytology, HPV testing, and genotyping for HPV 16/18: results from the Athena HPV study. Am J Obstet Gynecol. 2013 Mar;208(3):184.e1-184.e11.

Laboratory Manager

"I'm interested to learn more about

HPV v2

today."

Elevator Pitch- Value Proposition

"Xpert ResistancePlus MG FleXible detects not only M. genitalium, but also the mutations associated with macrolide resistance. Its technology allows you to get reliable and quick results for informed treatment and to avoid unnecessary costs associated with empiric therapy, confirmatory testing and system set-up & maintenance."

Customer Objections

I detect *M. genitalium* with a multiplex STI panel

- ResistancePlus MG FleXible could be used as a "second-line" test for positive samples to provide further information regarding macrolide resistance.

Having *M. genitalium* separately from the CT/NG test increase the cost too much for each patient.

- Are you testing every patient for *M. genitalium* or are you targeting only symptomatic ones? Are local guidelines recommending to screen for *M. genitalium*?

Your test does not detect the resistance to fluoroquinolones

- The European guidelines do not recommend testing for fluoroquinolone resistance due to the lack of clinical relevance. [2]

The fact that the reagent needs to be frozen will make the assay preparation process more complex

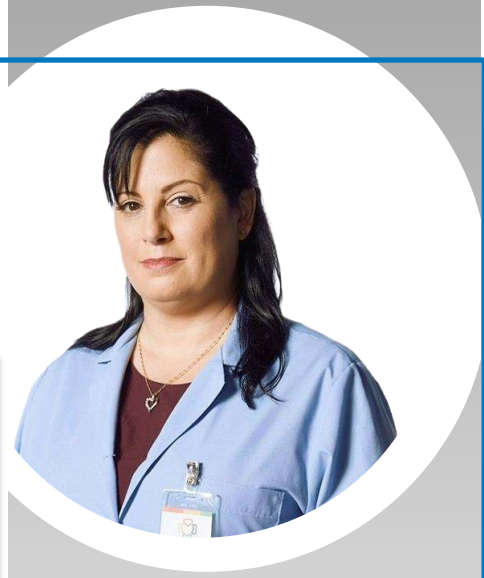
- Running the ResistancePlus MG FleXible on GeneXpert Systems is almost as easy as any Cepheid assay and still with a shorter hands-on time than any other PCR test.

Probing Questions

- Are you aware that the European Guidelines for *M. genitalium* strongly recommended that all positive tests are followed up with an assay capable of detecting macrolide resistance mediating mutations? [2]
- Do you know the percentage of macrolide resistance for *M. genitalium* in your country?

References

1. Package insert ResistancePlus MG FleXible (last update available on Seismic/ InfoMine).
2. Jensen JS, et al. 2016 European guideline on Mycoplasma genitalium infections. J Eur Acad Dermatol Venereol. 2016 Oct;30(10):1650-1656
3. Dumke R, et al. Prevalence of macrolide- and fluoroquinolone-resistant Mycoplasma genitalium strains in clinical specimens from men who have sex with men of two sexually transmitted infection practices in Berlin, Germany. 019 Sep;18:118-121.



Laboratory Manager

"I'm interested to learn more about

ResistancePlus MG Flexible#

today."

Exclusively distributed by Cepheid under the FleXible for GeneXpert System program. Manufactured by SpeeDx.

Elevator Pitch- Value Proposition

"Xpert HBV Viral load assay delivers high quality results, on demand and provides flexible throughput to suit your daily testing needs. Samples can be tested as they arrive in the lab, saving on staff time and improving result TAT. Urgent or one-off sample for confirmation or viral load can be tested as required."*

Customer Objections

Your costs are higher

- Consider true cost per reportable result including staff time, consumables, external controls and number of batches. Xpert HBV Viral Load offers throughput flexibility that means you can test one to many samples at any time and there are no wasted reagents/ tests due to low throughput.

We have been monitoring patients with our current system for a long time. We need to do a lot of work to show that we can change methods.

- We have clinical and analytical performance in the package insert and we are starting to gather more independent data [1,3,4]. You could evaluate the test locally.

I don't need a faster TAT*. My clinicians are happy with the service.

- The clinicians may be unaware that they could have faster TAT* and there may be situations where they would find great benefit to confirm a serology positive or measure viral load quickly. Are they involved in any programs for hepatitis elimination where fast results could be useful? [5,6]
- Depending on your test volume, batch-based assays may be expensive and inefficient. The Xpert HBV Viral Load offers scalability. [1]

* TAT: Turnaround time

Probing Questions

- Could you describe the different steps in your current viral load process from when the sample arrives in the lab to result? How often do you batch samples, and what challenges do you face with batching samples?
- How do you confirm a positive antibody test and how quickly can this be done currently? Are there times when you have less than 1 ml of plasma or serum to test?
- What would it mean for your service to be able to perform HBV Viral Load testing as required and achieve high quality performance?

References

1. Package insert Package insert Xpert HBV Viral Load (lastupdate available on Seismic/InfoMine)
2. Abravanel F, et al. Performance of the XpertHBV Viral Load assay versus the Aptima Quantassay for quantifying hepatitis B virus DNA.Diagn Microbiol Infect Dis. 2019 Nov16:114946.
3. Auzin AM, et al. Rapid, random-access, andquantification of hepatitis B virus using theCepheid Xpert HBV viral load assay. J MedVirol. 2021 Jun;93(6):3999-4003.
4. Marcuccilli F, et al. Multicenter Evaluation of the Cepheid Xpert® HBV Viral LoadTest. Diagnostics (Basel). 2021;11(2):297.
5. Sara C, et al. A new tool for simplified HBV Viral Load testing and disease management. PosterPresentation. 22nd ESCV (European SocietyFor Clinical Virology) Annual Meeting. 11-14September 2019. Copenhagen, Denmark.
6. Rahamat-Langendoen JC, et al. Rapidquantification of HBV viral load using the XpertHBV Viral Load assay. Poster Presentation.22nd ESCV (European Society For ClinicalVirology) Annual Meeting. 11-14 September2019. Copenhagen, Denmark.

Laboratory Manager

"I'm interested to learn more about

HBV Viral Load

today."

Elevator Pitch- Value Proposition

"The Xpert HCV Viral load assay delivers high quality, on demand results with a flexible throughput solution to suit your daily testing needs. There is no need to wait for enough samples to run a batch. Samples can be tested as they arrive in the lab, saving on staff time and improving result TAT. Urgent or one-off sample for confirmation or viral load can be tested as required. It is currently the only WHO pre-qualified HCV Viral Load assay.[3]."*

Customer Objections

We need to have pre-analytics and primary tube loading for sample traceability

- As soon as they arrive in the lab, most labs will centrifuge and aliquot samples into 2 tubes and then either store samples or test them in the next run. How do you aliquot your samples?
- Our Cepheid Link solution ensures sample traceability in these pre-analytic steps simply and without adding extra time to the process. After the sample is loaded into the cartridge, simply run the test on the GeneXpert without other manual steps.

We have been monitoring patients with our current system for a long time. We need to do a lot of work to show that we can change methods

- We have sources that show how well our solution compares with other suppliers[1,2,4,5]. We can provide a suitable reference and support your discussions with end users.

With our current methods, we can test smaller volume of sample

- The HCV Viral Load assay requires 1 ml plasma or serum volume. Technical support can help with information regarding this request.[5]

We are satisfied with our current method (batch PCR)

- Depending on your test volume, batch-based assays may be expensive and inefficient. The Xpert HCV Viral Load offers scalability. [5]

* TAT: Turnaround time

Probing Questions

- Could you describe the different steps in your current viral load process from when the sample arrives in the lab to delivering the result?
- How does batching samples impact on your daily routine and the clinician waiting for the result?
- How do you deal with urgent samples and how are antibody positive samples currently confirmed?
- What do you consider to be a high performing HCV assay?

References

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2. Gupta E, et al. Point -of -care testing (POCT) in molecular diagnostics: Performance evaluation of GeneXpert HCV RNA test in diagnosing and monitoring of HCV infection. J Clin Virol. 2017 Mar; 88:46-51.
3. WHO, PQ Public Report, July 2019. Prequalification of In Vitro Diagnostics Public Report. Product: Xpert HCV Viral Load with GeneXpert® Dx, GeneXpert® Infinity-48s, and GeneXpert® Infinity-80 WHO reference number: PQDx 0260-07000.
4. Rahamat-Langendoen JC, et al Rapid quantification of hepatis C virus using the Cepheid HCV assay: a comparison with cobas AmpliPrep/Cobas TaqMan HCV test. 22nd ESCV (European Society For Clinical Virology) Annual Meeting. 11-14 September 2019. Copenhagen, Denmark.
5. Cepheid Xpert HCV Viral Load Brochure (latest version available on Seismic).

Laboratory Manager

"I'm interested to learn more about

HCV Viral Load

today."

Elevator Pitch- Value Proposition

"The Xpert HIV-1 Viral load XC assay with dual targets, delivers high quality results on demand and provides flexible throughput to suit your daily testing needs. Samples can be tested as they arrive in the lab, saving on staff time and improving the turnaround time."

Customer Objections

Your costs are higher

- Consider true cost per reportable result including staff time, consumables, external controls and number of batches. Xpert HIV-1 XC Viral Load offers a solution that simplifies workflow, speeds up time to results, can save staff time and potentially improve lab productivity.[1]
- Depending on your test volume, batch-based assays may be expensive and inefficient. The GeneXpert offers scalability.[5]

We need to have pre-analytics and primary tube loading for sample traceability

- Most labs will aliquot samples after centrifugation and before running samples. How and when do you aliquot your samples? Cepheid Beyond Trust solution ensures sample traceability in these pre-analytic steps simply and without adding extra time to the process. After the sample is loaded into the cartridge, simply run the test on the GeneXpert without other manual steps. [5]

We have been monitoring patients with our current system for a long time. We need to do a lot of work to show that we can change methods.

- We have independent sources that show how well our solution compares with other suppliers. [2, 3] We can also provide a suitable reference and support your discussions with end users.

Probing Questions

- Could you describe the different steps in your current viral load process, from when the sample arrives in the lab to delivering the result?
- How would you like to improve the viral load testing service and how do you deal with urgent tests?
- How does batching samples affect your routine service and how does this impact?

References

1. Bouige A, et al. Implementation of the GeneXpert technology for the routinely viral load monitoring of HIV-positive patients. Poster presentation. 27th ECCMID (European Congress of Clinical Microbiology and Infectious Diseases), 22- 25 April 2017 .Vienna, Austria .
2. Ehret et al, 2022, J Clin Vir. Performance assessment of the new Xpert® HIV-1 viral load XC assay for quantification of HIV-1 viral loads, https://doi.org/10.1016/j.jcv.2022.105127
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Laboratory Manager

"I'm interested to learn more about

HIV-1 Viral Load XC

today."

Elevator Pitch- Value Proposition

"Sensitive, standardized and easy to use quantitative monitoring of BCR-ABL1 mRNA both major or minor breakpoints in patients with Chronic Myeloid Leukemia[4] (CML) or Acute Lymphoblastic leukemia[3] (ALL) in 150 minutes, offering the ability to optimize patient pathways."

Customer Objections

I am happy with our CML monitoring testing as it is, no need to change

- Talk me through your current process? What would you improve if you could? What is key for you? (or your Clinicians? or the Hospital?).
- Does the Hospital or Lab have strategic plans such as centralization/ expansion/ Cancer service improvements? [1]

You don't report copy number for each patient sample

- Copy number requirement is a sensitivity measure; we have data within our PI showing monitoring results are produced with copy number levels reaching that sensitivity required[7]

The cartridges are too expensive

- What are you comparing our pricing to? What does this include? How did you get to that value? What steps are involved, and how much does it cost to standardize your current testing procedure?
- Explore with the Customer their TRUE current cost for testing. Question around batching/wasted reagents; costs to standardize to IS; failure rate/repeats due to delayed batch testing (mRNA degradation); all hidden costs. Include staff level and hands on time. Consider CE-IVDR regulation requirements.

Probing Questions

- Tell me about your current CML and ALL monitoring test algorithm?
- How long does it take to get monitoring results to the Clinicians?
- How would a sample to answer, non-batch on demand monitoring test impact the lab workflow?

References

1. The Cepheid-Menu-Test-Overview-CE-IVD (last update available on Seismic).
2. Package Insert Xpert BCR-ABL Ultra (last update available on Seismic/InfoMine)
3. Hochhaus et al. European LeukemiaNet 2020 recommendations for treating chronic myeloid leukemia. Leukemia, Apr;34(4):966-984.
4. Cepheid Xpert BCR ABL Flyer: Improving the Quality of Life for your Patients. A Patient Survey Analysis (Last update available).
5. NCCN Guidelines for Patients Acute Lymphoblastic Leukemia, 2021
6. ESMO Clinical Practice Guidelines for diagnosis, treatment, and follow-up of Acute Lymphoblastic Leukaemia
7. Cepheid Xpert BCR-ABL Ultra Package Insert, 301-2194
8. Cepheid Xpert BCR ABL p190 Package Insert, 302-3773
9. Goldberg S, et al. First-line treatment selection and early monitoring patterns in chronic phasechronic myeloid leukemia in routine clinical practice: SIMPLICITY. Am Hematol. 2017 Jul 28;92:1214–1223.

Laboratory Manager

"I'm interested to learn more about

BCR-ABL Ultra &
BCR-ABL Ultra p190

today."

CE-IVD. *In Vitro* Diagnostic Medical Device. Not all tests available in all countries

Elevator Pitch- Value Proposition

""Xpert NPM1 Mutation is an automated test for quantifying the amount of mutant NPM1 mRNA transcripts as a ratio of NPM1 Mutation/ABL1 with high sensitivity, in less than 3 hours following sample reception.[1] Facilitating the decision-making process at critical moments thanks to the sensitivity and quality of the test."

Customer Objections

There is no need for a faster turn-around time

- Convenience of testing and fast results could potentially help reduce patient anxiety.
- The possibility of providing a result in less than 3 hours following sample reception[1] allows the early prediction of a relapse and monitor the treatment and care effectively.
- Relapse remains the most common cause of treatment failure for AML patients.[2] Timely monitoring ensures measurement of treatment response and detection of potential relapse.[3]

Your price is too high

- What are you comparing our pricing to? What does this include? How did you get to that value? What steps are involved, and how much does it cost to standardize your current testing procedure? Explore with the customer their TRUE current cost for testing.
- Question around batching/wasted reagents; costs to standardize to IS; failure rate/repeats due to delayed batch testing (mRNA degradation); all hidden costs. Include staff level and hands on time. Consider CE-IVDR regulation requirements.

Probing Questions

- Tell me about your current AML monitoring test algorithm?
- How long does it take to get monitoring results to the Clinicians?
- How would a sample to answer, non-batch on demand' monitoring test impact the lab workflow?

References

1. Instructions for use of the Xpert NPM1 Mutation (302-8304)
2. Dillon R, Hills R, Freeman S, Potter N, Jovanovic J, Ivey A, Kanda AS, Runglall M, Foot N, Valganon M, Khwaja A, Cavenagh J, Smith M, Ommen HB, Overgaard UM, Dennis M, Knapper S, Kaur H, Taussig D, Mehta P, Raj K, Novitzky-Basso I, Nikolousis E, Danby R, Krishnamurthy P, Hill K, Finnegan D, Alimam S, Hurst E, Johnson P, Khan A, Salim R, Craddock C, Spearing R, Gilkes A, Gale R, Burnett A, Russell NH, Grimwade D. Molecular MRD status and outcome after transplantation in NPM1-mutated AML. Blood. 2020 Feb 27;135(9):680-688. doi: 10.1182/blood.2019002959. PMID: 31932839; PMCID: PMC7059484.
3. Hafez M, Ye F, Jackson K, Yang Z, Karp JE, Labourier E, Gocke CD. Performance and clinical evaluation of a sensitive multiplex assay for the rapid detection of common NPM1 mutations. J Mol Diagn. 2010 Sep;12(5):629-35. doi: 10.2353/jmoldx.2010.090219. Epub 2010 Jul 8. PMID: 20616361; PMCID: PMC2928427.

Laboratory Manager

"I'm interested to learn more about

NPM1 Mutation

today."

Meet Our Infection Control (Preventive) Specialist, Infection Prevention Nurse, Hygienist

Goals

- Reduce Healthcare associated infections in the hospital
- Limit spread of antimicrobial resistance
- Prevent outbreaks

Challenges

- Adherence to infection control procedures in the hospital

What they care about

- Protecting patients from HAI*
- –Fast detection of HAI*
- –Stopping the spread of infections in the hospital

What is the Cepheid Story?

Optimize patient management and prevent spread

- Fast and accurate results from screening and clinical samples enable quick initiation of infection control procedures to control spread and manage outbreaks

*HAI- Healthcare associated Infections

They might be interested in :

Click on the colored **bold** tests to learn mor
test to learn more

Respiratory	**Xpress CoV-2/Flu/RSV *plus***
	Xpress CoV-2 *plus*
	Xpress Strep A
	Xpress Flu/RSV
HAI & Other Infectious Diseases	**MRSA NxG**
	SA Nasal Complete
	MRSA/SA Blood Culture
	MRSA/SA SSTI
	Carba-R
	Norovirus
	***C. difficile* BT**
	vanA/vanB
TB & Emerging Infectious Diseases	**MTB/RIF Ultra**
	MTB/XDR
	Ebola
Blood Virology, Women's Health & Sexual Health	CT/NG
	HPV v2
	Xpress GBS
	TV
	*Resistance*Plus® MG FleXible#
	HBV Viral Load
	HCV Viral Load
	HCV VL Fingerstick
	HIV-1 Qual XC
	HIV-1 Viral Load XC
Oncology & Human Genetics	Bladder Cancer Detection
	Bladder Cancer Monitor
	Breast Cancer STRAT4
	BCR-ABL Ultra
	BCR-ABL Ultra p190
	NPM1 Mutation (AML)
	Thrombophilia (FII & FV)

Elevator Pitch - Value Proposition

"Xpert Xpress CoV-2/Flu/RSV plus assay is designed to deliver fast and accurate diagnostic tests to enable better decision making, limiting the spread of infectious diseases, improving infection control management and avoiding empirical treatment."

Customer Objections

I have faster results with other tests such as antigen tests

- The antigenic tests have lower sensitivity and specificity compared to molecular.[1,2]
- How does performance impact infection control measures?[3,4,5,6,7]

We have a strong infection control program in place. All suspect patients are isolated until test results

- Knowing infection status prior to in-hospital disposition can ensure isolation precautions are in place to prevent infections spreading to other patients and hospital staff members.
- Xpert Xpress CoV-2/Flu/RSV plus provides fast identification of infection, improving isolation and infection control measures and enhancing patient flow and bed utilization. [8]

Your assay is more expensive than other SARS-CoV-2 assays

- Consider the hidden costs of collapsed emergencies, wrong treatment prescription or incorrect patient discrimination.

Probing Questions

- What is your current infection control protocol?
- How satisfied are with your current algorithm and infection control measures?
- What are the consequences of a delay in a result in terms of patient/bed management?

References

1. Mak GC, Lau SS, Wong KK, Chow NL, Lau CS, Lam ET, Chan RC, Tsang DN. Analytical sensitivity and clinical sensitivity of the three rapid antigen detection kits for detection of SARS-CoV-2 virus. J Clin Virol. 2020 Dec;133:104684
2. Stockl et al. Use of Antigen and Molecular Testing for the Diagnosis of Coronavirus Disease 2019 (COVID-19) among Patients with Influenze-like Illness (ILI) in the Non-inpatient Setting. Association for Molecular Pathology 2023 Annual Meeting Abstracts. J Mol Diagn 2023, p 53 Abstract 006
3. Linehan E, et al Impact of introduction of Xpert flu assay for influenza PCR testing on obstetric patients: a quality improvement project. J Matern Fetal Neonatal Med. 2018 Apr;31(8):1016-1020
4. Serei VD, et al. Comparison of abbott ID NOW COVID-19 rapid molecular assay to cepheid xpert xpress SARS-CoV-2 assay in dry nasal swabs. Diagn Microbiol Infect Dis. 2021 Apr;99(4):115208.
5. Basu A, et al. Performance of Abbott ID Now COVID-19 Rapid Nucleic Acid Amplification Test Using Nasopharyngeal Swabs Transported in Viral Transport Media and Dry Nasal Swabs in a New York City Academic
6. Hinson JS, et al. Targeted rapid testing for SARS-CoV-2 in the emergency department is associated with large reductions in uninfected patient exposure time
7. Mostafa HH, et al. Multi-center Evaluation of the Cepheid Xpert® Xpress CoV-2/Flu/RSV Test. J Clin Microbiol. 2021 Feb 18;59(3): e02955-20
8. Hale B et al. Clinical impact of rapid molecular tests in patients with viral respiratory symptoms: a systematic literature review. Presented at ISPOR Europe, November 2023, Copenhagen, Denmark. Poster MT10.

Infection Control Specialist

"I'm interested to learn more about

Xpress** CoV-2/Flu/RSV **plus

today."

Elevator Pitch- Value Proposition

"The Xpert Xpress CoV-2 plus test is designed to deliver fast and accurate diagnostic tests to enable better decision making, in as little as 20 minutes Thus limiting the spread of infectious diseases, improving infection control management and avoiding empirical treatment."*

Customer Objections

I have faster results with other tests such as antigen tests

- The antigenic tests have lower sensitivity and specificity compared to molecular.[1,2]
- How does performance impact infection control measures? [3,4,5]

We have a strong infection control program in place. All suspect patients are isolated until test results

- Knowing infection status prior to in-hospital disposition can ensure isolation precautions are in place to prevent infections spreading to other patients and hospital staff members. [6]

Your assay is more expensive than other SARS-CoV-2 assays

- Consider the hidden costs of collapsed emergencies, wrong treatment prescription or incorrect patient discrimination. [7]

*with early termination for positive results

Probing Questions

- What is your current infection control protocol?
- How satisfied are with your current algorithm and infection control measures?
- What is the rate of false neg you observe with Ag testing for symptomatic patients?

References

1. Mak GC, Lau SS, Wong KK, Chow NL, Lau CS, Lam ET, Chan RC, Tsang DN. Analytical sensitivity and clinical sensitivity of the three rapid antigen detection kits for detection of SARS-CoV-2 virus. J Clin Virol. 2020 Dec;133:104684
2. Stockl et al. Use of Antigen and Molecular Testing for the Diagnosis of Coronavirus Disease 2019 (COVID-19) among Patients with Influenze-like Illness (ILI) in the Non-inpatient Setting. Association for Molecular Pathology 2023 Annual Meeting Abstracts. J Mol Diagn 2023, p 53 Abstract 006
3. Serei VD, et al. Comparison of abbott ID NOW COVID-19 rapid molecular assay to cepheid xpert xpress SARS-CoV-2 assay in dry nasal swabs. Diagn Microbiol Infect Dis. 2021 Apr;99(4):115208.
4. Basu A, et al. Performance of Abbott ID Now COVID-19 Rapid Nucleic Acid Amplification Test Using Nasopharyngeal Swabs Transported in Viral Transport Media and Dry Nasal Swabs in a New York City Academic
5. Hinson JS, et al. Targeted rapid testing for SARS-CoV-2 in the emergency department is associated with large reductions in uninfected patient exposure time
6. Hale B et al. Clinical impact of rapid molecular tests in patients with viral respiratory symptoms: a systematic literature review.
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Infection Control Specialist

"I'm interested to learn more about

Xpress** CoV-2 **plus

today."

Elevator Pitch- Value Proposition

"Xpert Xpress Flu/RSV is a fast and accurate diagnostic test to enable better decision making, limit the spread of infectious diseases, improve infection control management and avoid empirical treatment."

Customer Objections

I have faster results with other tests

- Even if you can obtain faster results, could you tell me more about how well they perform?
- How does performance impact infection control measures? [1,2,3,4,5]
- Performance is key: Multiple and unique independent targets ensure optimum coverage and anticipate potential seasonal mutations [1,6]

I am not a diagnostic specialist

- The test provides accurate results in 20 mins direct from sample. Which clinical impact could this have? [1,7]

We have a strong infection control program in place. All suspect patients are isolated until test results

- Knowing infection status prior to in-hospital disposition can ensure isolation precautions are in place to prevent infections spreading to other patients and hospital staff members.
- Xpert Xpress Flu/RSV provides fast identification of infection, improving isolation and infection control measures and enhancing patient flow and bed utilization. [2,7,8,9]

*With EAT: Early Assay Termination

Probing Questions

- Do you know the current method used by the lab for testing?
- How quickly do you get results back and how does it help in patient management?
- How confident are you with the results your lab provides?
- How could a test that takes 20 minutes* help you to prevent the spread of infection and to protect patients?

References

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2. Muller MP, et al. Reduction in total patient isolation days with a change in influenza testing methodology. American journal of infection control 44(11) · November 1, 2016Volume 44, Issue 11, Pages 1346–1349
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6. Jørgensen, R. L. et al. Emergence of circulating influenza A H3N2 viruses with genetic drift in the matrix gene: be alert of false-negative test results. *APMIS* 130, 612–617(2022)
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8. Linehan E, et al. Impact of introduction of Xpert flu assay for influenza PCR testing on obstetric patients: a quality improvement project. J Matern Fetal Neonatal Med. 2018 Apr;31(8):1016-1020
9. Hale B et al. Clinical impact of rapid molecular tests in patients with viral respiratory symptoms: a systematic literature review.
Presented at ISPOR Europe, November 2023, Copenhagen, Denmark. Poster MT10.

Infection Control Specialist

"I'm interested to learn more about

***Xpress** Flu/RSV*

today."

CE-IVD. *In Vitro* Diagnostic Medical Device. Not all tests available in all countries

Elevator Pitch- Value Proposition

"CPE outbreaks are growing in frequency, spread quickly and cause severe clinical disruption. Xpert Carba-R delivers fast, accurate and easy PCR results in 50 minutes, helping reduce onward transmission, outbreaks & service disruption. Fast identification supports appropriate bed-management and patient flow."

Customer Objections

We do not have many CPE positive patients

- ECDC data and recent literature are citing near-universally increasing CPE rates.[1]
- How are you defining your high-risk criteria? A single CPE+ can result in far-reaching service disruption and prolonged length of stay. Proactive, preventative measures are required to prevent transmission.[2]

We are happy with our current process

- On-demand PCR results have been shown to help further reduce CPE rates, remove the requirement for x3 culture sampling and make more effective use of isolation facilities.[3,4]
- On-demand PCR can provide same-day results, even during out of hours.[5]

We do not have the budget/resources to undertake CPE surveillance by PCR

- Identification of high-risk patients upon admission reduces onward transmission (helping prevent outbreaks), while prompt enabling de-isolation for negatives, keeping patients flowing, and reducing hospital costs.[4]

Probing Questions

- How are you defining your high-risk criteria?
- What is your current process for CPE surveillance testing? How long does this take?
- How are patients / contact patients currently managed who are awaiting CPE results?
- How do you manage high-risk patients admitted during evenings/ weekends?
- What impact would having CPE results in 50minutes have on patient management and use of isolation beds and contact precautions?
- Are you concerned about a possible increase inCPE transmissions following COVID-19?

References

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Infection Control Specialist

"I'm interested to learn more about

Carba-R

today."

Elevator Pitch- Value Proposition

"MRSA remains a primary cause of HAIs, are spread quickly and can cause severe clinical disruption. Xpert MRSA NxG delivers fast, accurate and easy PCR results in 70 minutes, helping reduce onward transmission, outbreaks & service disruption. Fast identification supports appropriate bed-management and patient flow."

Customer Objections

We do not have the budget/resources to undertake MRSA surveillance

- Identification of high-risk patients upon admission reduces onward transmission(helping prevent outbreaks), while enabling prompt de-isolation for negatives, keeping patients flowing and reducing hospital costs.[1]

We are happy with our current process

- On-demand PCR results have been shown to help further reduce MRSA rates and make more effective use of isolationfacilities.[1]
- On-demand PCR can provide same-day results, even during out of hours.[2]

MRSA is well managed and no longer an issue for our institution

- MRSA is still a major cause of HAIs.[3]
- The incidence of MRSA has increased, notably in infants and those aged 55+.Maintaining robust preventative strategies are critical to preventing the spread.[4]
- How are you managing high-risk patients for VRE or CPE?

Probing Questions

- How are you defining your high-risk criteria?
- What is your current process for MRSA surveillance testing? How long does this take?
- How are patients / contact patients currently managed who are awaiting MRSA results?
- How do you manage high-risk patients admitted during evenings/weekends?
- What impact having MRSA results in 70minutes have on patient management and use of isolation beds and contact precautions?

References

1. Yarbrough M, et al. Multicenter evaluation of theXpert MRSA NxG assay for detection ofmethicillin-resistant Staphylococcus aureus inNasal Swabs. J Clin Microbiol. 2017 Dec;56(1)
2. Dewar S, et al. Point-of-care testing by healthcareworkers for detection of meticillin-resistant Staphylococcus aureus, Clostridioidesdifficile, and norovirus. 2019 Aug;103(4):447-453
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4. Cassini A, et al. Attributable deaths and disability-adjusted life-years caused by infections withantibiotic-resistant bacteria in the EU and theEuropean Economic Area in 2015: a population-level modelling analysis. Lancet Infect Dis. 2019Jan;19(1):56-66

Infection Control Specialist

"I'm interested to learn more about

MRSA NxG

today."

Elevator Pitch- Value Proposition

"Norovirus outbreaks are common, spread quickly and cause severe clinical disruption. Xpert Norovirus delivers fast, accurate and easy PCR results in as soon as 57 minutes, helping reduce onward transmission, outbreaks & service disruption. Fast identification supports appropriate bed-management and patient flow."*

Customer Objections

There is no treatment for Norovirus and symptoms are self-limiting

- Although no specific antimicrobial therapy is used, a fast and accurate diagnosis can expedite appropriate infection prevention measures and reduce the necessity of additional diagnostic procedures, helping to prevent transmission andoutbreaks.[1]
- Norovirus can cause complications in vulnerable patients and the infectious dose is very low meaning it can be easily spread.[2]

We are happy with our current process / you are more expensive than our current process

- PCR is the gold standard for Norovirus.[3]
- On-demand PCR results have been shown to help better manage Norovirus patients, remove the requirement for additional confirmation testing and make more effective use of isolationfacilities.[1,2,3]
- On-demand PCR can provide same-day definitive results, even during out of hours.[4]

*For positive Norovirus reporting with Early Assay Termination (EAT). Reporting negatives in 90 minutes.

Probing Questions

- What is your current process for Norovirus testing? How long does this take?
- How are patients / contact patients currently managed who are awaiting Norovirus results?
- How do you manage potential cases of Norovirus or outbreaks during evenings/weekends?
- What impact would having Norovirus results in 57minutes* have on patient management and use of isolation beds and contact precautions?

References

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Infection Control Specialist

"I'm interested to learn more about

Norovirus

today."

Elevator Pitch- Value Proposition

"CDI outbreaks are common, spread quickly and cause severe clinical disruption. Xpert C. difficile BT delivers fast, accurate and easy PCR results in 43 minutes, helping reduce onward transmission, outbreaks & service disruption. Fast identification supports appropriate bed-management and patient flow."*

Customer Objections

We are happy with our prevention strategy / you are more expensive than our current process

- NAAT offers the combination of speed, sensitivity, high negative predictive value, and cost-effectiveness when used appropriately. [1]
- Missing CDI cases is costly to the hospital and results in poorer patient outcomes (increased transmission and extended stays).[2]
- GDH and EIA testing methods can risk missing positive CDI patients.[3]
- On-demand PCR can provide same-day results, even during out of hours.[4]

There are other causes of gastrointestinal (GI)symptoms, I need these with my initial result

- Most hospital-acquired GI are caused by Norovirus and C. difficile.[5]
- Panels are useful as a reflex test for immunocompromised

*CDI: Clostridioides difficile infection

Probing Questions

- What is your current process for CDI testing? How long does this take?
- What are the consequences of a delay in a result in terms of patient/bed management?
- How do you manage potential cases of CDI outbreaks during evenings/weekends?
- In a case of a false negative, what will be the impact in terms of infection control and risk of transmission?
- How does this impact the team handling patient/bed management?

References

1. Bai Y, Hao Y, Song Z, Chu W, Jin Y, Wang Y. Evaluation of the Cepheid Xpert C. difficile diagnostic assay: an update meta-analysis. Braz J Microbiol. 2021 Dec;52(4):1937-1949
2. Schroeder L, et al. Economic evaluation of laboratory testing strategies for hospital-associated Clostridium difficile infection. JCM.2013 Feb;52(2):489
3. Carroll K & Mizusawa M, Laboratory tests forthe diagnosis of Clostridium difficile. Clin ColonRectal Surg. 2020 Mar;33(2):73-81
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6. Hanson K. Multiplexed molecular diagnostics for respiratory, gastrointestinal, and central nervous system infections. Clin Infect Dis. 2016 Nov;63(10):1361-1367.

Infection Control Specialist

"I'm interested to learn more about

C. difficile BT

today."

Elevator Pitch- Value Proposition

"VRE outbreaks are growing in frequency, spread quickly and cause severe clinical disruption. Xpert vanA/vanB delivers fast, accurate and easy PCR results in 48 minutes, helping reduce onward transmission, outbreaks & service disruption. Fast identification supports appropriate bed-management and patient flow."

Customer Objections

We do not have many VRE positive patients

- ECDC reports "*High percentages of resistance to third-generation cephalosporins and carbapenems in K. pneumoniae, and high percentages of carbapenem resistant Acinetobacter spp. in several countries, are of concern.*"[1]
- How are you defining your high-risk criteria? There is significantly increased risk of infection among colonized high-risk patients.[2]
- VRE outbreaks can result in service disruption and prolonged length of stay. Preventative measures help reduce transmission.[3]

We are happy with our current process

- On-demand PCR results have been shown to help better manage high-risk VRE patients, remove the requirement for x3 culture sampling and make more effective use of isolation facilities.[3,4]
- On-demand PCR can provide same-day results, even during out of hours.

We do not have the budget/resources to undertake VRE surveillance by PCR

- Identification of high-risk patients upon admission reduces onward transmission (helping prevent outbreaks), while enabling prompt de-isolation for negatives, keeping patients flowing and reducing hospital costs.[3,4]

Probing Questions

- How are you defining your high-risk criteria?
- What is your current process for VRE surveillance testing? How long does this take?
- How are patients / contact patients currently managed who are awaiting VRE results?
- How do you manage high-risk patients admitted during evenings/weekends?
- What impact would having VRE results in 48minutes have on patient management and use of isolation beds and contact precautions?
- Are you concerned about a possible increase in VRE transmissions following COVID-19?

References

1. ECDC Surveillance Report. Surveillance of antimicrobial resistance in Europe 2023 https://www.ecdc.europa.eu/en/publications-data/antimicrobial-resistance-surveillance-europe-2023-2021-data
2. Alevizakos M, et al. Colonization with vancomycin-resistant enterococci and risk for bloodstream infection among patients with malignancy: a systematic review and meta-analysis. Open Forum Infect Dis. 2016Dec;4(1):ofw246
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4. Saliba R, et al. Can real-time polymerase chain reaction allow a faster recovery of hospital activity in cases of an incidental discovery of carbapenemase-producing Enterobacteriaceae and vancomycin-resistant Enterococci carriers? J Hosp Infect. 2019 Oct;103(2):115-120

Infection Control Specialist

"I'm interested to learn more about

vanA/vanB

today."

CE-IVD. *In Vitro* Diagnostic Medical Device. Not all tests available in all countries

Elevator Pitch- Value Proposition

"Cepheid Xpert MTB/RIF Ultra provides you with fast accurate results to enable you to prevent outbreaks and optimize bed management and ultimately protect patients."

Customer Objections

The current method is working quite well, why should I change an existing process?

- You play a key role to maintain and improve processes and our assay is recommended by WHO to help institutions to do this. [1]

I haven't had a TB outbreak for a long time

- Our solution would prepare your organization to avoid outbreaks by identifying TB very early, which would be very useful to prepare for future eventualities. [1,2,3]

Probing Questions

- How quickly do you get results back and how does it help in bed management?
- How could a lab test that takes 77 mins help you to prevent the spread of the infection and to protect patients?
- How would timely, accurate results support the de-isolation insight of the TB ward?

References

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3. Diel R, et al. Cost-benefit analysis of Xpert MTB/RIF for tuberculosis suspects in German hospitals. Eur Respir J. 2016 Feb;47(2):575-87

Infection Control Specialist

"I'm interested to learn more about

MTB/RIF Ultra

today."

Elevator Pitch- Value Proposition

"Cepheid Xpert MTB/XDR detects genes associated with resistance to 6 antibiotics used for TB treatment directly from patient's specimens in <90 mins. Identifying cases with drug resistance fast and early will enable correct measures to prevent transmission to be enforced as soon as possible."

Customer Objections

We must isolate all patients with TB to prevent transmission regardless of the type of resistance

- If you were able to detect cases with multiple resistances early, it would allow the most effective treatments to be given early and potentially reduce the time in hospital.

Multiple drug resistances are rare

- Our test can be run on demand and is low complexity so is a perfect solution in these cases and will ensure you can act fast to prevent transmission.
- WHO recommended new 4-month all-oral drug-susceptible TB regimen[6]. Cepheid's solution provides information to support the new 4-month all-oral regimen which includes Moxifloxacin (FLQ)

Probing Questions

- How do you manage TB patients and resistance testing?
- What are the precautions you take while waiting for TB resistance results?
- What would be different if you were able to have the resistance results within hours of TB positive being confirmed?

References

1. Nahid P, et al. Treatment of Drug-Resistant Tuberculosis An Official ATS/CDC/ERS/IDSA Clinical Practice Guideline. Am J Respir Crit Care Med Vol 200, Iss 10, pp e93–e142, Nov 15, 2019
2. WHO, December 2019, Rapid Communication: Key changes to the treatment of drug-resistant tuberculoses
3. WHO, Publication, 16 February 2021. Update on the use of nucleic acid amplification tests to detect TB and drug-resistant TB: rapid communication
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6. WHO consolidated guidelines on tuberculosis. Module 4: treatment - drug-susceptible tuberculosis treatment. Accessed in Nov 2023 Module 4: Drug-resistant tuberculosis treatment | TB Knowledge Sharing (tbksp.org)

Infection Control Specialist

"I'm interested to learn more about

MTB/XDR

today."

Meet Our Antimicrobial Stewardship Team Pharmacist, Microbiologist

Goals

- Control the use of antibiotics
- Reduce or stop increases in antimicrobial resistant organisms
- Consult on appropriate antibiotic use
- Educate clinical teams on antibiotic stewardship

Challenges

- Avoid empiric use of antibiotics
- Control the use of last resort antibiotics
- Manage antibiotic costs

What they care about

- Early action for infections with the right treatment
- Overuse of expensive or last-line treatments

What is the Cepheid Story?

Optimize antibiotic stewardship and therapy management through highly accurate fast results

- Accurate and fast diagnostic tests that detect the cause of infection and identify resistance markers can help guide the choice of antibiotics
- Early treatments with the right antibiotic can improve patient outcomes

They might be interested in :

Click on the colored **bold** tests to learn more

Respiratory	**Xpress CoV-2/Flu/RSV *plus***
	Xpress CoV-2 *plus*
	Xpress Strep A
	Xpress Flu/RSV
HAI & Other Infectious Diseases	MRSA NxG
	SA Nasal Complete
	MRSA/SA Blood Culture
	MRSA/SA SSTI
	Carba-R
	Norovirus
	C. *difficile* BT
	vanA/vanB
TB & Emerging Infectious Diseases	MTB/RIF Ultra
	MTB/XDR
	Ebola
	CT/NG
	HPV v2
	Xpress GBS
	TV
Blood Virology, Women's Health & Sexual Health	***Resistance****Plus*® MG FleXible#
	HBV Viral Load
	HCV Viral Load
	HCV VL Fingerstick
	HIV-1 Qual XC
	HIV-1 Viral Load XC
Oncology & Human Genetics	Bladder Cancer Detection
	Bladder Cancer Monitor
	Breast Cancer STRAT4
	BCR-ABL Ultra
	BCR-ABL Ultra p190
	NPM1 Mutation (AML)
	Thrombophilia (FII & FV)

CE-IVD. *In Vitro* Diagnostic Medical Device. Not all tests available in all countries

Manufactured by SpeeDx and exclusively distributed by Cepheid under the FleXible for GeneXpert System program

Elevator Pitch- Value Proposition

"Early detection and appropriate prescription of the correct treatment for patients with overlapping clinical symptomatology is more effective to manage symptoms and limit spread. Prompt diagnosis of SARS-CoV-2 with the option to include Flu and RSV in 36 minutes can help direct therapies more effectively; saving time, resource and money." [1]

Customer Objections

The lab oversees Molecular respiratory testing in my organization, and this is not my remit.

- We would be happy to coordinate a meeting between yourself and the laboratory to discuss.
- Another option many hospitals are currently adopting is to use our technology at the POC in admissions or emergency units to speed up the time to result and therefore the impact. We have case studies to show how this has worked. [2, 3, 4]

Probing Questions

- How many prescriptions of Tamiflu/Relenza did you issue last Flu season? Were some of these unnecessary?
- What is the cost of each dose of antiviral medication in your institution?
- How satisfied are you with the current service other Departments provide for you?

Pharmacist/ Microbiologist

"I'm interested to learn more about

Xpress** CoV-2/Flu/RSV **plus

today."

References

1. JHale B et al. Clinical impact of rapid molecular tests in patients with viral respiratory symptoms: a systematic literature review.
Presented at ISPOR Europe, November 2023, Copenhagen, Denmark. Poster MT10.
2. Hinson JS, et al. Targeted rapid testing for SARS-CoV-2 in the emergency department is associated with large reductions in uninfected patient exposure time. J Hosp Infect 107, 35–39 (2021).
3. Garvey MI, et al. Impact of a PCR point of care test for influenza A/B on an acute medical unit in a large UK teaching hospital: results of an observational, pre and post intervention study. Antimicrob Resist Infect Control. 2019 Jul 16;8:120
4. Fenstermacher K et al. Pre- and Post-Implementation Comparison of the Impact of Emergency Department (ED)-Based COVID-19 Point-of-Care Testing on ED Patient Metrics. Annals of Emergency Medicine. Vol 82, Issue 4, S172, October 2023. doi: 10.1016/j.annemergmed.2023.08.422

Elevator Pitch- Value Proposition

"The Xpert Xpress CoV-2 plus test is designed to deliver fast and accurate diagnostic tests to enable better decision making, in as little as 20 minutes
Balancing timely treatment with an accurate triage, leading to correct use of Isolation pathways at ED and reducing costs."*

Pharmacist/ Microbiologist

"I'm interested to learn more about

Xpress** CoV-2 **plus

today."

Customer Objections

The lab oversees Molecular respiratory testing in my organization, and this is not my remit.

- We would be happy to coordinate a meeting between yourself and the laboratory to discuss.
- Another option many hospitals are currently adopting is to use our technology at the POC in admissions or emergency units to speed up the time to result and therefore the impact. We have case studies to show how this has worked.[1,2, 3, 4, 5]

Probing Questions

- How many prescriptions of Tamiflu/Relenza did you issue last Flu season? Were some of these unnecessary?
- What is the cost of each dose of antiviral medication in your institution?

*with EAT: Early assay termination for SARS-CoV-2 positive results utilizing Xpert Xpress CoV-2/Flu/RSV; 36 minutes for negative results

References

1. Hinson JS, et al. Targeted rapid testing for SARS-CoV-2 in the emergency department is associated with large reductions in uninfected patient exposure time. J Hosp Infect 107, 35–39 (2021).
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Elevator Pitch- Value Proposition

"Early and appropriate prescription of Oseltamivir (Tamiflu) or Zanamivir (Relenza) for patients with Flu is needed to manage symptoms and limit spread. Often prescriptions are given unnecessarily or too late to be effective. Prompt diagnosis of Flu and RSV in 20 minutes can help physicians make therapy decisions more effectively, saving time, resource and money. New therapies for both Flu and RSV are in latter stage clinical trials and are likely to increase this need for early and accurate diagnosis"*

Customer Objections

Antivirals for Flu are not expensive, and we have large stocks

- We have data to suggest single prescriptions can be as much as £18 per dose in the U.K. [1]
- Clearly money can easily be saved on use where it is not required or too late to be effective. Data suggest that our Xpert Xpress Flu/RSV test can provide an effective return on investment [2] and assist optimized antiviral usage.[3]

The lab oversees the Flu testing in my organization, and this is not my remit.

- We would be happy to coordinate a meeting between yourself and the laboratory to discuss.
- Another option many hospitals are currently adopting is to use our technology at the POC in admissions or emergency units to speed up the time to result and therefore the impact. We have some nice case studies to show how this has worked. [4,5,6,7]

Probing Questions

- How many prescriptions of Tamiflu/Relenza did you issue last Flu season? Were some of these unnecessary?
- What is the cost of each dose of antiviral medication in your institution?
- Could 20 minutes* test for Flu A/B/RSV improve your prescription efficiency and reduce unnecessary prescriptions? [7]
- Are you aware of new antivirals coming to market, will you plan to adopt and what is your plan to ensure appropriate use?

References

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Presented at ISPOR Europe, November 2023, Copenhagen, Denmark. Poster MT10

*with EAT: Early assay termination for SARS-CoV-2 positive results utilizing Xpert Xpress CoV-2/Flu/RSV; 36 minutes for negative results

Pharmacist/ Microbiologist

"I'm interested to learn more about

***Xpress** Flu/RSV*

today."

CE-IVD. *In Vitro* Diagnostic Medical Device. Not all tests available in all countries

Elevator Pitch- Value Proposition

*"Antibiotics of last resort are under increasing threat from CPE. Xpert Carba-R delivers fast, accurate and easy PCR results in 50 minutes for the "big five" carbapenemase gene families, providing on-demand answers for clinical teams to help optimize therapy management." **

Customer Objections

We typically prescribe colistin to treat CPE infections

- Colistin monotherapy is not recommended. It is nephrotoxic and has poor pulmonary penetration.[1]
- Combinatory therapies with at least two suspectable antimicrobial agents are recommended for greater effectiveness in critically ill patients.[1]

Most new antimicrobial agents treat most common CPE infections

- CPE are spreading and have become resistant to nearly all antibiotics. Empirically prescribing further accelerates AMR.[2]
- Not all antimicrobial agents are effective against all carbapenemase classes/gene families. Fast diagnostics differentiating carbapenemase genes should be integrated into antimicrobial stewardship programs to impact patient management and therapeutic choices in a timely manner.[3,4]

*From testing pure colonies with Xpert Carba-R. See Xpert Carba-R Product Insert (301-9242, Rev. C June 2020) for additional details

*CDI: Clostridioides difficile infection

Probing Questions

- How do you manage/treat patients with CPE carriage or infection?
- Are you always able to prescribe patients with full knowledge of their CPE status (including gene family and resistance mechanism)?
- Are you concerned about the over-use of antibiotics following the COVID-19 pandemic accelerating antimicrobial resistance?
- What impact would CPE results (including gene family) in 50 minutes have on patient therapy management?

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Pharmacist/ Microbiologist

"I'm interested to learn more about

Carba-R

today."

Meet Our Intensive Care Unit Physician

Goals

- Decrease length of stay, limit health care associated infections and prevent mortality

Challenges

- Treating complex patients with severe infections and multidrug resistance

What they care about

- High quality patient care
- Improve patient outcome

What is the Cepheid Story?

Decrease HAIs* through high-risk patient screening & early diagnosis to optimize antibiotic stewardship

- Help prevent transmission of HAIs and drug-resistant bacteria
- Increase the appropriate usage of antibiotics based on an early and accurate diagnosis
- Quick molecular results enable a switch from empiric treatment to targeted treatment

*HAI- Healthcare associated Infections

They might be interested in :

Click on the colored **bold** tests to learn more

Respiratory	**Xpress** CoV-2/Flu/RSV ***plus***
	Xpress CoV-2 ***plus***
	Xpress Strep A
	Xpress Flu/RSV
	MRSA NxG
HAI & Other Infectious Diseases	SA Nasal Complete
	MRSA/SA Blood Culture
	MRSA/SA SSTI
	Carba-R
	Norovirus
	***C. difficile* BT**
	vanA/vanB
TB & Emerging Infectious Diseases	MTB/RIF Ultra
	MTB/XDR
	Ebola
Blood Virology, Women's Health & Sexual Health	CT/NG
	HPV v2
	Xpress GBS
	TV
	***Resistance*Plus®** MG FleXible#
	HBV Viral Load
	HCV Viral Load
	HCV VL Fingerstick
	HIV-1 Qual XC
	HIV-1 Viral Load XC
Oncology & Human Genetics	Bladder Cancer Detection
	Bladder Cancer Monitor
	Breast Cancer STRAT4
	BCR-ABL Ultra
	BCR-ABL Ultra p190
	NPM1 Mutation (AML)
	Thrombophilia (FII & FV)

CE-IVD. *In Vitro* Diagnostic Medical Device. Not all tests available in all countries

Elevator Pitch- Value Proposition

"MRSA transmission in ICUs remains a cause for concern. Xpert MRSA NxG delivers fast, accurate and easy PCR results in 70 minutes, helping to prevent transmission of drug-resistant bacteria to vulnerable high-risk patients in ICUs. Fast identification of MRSA patients supports appropriate bed-management and therapy."

Customer Objections

We are performing culture on high-risk patients, and it works well

- Fast, on-demand PCR can help reduce MRSA rates, make more effective use of isolation facilities and optimize therapy.[1]
- On-demand PCR can provide same-day results, even during out of hours.[2]

We are more concerned with infectious organisms other than MRSA

- MRSA is still one of the main causes of HAIs.[3]
- The incidence of MRSA has increased, notably in infants and those aged 55+.Maintaining robust preventative strategies are critical to preventing the spread.[4]
- How are you managing high-risk patients for VRE or CPE?

Probing Questions

- What is your current process for MRSA surveillance testing for admittance to high-dependency wards?
- How are you defining your high-risk criteria?
- How do you ensure patients admitted with an unknown MRSA status are managed appropriately to avoid transmission?
- How do you manage high-risk patients admitted during evenings/weekends?
- What impact would actionable MRSA results in 70minutes have on patient management and use of isolation beds and contact precautions?

References

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4. Cassini A, et al. Attributable deaths and disability-adjusted life-years caused by infections with antibiotic-resistant bacteria in the EU and the European Economic Area in 2015: a population-level modelling analysis. Lancet Infect Dis. 2019Jan;19(1):56-66

Intensive Care Physician

"I'm interested to learn more about

MRSA NxG

today."

CE-IVD. *In Vitro* Diagnostic Medical Device. Not all tests available in all countries

Elevator Pitch- Value Proposition

"CPE transmission and outbreaks in ICUs are increasing in frequency. Xpert Carba-R delivers fast, accurate and easy PCR results in 50 minutes, helping to prevent transmission of drug-resistant bacteria to vulnerable high-risk patients. Fast identification of CPE patients supports appropriate bed-management and therapy."

Customer Objections

We are performing culture on high-risk patients and it works well

- Fast, on-demand PCR can help reduce CPE rates, make more effective use of isolation facilities and optimise therapy.[1,2]
- On-demand PCR can provide same-day results, even during out of hours.[3]

You are more expensive than our current methodology

- It is important to consider the impact of rapid results on the whole hospital.
- Targeted screening using fast PCR with pre-emptive isolation minimizes transmission opportunities (helping prevent outbreaks, especially in ICUs), while enabling appropriate use of costly isolation facilities and therapy.[1]

Probing Questions

- What is your current process for CPE surveillance testing for admittance to high-dependency wards? How long does this take? What would you like to improve?
- How are you defining your high-risk criteria?
- How do you ensure patients admitted with an unknown CPE status are managed appropriately to avoid transmission?
- How do you manage high-risk patients admitted during evenings/weekends?
- What impact would actionable CPE results in 50 minutes have on patient management and use of isolation beds?

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3. Ambretti S, et al. Screening for carriage of carbapenem-resistant Enterobacteriaceae in settings of high endemicity: a position paper from an Italian working group on CRE infections. Antimicrob Resist Infect Control. 2019 Aug;13(8):136

Intensive Care Physician

"I'm interested to learn more about

Carba-R

today."

Elevator Pitch- Value Proposition

"CDI transmission in ICUs are a cause for concern. Xpert C. difficile BT delivers fast, accurate and easy PCR results in 43 minutes, helping to prevent transmission of CDI to vulnerable high-risk patients. Fast identification of CDI patients supports appropriate bed-management and therapy."

Customer Objections

We are happy with our current process / you are more expensive than our current process

- Fast, on-demand PCR can help reduce CDI rates, remove the requirement for additional sampling/steps (delaying time to result) and make more effective use of isolation facilities and optimise therapy.[1]
- Xpert C. difficile BT additionally offers presumptive 027 detection, a predictor of severe CDI and mortality.[2]
- GDH and EIA testing methods can risk missing positive CDI patients.[3]
- On-demand PCR can provide same-day results, even during out of hours.[4]

PCR risks over diagnosing asymptomatic *C. difficile* carriage

- Testing should be limited to unformed stools, with the clinical context considered.[5]
- Rapid and sensitive commercial PCR as a stand-alone assay together with clear sampling guidance can offer an optimal approach to patient management.[1]

*CDI: Clostridioides difficile infection

Probing Questions

- What is your current process for CDI testing? Do you treat only once results are returned?
- How are patients / contact patients currently managed who are awaiting CDI results?
- How do you manage potential cases of CDI or outbreaks during evenings/weekends?
- What impact would having CDI results (including presumptive 027 strain identification) in 43minutes have on patient therapy management and use of isolation beds?

References

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4. Dewar S, et al. Point-of-care testing by healthcare workers for detection of meticillin-resistant Staphylococcus aureus, Clostridioides difficile, and norovirus.2019 Aug;103(4):447-453
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Intensive Care Physician

"I'm interested to learn more about

C. difficile BT

today."

Meet Our Point of Care Manager / Near Patient Testing Responsible (Clinician/Biologist /Midwife /Nurse#)

Goals

- Leverage molecular diagnostics to improve care delivery
- Faster clinical decision making

Challenges

- Work with different stakeholders and wards.

What they care about

- High quality patient care and satisfaction
- Improve public health

What is the Cepheid Story?

Harness the power of molecular testing to improve delivery of care

- Easy to use GeneXpert Systems, with no environmental constraints and minimal training
- Scalable and flexible platform for optimized testing in any setting
- Improved patient satisfaction through faster results

*HAI- Healthcare associated Infections
(ID/ HIV/ Sexual Health)

They might be interested in :

Click on the colored **bold** tests to learn more

GeneXpert® Systems

Respiratory	**Xpress CoV-2/Flu/RSV plus** **Xpress CoV-2 plus** Xpress Strep A **Xpress Flu/RSV**
HAI & Other Infectious Diseases	MRSA NxG SA Nasal Complete MRSA/SA Blood Culture MRSA/SA SSTI Carba-R Norovirus *C. difficile* BT *vanA/vanB*
TB & Emerging Infectious Diseases	MTB/RIF Ultra MTB/XDR Ebola
Blood Virology, Women's Health & Sexual Health	**CT/NG** HPV v2 **Xpress** GBS TV *ResistancePlus*® MG FleXible# HBV Viral Load HCV Viral Load **HCV VL Fingerstick** **HIV-1 Qual XC** HIV-1 Viral Load XC
Oncology & Human Genetics	Bladder Cancer Detection Bladder Cancer Monitor Breast Cancer STRAT4 BCR-ABL Ultra BCR-ABL Ultra p190 NPM1 Mutation (AML) Thrombophilia (FII & FV)

Elevator Pitch- Value Proposition

"Our GeneXpert family of systems sets new standards in molecular workflow flexibility, 24/7 testing, accuracy, and user-friendly design offering a single, standardized solution capable of running multiple tests on one space-saving system. This fully scalable, and consolidated workstation is available in 1 module to 4 modules to address decentralized testing needs, to up to 80 modules configuration for central labs with high throughput. The number of modules can be adjusted to follow the evolution of your needs through time, and to offer the same quality of testing than in the central lab.

All the systems have our proven GeneXpert module at their analytic heart, and each one uses the same patented cartridge technology for every Xpert® test. "

Customer Objections

The central lab doesn't want to handle decentralized testing

- All GeneXpert systems share the exact same module and use the same assays. This is a robust easy-to-use technology which does not require dedicated skilled operators.
- What would be the impact on a faster time-to-result on your patient pathway?

I don't have a proper setting to run molecular testing

- The GeneXpert workflow is straightforward: the operator opens the cartridge, next transfer the sample into the cartridge and finally load the cartridge into the module. This ~1 min hands-on time* doesn't require complex equipment.
- Do you have 40 cm of workbench available?

Probing Questions

- What would be the impact on your patients if they could undergo the same tests as those conducted in the central lab, but in a near-patient setting?
- What is your time-to-result when you have to send out some analysis included in our test menu? [1]

References

1. Cepheid-Menu-Test-Overview-CE-IVD (last update available on Seismic).

*Sample preparation times may vary. See package inserts for details.

Point of Care Manager

"I'm interested to learn more about

GeneXpert System

today."

Elevator Pitch - Value Proposition

"Early detection and appropriate prescription of the correct treatment for patients with overlapping clinical symptomatology is more effective to manage symptoms and limit spread. Prompt diagnosis of SARS-CoV-2 with the option to include Flu and RSV in 36 minutes can help direct therapies more effectively; saving time, resource and money."

Customer Objections

I don't have enough resources to perform this test on site.

- Xpert Xpress CoV-2/Flu/RSV is easy to run, providing rapid test results supports real- time medical decision making during the patient presentation.[1,2]

It is difficult to perform molecular screening at point of care settings

- Point of care testing significantly reduces the average turnaround time and speeds up treatment decisions improving patient flow in a busy acute medical unit. [2,3,4,5]

*with EAT: Early assay termination for SARS-CoV-2 positive results utilizing Xpert Xpress CoV-2/Flu/RSV; 36 minutes for negative results

Probing Questions

- How often do you have an overload of patients in your department?
- What was your biggest challenge handling the last Flu/RSV season?
- If you knew the CoV-2/Flu/RSV status of the patients in 25 mins*, how that would impact the management of the patients in high season?

References

1. Hinson JS, et al. Targeted rapid testing for SARS-CoV-2 in the emergency department is associated with large reductions in uninfected patient exposure time. J Hosp Infect 107, 35–39 (2021).
2. Wolters F, et al. Multi-center evaluation of cepheid xpert® xpress SARS-CoV-2 point-of-care test during the SARS-CoV-2 pandemic . J Clin Virol. 2020 Jul;128:104426
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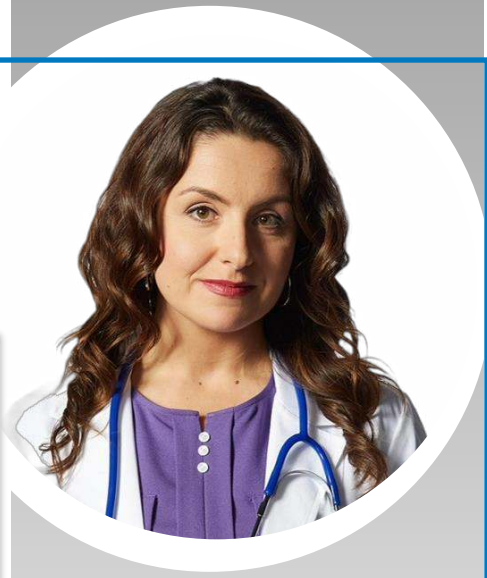

Point of Care Manager

"I'm interested to learn more about

Xpress CoV-2/Flu/RSV plus, Xpress CoV-2 plus, Xpress Flu/RSV

today."

Elevator Pitch- Value Proposition

"Xpert CT/NG provides a fast and on-demand test that detects and differentiates genomic DNA from Chlamydia trachomatis and/or Neisseria gonorrhoea to aid in the diagnosis of chlamydial and gonorrhoeal urogenital disease.

It also helps to reduce time of notification to the patient and onward transmission of the infection to the partner. [1]"

Customer Objections

We do not have skills to perform CT/NG testing.

- Does not require advanced skills. Training is quick and will be provided by a Cepheid's highly skilled technicians.[1]

We have no funds available to perform this testing in-house.

- Have you discussed this with Regional Health Agencies? We can support you to develop a business case.

We have good relationships with our lab provider.

- The relationship with your laboratory will be maintained for the validation and accreditation process.[1]

Probing Questions

- Who is your current lab provider and what would you like to improve about the service?
- How do you link patients to care?
- How could targeted and fast testing improve your service to your patients?
- Have you considered women patients taking their own vaginal swabs samples?

References

1. Berçot B, et al. Assessment of Coinfection ofSexually Transmitted Pathogen Microbes byUse of the Anyplex II STI-7 Molecular Kit. J ClinMicrobiol. 2015 Mar ;53(3):991

Point of Care Manager

"I'm interested to learn more about

CT/NG

today."

Elevator Pitch- Value Proposition

"Xpert HIV-1 Qual provides an on-demand, rapid detection of HIV RNA and DNA directly from 100ul of whole blood or dried blood spots. The test can be used in a near patient setting to detect HIV-1 total nucleic acids to aid early diagnosis of HIV-1 including acute infections and managing Patients on PrEP."

Customer Objections

There isn't enough budget

- By creating efficiencies through clinic flow and reduction in onward transmission, there is likely to be a saving. We can support work to make sure policymakers and funders are aware of the benefits.[1]

We don't have technical staff to do the PCR test

- The Xpert HIV-1 Qual XC test is simple to do with minimal hands-on time. The test is run in several other settings like this.[1,2]

Your test takes too long. Our current POC test takes 20 mins

- The Xpert HIV-1 Qual XC can help in earlier detection of acute HIV infection in people who test negative by antibody testing. Normally this patient would have to wait several weeks to confirm their negative status. Our solution will shorten that time [2,3,4].

PrEP: Pre-Exposure Prophylaxis

Probing Questions

- How do you manage clients with a high risk of acute infection but who have a negative result with a HIV antibody test?
- How do you confirm a positive antibody result, how long does that take and when do you start treatment for the patient?
- How does waiting for confirmation of negative or positive antibody results impact on your management of the patient and risk of further transmission?

References

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Point of Care Manager

"I'm interested to learn more about

HIV-1 Qual XC

today."

Elevator Pitch- Value Proposition

"Xpert HCV VL Fingerstick simplifies HCV testing by providing RNA detection and a viral load directly from a drop of blood in less than an hour. Near patient testing offers better opportunity to diagnose HCV in the undiagnosed in outreach settings, to improve linkage to care and to respond to the WHO Hepatitis elimination goal."

Customer Objections

We do not have technicians that can perform a molecular test in the site

- Does not require advanced skills. The test has been delivered in non-clinical settings and using non-technical staff very successfully[1,2]. Training is quick and will be provided by Cepheid.

Near patient testing is not reimbursed

- EU countries have signed up to the WHO call to eliminate the burden of hepatitis by 2030 [3].With a 2-step diagnostic algorithm, data suggest that 46% of HCV antibody positive tests are not confirmed with an RNA test. Improving access to a rapid and simple diagnosis (ideally one step) is crucial for achieving HCV elimination [3].

We test for all three Blood-Borne Viruses

- HCV is of biggest concern in some settings and a rapid near patient test could help to reduce the loss of patient follow-up. [3,4].

Probing Questions

- What are the challenges around the process of finding patients with acute Hepatitis C infection and linking them to care?
- How does the time taken to diagnose HCV in the current process impact on getting patients onto treatment?
- How would being able to collect a fingerstick blood sample and offer a near patient test to detect and quantify HCV RNA impact on your patient diagnostics pathway?

References

1. Lamoury FMJ, et al. Evaluation of the Xpert HCV Viral Load Finger-Stick Point-of-Care Assay. J Infect Dis. 2018 May25;217(12):1889-1896
2. Bajis S, et al., Acceptability and preferences of point-of-care finger-stick whole-blood and Venepuncture hepatitis C virus testing among people who inject drugs in Australia. Int J Drug Policy. 2018 Nov;61:23-30
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5. Mohamed Z, et al. Time matters: Point of care screening and streamlined linkage to care dramatically improves hepatitis C treatment uptake in prisoners in England. Int J Drug Policy. 2019 Nov 20;75:102608.
6. Cepheid website. Product Information: Xpert HCV VL Fingerstick , Educational Materials, Webinar: : Jason Grebely Associate Professor, Viral Hepatits Clinical Program The Kirby Institute, UNSW Sydney, Sydney Australia "Simplification of testing and treatment in the quest to eliminate hepatitis C infection"

Point of Care Manager

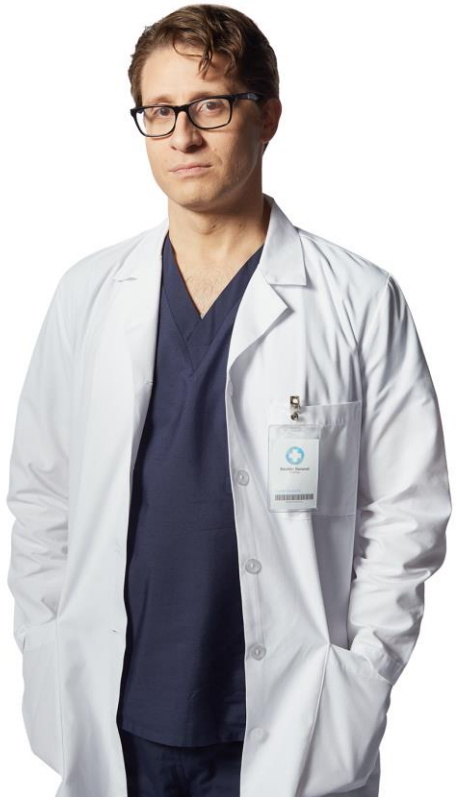
"I'm interested to learn more about

HCV VL Fingerstick

today."

CE-IVD. *In Vitro* Diagnostic Medical Device. Not all tests available in all countries

Meet Our Emergency Clinician



Goals

- Provide quality care quickly
- Reduce length of stay and patient flow (door to discharge)

Challenges

- Lack of beds
- Lack of staff
- Decrease patient´s waiting times

What they care about

- Improve productivity and efficiency
- Improve patient care
- Save time and oversight

What is the Cepheid Story?

Fast Clinical Decision Making

- Give a clear and accurate diagnosis for the patient
- Adapt treatment for the patient quicker
- Fast turnaround time for results enables shortening of length of stay, increased bed efficiency and increased patient satisfaction

They might be interested in :

Click on the colored **bold** tests to learn more

Respiratory	**Xpress CoV-2/Flu/RSV plus** **Xpress CoV-2 plus** Xpress Strep A **Xpress Flu/RSV**
HAI & Other Infectious Diseases	MRSA NxG SA Nasal Complete MRSA/SA Blood Culture MRSA/SA SSTI Carba-R Norovirus *C. difficile* BT *vanA/vanB*
TB & Emerging Infectious Diseases	MTB/RIF Ultra MTB/XDR Ebola
Blood Virology, Women's Health & Sexual Health	CT/NG HPV v2 **Xpress** GBS TV ***ResistancePlus*® MG FleXible#** HBV Viral Load HCV Viral Load HCV VL Fingerstick HIV-1 Qual XC HIV-1 Viral Load XC
Oncology & Human Genetics	Bladder Cancer Detection Bladder Cancer Monitor Breast Cancer STRAT4 BCR-ABL Ultra BCR-ABL Ultra p190 NPM1 Mutation (AML) Thrombophilia (FII & FV)

CE-IVD. *In Vitro* Diagnostic Medical Device. Not all tests available in all countries

Elevator Pitch- Value Proposition

*"Cepheid provides a quick reliable test for SARS-CoV-2 and combination of SARS-CoV-2, flu and RSV that allows you to do a quick triage of your outpatients with respiratory symptoms in as soon as 25 minutes *."*

Customer Objections

I have faster results with other tests such as antigen tests

- The antigenic tests have lower sensitivity and specificity compared to molecular.[1,2,3]
- How does performance impact infection control measures?[4,5,6,7,8]

It is difficult to perform molecular screening at point of care settings

- Point of care testing significantly reduces the average turnaround time and speeds up treatment decisions improving patient flow in a busy acute medical unit. [9]
- Xpert Xpress CoV-2/Flu/RSV plus provides fast identification of infection, improving isolation and infection control measures and enhancing patient flow and bed utilization. [8,9]

Your assay is more expensive than other SARS-CoV-2 assays

- Less re-runs are important for fast patient discrimination specially among those who need urgent care.
- Consider the hidden costs of collapsed emergencies, wrong treatment prescription or incorrect patient discrimination. [10]

* with EAT: Early assay termination for SARS-CoV-2 positive results utilizing Xpert Xpress CoV-2/Flu/RSV; 36 minutes for negative results.

Probing Questions

- What are the main challenges you face regarding fast accurate respiratory triage?
- What is the rate of false negative results you observe with ag testing?
- How would definitive information help them better manage patients?

References

1. Mak GC, Lau SS, Wong KK, Chow NL, Lau CS, Lam ET, Chan RC, Tsang DN. Analytical sensitivity and clinical sensitivity of the three rapid antigen detection kits for detection of SARS-CoV-2 virus. J Clin Virol. 2020 Dec;133:104684
2. Hinson JS, et al. Targeted rapid testing for SARS-CoV-2 in the emergency department is associated with large reductions in uninfected patient exposure time
3. Stockl et al. Use of Antigen and Molecular Testing for the Diagnosis of Coronavirus Disease 2019 (COVID-19) among Patients with Influenze-like Illness (ILI) in the Non-inpatient Setting. Association for Molecular Pathology 2023 Annual Meeting Abstracts. J Mol Diagn 2023, p 53 Abstract 006
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5. Serei VD, et al. Comparison of abbott ID NOW COVID-19 rapid molecular assay to cepheid xpert xpress SARS-CoV-2 assay in dry nasal swabs. Diagn Microbiol Infect Dis. 2021 Apr;99(4):115208.
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10. Hale B et al. Clinical impact of rapid molecular tests in patients with viral respiratory symptoms: a systematic literature review. Presented at ISPOR Europe, November 2023, Copenhagen, Denmark. Poster MT10.

Emercengy Clinician

"I'm interested to learn more about

Xpress** CoV-2/Flu/RSV **plus

today."

CE-IVD. *In Vitro* Diagnostic Medical Device. Not all tests available in all countries

Elevator Pitch- Value Proposition

"The Xpert Xpress CoV-2 plus test is designed to deliver fast and accurate diagnostic tests to enable better decision making, in as little as 20 minutes. Balancing timely treatment with an accurate triage, leading to correct use of isolation pathways at ED and reducing costs."*

Customer Objections

I have faster results with other tests such as antigen tests

- The antigenic tests have lower sensitivity and specificity compared to molecular.[1,2]
- How does performance impact infection control measures?[1,3,4,5,6]

It is difficult to perform molecular screening at point of care settings

- Point of care testing significantly reduces the average turnaround time and speeds up treatment decisions improving patient flow in a busy acute medical unit. [7]

Your assay is more expensive than other SARS-CoV-2 assays

- Less re-runs are important for fast patient discrimination specially among those who need urgent care.
- Consider the hidden costs of collapsed emergencies, wrong treatment prescription or incorrect patient discrimination. [8]

**For positives only with EAT (Early Assay Termination); reporting of negatives in approximately 30 minutes.*

Probing Questions

- Which guidelines are you following?
- How would you benefit from actionable results 24/7?
- What is the rate of false neg you observe with Ag testing for symptomatic patients?

References

1. Mak GC, Lau SS, Wong KK, Chow NL, Lau CS, Lam ET, Chan RC, Tsang DN. Analytical sensitivity and clinical sensitivity of the three rapid antigen detection kits for detection of SARS-CoV-2 virus. J Clin Virol. 2020 Dec;133:104684
2. Stockl et al. Use of Antigen and Molecular Testing for the Diagnosis of Coronavirus Disease 2019 (COVID-19) among Patients with Influenze-like Illness (ILI) in the Non-inpatient Setting. Association for Molecular Pathology 2023 Annual Meeting Abstracts. J Mol Diagn 2023, p 53 Abstract 006
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5. Hinson JS, et al. Targeted rapid testing for SARS-CoV-2 in the emergency department is associated with large reductions in uninfected patient exposure time
6. Hale B et al. Clinical impact of rapid molecular tests in patients with viral respiratory symptoms: a systematic literature review.
Presented at ISPOR Europe, November 2023, Copenhagen, Denmark. Poster MT10.
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Emercengy Clinician

"I'm interested to learn more about

Xpress** CoV-2 **plus

today."

Elevator Pitch- Value Proposition

"Cepheid provides a quick reliable test for Flu & RSV that allows you to do a quick triage of your outpatients with Influenza Like Illness (ILI)."

Customer Objections

I have faster results with other tests

- Even if you can obtain faster results, could you tell me more about how well they perform?
- How does performance impact infection control measures? [1,2,3,4,5]
- Performance is key: Multiple and unique independent targets ensure optimum coverage and anticipate potential seasonal mutations [1,6]

The number of patients with Influenza like illness is too high; I don't want to test everybody.

- Fast detection of Flu infection for emergency patients enables better decisions to be made for isolation, treatment and discharge. [7,8,9]
- Performance is key: Multiple and unique independent targets ensure optimum coverage and anticipate potential seasonal mutations [1,6]

I don't have enough resources to perform this test on site

- Xpert Xpress FLU/RSV is easy to run, providing rapid test results supports real-time medical decision-making during the patient presentation [10]

It is difficult to convince the general management to allocate budget for molecular screening especially in point of care settings

- Point of care testing significantly reduces the average turnaround time and speeds up treatment decisions improving patient flow in a busy acute medical unit. [1,2,3,4,5,11,12]

Probing Questions

- What are the main challenges you face regarding fast accurate respiratory triage?
- What is the rate of false neg you observe with Ag testing for symptomatic patients?
- How would you benefit from actionable results 24/7?

References

1. Xpert Xpress Flu/RSV Performance is key, Flyer (available on Seismic).
2. Muller MP, et al. Reduction in total patient isolation days with a change in influenza testing methodology. American journal of infection control 44(11) · November 1, 2016Volume 44, Issue 11, Pages 1346–1349
3. Valentin T, et al. Prospective evaluation of three rapid molecular tests for seasonal influenza in patients presenting at an emergency unit. J Clin Virol. 2019 Jan 7;111:29
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Emercengy Clinician

"I'm interested to learn more about

***Xpress** Flu/RSV*

today."

CE-IVD. *In Vitro* Diagnostic Medical Device. Not all tests available in all countries

Meet Our Cytologist

Goals

- Support clinicians by providing actionable and accurate results
- –Reduce length of stay and patient flow (door to discharge)

Challenges

- Competition with other biologists providing molecular diagnostics
- Not familiar with molecular biology

What they care about

- Provide quality results to clinicians
- Develop their activities

What is the Cepheid Story?

Develop activities by increasing the service offering to clinicians

- Easy and convenient to use GeneXpert System, with no environmental constraints and minimal training
- Scalable and flexible platform for optimized testing in any setting

They might be interested in :

Click on the colored **bold** tests to learn more

Respiratory	**Xpress** CoV-2/Flu/RSV plus **Xpress** CoV-2 plus Xpress Strep A **Xpress** Flu/RSV
HAI & Other Infectious Diseases	MRSA NxG SA Nasal Complete MRSA/SA Blood Culture MRSA/SA SSTI Carba-R Norovirus *C. difficile* BT *vanA/vanB*
TB & Emerging Infectious Diseases	MTB/RIF Ultra MTB/XDR Ebola CT/NG **HPV v2** **Xpress** GBS TV ***ResistancePlus*®** MG FleXible#
Blood Virology, Women's Health & Sexual Health	HBV Viral Load HCV Viral Load HCV VL Fingerstick HIV-1 Qual XC HIV-1 Viral Load XC
Oncology & Human Genetics	Bladder Cancer Detection Bladder Cancer Monitor Breast Cancer STRAT4 BCR-ABL Ultra BCR-ABL Ultra p190 NPM1 Mutation (AML) Thrombophilia (FII & FV)

CE-IVD. *In Vitro* Diagnostic Medical Device. Not all tests available in all countries

Elevator Pitch- Value Proposition

"Xpert HPV v2 test can be used with a Pap specimen or as a first-line primary screening, as well as providing partial genotyping, with individual call-outs for high-risk HPV types 16 and 18/45, for primary screening of women who are at risk of developing cervical cancer.

Customer Objections

We don't have staff with molecular diagnostic skills to run the HPV test.

- The Xpert HPV v2 is adaptable, tests can be performed in a decentralized setting in a lab environment, in a cytology centre, or in a molecular laboratory.

This is a screening test and there is no need for a quicker result.

- Have you considered the benefit of quick results to get full ownership of combined cytology and HPV results for better patient management?
- HPV results in around 60 minutes for same-visit clinician/ patient consult, minimizes the need for repeat visits, and follows the **WHO screen-and-treat approach**[1].

We send samples out to the molecular lab close by

- Most NAAT can be complicated to use and batch testing can delay results for colposcopy referral. [2,3]

Probing Questions

- How do you process HPV tests in your cytology laboratory?
- What will be the impact if you began to run molecular HPV tests in your cytology laboratory?
- How many samples do you process annually?

References

1. WHO guideline for screening and treatment of cervical pre-cancer lesions for cervical cancer prevention, second edition. Geneva: World Health Organization; 2021
2. Kundrod, K et al. Advances in technologies for cervical cancer detection in low-resource settings. Expert Rev Mol Diagn. 2019 Aug;19(8):695-714.
3. Cox JT, et al. Comparison of cervical cancer screening strategies incorporating different combinations of cytology, HPV testing, and genotyping for HPV 16/18: results from the Athena HPV study. Am J Obstet Gynecol. 2013 Mar;208(3):184.e1-184.e11.

Cytologist

"I'm interested to learn more about

HPV v2

today."

CE-IVD. *In Vitro* Diagnostic Medical Device. Not all tests available in all countries

Meet Our Hepatologist /Gastroenterologist

Goals

- Improve patient care
- Practice efficient medicine

Challenges

- Early Diagnosis to give correct patient treatment
- Prevent transmission of disease

What they care about

- Patient care and satisfaction

What is the Cepheid Story?

Improve patient outcomes with timely and accurate diagnosis

- Improve quality of care by providing the right treatment quickly, decreasing infection and spread
- Improve patient satisfaction through fast results

They might be interested in :

Click on the colored **bold** tests to learn more

Respiratory	**Xpress** CoV-2/Flu/RSV plus
	Xpress CoV-2 plus
	Xpress Strep A
	Xpress Flu/RSV
HAI & Other Infectious Diseases	MRSA NxG
	SA Nasal Complete
	MRSA/SA Blood Culture
	MRSA/SA SSTI
	Carba-R
	Norovirus
	C. difficile BT
	vanA/vanB
TB & Emerging Infectious Diseases	MTB/RIF Ultra
	MTB/XDR
	Ebola
Blood Virology, Women's Health & Sexual Health	CT/NG
	HPV
	Xpress GBS
	TV
	Resistance*Plus*® MG FleXible#
	HBV Viral Load
	HCV Viral Load
	HCV VL Fingerstick
	HIV-1 Qual XC
	HIV-1 Viral Load XC
Oncology & Human Genetics	Bladder Cancer Detection
	Bladder Cancer Monitor
	Breast Cancer STRAT4
	BCR-ABL Ultra
	BCR-ABL Ultra p190
	NPM1 Mutation (AML)
	Thrombophilia (FII & FV)

CE-IVD. *In Vitro* Diagnostic Medical Device. Not all tests available in all countries

Elevator Pitch - Value Proposition

"Xpert HBV Viral Load simplifies Hepatitis B disease management. Tests can be performed on demand in 57 minutes, and close to where the sample is taken and avoid delays due to send out and test numbers per batch.

It offers clinicians potential to deliver fast results for patients on treatment and to confirm diagnosis."

Customer Objections

Switching to another assay will affect my patient monitoring

- We have data from clinical trials and marketing studies comparing the Xpert HBV Viral Load with other suppliers test [1,2]. We can support you through a transition period where the two methods are compared as part of the verification.

I would like a faster service, but I don't know how to convince the lab to do this?

- The lab provides a service so that you can manage patients. If they understood what difference it would make to you it might help. Could you explain what impact a fast service would have on how you manage patient.

I suppose your costs are higher than the current lab method

- The value of our solution is in the impact on clinical management with a fast and accurate TAT*. It would be good to consider the costs linked to the clinical activities/administration when results take a long time[4,5].

*TAT: Turnaround time
** STI: Sexually Transmitted Infections

Probing Questions

- What are your current challenges with HBV Viral Load results and what would you like to improve about testing process? Are you currently happy with the TAT* and result quality?
- Could you tell me a little about your patients and how they get referred to you? In which situations/patients would it help to have a faster TAT*? What happens now if you need results urgently?
- Are there settings where you work (e.g. community/outreach) where a near patient HBV Viral load test/ co-testing (HIV, Hepatitis, STI**,TB) testing may be in could be beneficial?

References

1. Package insert Xpert HBV Viral Load (last update available on Seismic/InfoMine).
2. Abravanel F, et al. Performance of the Xpert HBV Viral Load assay versus the Aptima Quant assay for quantifying hepatitis B virus DNA Diagn Microbiol Infect Dis. 2019 Nov 16:114946
3. Auzin AM, et al. Rapid, ran dom-access, and quantification of hepatitis B virus using the Cepheid Xpert HBV viral load assay. J MedVirol. 2021 Jun;93(6):3999-4003.
4. Marcuccilli F, et al. Multicenter Evaluation of the Cepheid Xpert® HBV Viral Load Test. Diagnostics (Basel). 2021;11(2):297.
5. Sara C, et al. A new tool for simplified HBV Viral Load testing and disease management. Poster Presentation. 22nd ESCV (European Society For Clinical Virology) Annual Meeting. 11-14September 2019. Copenhagen, Denmark.
6. Rahamat-Langendoen JC, et al. Rapid quantification of HBV viral load using the Xpert HBV Viral Load assay. Poster Presentation.22nd ESCV (European Society For Clinical Virology) Annual Meeting. 11-14 September2019. Copenhagen, Denmark.
7. Cepheid-Viral-Load-Flyer-CEIVD (last update available on Seismic).

Hepatologist

"I'm interested to learn more about

HBV Viral Load

today."

CE-IVD. *In Vitro* Diagnostic Medical Device. Not all tests available in all countries

Elevator Pitch - Value Proposition

"Xpert HCV Viral load solution delivers fast results monitoring patients HCV Viral Load, comparable to current gold standard tests and for fast confirmation of HCV antibody positive patients. The high level of sensitivity provides greater confidence in monitoring for Sustained Virological Response (SVR) in patients on treatment.[1]"

Customer Objections

I think the lab use the same supplier for all viral load tests. I am not sure of the influence that I have over what tests they use

- We would like to understand what you would like to improve about the current services and how that could make a difference to the patient management. There may be a way to overcome these with our solution and discuss this with the lab.

My patients are being monitored with a different method currently. Changing test would impact their viral load results

- We have data [5] from clinical trials, independent proof sources that demonstrate that Xpert HCV Viral Load provides comparable results with another supplier's test, [1,2,3,4,6]. We can support you through a transition period where the two methods are compared.

The samples are sent to another lab to be tested so same day results is not a reality

- Our test is easy to perform and does not have to be restricted to a molecular lab. You could consider performing the testing onsite or a setting nearer to where the sample is taken[2,4].

*LOD: Limit of detection
** SVR: Sustained Virological Response

Probing Questions

- How long does it take to confirm with an HCV RNA test in antibody positive patients and how could it benefit you to have the confirmation of an antibody positive same day?
- How important is the performance of the VL assay for the range of genotypes to you and LOD* for detection of resistance, treatment failure and SVR**?
- Are there settings where you work (e.g. community/outreach) where a near-patient HBV Viral load test/ co-testing (HIV, Hepatitis, STI, TB) testing may be in could be beneficial?

References

1. McHugh MP, et al. Multicenter Evaluation of the Cepheid Xpert Hepatitis C Virus Viral Load AssayJ Clin Microbiol. 2017 May;55(5):1550-1556.
2. Gupta E, et al. Point -of -care testing (POCT) in molecular diagnostics: Performance evaluation of GeneXpert HCV RNA test in diagnosing and monitoring of HCV infection. J Clin Virol. 2017Mar;88:46-51.
3. WHO Prequalification of In Vitro Diagnostics PUBLIC REPORT Product: Xpert HCV Viral Load with GeneXpert Dx, GeneXpert Infinity-48s, and GeneXpert Infinity-80.
4. Rahamat-Langendoen JC, et al Rapid quantification of hepatis C virus using the Cepheid HCV assay: a comparison with cobas AmpliPrep/Cobas TaqMan HCV test. 22nd ESCV(European Society For Clinical Virology) Annual Meeting. 11-14 September 2019. Copenhagen, Denmark.poster_ESCV_HCV_Radboud UMC.pdf
5. Package insert Xpert HCV Viral Load (last update available on Seismic/InfoMine)
6. Cepheid-Viral-Load-Flyer-CEIVD (last update available on Seismic).

Hepatologist

"I'm interested to learn more about

HCV Viral Load

today."

CE-IVD. *In Vitro* Diagnostic Medical Device. Not all tests available in all countries

Meet Our Infectious Diseases Specialist, Pulmonologist

Goals

- Improve patient outcomes
- Provide long term care to patients with chronic infections/diseases
- –Identify the source of infection/ disease diagnosis early

Challenges

- Diagnose early their patient to treat
- Prevent transmission of disease

What they care about

- Patient care and satisfaction
- Improve patient quality of life

What is the Cepheid Story?

Improve quality of care by providing quicker the right treatment, decreasing infection and spread.

- Improve patient satisfaction through faster results

N.B. There are 2 different personas pages for Respi and MTB tests

They might be interested in :

Click on the colored **bold** tests to learn more

Respiratory	**Xpress** CoV-2/Flu/RSV ***plus***
	Xpress CoV-2 *plus*
	Xpress Strep A
	Xpress Flu/RSV
HAI & Other Infectious Diseases	MRSA NxG
	SA Nasal Complete
	MRSA/SA Blood Culture
	MRSA/SA SSTI
	Carba-R
	Norovirus
	C. difficile BT
	vanA/vanB
TB & Emerging Infectious Diseases	**MTB/RIF Ultra**
	MTB/XDR
	Ebola
Blood Virology, Women's Health & Sexual Health	CT/NG
	HPV v2
	Xpress GBS
	TV
	ResistancePlus® MG FleXible#
	HBV Viral Load
	HCV Viral Load
	HCV VL Fingerstick
	HIV-1 Qual XC
	HIV-1 Viral Load XC
Oncology & Human Genetics	Bladder Cancer Detection
	Bladder Cancer Monitor
	Breast Cancer STRAT4
	BCR-ABL Ultra
	BCR-ABL Ultra p190
	NPM1 Mutation (AML)
	Thrombophilia (FII & FV)

CE-IVD. *In Vitro* Diagnostic Medical Device. Not all tests available in all countries

Elevator Pitch - Value Proposition

"The Xpert Xpress CoV-2 plus test is designed to deliver fast and accurate diagnostic tests to enable better decision making, in as little as 20 minutes. Balancing timely treatment with an accurate triage, leading to correct use of isolation pathways at ED and reducing costs".*

Customer Objections

I have faster results with other tests such as antigen tests

- The antigenic tests have lower sensitivity and specificity compared to molecular.[1,2]
- How does performance impact infection control measures?[1,3,4,5,6]

Your assay is more expensive than other SARS-CoV-2 assays

- Less re-runs are important for fast patient discrimination specially among those who need urgent care.
- Consider the hidden costs of collapsed emergencies, wrong treatment prescription or incorrect patient discrimination. [7]

**For positives only with EAT (Early Assay Termination); reporting of negatives in approximately 30 minutes.*

Probing Questions

- How long does it take to get your SARS-CoV-2 result?
- How would you benefit from actionable results 24/7?
- What is the rate of false neg you observe with Ag testing for symptomatic patients?

References

1. Mak GC, Lau SS, Wong KK, Chow NL, Lau CS, Lam ET, Chan RC, Tsang DN. Analytical sensitivity and clinical sensitivity of the three rapid antigen detection kits for detection of SARS-CoV-2 virus. J Clin Virol. 2020 Dec;133:104684
2. Stockl et al. Use of Antigen and Molecular Testing for the Diagnosis of Coronavirus Disease 2019 (COVID-19) among Patients with Influenze-like Illness (ILI) in the Non-inpatient Setting. Association for Molecular Pathology 2023 Annual Meeting Abstracts. J Mol Diagn 2023, p 53 Abstract 006
3. Serei VD, et al. Comparison of abbott ID NOW COVID-19 rapid molecular assay to cepheid xpert xpress SARS-CoV-2 assay in dry nasal swabs. Diagn Microbiol Infect Dis. 2021 Apr;99(4):115208.
4. Basu A, et al. Performance of Abbott ID Now COVID-19 Rapid Nucleic Acid Amplification Test Using Nasopharyngeal Swabs Transported in Viral Transport Media and Dry Nasal Swabs in a New York City Academic
5. Hinson JS, et al. Targeted rapid testing for SARS-CoV-2 in the emergency department is associated with large reductions in uninfected patient exposure time
6. Hale B et al. Clinical impact of rapid molecular tests in patients with viral respiratory symptoms: a systematic literature review.
Presented at ISPOR Europe, November 2023, Copenhagen, Denmark. Poster MT10.
7. PLOS ONE, 3 August 2023, Point-of-care PCR testing of SARS-CoV-2 in the emergency department: Influence on workflow and efficiency. Accessed August 2023. https//doi.org/10.1371/journal.pone.0288906

Pulmonologist

"I'm interested to learn more about

Xpress** CoV-2 **plus

today."

Elevator Pitch - Value Proposition

"Xpert MTB/RIF Ultra for a rapid active case finding in TB suspected patients is recommended by WHO guidelines [1]"

Customer Objections

The lab decides which tests to use

- The choice of the test does influence your patient management. Isn't it in your interest to inform the laboratory how this test could impact your patient management? [1,2,3,4]

It doesn't fit into my current algorithm

- The WHO European Region Office recommends an algorithm with Xpert MTB/RIF Ultra as frontline diagnostic test prioritized over smear microscopy [1]

I have no time to talk to you about TB diagnostics

- I understand how busy you are, but you may be able to make more informed patient decisions when your lab uses the diagnostics you prefer?[1]

**For positives only with EAT (Early Assay Termination); reporting of negatives in approximately 30 minutes.*

Probing Questions

- How would a fast and accurate lab result influence your patient management?
- How do you guarantee fast active case detection?
- How important is quick exclusion of TB in your setting?

References

1. The World Health Organization (WHO). European Tuberculosis Laboratory Initiative. Algorithm for laboratory diagnosis and treatment-monitoring of pulmonary tuberculosis and drug-resistant tuberculosis using state-ofthe-art rapid molecular diagnostic technologies.
2. Dorman SE, et al. Lancet Infect Dis. 2018 Jan; 18(1):76-84. Xpert MTB/RIF Ultra for detection of Mycobacterium tuberculosis and rifampicin resistance: a prospective multicentre diagnostic accuracy study.
3. Luetkemeyer AF, et al. Clin Infect Dis. 2016 May 1;62(9):1081-8. Evaluation of Xpert MTB/RIF versus AFB Smear and Culture to Identify Pulmonary Tuberculosis in Patients with Suspected Tuberculosis from Low and Higher Prevalence Settings.
4. Parcell BJ, et al. J Infect. 2017 May;74(5):466- 472. Three-year evaluation of Xpert MTB/RIF in a low prevalence tuberculosis setting: A Scottish perspective

Infectious Disease Specialist/ Pulmonologist

"I'm interested to learn more about

Xpert MTB/RIF Ultra

today."

CE-IVD. *In Vitro* Diagnostic Medical Device. Not all tests available in all countries

Elevator Pitch - Value Proposition

"Cepheid Xpert MTB/XDR provide results for INH, FLQ and Second Line Injectable Drugs resistances in <90mins with equivalent accuracy to sequencing[1]. This means that you can test and treat TB patients with the most appropriate treatment within hours of their diagnosis."

Customer Objections

Phenotypic DST is still considered the as the gold standard and we can test more drugs.

- The treatment guidelines are calling for resistance testing to be performed to exclude drug resistance before treatment starts and highlight the need for using Molecular DST [2,3,4]
- We have good clinical and independent data to show the test compares very well with Phenotypic and sequencing based DST[4,5,6,7]. The value of the Xpert MTB/XDR is that it can be done in many more settings, with minimal training and it provides accurate results fast so that clinicians can offer patients the most appropriate treatment.

Most of our resistance cases are due to RIF and/or INH we don't see many XDR cases.

- By using the Xpert MTB/RIF Ultra as a frontline test and if positive for MTB testing the sample with Xpert MTB/XDR you have the best chance for detecting positive cases and for identifying RIF, INH and the second line resistances including resistance for the Fluoroquinolones
- WHO recommended new 4-month all-oral drug-susceptible TB regimen[7]. Cepheid's solution provides information to support the new 4-month all-oral regimen which includes Moxifloxacin (FLQ)

**For positives only with EAT (Early Assay Termination); reporting of negatives in approximately 30 minutes.*

Probing Questions

- How do you manage the treatment of patients diagnosed with TB? How often would you start treatment before you receiving the resistance results?
- How would having the resistance results within a day instead of wait make a different to you and your patients?
- Which patient groups would benefit most from having fast resistance results and why?

References

1. Xpert MTB-XDR Package Insert (last update available on Seismic/InfoMine).
2. Nahid P et al. Treatment of Drug-Resistant Tuberculosis An Official ATS/CDC/ERS/IDSA Clinical Practice Guideline. Am J Respir Crit Care Med Vol 200, Iss 10, pp e93–e142, Nov 15, 2019
3. WHO, December 2019, Rapid Communication: Key changes to the treatment of drug-resistant tuberculoses
4. WHO, Publication, 16 February 2021. Update on the use of nucleic acid amplification tests to detect TB and drug-resistant TB: rapid communication
5. Chakravorty S, et al. Improving Detection of Mycobacterium tuberculosis and Resistance to Rifampin in an Assay Suitable for Point-of-Care Testing.MBio 2017 Aug 29;8(4).
6. Chakravorty S, et al. Detection of Isoniazid-, Fluoroquinolone-, Amikacin-, and KanamycinResistant Tuberculosis in an Automated, Multiplexed 10-Color Assay Suitable for Pointof-Care Use. J clin Micro 55 2017.
7. WHO consolidated guidelines on tuberculosis. Module 4: treatment - drug-susceptible tuberculosis treatment. Accessed in Nov 2023 Module 4: Drug-resistant tuberculosis treatment | TB Knowledge Sharing (tbksp.org)

Infectious Disease Specialist/ Pulmonologist

"I'm interested to learn more about

Xpert MTB/XDR

today."

Elevator Pitch - Value Proposition

"Xpert HBV Viral Load simplifies Hepatitis B disease management. Tests can be performed on demand in 57 minutes, and close to where the sample is taken. It offers clinicians potential to deliver fast results for patients on treatment and to confirm diagnosis. "

Customer Objections

Switching to another assay will affect my patient monitoring

- We have data from clinical trials and marketing studies comparing the HBV with other suppliers test [1,2,4,5,6]. We can support you through a transition period where the two methods are compared as part of the verification.

The blood samples are sent to a central lab and I don't know how to change the whole process

- The Xpert HBV Viral Load test is simple to process and can be done in another setting closer to the patient to get fast results. Could we explore this?[3]

I suppose your costs are higher than the current lab method

- The value of our solution is in the impact on clinical management with a fast and accurate result. It would be good to consider the costs linked to the clinical activities/administration when results take a long time. [4,5]

*TAT: turnaround time
**STI: Sexually Transmitted Infections.

Probing Questions

- What are your current challenges with HBV Viral Load results and what would you like to improve about testing process? Are you currently happy with the TAT* and result quality?
- Could you tell me a little about your patients and how they get referred to you? In which situations/patients would it help to have a faster TAT*? What happens now if you need results urgently?
- Are there settings (community/outreach) where a near patient HBV Viral load test/ co-testing (HIV, Hepatitis, STI**, TB) testing may be in could be beneficial?

References

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2. Abravanel F, et al. Performance of the Xpert HBV Viral Load assay versus the Aptima Quant assay for quantifying hepatitis B virus DNA. Diagn Microbiol Infect Dis. 2019 Nov 16:114946.
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4. Marcuccilli F, et al. Multicenter Evaluation of the Cepheid Xpert® HBV Viral Load Test. Diagnostics (Basel). 2021;11(2):297.
5. Sara C, et al. A new tool for simplified HBV Viral Load testing and disease management. Poster Presentation. 22nd ESCV (European Society For Clinical Virology) Annual Meeting. 11-14 September 2019. Copenhagen, Denmark.
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Infectious diseases specialist

"I'm interested to learn more about

HBV Viral Load

today."

CE-IVD. *In Vitro* Diagnostic Medical Device. Not all tests available in all countries

Elevator Pitch - Value Proposition

"Xpert HCV Viral load solution delivers fast on demand results comparable to current gold standard tests for patients' viral load and confirmation of HCV antibody positive patients. The highest level of sensitivity provides greater confidence in monitoring for patients achieving Sustained Virological Response (SVR). [1]"

Customer Objections

I think the lab use the same supplier for all viral load tests. I am not sure the influence that I have over what tests they use.

- Please could you explain your main pain points? There may be a way to overcome these with our solution and discuss this with the lab.

My patients are being monitored with a different method currently. Changing test would impact on their viral load.

- We have data[5] from clinical trials and marketing studies comparing Xpert HCV Viral Load with another supplier's test, and a publication [1,2,3,4,6]. We can support you through a transition period where the two methods are compared.

The samples are sent to another lab to be tested so same day results is not a reality

- Our test is easy to perform and does not have to be restricted to a molecular lab. You could consider performing the testing onsite or a setting nearer to where the sample is taken [2,4].

*LOD: Limit of detection
** SVR: Sustained Virological Response

Probing Questions

- How long does it take to confirm with an HCV RNA test in antibody positive patients and how could it benefit you to have the confirmation of an antibody positive same day?
- How important is the performance of the VL assay for the range of genotypes to you and LOD* for detection of resistance, treatment failure and SVR**?
- Are there settings where you work (eg. community/outreach) where a near-patient HBV Viral load test/ co-testing (HIV, Hepatitis, STI, TB) testing may be in could be beneficial?

References

1. McHugh MP, et al. Multicenter Evaluation of the Cepheid Xpert Hepatitis C Virus Viral Load AssayJ Clin Microbiol. 2017 May;55(5):1550- 1556.
2. Gupta E, et al. Point -of -care testing (POCT) in molecular diagnostics: Performance evaluation of GeneXpert HCV RNA test in diagnosing and monitoring of HCV infection. J Clin Virol. 2017 Mar; 88:46-51.
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4. Rahamat-Langendoen JC, et al Rapid quantification of hepatis C virus using the Cepheid HCV assay: a comparison with cobas AmpliPrep/Cobas TaqMan HCV test. 22nd ESCV (European Society For Clinical Virology) Annual Meeting. 11-14 September 2019. Copenhagen, Denmark.
5. Package insert Xpert HCV Viral Load (last update available on Seismic/InfoMine).
6. Cepheid-Viral-Load-Flyer-CEIVD (last update available on Seismic).

Infectious diseases specialist

"I'm interested to learn more about

HCV Viral Load

today."

Elevator Pitch - Value Proposition

"Xpert HIV-1 Viral Load XC with dual targets, provides fast results and has the potential for same day results for monitoring patients. This means that the number of appointments to manage by clinical teams and for patients to attend could be reduced, improving patient satisfaction as well as service efficiency."

Customer Objections

I have the results in time for my next appointment with patients. I don't see how having results faster would make a difference.

- Could you summarize your main pain points with patient management? Having more timely results is only one benefit of our solution that could help with certain patients.
- Patients may be more motivated to adhere when they receive their VL results soon after their doctor's visit.

It would be difficult to change methods as we are monitoring patients for years. we have data to compare different methods.

- We have proof sources showing how well our solution compares with other suppliers[1,2,3,4]. We can provide a suitable reference and support your discussions with end users.

I suppose your costs are higher than the current lab

- The value of our solution is in the impact on clinical management with a faster and accurate TAT*. It would be good to consider the costs linked to the clinical activities/administration when results take a long time.[5]

*TAT – Turn around time

Probing Questions

- What could be the impact on your patient management if you could have the viral load results in the same day/one visit and how could this help patients (especially those travelling from afar)?
- What would you like to improve in your current Viral Load testing service/process and how could that make a difference to you and patients?
- Are there settings or patients that you work with (e.g. Hospital/community/outreach), where a near patient HIV Viral load test/co-testing (HIV, HBV/HCV/STI/TB) testing could be beneficial?

References

1. Nash M, et al., Performance of the Xpert, HIV-1viral load assay: a systematic review and meta-analysis. J Clin Microbiol. 2018 Mar 26;56(4).
2. Bouige A, et al. Implementation of the GeneXpert technology for the routinely viral load monitoring of HIV-positive patients. Poster presentation. 27th ECCMID (European Congress of Clinical Microbiology and Infectious Diseases), 22- 25 April 2017 . Vienna, Austria.Virology ECCMID 2017 Bouige et al HI
3. Mor O, et al. Evaluation of the RealTime HIV-1,Xpert HIV-1, and Aptima HIV-1 Quant Dx Assays in Comparison to the NucliSens EasyQ HIV-1v2.0 Assay for Quantification of HIV-1 Vira lLoad viral load. J Clin Microbiol 53:3458 –3465.
4. Jordan JA, et al., Multi-site clinical evaluation of the Xpert HIV-1 viral load assay. J Clin Virol.2016 80:27- 32.
5. Cepheid-Sexual-Health-Virology-POCT-Community-Clinic-Flyer-CE-IVD-3182 (latest update available on Seismic).

Infectious disease specialist

"I'm interested to learn more about

HIV-1 Viral Load XC

today."

Meet Our Gynaecologist, Urologist, Midwife, Obstetrician, Paediatrician, Neonatologist

Goals

- Provide quality care
- Practice efficient medicine

Challenges

- Diagnose and treat efficiently their patients

What they care about

- Patient care and satisfaction
- Compliance to treatment
- Public health

What is the Cepheid Story?

Improve patient care with impactful diagnosis results

- Improve quality of care by providing quicker the right treatment, decreasing infection and transmission
- Improve patient satisfaction through faster results

* There are 3 persona pages for Xpert Xpress GBS (Gynaecologist, Midwife, Paediatrician)

Exclusively distributed by Cepheid under the FleXible for GeneXpert System program

They might be interested in :

Click on the colored **bold** tests to learn more

Respiratory	**Xpress** CoV-2/Flu/RSV ***plus***
	Xpress CoV-2 ***plus***
	Xpress Strep A
	Xpress Flu/RSV
HAI & Other Infectious Diseases	MRSA NxG
	SA Nasal Complete
	MRSA/SA Blood Culture
	MRSA/SA SSTI
	Carba-R
	Norovirus
	C. difficile BT
	vanA/vanB
TB & Emerging Infectious Diseases	MTB/RIF Ultra
	MTB/XDR
	Ebola
Blood Virology, Women's Health & Sexual Health	**CT/NG**
	HPV v2
	Xpress GBS*
	TV
	***ResistancePlus*® MG FleXible#**
	HBV Viral Load
	HCV Viral Load
	HCV VL Fingerstick
	HIV-1 Qual XC
	HIV-1 Viral Load XC
Oncology & Human Genetics	Bladder Cancer Detection
	Bladder Cancer Monitor
	Breast Cancer STRAT4
	BCR-ABL Ultra
	BCR-ABL Ultra p190
	NPM1 Mutation (AML)
	Thrombophilia (FII & FV)

CE-IVD. *In Vitro* Diagnostic Medical Device. Not all tests available in all countries

Elevator Pitch - Value Proposition

" Xpert CT/NG enables health care professionals to improve the treatment outcomes of Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (NG) infections with accurate results in 88 minutes and supports the prevention of antibiotic resistance

Xpert CT/NG detects DNA from C. trachomatis and N. gonorrhoeae from Vaginal, Endocervical, Pharyngeal, Rectal, and Urine specimens, for Female and Male.[1]"

Customer Objections

In most cases, I can make a diagnosis with a physical examination and offer the patient treatment during the appointment

- Different STIs* have similar symptoms but need different treatment method and antibiotics. Are there times when the lab results mean you need to change the treatment?

A shorter TAT* of test results won't help.

- Fast results mean the most appropriate treatment can be given, resolving infection and helping to prevent transmission.

I have no influence on the laboratory or their selection criteria for CT/NG testing

- Could you request a shorter delay (same day) to your laboratory to receive the results, which will impact the service to your patients by enabling quicker treatment.

Our IT system is very old and slow, therefore, faster results doesn't benefit our service

- A fast test helps manage your time better - so you only manage positive patients to diagnose and treat.

* STI: Sexually Transmitted Infections
** turnaround time

Probing Questions

- What is the current TAT** from the lab for CT/NG testing today?
- Would a fast and accurate CT/NG test help you in clinical diagnosis and treatment for at risk patients (Asymptomatic vs Symptomatic)?
- How could targeted fast testing improve your service to your patients?

References

1. Package insert Xpert CT/NG (last update available on Seimic/InfoMine)
2. Berçot B, et al . Assessment of Coinfection of Sexually Transmitted Pathogen Microbes by Use of the Anyplex II STI Molecular Kit. J ClinMicrobiol. 2015;53(3):991-3.

Gynaecologist

"I'm interested to learn more about

CT/NG

today."

Elevator Pitch - Value Proposition

"Xpert HPV v2 provides fast results for early detection and prevention of HPV-related diseases, minimizing the need for repeat visits. It can be used with a Pap specimen or as a first-line primary screening."

Customer Objections

I am not the decision maker for the HPV test selection

- Xpert HPV v2 provides partial genotyping, with individual call-outs for high-risk **HPV types 16 and 18/45**, for **primary screening** of women who are at risk of developing cervical cancer.
- The Xpert HPV v2 is easy to use when compared to other NAATs that can be complicated to use and batch testing can delay results for colposcopy referral. [1,2]

I don't need a rapid turn-around test

- Xpert HPV v2 provides fast results for early detection and prevention of HPV-related diseases, minimizing the need for repeat visits. It can be used with a Pap specimen or as a first-line primary screening.
- Rapid Results: HPV results in around 60 minutes for same-visit clinician/ patient consult, minimizes the need for repeat visits, and follows the WHO screen-and-treat approach[3].

Probing Questions

- What is the time between the collection of the sample and the communication of the results to the patients?
- How do you detect/identify the important other high-risk HPV genotypes?
- How important is it for you to receive quicker results to help you to guide patient management?

References

1. Kundrod, K et al. Advances in technologies for cervical cancer detection in low-resource settings. Expert Rev Mol Diagn. 2019 Aug;19(8):695-714.
2. Cox JT, et al. Comparison of cervical cancer screening strategies incorporating different combinations of cytology, HPV testing, and genotyping for HPV 16/18: results from the Athena HPV study. Am J Obstet Gynecol. 2013 Mar;208(3):184.e1-184.e11.
3. WHO guideline for screening and treatment of cervical pre-cancer lesions for cervical cancer prevention, second edition. Geneva: World Health Organization; 2021

Gynaecologist

"I'm interested to learn more about

HPV v2

today."

Elevator Pitch - Value Proposition

"A fast and accurate intrapartum & antepartum PCR test for GBS could allow you to limit IAP to only those women who are in need and avoid inappropriate antibiotic prescriptions.[1]"*

Customer Objections

We are happy with our current algorithmantepartum screening by culture

- Antenatal culture performance may be suboptimal, so newborns may still be at risk of Early-Onset GBS infections and inadequate IAP* may be administered to the mothers [2,3,4]
- By the time the women show up to deliver, it is too late to get the result on time. With Xpert Xpress GBS, results are obtained in as quick as approximately 30 minutes with a procedure that has less than one-minute hands-on time. Testing can be done in the near patient setting (for example in the delivery room).[5]

We prefer risk-based screening as it'simple.

- Universal PCR-screening is even simpler asprotocols can be agreed beforehand based onthe test results. [6]

We are delivering IAP to all women with unknown status.**

- Are you aware of the impact of IAP** on thenewborn microbiota? Treating the patient only when is necessary, directly affects the health of the newborn: any disturbance of the initial process of colonization by the microbiome could affect the health of the child in the long term: obesity, diabetes, inflammatory diseases of the digestive tract, and allergies.

In my hospital, we have only a few (less than 5) Group B streptococcus infections per year.

- Even if the number of EOD** faced in your institution is small, the clinical conditions of the newborns can be severe and can lead to sequelae and generate extra-costs due to prolonged length of stay. [6]

*IAP: Intrapartum antibiotic prophylaxis

**EOD: Early Onset Disease

Probing Questions

- What is your current standard practice to determine who is receiving IAP*?
- Do you know that there is a high risk of GBS status change following screening at 35-37 weeks of gestation?
- Do you know the European consensus paper on Intrapartum GBS screening and antibioticprophylaxis? [1]

References

1. Xpert Xpress GBS Flyer-CEIVD (last update available on Seismic)
2. Intrapartum GBS screening and antibiotic prophylaxis: a European consensus conference; J Matern Fetal Neonatal Med. 2015 May;28(7):
3. Zietek M, Jaroszewicz-Trzaska J, Szczuko M, Mantiuk R, Celewicz Z. Intrapartum PCR assay is a fast and efficient screening method for Group B Streptococcus detection in pregnancy. Ginekol Pol. 2020;91(9):549-553. doi: 10.5603/GP.2020.0088. PMID: 33030736.
4. Picchiassi E, et al. Intrapartum test for detection of Group B Streptococcus colonization during labor. J Matern Fetal Neonatal Med. 2017 Aug 31:1-8.
5. Arboleya S, et al. Intestinal microbiota development in preterm neonates and effect of perinatal antibiotics. J Pediatr. 2015 Mar;166(3):538-44
6. Björklund V, et al, Replacing risk-based early-onset-disease prevention with intrapartum group B streptococcus PCR testing. J Matern Fetal Neonatal Med. 2017 Feb;30(3):368-373.
7. Zimmermann P, et al. Effect of intrapartum antibiotics on the intestinal microbiota of infants: a systematic review. Arch Dis Child Fetal Neonatal Ed.2020 Mar;105(2):201–8.
8. Blaser MJ et al., Infant antibiotic exposures and early-life body mass, Int J Obes (Lond). 2013 January; 37(1): 16–23

Gynaecologist

"I'm interested to learn more about

Xpress GBS

today."

Elevator Pitch - Value Proposition

With Xpert Xpress GBS, you can perform GBS testing and obtain reliable and fast results. Running the test is very easy and enables a real impact on IAP treatment with benefits for the mother and newborn.*

Customer Objections

I have no time to perform any test at the time of delivery

- With Xpert Xpress GBS, you can perform GBS testing and obtain reliable results with a procedure requiring very little hands-on time.[1]

I have no lab skills to perform the test

- Xpert Xpress GBS assay solution is very easy to use, requires minimal training with no environmental constraint and can be run by non-specialized staff in molecular biology [2] . Morover, the sample adequacy control ensures the swab has been incorporated correctly into the cartridge [3].

It is not my duty to perform lab testing.

- Using Xpert Xpress GBS at the time of delivery will bring benefits for the mother and new-born. The test is easy to use and aimed at being used in delivery rooms.

How do we manage women who give birth in less than 4 hours and for whom we do not have time to administer antibiotics if needed?

- What is the % of women who give birth in less than 4 hours in your institution? Xpert Xpress GBS test is an on-demand test that is extremely easy to use (less than 1 minute handling time), with a fast turnaround time (42 minutes for negative results and approximately 30 minutes for positive results). It provides accurate and actionable results for appropriate antibiotic prophylaxis administration. For very rapid deliveries (<4 hours), it will be necessary to follow your institution's protocol concerning the monitoring of newborns at risk of neonatal infections. Intrapartum GBS positive results may help doctors decide whether both mothers and babies should be monitored for longer in the hospital and promptly act in case of sepsis developed during hospital stay.

*IAP: intrapartum antibiotic prophylaxis

Probing Questions

- How could a rapid test available to determine GBS carriage at the time of delivery improve patient care?
- What other tests do you perform for pregnant women at the time of delivery?
- Are you willing to provide better support to your patients?
- Do you want to have a tool that will help you for the right use of IAP*?

References

1. Arboleya S, et al. Intestinal microbiota development in preterm neonates and effect of perinatal antibiotics. J Pediatr. 2015 Mar;166(3):538-44.
2. Helmig RB, et al. Diagnostic accuracy of polymerase chain reaction for intrapartum detection of group Bstreptococcus colonization. Acta Obstet Gynecol Scand. 2017 Sep;96(9):1070-1074.
3. 3. Helmig RB, et al. Intrapartum PCR-assay for detectionof Group B Streptococci (GBS). European Journal of Obstetrics & Gynecology and Reproductive Biology: X. 2019 Oct;4:10008

Midwife

"I'm interested to learn more about

Xpress GBS

today."

Elevator Pitch - Value Proposition

"With intrapartum testing by Xpert Xpress GBS, intravenous antibiotics can be delivered in labour to all GBS carrier women with the goal of preventing GBS infection in newborn babies.[1]"

Customer Objections

No technique is available today to get GBS carriage status at the time of delivery

- Yes, Xpert Xpress GBS will allow intrapartum testing at the time of delivery.[1,3,4]

We are delivering IAP to all women with unknown status**

- Are you aware of the impact of IAP** on the newborn microbiota? 5 Treating the patient only when is necessary, directly affects the health of the newborn: any disturbance of the initial process of colonization by the microbiome could affect the health of the child in the long term: obesity, diabetes, inflammatory diseases of the digestive tract, and allergies.[6]

How do we manage women who give birth in less than 4 hours and for whom we do not have time to administer antibiotics if needed?

- What is the % of women who give birth in less than 4 hours in your institution?
- Xpert Xpress GBS test is an on-demand test that is extremely easy to use (less than 1 minute handling time), with a fast turnaround time (42 minutes for negative results and approximately 30 minutes for positive results). It provides accurate and actionable results for appropriate antibiotic prophylaxis administration.
- For very rapid deliveries (<4 hours), it will be necessary to follow your institution's protocol concerning the monitoring of newborns at risk of neonatal infections. Intrapartum GBS positive results may help doctors decide whether both mothers and babies should be monitored for longer in the hospital and promptly act in case of sepsis developed during hospital stay.

Neonatal GBS infection rates are now very low, demonstrating that antenatal culture provides good results and that this method meets our needs

- How many neonatal infections do you have in your hospital?
- The culture has indeed contributed to a decrease in neonatal infections but is done at the right time (the time of delivery) and it takes time. There is a risk of change in GBS carriage status after screening at 35-37 weeks of pregnancy.[7] There is a low correlation between the results of antenatal culture screening and intrapartum PCR tests.[8]

In addition, some women may present at delivery with an unknown status.

IAP: intrapartum antibiotic prophylaxis

Probing Questions

- What is the GBS infection rate in your Hospital?
- Does your laboratory offer an intrapartum GBS screening test? If not, do you think such a program could be helpful to avoid/reduce GBS disease?
- Are you aware of the impact of antibiotics exposure on newborns?[2]

References

1. Xpert Xpress GBS Flyer-CEIVD (last update available on Seismic)
2. Björklund V, et al. Replacing risk-based early-onsetdisease prevention with intrapartum group B streptococcus PCR testing. J Matern Fetal Neonatal Med. 2017 Feb;30(3):368-373.
3. Helmig RB, et al. Diagnostic accuracy of polymerase chain reaction for intrapartum detection of group B streptococcus colonization. Acta Obstet Gynecol Scand. 2017 Sep;96(9):1070-1074.
4. Intrapartum GBS screening and antibiotic prophylaxis: a European consensus conference; J Matern Fetal Neonatal Med. 2015 May;28(7).
5. Zimmermann P, et al. Effect of intrapartum antibiotics on the intestinal microbiota of infants: a systematic review. Arch Dis Child Fetal Neonatal Ed. 2020 Mar;105(2):201–8.
6. Blaser MJ et al., Infant antibiotic exposures and early-life body mass, Int J Obes (Lond). 2013 January; 37(1): 16–23
7. Zietek M, et al. Intrapartum PCR assay is a fast and efficient screening method for Group B Streptococcus detection in pregnancy. Ginekol Pol. 2020;91(9):549–53
8. Young BC, Dodge LE, Gupta M, Rhee JS, Hacker MR. Evaluation of a rapid, real-time intrapartum group B streptococcus assay. Am J Obstet Gynecol. 2011 Oct;205(4):372.e1-6.

Paediatrician

"I'm interested to learn more about

Xpress GBS

today."

CE-IVD. *In Vitro* Diagnostic Medical Device. Not all tests available in all countries

Elevator Pitch - Value Proposition

"MG FleXible detects not only M. genitalium, but also the mutations associated with macrolide resistance. Its technology allows you to get reliable and quick results for informed treatment and to avoid unnecessary costs associated with empiric therapy, confirmatory testing andsystem set-up & maintenance. It also helps to reduce time of notification to the patient and onward transmission of the infection to the partner. [5] "

Customer Objections

I do not have many cases that present a resistance to Azithromycin (macrolides)

- Macrolide resistance mediating mutations are continuously increasing, and rates vary from country to country (20-80%). [4]

Your test does not detect the resistance to fluoroquinolones

- The European guidelines do not recommend testing for fluoroquinolones resistance due to the lack of clinical relevance. [2]

I am satisfied with the outcome of my patients using empirical antibiotic treatment

- With the widespread macrolide resistance in Europe, it is strongly recommended that all positive tests be followed up with an assay capable of detecting macrolide resistance mediating mutations.[2]
- There is also evidence of a considerable improvement in cure rate (from 48% to 95%) over the last years linked to appropriate therapy administration [6].

Probing Questions

- Are you aware that the EuropeanGuidelines for *M. genitalium* strongly recommended that all positive tests should be followed up with an assay capable of detecting macrolide resistance mediating mutations? [2]
- Do you know the percentage of macrolide resistancefor *M. genitalium* in your country? [3]
- Do you give empirical treatment to your patients while you are waiting for the results of a diagnostic test?
- Can you describe the patient flow from check inthrough results reporting?
- Are you aware that testing for macrolide resistance has been proven to reduce time to cure from 48 to 95%?

References

1. Package insert ResistancePlus MG FleXible (last update available on Seismic/InfoMine).
2. Jensen JS, et al. 2016 European guideline on Mycoplasma genitalium infections. J Eur Acad Dermatol Venereol. 2016 Oct;30(10):1650-1656
3. Dumke R, et al. Prevalence of macrolide- and fluoroquinolone-resistant Mycoplasma genitalium strains in clinical specimens from men who have sex with men of two sexually transmitted infection practices in Berlin, Germany. 019 Sep;18:118-121. doi: 10.1016/j.jgar.2019.06.015 Available at
4. Tabrizi SN, et al. Prospective Evaluation of ResistancePlus MG, a New Multiplex Quantitative PCR Assay for Detection of Mycoplasma genitalium and Macrolide Resistance. J Clin Microbiol. 2017 Jun; 55(6): 1915–1919
5. Bercot B, et al . Assessment of Coinfection of Sexually Transmitted Pathogen Microbes by Use of the Anyplex II STI-7 Molecular Kit. J Clin Microbiol. 2015 ;53(3):991-3
6. Read TRH, et al. Outcomes of Resistance-guided Sequential Treatment of Mycoplasma genitalium Infections: A Prospective Evaluation. Clin Infect Dis. 2019 Feb 1;68(4):554-560

* Manufactured by SpeeDx and exclusively distributed byCepheid under the FleXible for GeneXpert System program

Gynaecologist

"I'm interested to learn more about

ResistancePlus® MG FleXible

today."

Meet Our Haematologist, Clinician Haematology Nurse

Goals

- Improving Patient outcomes and care
- Best Service Provision

Challenges

- Fast and accurate identification of deviations from target guideline responses
- Patient Treatment Adherence

What they care about

- Patient care and satisfaction
- Adhering to guideline recommendations

What is the Cepheid Story?

Improve quality of care with a fast and sensitive monitoring test

- Reduce waiting times
- Optimize patient treatment adherence
- Improve patient satisfaction

They might be interested in :

Click on the colored **bold** tests to learn more

Respiratory	**Xpress** CoV-2/Flu/RSV ***plus***
	Xpress CoV-2 ***plus***
	Xpress Strep A
	Xpress Flu/RSV
HAI & Other Infectious Diseases	MRSA NxG
	SA Nasal Complete
	MRSA/SA Blood Culture
	MRSA/SA SSTI
	Carba-R
	Norovirus
	C. difficile BT
	vanA/vanB
TB & Emerging Infectious Diseases	MTB/RIF Ultra
	MTB/XDR
	Ebola
Blood Virology, Women's Health & Sexual Health	CT/NG
	HPV
	Xpress GBS
	TV
	Resistance*Plus*® MG FleXible#
	HBV Viral Load
	HCV Viral Load
	HCV VL Fingerstick
	HIV-1 Qual XC
	HIV-1 Viral Load XC
Oncology & Human Genetics	Bladder Cancer Detection
	Bladder Cancer Monitor
	Breast Cancer STRAT4
	BCR-ABL Ultra
	BCR-ABL Ultra p190
	NPM1 Mutation (AML)
	Thrombophilia (FII & FV)

CE-IVD. *In Vitro* Diagnostic Medical Device. Not all tests available in all countries

Elevator Pitch - Value Proposition

*"Sensitive, standardized and easy to use quantitative monitoring of BCR-ABL1 mRNA both major or minor breakpoints in patients with Chronic Myeloid Leukemia[1] (CML) or Acute Lymphoblastic leukemia[2] (ALL) in **150 minutes**, offering the ability to optimize patient pathways."*

Customer Objections

Lack of additional Hematology menu

- Cepheid are actively working on increasing their Haematology Menu; meanwhile let's look at the volumes for the other tests you are interested in, and short-term options fortheir testing.[3]

I need copy number in my reports

- Copy number requirement is a sensitivity measure; we have data within our PI showing results are produced with copy number levels reaching that sensitivity required.[4]

There is no need for a faster turn-around time

- Current guidelines and publications show early and routine monitoring of CML patients is crucial to achieve long-term treatment goals[5]. Frequent Molecular Monitoring is also associated with greater treatment adherence [6]. In fact, a recent study has shown monitoring of clinical response in the first year of TKI treatment is not performed as frequently as guidelines suggest; only 36% in the first 3 months [7].

Your price is too high

- What are you comparing our pricing to? What does this include? How did you get to that value? What steps are involved, and how much does it cost to standardize your current testing procedure? Explore with the Customer their TRUE current cost for testing. Question around batching/wasted reagents; costs to standardize to IS; failure rate/repeats due to delayed batch testing (mRNA degredation); all hidden costs. Include staff level and hands on time. Consider CE-IVDR regulation requirements.

Probing Questions

- Tell me about your current monitoring test algorithm?
- How do you feel it could be improved for the benefit of your patients and yourself as their Clinician?
- Are you or your patients chasing ALL or CML treatment monitoring results?

References

1. Cepheid Xpert BCR ABL Flyer: Improving the Quality of Life for your Patients. A Patient Survey Analysis (Last update available).
2. Hochhaus et al. European LeukemiaNet 2020 recommendations for treating chronic myeloid leukemia. Leukemia, Apr;34(4):966-984.
3. Cepheid-Menu-Test-Overview-CE-IVD (last update available on Seismic)
4. Package Insert Xpert BCR-ABL Ultra (last update available on Seismic/InfoMine).
5. Goldberg SL, et al. First-line treatment selection and early monitoring patterns in chronic phase-chronic myeloid leukemia in routine clinical practice: SIMPLICITY. Am J Hematol. 2017 Nov; 92(11): 1214- 1223
6. Westerweel PE, et al. Impact of hospital experience on the quality of tyrosine kinase inhibitor response monitoring and consequence for chronic myeloid leukemia patient survival. Haematologica. 2017 Dec;102(12): e486–e489
7. Gambacorti-Passerini C, et al. Treatment patterns and clinical outcomes of tyrosine kinase inhibitors in chronic-phase CML in clinical practice: 3-year European SIMPLICITY data. Eur J Haematol. 2021;106(1):82-89.

Haematologist

"I'm interested to learn more about

BCR-ABL Ultra &
BCR-ABL Ultra p190

today."

CE-IVD. *In Vitro* Diagnostic Medical Device. Not all tests available in all countries

Elevator Pitch - Value Proposition

"Xpert NPM1 Mutation is an automated test for quantifying the amount of mutant NPM1 mRNA transcripts as a ratio of NPM1 Mutation/ABL1 with high sensitivity, in less than 3 hours following sample reception.[1] Facilitating the decision-making process at critical moments thanks to the sensitivity and quality of the test."

Customer Objections

There is no need for a faster turn-around time

- Convenience of testing and fast results could potentially help reduce patient anxiety.
- The possibility of providing a result in less than 3 hours following sample reception[1] allows the early prediction of a relapse to be quickly identified and monitor the treatment and care effectiveness.
- Relapse remains the most common cause of treatment failure for AML patients.[2] Timely monitoring ensures measurement of treatment response and detection of potential relapse.[3]

Your price is too high

- What are you comparing our pricing to? What does this include? How did you get to that value? What steps are involved, and how much does it cost to standardize your current testing procedure? Explore with the customer their TRUE current cost for testing. Question around batching/wasted reagents; costs to standardize to IS; failure rate/repeats due to delayed batch testing(mRNA degradation); all hidden costs. Include staff level and hands on time. Consider CE-IVDR regulation requirements

Probing Questions

- Tell me about your current monitoring test algorithm?
- How do you feel it could be improved for the benefit of your patients and yourself as their Clinician?
- Are you or your patients chasing AML treatment monitoring results?

References

1. Instructions for use of the Xpert NPM1 Mutation (302-8304)
2. Dillon R, Hills R, Freeman S, Potter N, Jovanovic J, Ivey A, Kanda AS, Runglall M, Foot N, Valganon M, Khwaja A, Cavenagh J, Smith M, Ommen HB, Overgaard UM, Dennis M, Knapper S, Kaur H, Taussig D, Mehta P, Raj K, Novitzky-Basso I, Nikolousis E, Danby R, Krishnamurthy P, Hill K, Finnegan D, Alimam S, Hurst E, Johnson P, Khan A, Salim R, Craddock C, Spearing R, Gilkes A, Gale R, Burnett A, Russell NH, Grimwade D. Molecular MRD status and outcome after transplantation in NPM1-mutated AML. Blood. 2020 Feb 27;135(9):680-688. doi: 10.1182/blood.2019002959. PMID: 31932839; PMCID: PMC7059484.
3. Hafez M, Ye F, Jackson K, Yang Z, Karp JE, Labourier E, Gocke CD. Performance and clinical evaluation of a sensitive multiplex assay for the rapid detection of common NPM1 mutations. J Mol Diagn. 2010 Sep;12(5):629-35. doi: 10.2353/jmoldx.2010.090219. Epub 2010 Jul 8. PMID: 20616361; PMCID: PMC2928427.

Haematologist

"I'm interested to learn more about

NPM1 Mutation

today."

Meet Our Hospital/Health Care Executive, Hospital Manager, Finance Manager

Goals

- Achieve Hospital goals which include finance
- Provide High quality service to the community

Challenges

- Competition with the other Hospitals
- Need to manage patient and physician satisfaction
- Declining reimbursements and budget

What they care about

- Generate income or volume
- –Improve patient care
- –Reduces cost through time saving or other means

What is the Cepheid Story?

Cepheid is Your Technology & Business Partner Today and Tomorrow

- Improve quality through standardized molecular testing
- Cost-efficiency by consolidating platforms/technology
- System capacity, flexible, scalable and adaptable to fit every testing volume need and through-put variation.
- Optimized care through faster, more accurate results

They might be interested in :

Click on the GeneXpert®Systems to learn more

GeneXpert Systems

Respiratory	**Xpress** CoV-2/Flu/RSV ***plus***
	Xpress CoV-2 ***plus***
	Xpress Strep A
	Xpress Flu/RSV
HAI & Other Infectious Diseases	MRSA NxG
	SA Nasal Complete
	MRSA/SA Blood Culture
	MRSA/SA SSTI
	Carba-R
	Norovirus
	C. difficile BT
	vanA/vanB
TB & Emerging Infectious Diseases	MTB/RIF Ultra
	MTB/XDR
	Ebola
Blood Virology, Women's Health & Sexual Health	CT/NG
	HPV
	Xpress GBS
	TV
	Resistance*Plus*® MG FleXible#
	HBV Viral Load
	HCV Viral Load
	HCV VL Fingerstick
	HIV-1 Qual XC
	HIV-1 Viral Load XC
Oncology & Human Genetics	Bladder Cancer Detection
	Bladder Cancer Monitor
	Breast Cancer STRAT4
	BCR-ABL Ultra
	BCR-ABL Ultra p190
	NPM1 Mutation (AML)
	Thrombophilia (FII & FV)

CE-IVD. *In Vitro* Diagnostic Medical Device. Not all tests available in all countries

Elevator Pitch - Value Proposition

"Cepheid's GeneXpert System provides fast, accurate and on-demand PCR results, 24/7, helping to ensure uninterrupted clinical service delivery, optimized patient flow and improved outbreak prevention. Cepheid's solution enables rapid deployment of high-volume, standardized and consolidated testing within and across your healthcare institutions, for equity of service and efficiency."

Customer Objections

Your solution is too expensive

- What do you mean by expensive? What are you comparing our pricing to? What does this include?
- It is important to note the impact of rapid results on the whole hospital. Have you considered the benefits and cost-savings in terms of length of stay, avoiding unnecessary treatments/isolations and improved outbreak prevention? On-demand, 24/7 PCR is associated with more effective use of hospital resources and reduced costly clinical service disruption.[1,2]

Your solution is good for urgent samples, but not for higher volume testing

- Cepheid's uniquely scalable solution enables rapid deployment of standardized testing to meet increasing clinical demand. With testing capabilities from 1 to 2,000 results per day,^ Cepheid provides a high-volume, flexible solution for all healthcare institution requirements.

*Turnaround times vary by test. See individual Product Inserts for specific turnaround times.

^Cepheid internal study based on 30-minute test results

Probing Questions

- What would it mean for your healthcare professionals, patients and your wider hospital/institution if you were able to provide actionable, on-demand PCR results in 1 hour* average, 24/7, including weekends?
- What impact has providing fast and accurate urgent results for COVID-19 in under 1 hour had on patient flow and managing transmission and outbreaks?
- Did you know you can easily consolidate testing for other infectious diseases commonly associated with large outbreaks and severe clinical service disruption, such as Flu, MRSA, C. difficile and carbapenem-resistant bacteria?
- Would you be interested in reducing the number of molecular platforms used in your Hospital? Do you know the cost-savings this could enable in term of maintenance, training and staff organisation?

References

1. Corless C, et al. Impact of different carbapenemase-producing Enterobacterales screening strategies in a hospital setting. IPIP. 2020 May;3(2):100011
2. Casari E, et al. Reducing rates of C. difficile infection by switching to a stand-alone NAA with clear sampling criteria. Antimicrob Resist Infect Control. 2018 Mar;7(40)

Other useful documents:
- Cepheid GeneXpert Systems Infographic (last update available on Seismic).
- Cepheid GeneXpert Infinity System Brochure (last update available on Seismic).
- GeneXpert System Test Menu Flyer (last update available on Seismic).

Health Care Executive

"I'm interested to learn more about

GeneXpert System

today."

Thank You

www.cepheid.com

Cepheid
A better way.