

# Assay Technical Training Xpert<sup>®</sup> Carba-R

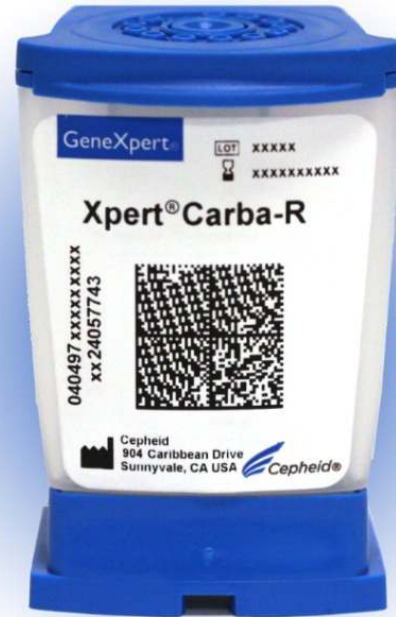
For CE-IVD Use Only (not available in all countries)

*Cepheid Training Center*



# Training Agenda

- **Xpert Carba-R Training**
  - Reagents
  - Sample collection
  - Kit storage and handling
  - Preparing the cartridge
  - Quality Controls
  - Results analysis
- **Discussion**





# Training Objectives

- **At the end of the training, users will be able to:**
  - Store and handle the Xpert<sup>®</sup> Carba-R kit
  - Follow proper laboratory safety precautions
  - Collect and transport appropriate specimen(s)
  - Prepare a cartridge and run the assay
  - Report and understand various software generated results
  - Understand the assay control strategy

# The Cepheid Solution



- Simultaneous detection and differentiation of five common classes of carbapenem-resistance genes
  - KPC, NDM, VIM, OXA-48, IMP
- On-board internal controls for each sample
  - Probe Check Control (PCC)
  - Sample Processing Control (SPC)
- Closed cartridge system minimizes risk of contamination
- On-demand results
- Random access

# Intended Use

- The Xpert® Carba-R Assay, performed on the GeneXpert® Instrument Systems, is a qualitative *in-vitro* diagnostic test designed for the **detection and differentiation of the *bla*<sub>KPC</sub>, *bla*<sub>NDM</sub>, *bla*<sub>VIM</sub>, *bla*<sub>OXA-48</sub>, and *bla*<sub>IMP</sub> gene sequences associated with carbapenem-non-susceptibility**. The test utilizes automated real-time polymerase chain reaction (PCR).
- The Xpert Carba-R Assay is intended as an aid to infection control in the detection of carbapenem-non-susceptible bacteria that colonize patients in healthcare settings. A negative Xpert Carba-R Assay result does not preclude the presence of other resistance mechanisms.

(Continued to next page)

# Intended Use

The Xpert Carba-R Assay is for use with the following sample types:

## Pure Colonies

- The assay is performed on carbapenem-non-susceptible pure colonies of *Enterobacteriaceae*, *Acinetobacter baumannii*, or *Pseudomonas aeruginosa*, when grown on blood agar or MacConkey agar. For testing pure colonies, the Xpert Carba-R Assay should be used in conjunction with other laboratory tests including phenotypic antimicrobial susceptibility testing.
- The identification of a *bla*<sub>IMP</sub>, *bla*<sub>NDM</sub>, or *bla*<sub>VIM</sub> metallo-beta-lactamase gene (i.e., the genes that encode the IMP, NDM, and VIM metallo-beta-lactamases, respectively) **may be used as an aid to clinicians in determining appropriate therapeutic strategies for patients with known or suspected carbapenem-non-susceptible bacterial infections.**

## Rectal and Perirectal Swab Specimens

- The assay is performed on rectal and perirectal swab specimens from patients at risk for intestinal colonization with carbapenem-non-susceptible bacteria. Concomitant cultures are necessary to recover organisms for epidemiological typing, antimicrobial susceptibility testing, and for further confirmatory bacterial identification.
- The Xpert Carba-R Assay, when performed on rectal and perirectal swab specimens, is not intended to guide or monitor treatment for carbapenem-non-susceptible bacterial infections or to determine infection from carbapenem-non-susceptible bacteria.

# Carba-R Requirements

## GeneXpert Systems

- GeneXpert Software **v4.3** or higher

## Test Kits

- GXCARBARP-CE-10 and GXCARBARP-CE-120

## Sample Collection

- Cepheid Specimen Collection Device- Catalog Number 900-0370

## Other materials

- Blood or MacConkey agar
- 10 µg meropenem disks
- Sterile forceps
- Disposable, sterile 10 µL inoculating loops
- Vortex mixer
- Personal Protective Equipment (PPE)
- 1:10 bleach
- 70% ethanol or denatured ethanol

## Optional

- Uninterruptible Power Supply /Surge Protector
- Printer
- Vortex



# Good Laboratory Practice

## Personnel Protective Equipment (PPE)

- Wear clean lab coats and gloves
- Change gloves between processing samples

## Lab Bench area

- Clean work surfaces routinely with:
  - ✓ 1:10 dilution of household bleach
  - ✓ 70% ethanol solution
- \* Final active chlorine concentration should be 0.5% regardless of the household bleach concentration in your country
- After cleaning, ensure that the work surfaces are dry

## Specimens, Samples, and Kits Storage

- Store specimens and sample away from kit to prevent contamination

## Equipment

- Use filtered tips when recommended
- Follow the manufacturer's requirements for calibration and maintenance of equipment



# Kit Handling



# Xpert Carba-R Kit Contents

	<b>GXCARBARP-CE-10 GXCARBARP-CE-120</b>
<b>Cartridges Per Kit</b>	10/120
<b>Reagent Vials</b>	10/120
<b>Transfer Pipettes</b>	10/120
<b>Kit CD</b>	Assay Definition File (ADF)
	Assay Import Instructions
	Package Insert (PDF)
<b>Storage</b>	2-28 °C



*Cartridges contain chemically hazardous substances-please see Package Insert and Safety Data Sheet for more detailed information.*



# Xpert Carba-R Kit Storage and Handling

- Store the Xpert Carba-R cartridges and reagents at 2–28°C
- Follow your institution's safety procedures for working with chemicals and handling biological samples
- Do not use collection devices that have not been validated by Cepheid
- Open the assay cartridge lid only when adding the sample, close the lid and proceed with processing





# Warnings and Precautions

- Do not shake the cartridge
- Do not use a cartridge that... :
  - appears wet, has leaked, or has a lid seal appears to have been broken
  - appears damaged
  - has been dropped after removing it from packaging
  - has been dropped or shaken after adding the sample to it
  - has a damaged reaction tube
  - has been used; each cartridge is single-use to process one test
  - is expired
- Do not reuse disposable pipettes

# Warnings and Precautions

- Biological specimens, transfer devices, and used cartridges should be considered capable of transmitting infectious agents and require use of standard precautions.
- Follow your institution's environmental waste procedures for proper disposal of used cartridges and unused reagents. These materials may exhibit characteristics of chemical hazardous waste requiring specific national or regional disposal procedures.
- If national or regional regulations do not provide clear direction on proper disposal, biological specimens and used cartridges should be disposed per WHO [World Health Organization] medical waste handling and disposal guidelines.

# Specimen Collection, Storage and Transport



# Rectal/Perirectal Specimen Collection Device



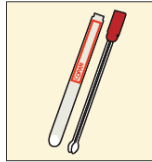
**Cepheid Part Number 900-0370**

SCORE MARK

# Rectal/Perirectal Swab Specimen Collection Protocol

## Rectal/Perirectal Specimen Collection

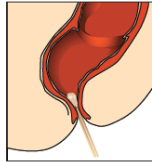
- 1 Use Cepheid Collection Device #900-0370 to collect the specimen.



- 2 OR

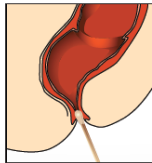
### Rectal Swab Sample

Carefully insert both swab tips approximately 1 cm beyond the anal sphincter and rotate gently.

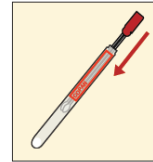


### Perirectal Swab Sample

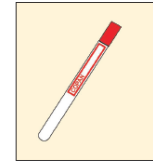
Carefully insert both swab tips no more than 1 cm into the anal opening before the anal sphincter and rotate gently.



- 3 Place the swab pair back into the transport tube.

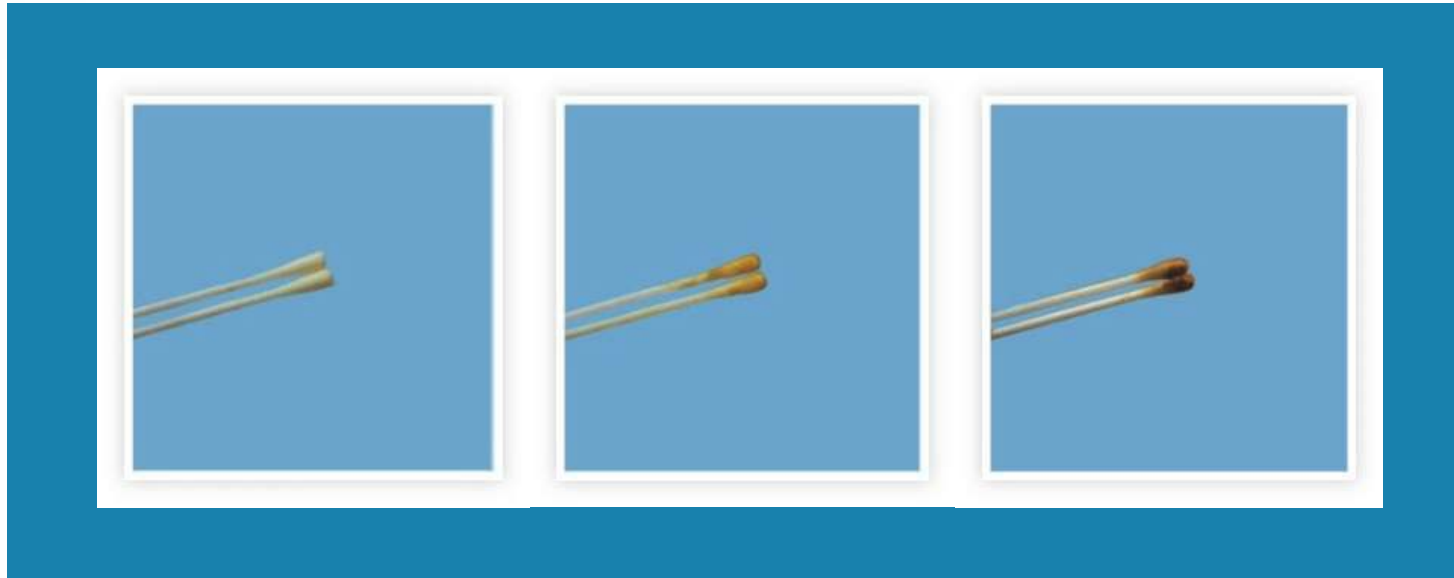


- 4 Swabs in the transport tube can be stored at 15-28 °C for up to five days.





# Acceptable Swab Specimens



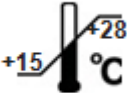
# Unacceptable Swab Specimens



**Examples of Highly Soiled Swabs**  
**Do not use with the Xpert Carba-R Assay**



# Specimen Collection, Transport and Storage

Sample Type	Transport and Storage Conditions
Rectal/ Perirectal Swab Specimen	 up to 5 days

# Bacterial Isolate Sample Preparation

## Xpert® Carba-R Cartridge Preparation

preparing 0.5 McFarland suspension of a carbapenem-non-susceptible bacterial isolate

Refer to the package insert for detailed instructions, precautions, and warnings.

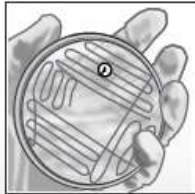
For a copy of the SDS, visit [www.cepheid.com](http://www.cepheid.com) or [www.cepheidinternational.com](http://www.cepheidinternational.com)

Cepheid Technical Support  
US office  
(888) 838-3222  
[techsupport@cepheid.com](mailto:techsupport@cepheid.com)

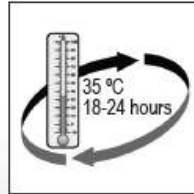
European office  
+33 563 82 53 19  
[support@cepheideurope.com](mailto:support@cepheideurope.com)



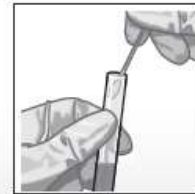
- 1 Inoculate the organism onto either a blood or MacConkey agar plate, streak for isolation and place a 10 µg meropenem disk in the first streak quadrant to ensure that the isolate is still carbapenem-non-susceptible.



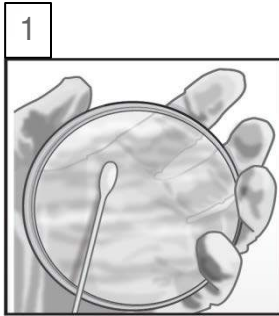
- 2 Incubate the plate at 35 °C for 18-24 hours in ambient air.



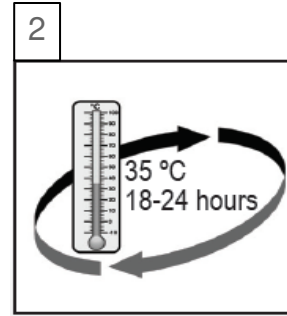
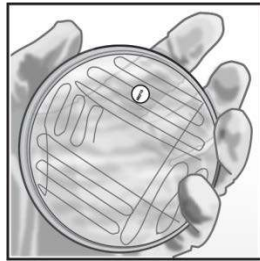
- 3 Use the direct colony suspension method by touching isolated colonies with a swab or loop to prepare a 0.5 McFarland suspension of the bacterial isolate. Refer to the package insert for further details.



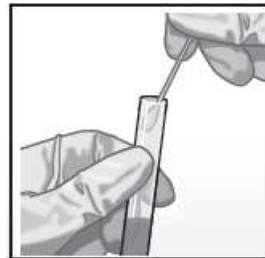
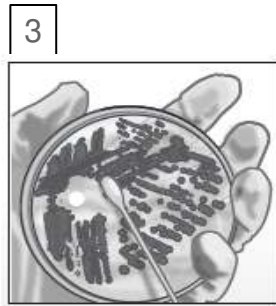
# Bacterial Isolate Sample Preparation



Inoculate the organism onto either a blood or MacConkey agar plate, streak for isolation and place a 10 µg meropenem disk in the first streak quadrant to ensure that the isolate is still carbapenem-non-susceptible.



Incubate the plate at 35 °C for 18-24 hours in the ambient air.



Use the direct colony suspension method by touching isolated colonies with a swab or loop to prepare a 0.5 McFarland suspension of the bacterial isolate. Refer to the package insert for further details.

# Cartridge Preparation



# Rectal/Perirectal Swab Cartridge Preparation

## Xpert® Carba-R Cartridge Preparation using rectal or perirectal swab

Refer to the package insert for detailed instructions, precautions, and warnings.

For a copy of the SDS, visit [www.cepheid.com](http://www.cepheid.com) or [www.cepheidinternational.com](http://www.cepheidinternational.com)

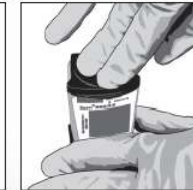
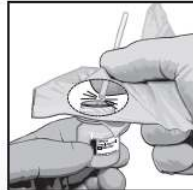
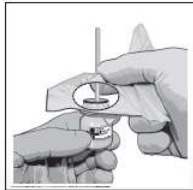
Cepheid Technical Support

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[support@cepheideurope.com](mailto:support@cepheideurope.com)



- 1 Obtain one Xpert cartridge and one Sample Reagent vial for each sample.
- 2 Insert the swab into the Sample Reagent vial.
- 3 Break the swab at the score mark near the opening of the vial.
- 4 Recap the Sample Reagent vial and vortex for 10 seconds.
- 5 Open the Xpert cartridge lid.
- 6 Aspirate the Sample Reagent up to the line on the supplied pipette.
- 7 Empty the pipette into the sample chamber.
- 8 Close the Xpert cartridge lid.
- 9 Start the test within the timeframe specified in the package insert.



Note: Do not hold the swab below the score mark. Use gauze or its equivalent to minimize the risk of contamination.

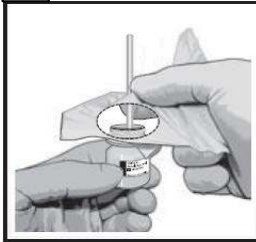
# Rectal/Perirectal Swab Cartridge Preparation

1



Obtain one Xpert cartridge and one Sample Reagent vial for each sample.

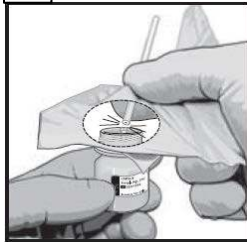
2



Insert the swab into the Sample Reagent vial.

Note: Do not hold the swab below the score mark. Use gauze or its equivalent to minimize the risk of contamination.

3



Break the swab at the score mark near the opening of the vial.

4



Recap the Sample Reagent vial and vortex at high speed for 10 seconds.

5



Open the Xpert cartridge lid.

6



Aspirate the Sample Reagent up to the line on the supplied pipette.

7



Empty the pipette into the sample chamber.

8



Close the Xpert cartridge lid.

9

Start the test within the timeframe specified in the package insert.



# Bacterial Isolate Cartridge Preparation

## Xpert® Carba-R Cartridge Preparation using a prepared 0.5 McFarland suspension of a carbapenem non-susceptible bacterial isolate

Refer to the package insert for detailed instructions, precautions, and warnings.

For a copy of the SDS, visit [www.cepheid.com](http://www.cepheid.com) or [www.cepheidinternational.com](http://www.cepheidinternational.com)

Cepheid Technical Support

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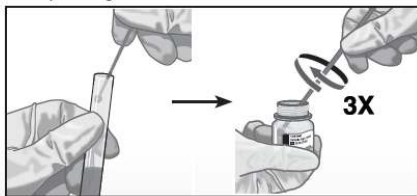
European office  
+33 563 82 53 19  
[support@cepheideurope.com](mailto:support@cepheideurope.com)



- 1 Remove a Xpert Carba-R Assay cartridge, a Sample Reagent vial and a transfer pipette from the kit. Open the vial of Sample Reagent.



- 2 Vortex the 0.5 McFarland suspension. Using a 10 µL loop, transfer 10 µL of the 0.5 McFarland suspension to the Sample Reagent vial.



Swirl the loop a minimum of 3 times in the Sample Reagent.

- 3 Close the Sample Reagent cap tightly and vortex at high speed for 10 seconds.



- 4 Open the Xpert cartridge lid.



- 5 Using the transfer pipette provided, aspirate prepared sample up to the mark on the pipette (approximately 1.7 mL).



- 6 Empty the pipette into the sample chamber.



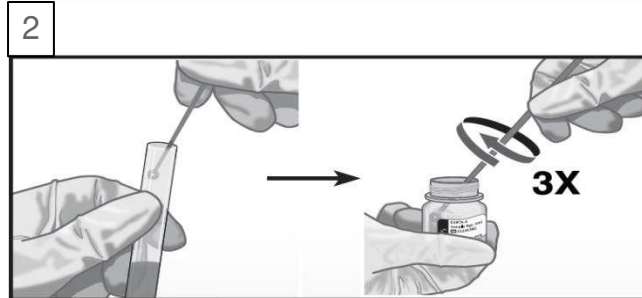
- 7 Close the Xpert cartridge lid. Start the test within the timeframe specified in the package insert.



# Bacterial Isolate Cartridge Preparation: using 0.5 McFarland suspension of bacterial isolate

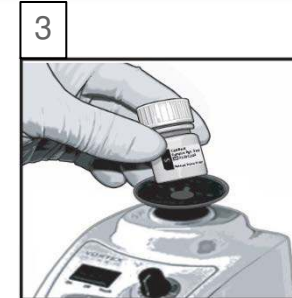


Remove a Xpert Carba-R Assay cartridge, a Sample Reagent vial and a transfer pipette from the kit. Open the vial of Sample Reagent.

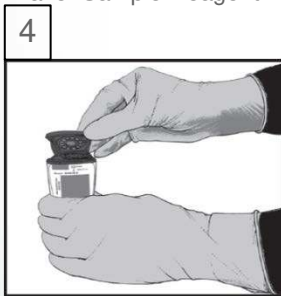


Vortex the 0.5 McFarland suspension. Using a 10 µL loop, transfer 10 µL of the 0.5 McFarland suspension to the Sample Reagent vial.

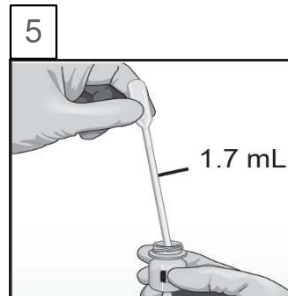
Swirl the loop a minimum of three times in the Sample Reagent.



Close the Sample Reagent cap tightly and vortex at high speed for 10 seconds.



Open the Xpert cartridge lid.



Using the transfer pipette provided, aspirate prepared sample up to the mark on the pipette (approximately 1.7 mL).



Empty the pipette into the sample chamber.



Close the Xpert cartridge lid. Start the test within the timeframe specified in the package insert.

# Run a Test

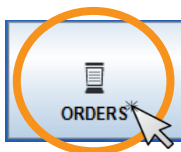
## 1 Create Test

### GeneXpert Dx



Start the test within **30 minutes** after adding the sample to the cartridge

### GeneXpert Infinity Xpertise



Place the cartridge on the conveyor within **30 minutes** of adding the sample.

## 2 Scan barcode : Cartridge, Patient and/or Sample ID




*By default, do not click on **Manual Entry** or **Cancel***

Order Test - Assay

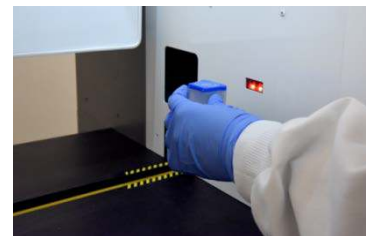
Scan Cartridge Barcode

Cartridge barcode is successfully scanned when you hear the beep.



Patient ID	P19005
Sample ID	S1900512345
Priority	Normal

## 3 Scan the cartridge



*"For complete details on how to run a test, refer to the Package Insert and the GeneXpert Dx or GeneXpert Infinity Xpertise Operator Manuals.*

# Create a Test on GeneXpert Dx Software

4 Complete the fields as required

5 The assay protocol is selected automatically

6 The module is selected automatically

7 Click on Start Test

8 A green light will flash on the module  
Load the cartridge into module and close the door

The screenshot shows the 'Create Test' window with the following fields and values:

- Patient ID: [Empty]
- Sample ID: [Empty]
- Patient ID 2: [Empty]
- Last Name: [Empty]
- Select Assay: Xpert Assay name
- Select Module: A3
- Reagent Lot ID\*: 16119
- Expiration Date\*: 2016/1/17
- Test Type: Specimen
- Sample Type: Other
- Notes: [Empty]

The 'Start Test' button is highlighted with an orange box and a mouse cursor is pointing at it.



# Create a Test on Xpertise Software

4 Complete the fields as required

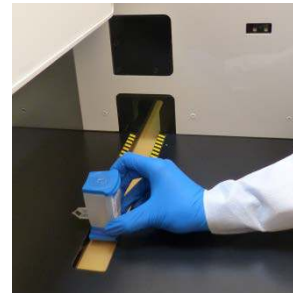
**Order Test - Test Information**

<b>Patient ID</b> patientid	
<b>Sample ID</b> sampleid	
<b>Last Name</b> patient	<b>First Name</b> id
<b>Assay*</b> Xpert Assay	
<b>Reagent Lot ID*</b> 12102	<b>Cartridge S/N*</b> 282769448
<b>Expiration Date*</b> 2018/11/04	<b>Priority</b> Normal
<b>Test Type</b> Specimen	<b>Other Sample Type*</b>
<b>Sample Type</b> Other	
<b>Notes</b>	

5 The Assay Name Protocol is selected automatically

6 Click on SUBMIT

7 Place the cartridge into the conveyor belt





# Automated Xpert Protocol



# Quality Controls





# Assay Control Strategy

CONTROL

## Xpert Assay Quality Controls

- Each Xpert cartridge is a self-contained test device
- Cepheid designed specific molecular methods including internal controls that enable the system to detect specific failure modes within each cartridge
  - Probe Check Control (PCC)
  - Sample Processing Control (SPC)

Refer to 301-4868 GeneXpert Quality Control Features for All Cepheid Xpert Assays





# Internal Quality Controls

## Probe Check Controls (PCC)

- Before the PCR step, fluorescence signal is measured on all probes and compared with default factory settings to monitor
  - bead rehydration
  - reaction tube filling
  - probe integrity
  - dye stability

## Sample Processing Control (SPC)

- Verifies that conditions for adequate sample processing were met
- Detects PCR inhibition
- Should be positive in a negative sample
- Can be positive or negative in a positive sample

# Commercially Available External Controls

Company	Description	Catalog Number
Maine Molecular Quality Controls, Inc.	<p><b>Positive control</b> - inactivated <i>E. coli</i> carrying plasmid with KPC, NDM, VIM, IMP, OXA-48 gene sequences</p> <p><b>Negative control</b> – inactivated <i>E.coli</i> with same plasmid minus carbapenemase gene sequences</p>	M219: Xpert Carba-R QC Panel (6 x 50 µL vials, each control)
American Type Culture Collection (ATCC) and National Collection of Type Cultures (NCTC)	<p><i>K. pneumoniae</i> KPC-2</p> <p><i>K. pneumoniae</i> NDM-1</p> <p><i>K. pneumoniae</i> VIM-1</p> <p><i>K. pneumoniae</i> OXA-48</p> <p><i>E. coli</i> IMP-1</p>	<p>ATCC BAA-1705</p> <p>ATCC BAA-2146</p> <p>NCTC 13439</p> <p>NCTC 13442</p> <p>NCTC 13476</p>

External controls should be used in accordance with local, state, and federal accrediting organizations, as applicable.

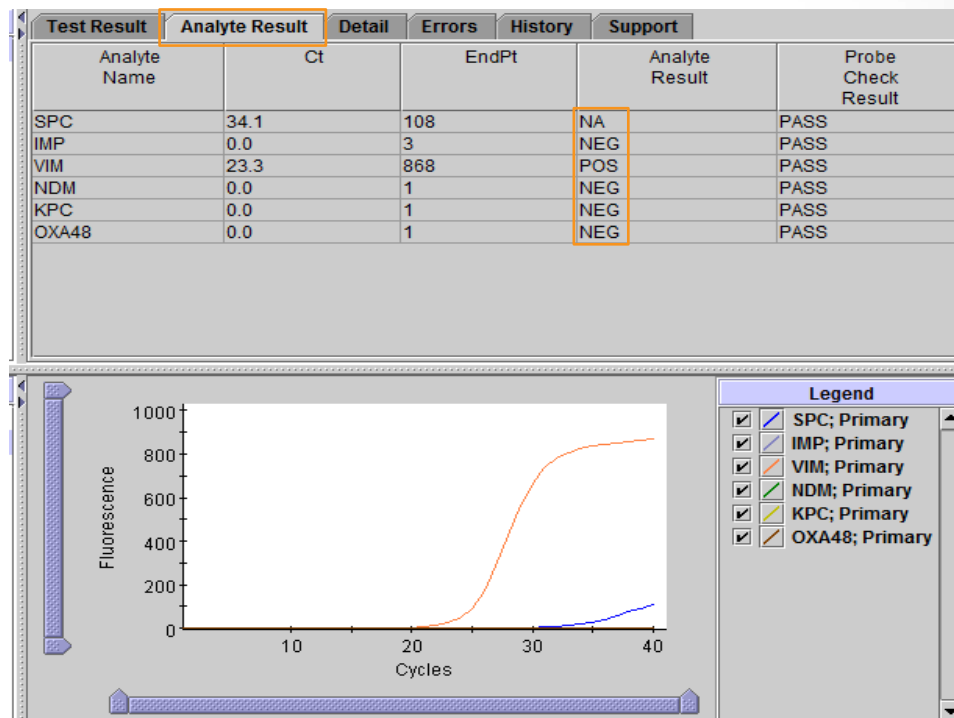
# Result Interpretation



# IMP NOT DETECTED; VIM DETECTED; NDM NOT DETECTED; KPC NOT DETECTED; OXA-48 NOT DETECTED

IMP NOT DETECTED;  
VIM DETECTED;  
NDM NOT DETECTED;  
KPC NOT DETECTED;  
OXA48 NOT DETECTED

- **VIM** target DNA sequence is detected
- IMP, NDM, KPC, and OXA-48 target DNA sequences are not detected.
- PCR amplification of the VIM target DNA gives a Ct value within the valid range and a fluorescence endpoint above the threshold setting; IMP, NDM, KPC, and OXA-48 target DNA sequences are absent or below the assay detection level.
- SPC: Not applicable. The SPC is ignored because VIM target DNA amplification may compete with this control.
- PCC: PASS; all probe check results pass.



# IMP NOT DETECTED; VIM NOT DETECTED; NDM DETECTED; KPC NOT DETECTED; OXA-48 DETECTED

IMP NOT DETECTED;  
VIM NOT DETECTED;  
NDM DETECTED;  
KPC NOT DETECTED;  
OXA48 DETECTED

- IMP, VIM, and KPC target DNA sequences are not detected.
- **NDM** and OXA-48 target DNA sequences are detected
- PCR amplification of the NDM and OXA-48 target DNAs give Ct values within the valid ranges and fluorescence endpoints above the threshold settings; IMP, VIM, and KPC target DNA sequences are absent or below the assay detection level.
- SPC: Not applicable. The SPC is ignored because NDM and OXA-48 target DNA amplifications may compete with this control.
- PCC: PASS; all probe check results pass.



# IMP, VIM, NDM DETECTED – THERAPEUTIC STRATEGIES

- Therapeutic strategies that include antimicrobial agents, such as beta-lactam/beta-lactamase inhibitor combinations with limited or no activity against bacteria producing metallo-beta-lactamases, should be used with caution when pure colonies of *Enterobacteriaceae*, *Pseudomonas aeruginosa*, and *Acinetobacter baumannii* are identified by Xpert® Carba-R as **IMP DETECTED**, **NDM DETECTED**, or **VIM DETECTED**, which indicates the presence of metallo-beta-lactamase genes.

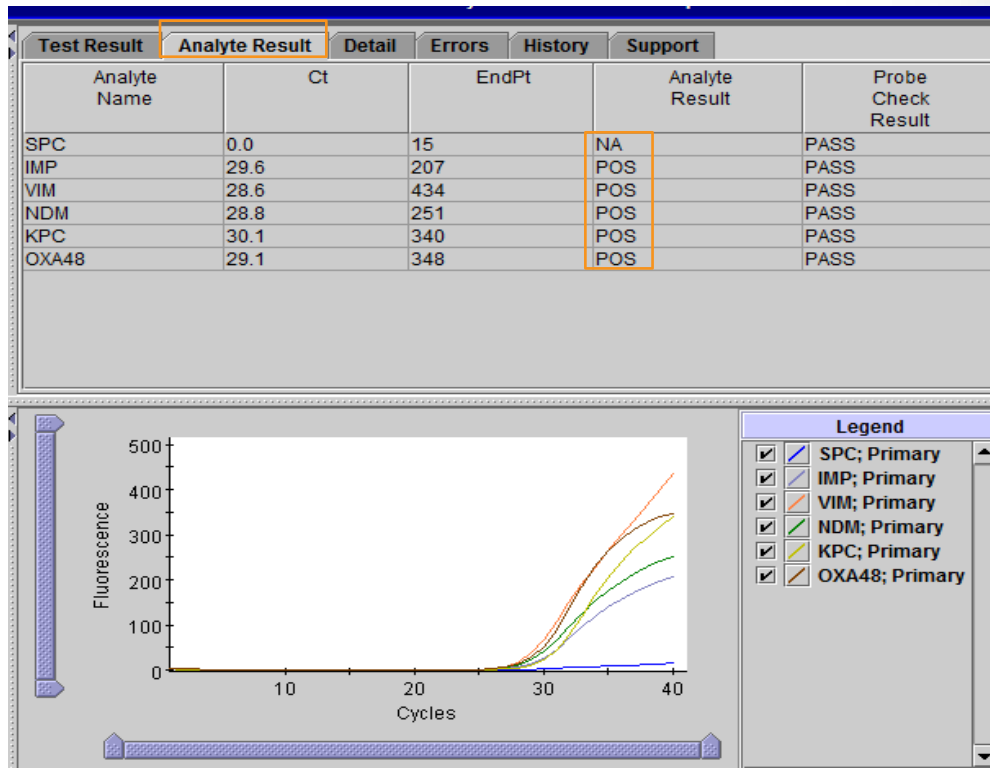
## Package Insert References:

10. van Duin D, et al. 2016. Ceftazidime/avibactam and ceftolozane/tazobactam: second-generation  $\beta$ -lactam/ $\beta$ -lactamase inhibitor combinations. Clin Infect Dis. 63(2):234-241.
11. Falcone M, Paterson D. 2016. Spotlight on ceftazidime/avibactam: a new option for MDR gram-negative infections. J Antimicrob. 71(10):2713-2722.
12. Navas, M and Jacobs M. 2016. Carbapenem Resistant *Enterobacteriaceae* - A review for laboratorians. American Association for Clinical Chemistry (AACC) Clinical Laboratory News.
13. Vasoo S, et al. 2015. *In vitro* activities of ceftazidime-avibactam, aztreonam-avibactam, and a panel of older and contemporary antimicrobial agents against carbapenemase-producing gram-negative bacilli. Antimicrob Agents Chemother. 59(12):7842-7846.
14. Avycaz package insert. Section 14.2 Microbiology.

# IMP DETECTED; VIM DETECTED; NDM DETECTED; KPC DETECTED; OXA-48 DETECTED

IMP DETECTED;  
VIM DETECTED;  
NDM DETECTED;  
KPC DETECTED;  
OXA48 DETECTED

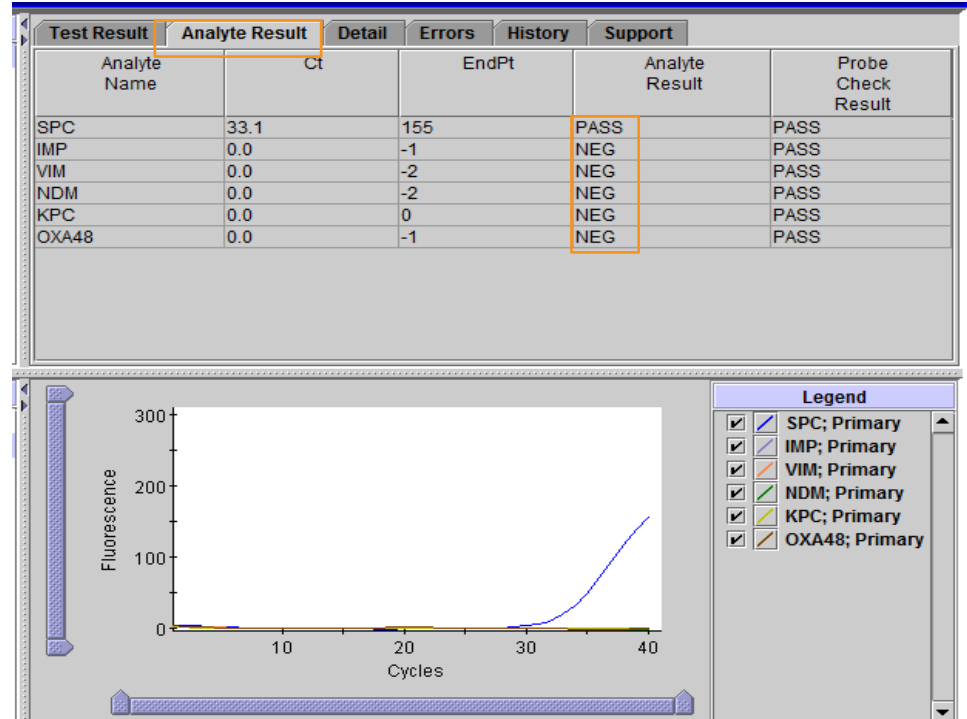
- IMP, VIM, NDM, KPC, and OXA-48 target DNA sequences are detected.
- PCR amplification of the IMP, VIM, NDM, KPC, and OXA-48 target DNAs give Ct values within the valid ranges and fluorescence endpoints above the threshold settings.
- SPC: Not applicable. The SPC is ignored because IMP, VIM, NDM, KPC, and OXA-48 target DNA amplifications may compete with this control.
- PCC: PASS; all probe check results pass.



# IMP NOT DETECTED; VIM NOT DETECTED; NDM NOT DETECTED; KPC NOT DETECTED; OXA-48 NOT DETECTED

IMP NOT DETECTED;  
VIM NOT DETECTED;  
NDM NOT DETECTED;  
KPC NOT DETECTED;  
OXA48 NOT DETECTED

- IMP, VIM, NDM, KPC, and OXA-48 target DNA sequences are not detected.
- IMP, VIM, NDM, KPC, and OXA-48 target DNA sequences are absent or below the assay detection level.
- SPC: PASS; PCR amplification of the SPC DNA sequence gives a Ct value within the valid range and a fluorescence endpoint above the threshold setting.
- PCC: PASS; all probe check results pass.





# Troubleshooting





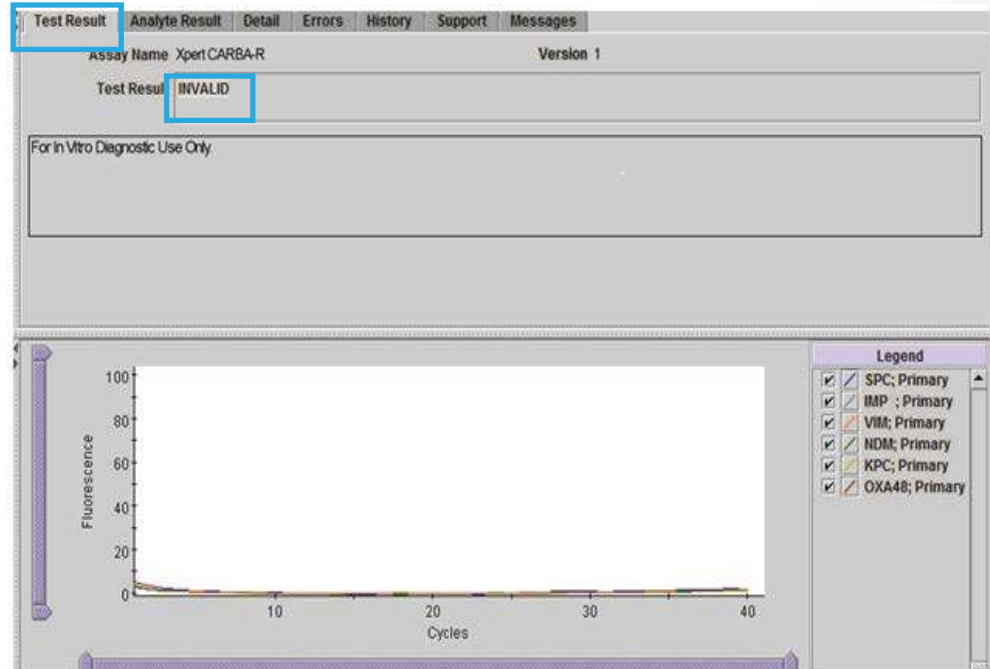
# Factors That Negatively Affect Results

- Improper specimen collection
  - The bacterial load in the specimen is below the detection limit of the test
  - Performance with other specimen types has not been assessed
- Improper transport or storage of collected specimen
  - Storage and transport conditions are specimen specific
  - Refer to the Package Insert for the appropriate handling instructions
- Improper testing procedure
  - Modification to the testing procedures may alter the performance of the test
  - Careful compliance with the Package Insert is necessary to avoid erroneous results

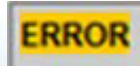
# INVALID Result

INVALID

- Presence or absence of IMP, VIM, NDM, KPC, and OXA-48 target DNA sequences cannot be determined. Use the instructions in Section 14, Retest Procedure, to repeat the test.
- SPC: FAIL; No PCR amplification of the SPC DNA sequence or the SPC Ct is not within valid range and the fluorescence endpoint is below threshold setting.
- PCC: PASS; all probe check results pass.



# ERROR



- Presence or absence of IMP, VIM, NDM, KPC, and OXA-48 target DNA sequences cannot be determined.
- SPC: NO RESULT
- PCC: FAIL\*; one or more of the probe check results failed. The PCC probably failed because the reaction tube was filled improperly or a probe integrity problem was detected.

\* If the probe check passed, the error is caused by a system component failure.

Assay Name: Xpert CARBA-R Version 1

Test Result: **ERROR**

For In Vitro Diagnostics Use Only

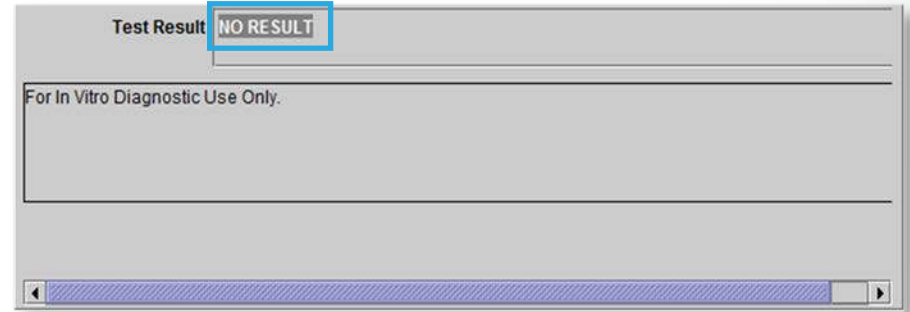
Troubleshoot

#	Description	Detail	Time
1	Operation terminated	Error 2008: Syringe pressure reading of 100.0 PSI exceeds the protocol limit of 100.0 PSI	05/08/13 15:51:28

# NO RESULT

NO RESULT

- Presence or absence of IMP, VIM, NDM, KPC, and OXA-48 target DNA sequences cannot be determined.
- Insufficient data were collected to produce a test result (for example, the operator stopped a test that was in progress or a power failure occurred).
- SPC: NO RESULT
- PCC: Not applicable





# Re-test Procedure for Rectal/Perirectal Swabs

1

Discard used cartridge

Follow your institution's safety guidelines for disposal of cartridges

2



Obtain the residual swab

If there is no residual swab, or the retest continues to return an **INVALID**, **ERROR**, or **NO RESULT**, collect a new specimen

3



Obtain a new cartridge, a new Sample Reagent vial, and a new transfer pipette from the kit

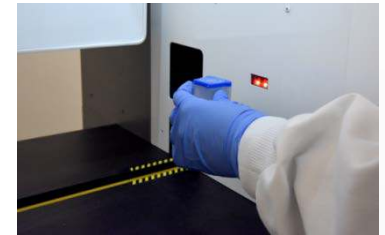
Label appropriately as retest on the new cartridge

Process the sample per the Package Insert

4



Run the test on the System



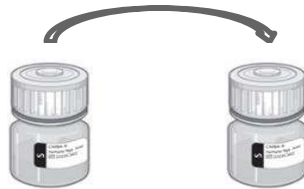
# Re-test Procedure for Bacterial Isolates

1

Discard used cartridge

Follow your institution's safety guidelines for disposal of cartridges

2



Transfer entire contents of the leftover sample in Sample Reagent vial, stored  $\leq 5$  days at 2-28°C, to a new Sample Reagent vial. Vortex for 10 seconds.

If the leftover sample volume is insufficient, or the retest continues to return an INVALID, ERROR, or NO RESULT, collect a new sample

3



Obtain a new cartridge

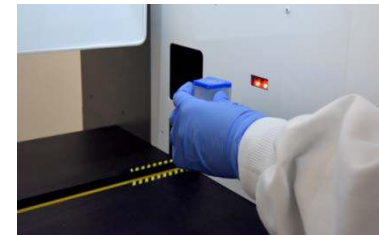
Label appropriately as retest on the new cartridge

Process the sample per the Package Insert

4



Run the test on the System





# Technical Assistance

- Before contacting Cepheid Technical Support, collect the following information:
  - Product name
  - Lot number
  - Serial number of the System
  - Error messages (if any)
  - Software version and, if applicable, Computer Service Tag number
- Log your complaint online using the following link <http://www.cepheid.com/us/support>

Region	Telephone	Technical Support Email
US	+ 1 888 838 3222	<a href="mailto:techsupport@cepheid.com">techsupport@cepheid.com</a>
Australia and New Zealand	+ 1800 107 884 (AU) + 0800 001 028 (NZ)	<a href="mailto:techsupportANZ@cepheid.com">techsupportANZ@cepheid.com</a>
Brazil and Latin America	+ 55 11 3524 8373	<a href="mailto:latamsupport@cepheid.com">latamsupport@cepheid.com</a>
China	+ 86 021 5406 5387	<a href="mailto:techsupportchina@cepheid.com">techsupportchina@cepheid.com</a>
France	+ 33 563 825 319	<a href="mailto:support@cepheideurope.com">support@cepheideurope.com</a>
Germany	+ 49 69 710 480 480	<a href="mailto:support@cepheideurope.com">support@cepheideurope.com</a>
India, Bangladesh, Bhutan, Nepal, and Sri Lanka	+ 91 11 48353010	<a href="mailto:techsupportindia@cepheid.com">techsupportindia@cepheid.com</a>
Italy	+ 39 800 902 567	<a href="mailto:support@cepheideurope.com">support@cepheideurope.com</a>
Japan	+ 0120 95 4886	<a href="mailto:support@japan.cepheid.com">support@japan.cepheid.com</a>
South Africa	+ 27 861 22 76 35	<a href="mailto:support@cepheideurope.com">support@cepheideurope.com</a>
United Kingdom	+ 44 3303 332 533	<a href="mailto:support@cepheideurope.com">support@cepheideurope.com</a>
Belgium and Netherlands	+33 563 825 3319	<a href="mailto:support@cepheideurope.com">support@cepheideurope.com</a>
Other European, Middle East, and African countries	+ 33 563 825 319 + 971 4 253 3218	<a href="mailto:support@cepheideurope.com">support@cepheideurope.com</a>
Other countries not listed above	+1 408 400 8495	<a href="mailto:techsupport@cepheid.com">techsupport@cepheid.com</a>





Thank You.



[www.Cepheid.com](http://www.Cepheid.com)

