



Xpert[®] TV

Technical Training for CE-IVD product only



Training Agenda

- **Xpert TV Training**
 - Reagents
 - Sample collection
 - Kit storage and handling
 - Limitations
 - Preparing cartridge
- Quality Control
- Results analysis
- **Discussion and Q&A**



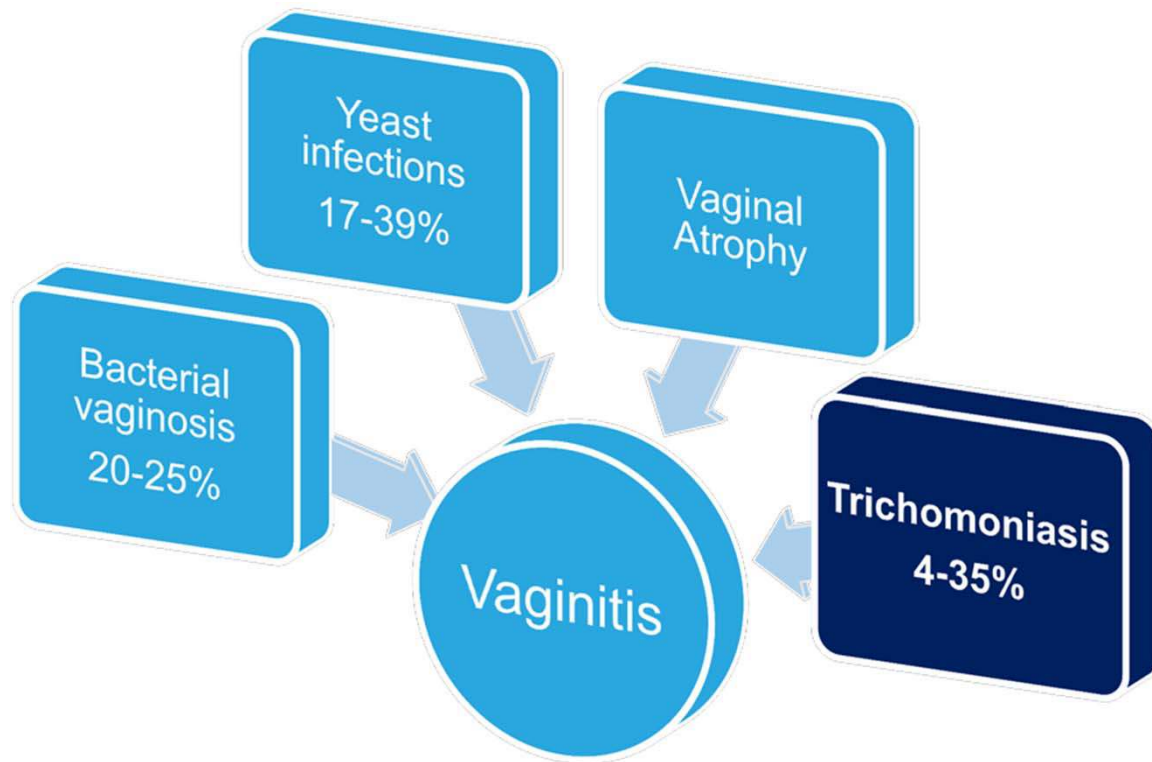
Xpert TV Training Objectives

At the end of the training, user will be able to:

- Properly store and handle the Xpert TV cartridge kit and specimen collection kits.
- Follow proper laboratory safety precautions.
- Collect appropriate specimen types and transport specimen.
- Perform the cartridge set up and run the assay.
- Report the various software-generated results.
- Understand assay control strategy.

Introduction on disease state

What is Trichomoniasis?



- Caused by *Trichomonas vaginalis* (TV)
- 170 M new cases estimated worldwide annually
- Trichomoniasis is common among persons with HIV
- TV is not a reportable STI

Trichomonas vaginalis

- Single cell protozoan
- Causes trichomoniasis
- Approximately 70% of those infected are asymptomatic

- Symptoms

- Itching
- Burning during urination
- Discharge from vagina/urethra
- Pain during intercourse

Complications	
♂	♀
<ul style="list-style-type: none">• Infertility• Chronic prostatitis• Nongonococcal urethritis	<ul style="list-style-type: none">• Infertility• HIV risk• Cervical neoplasia

- Treatment with antibiotics (Metronidazole or Tinidazole)
- Common methods for detection of *T. vaginalis* have variable sensitivity due to time and skill level constraints

Prevalence estimated by WHO

Methods and results used by WHO to generate 2005 estimates

Table 16. Prevalence estimates for *Trichomonas vaginalis* for 2005

WHO region	Percentage (%)		Cases (millions)		
	Females	Males	Females	Males	Total
African Region	18.12	3.82	32.40	6.80	39.20
Region of the Americas	14.8	1.43	33.90	3.32	37.22
South-East Asia Region	5.58	0.56	24.33	2.58	26.91
Eastern Mediterranean Region	5.58	0.56	7.49	0.80	8.29
European Region	6.22	0.62	14.1	1.42	15.52
Western Pacific Region	4.95	0.49	23.3	2.46	25.76
Global total	8.08	1.00	135.52	17.38	152.9

- **These estimates indicate in 2005 there were approximately:**
 - 98 million adults infected with *C. trachomatis*
 - 31 million adults infected with *N. gonorrhoeae*
 - 153 million adults infected with *Trichomonas vaginalis*.

Current situation

- **170 million new cases of *Trichomonas vaginalis* (TV) infections in adults estimated worldwide annually.**



Gaydos, C. GenProbe Symposium. 2010 National STD Prevention Conference, Atlanta, GA

The Cepheid Solution



- **Three internal controls for each individual sample**
 - Sample Adequacy Control (SAC)
 - Sample Processing Control (SPC)
 - Probe Check Control (PCC)
- **High sensitivity and specificity**
- **Simple and easy to use**
 - Closed cartridge system
- **For positive samples, results in approximately 45 minutes**
 - EAT (Early Assay Termination)
- **On-demand results 24/7**
- **Random access**

TV Testing *with* Xpert® TV

Xpert TV Sensitivity >95%*



Swab Transport
or Urine Transport



Transfer
1mL sample



Test &
Results

35-60 mins



Data Uploads
to LIS

Impact on patient care with accurate diagnoses and positive results as early as 35 minutes

Test and Treat

* Xpert TV product insert
TV : *Trichomona Vaginalis*

Intended Use

The Cepheid Xpert TV Assay, performed on the GeneXpert® Instrument Systems, is a qualitative *in vitro* diagnostic test for the detection of *Trichomonas vaginalis* genomic DNA. The test utilizes automated real-time polymerase chain reaction (PCR) to detect *Trichomonas vaginalis* genomic DNA. The Xpert TV Assay uses female or male urine specimens, endocervical swab specimens, or patient-collected vaginal swab specimens (collected in a clinical setting). The Xpert TV Assay is intended to aid in the diagnosis of trichomoniasis in symptomatic or asymptomatic individuals.



Sample Types

Urine

- Female
- Male



Swabs

- Endocervical
- Patient-Collected Vaginal

System and Reagent Requirements

GeneXpert Systems

- **GeneXpert Instrument System:**
 - **6 color modules**
 - **GeneXpert Software v4.3 or higher**
 - **Barcode Scanner**
 - **GeneXpert Instrument System Operator Manual**

Test kits

- **GXTV-CE-10**

Specimen collection kits

- **SWAB/A-50: Xpert Vaginal/Endocervical Specimen Collection Kit**
- **URINE/A-50-CE: Xpert Urine Specimen Collection Kit**

Xpert TV Kit

	Xpert TV Assay
Catalog Number	GXTV-CE-10
Tests per kit	10
Contents per test cartridge	Reagent beads
	Liquid Reagent
Kit CD	Assay Definition File (ADF)
	Instruction to import ADF
	Package Insert (PDF)
Transfer pipettes	10
Storage	2-28 °C



Sample Collection Kits


	Xpert Vaginal/Endocervical Specimen Collection Kit	Xpert Urine Specimen Collection Kit
Catalog #	SWAB/A-50	URINE/A-50-CE
Intended Use	The Cepheid® Xpert® Vaginal/Endocervical Specimen Collection Kit is designed to collect, preserve, and transport Chlamydia trachomatis, Neisseria gonorrhoeae, and Trichomonas vaginalis DNA in endocervical swab specimens (collected by a clinician) and patient collected vaginal swab specimens (collected in a clinical setting) from symptomatic and asymptomatic women prior to analysis with the Xpert CT/NG Assay and the Xpert TV Assay.	The Cepheid® Xpert® Urine Specimen Collection Kit is for use with the Xpert CT/NG Assay or the Xpert TV Assay. The Xpert Urine Specimen Collection Kit is intended to preserve and transport male or female urine specimens.
Kit Contents (50/kit)	<ul style="list-style-type: none"> • 1 large sterile cleaning swab • 1 flocked collection swab • 1 tube Swab Transport Reagent (pink cap) • 50 Vaginal specimen self collection instruction sheet • 1 Endocervical specimen collection instruction sheet 	<ul style="list-style-type: none"> • 1 urine transfer pipette • 1 tube Urine Transport Reagent (yellow cap) • 50 specimen collection sheets





Urine Specimen Collection


Urine Specimen Collection (First Catch)


- 1 Direct patient to provide first-catch urine (20-50mL) into a urine collection cup.
Note: The patient should not have urinated for at least 1 hour prior. Patient should not cleanse the genital area prior to collecting specimen.



- 2 The Xpert® Urine Specimen Collection kit contains
Ⓐ Large, disposable transfer pipette
Ⓑ Urine Transport Reagent tube

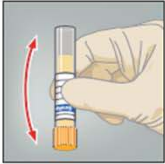

- 3 Open the package of disposable transfer pipette provided in the kit.



- 4 Remove the yellow cap from the transport tube.


- 5 Transfer approximately 7mL of urine into the transport tube, using the disposable transfer pipette. The correct volume is marked by the black dashed line on the label.


- 6 Replace the yellow cap on the transport tube and tighten securely.


- 7 Invert the transport tube 3-4 times to ensure that the specimen and reagent are well mixed.


- 8 Return the tube as instructed by your doctor, nurse or care-provider.
Note: Health care provider should label the transport tube with the sample identification information, including date of the collection, as required.



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301-5611, Rev. A October, 2015





Endocervical Specimen Collection


Endocervical Specimen Collection

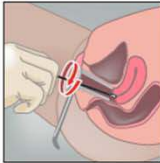
- 1 The Xpert Vaginal/Endocervical Specimen Collection kit contains
 ① Individual Collection Kit
 ② Cleaning Swab



- 2 Partially peel open the cleaning swab wrapper and remove the swab.
 Remove excess mucus from the cervical os and surrounding mucosa using the large individually wrapped cleaning swab ②. Discard the swab.



- 3 Open package ① that contains the pink-capped Xpert Swab Transport Reagent tube and the individually wrapped collection swab. Set the tube aside before beginning to collect sample. Open the collection swab wrapper by peeling open the top of the wrapper. Remove the swab, taking care not to touch the tip or lay it down. If the soft tip is touched, the swab is laid down, or the swab is dropped, use a new Xpert Vaginal/Endocervical Specimen Collection Kit.



- 4 Hold the swab in your hand, placing your thumb and forefinger in the middle of the swab shaft.


- 5 Insert the collection swab into the endocervical canal. Gently rotate the swab clockwise for 10-30 seconds in the endocervical canal. Withdraw the swab carefully.


- 6 While holding the swab in the same hand, unscrew the cap from the Xpert Swab Transport Reagent tube. Do not spill the contents of the tube. If the contents of the tube are spilled, use a new collection kit. Immediately place the specimen collection swab into the transport reagent tube.


- 7 Identify the scoreline on the collection swab shaft. Carefully break the swab shaft against the side of the tube at the scoreline. Discard the top portion of the swab shaft. Use care to avoid splashing the contents. Wash with soap and water if exposed.


- 8 Re-cap the swab transport reagent tube and tighten the cap securely. Invert or gently shake the tube 3-4 times to elute material from the swab. Avoid foaming. Label the transport tube with the sample identification information, including date of the collection, as required.



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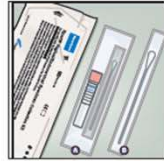
301-1526 Rev. A October, 2015



Patient-Collected Vaginal Swab Specimen Collection

Patient-Collected Vaginal Swab Specimen Collection

1 Wash hands before starting and undress from the waist down. Open the individual collection package ① that contains the pink-capped Xpert® Swab Transport Reagent tube and individually wrapped collection swab. Set the tube aside before beginning to collect sample. Discard the larger swab ②.



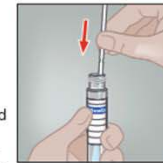
5 Gently rotate the swab for 10 – 30 seconds. Ensure the swab touches the walls of the vagina so that moisture is absorbed by the swab. Withdraw the swab and continue to hold it in your hand.



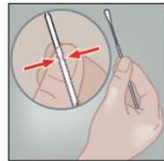
2 Open the collection swab wrapper by peeling open the top of the wrapper. Remove the swab, taking care not to touch the tip or lay it down. If the soft tip is touched, the swab is laid down, or the swab is dropped, request a new collection kit.



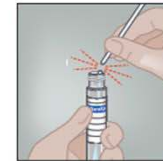
6 **⚠️ WARNING:** If the contents of the tube are spilled on your skin, wash the affected area with soap and water. If the contents of the tube are splashed in your eyes, immediately flush your eyes with water. Notify your doctor, nurse or care-provider if irritation develops. If the contents of the tube are spilled, your test result may be invalidated. Do not take internally.



3 Hold the swab in your hand, placing your thumb and forefinger in the middle of the swab shaft across the scoreline.



7 Identifying the scoreline on the collection swab shaft, carefully break the swab shaft against the side of the tube at the scoreline and discard the top portion of the swab shaft. Avoid splashing contents on the skin. Wash with soap and water if exposed.



4 Carefully insert the swab into your vagina about 5 cm (two inches) inside the opening of the vagina.



8 Re-cap the transport tube and tighten the cap securely. Return the tube as instructed by your doctor, nurse or care-provider. Note: Health care provider should invert or gently shake the tube 3-4 times to elute material from the swab. Avoid foaming. Label the transport tube with the sample identification information, including date of the collection, as required.



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Xpert TV Specimen Transport and Storage

Specimen	Transport and Storage Temperature (°C)	Storage Time
Unpreserved (neat), first catch urine	2-8 °C	4 days
	15-30 °C	4 hours
Urine in Xpert Urine Transport Reagent	2-8 °C	28 days
	15-30 °C	14 days
Endocervical or Vaginal swab in Xpert Swab Transport Reagent	2-30 °C	60 days

Good Laboratory Practice

PCR laboratory setup

- Cartridge/reagent preparation → Sample addition → Detection

Specimen and reagent storage

- Store specimens separately from reagents to prevent reagent contamination.

Equipment

- Use filtered pipette tips, when needed.
- Follow the manufacturer's recommendation for calibration and maintenance of the lab equipment.
- Perform regular maintenance on the GeneXpert Instrument.

Good Laboratory Practice, continued

Housekeeping

- Clean work surfaces with a final concentration of 1:10 dilution of household bleach in water and then a 70% ethanol solution. Wipe work surfaces dry.
- If contamination occurs, thoroughly clean the contaminated area with 1:10 dilution of household bleach in water* or 3% (w/v) hydrogen peroxide and rinse thoroughly with water. Wipe work surfaces dry.

Personnel*

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

Lab bench area

- Clean the lab bench area routinely.
- Keep the back of the instrument dust free.

** Final Active Chlorine concentration should be 0.5% regardless of the household bleach concentration in your country*

Xpert TV Warnings and Precautions

- **Store test kits at 2-28° C. Do not use expired cartridges.**
- **Each single-use cartridge is used to process one test. Do not reuse processed cartridges.**
- **Do not open a cartridge until ready to use.**
 - Cartridge should be run within 30 minutes after opening the cartridge lid.
- **Avoid cross contamination during sample handling steps.**
 - Change gloves if they come in contact with specimen or appear to be wet.
 - Change gloves before leaving work area and upon entry into work area.
 - Change gloves between processing each sample.
- **Do not use a cartridge that has been dropped or shaken after the sample has been transferred to the cartridge.**
- **Do not use a cartridge that has a damaged reaction tube.**

Xpert TV- Cartridge Preparation

Xpert® Cartridge Preparation *depicting urine or endocervical/vaginal sample in transport reagent tube.*

- Xpert CT/NG
- Xpert TV

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

For a copy of the SDS, visit www.cepheid.com or www.cepheidinternational.com

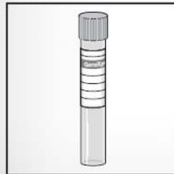
Cepheid Technical Support

US office
(888) 838-3222, Option 2
techsupport@cepheid.com

European office
+33 563 82 53 19
support@cepheideurope.com



- 1 Obtain one appropriately collected and labeled transport reagent tube.



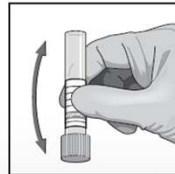
- 2 Obtain one Xpert cartridge and transfer pipette (provided in the assay kit).



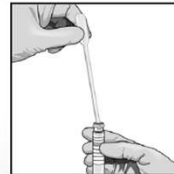
- 3 Open the Xpert cartridge lid.



- 4 Gently invert the transport tube 3 to 4 times to mix.



- 5 Fill the transfer pipette to the mark on the pipette shaft.



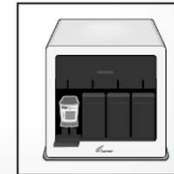
- 6 Empty the pipette contents into the sample chamber.



- 7 Close the Xpert cartridge lid.



- 8 Insert the cartridge and start the test.

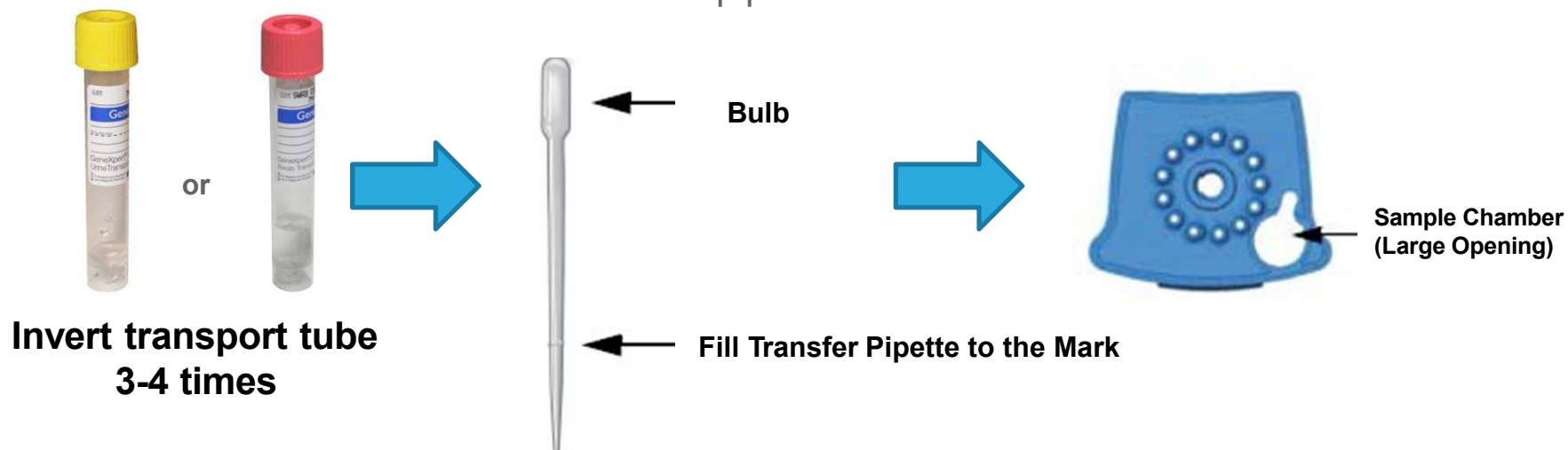


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301-1811, Rev. B December, 2015

Running the Test

- Gently invert the transport tube 3 to 4 times.
- Open the transport tube.
- Compress the bulb of the transfer pipette.
 - Insert the transfer pipette into the transport tube.
 - Fill the transfer pipette to the mark on the pipette (500uL).
 - Ensure fill is to the mark on the pipette. Avoid air bubbles.



Automated Xpert TV Test Steps



EAT (Early Assay Termination)

- **What is it?**

- Real-time monitoring of reaction progress
- Termination of the reaction when the cycle threshold of a particular reaction is crossed

- **What are the benefits?**

- Positive results are reported sooner
- For time-critical interventions, valuable minutes are saved for patients that need it the most

Quality Control

Refer to the Package Insert for complete details



Cepheid Assay Control Strategy

- **Each Xpert cartridge is a self-contained test device.**
 - Cepheid designed specific molecular methods to include internal controls that enable the system to detect specific failure modes within each cartridge.
 - Instrument system control: Check status
 - Reagent control: Probe Check
 - Sample processing control: SPC and SAC
 - Amplification control: SPC and SAC

Instrument System Control – Check Status

- **The Instrument System control checks the optics, temperature of the module, and mechanical integrity of each cartridge.**
 - If the system controls fail, an ERROR test result will be reported.

Reagent Control - Probe Check Control (PCC)

- **After sample preparation, bead reconstitution, and tube filling (prior to thermal cycling), multiple fluorescent readings are taken at different temperatures.**
- **The readings are compared to default settings established by Cepheid.**
- **The Probe Check controls for:**
 - Missing Target Specific Reagent (TSR) and/or Enzyme Reagent beads which contain all primers, probes, and internal control template
 - Incomplete reagent reconstitution
 - Incomplete reaction tube fill
 - Probe degradation
- **If the Probe Check fails, an ERROR test result will be reported.**

Sample Processing Control - SPC

- **The Sample Processing Control (SPC) assesses the effectiveness of the sample preparation steps, including reaction tube filling.**
- **SPC is *Bacillus globigii* DNA.**
- **The SPC controls for:**
 - Missing primer/probe or enzyme beads
 - Incomplete reagent reconstitution
 - Incomplete reaction tube fill
 - Enzyme degradation
 - Sample lysis, nucleic acid extraction, and integrity of nucleic acid
 - Sample inhibition
- **The SPC can be negative or positive in an analyte-positive sample.**
- **If the SPC fails in an analyte-negative sample, an INVALID test result will be reported.**

Sample Adequacy Control – SAC

- **Sample Adequacy Control (SAC) ensures the sample contains adequately lysed human cells.**
- **A negative SAC may be due to not enough human cells present in the sample following:**
 - Insufficient mixing of the sample
 - Improper sample collection
 - Inefficient sample lysis
- **If the SAC fails in an analyte-negative sample, an INVALID test result will be reported.**

Commercially Available External Controls

Vendor	Organism Name	Description	Part Number
ATCC www.ATCC.org	<i>Trichomonas vaginalis</i>	• TV Positive	30001
	<i>Neisseria gonorrhoeae</i>	• TV Negative	35201
Zeptomatrix www.zeptomatrix.com	<i>Trichomonas vaginalis</i> Z070	• TV Positive	NATTVPOS-6MC
	<i>N. gonorrhoeae strain</i>	• TV Negative	NATTVNEG-6MC

Please note: for negative samples, human cells must be present for a valid result

- **Other options:**
 - **Known patient positive and negative samples**

ZeptoMetrix TV External Controls



NATtrol™ *T. vaginalis* External Run Controls

Catalog #: NATTVPOS-6MC

Catalog #: NATTVNEG-6MC

PRODUCT DESCRIPTION:

NATtrol™ *T. vaginalis* External Run Controls (NATTVPOS-6MC and NATTVNEG-6MC) are formulated with purified, intact organisms that have been chemically modified to render them non-infectious and refrigerator stable*. Each control contains 6 x 1.2 mL vials of NATtrol™ *T. vaginalis* (Z070) or NATtrol™ *N. gonorrhoeae* (Z017).

*NATtrol™ Patents Pending

INTENDED USE:

- NATtrol™ *T. vaginalis* External Run Controls are full process controls designed to evaluate the performance of nucleic acid tests for determination of the presence of *T. vaginalis* nucleic acids. NATTVPOS-6MC and NATTVNEG-6MC can also be used for quality control of clinical assays and training of laboratory personnel.
- NATTVPOS-6MC and NATTVNEG-6MC contain intact organisms and should be run in a manner identical to that used for clinical specimens.

ETIOLOGIC STATUS/BIOHAZARD TESTING:

- NATtrol™ inactivation was carried out on the organism stocks used to formulate each control pack. The inactivation was verified by the absence of growth in validated growth protocols.

PRECAUTIONS:

- Although NATtrol™ *T. vaginalis* External Run Controls contain inactivated organisms, they should be handled as if potentially infectious.
- Use Universal Precautions when handling these products.
- To avoid cross-contamination, use separate pipette tips for all reagents.

RECOMMENDED STORAGE:

- NATtrol™ *T. vaginalis* External Run Controls should be stored at 2-8°C.

INSTRUCTIONS FOR USE WITH Xpert® TV ASSAY:

- Vortex NATtrol™ sample for 5-10 seconds.
- Using a clean transfer pipette (supplied in Xpert® TV test kit), insert pipet into transport tube and release the bulb to fill the transfer pipet to the mark (500µL) on the pipet shaft.
- Ensure the pipette is filled with no air bubbles present.
- Empty the pipette's contents into the sample chamber of the cartridge.
- Close cartridge lid and follow manufacturer's instructions.

Table 1: Expected Results

Catalog Number	Organism	Xpert® TV Expected Result
NATTVPOS-6MC	<i>T. vaginalis</i> (Z070)	TV DETECTED
NATTVNEG-6MC	<i>N. gonorrhoeae</i> (Z017)	TV NOT DETECTED

DO NOT USE IN HUMANS

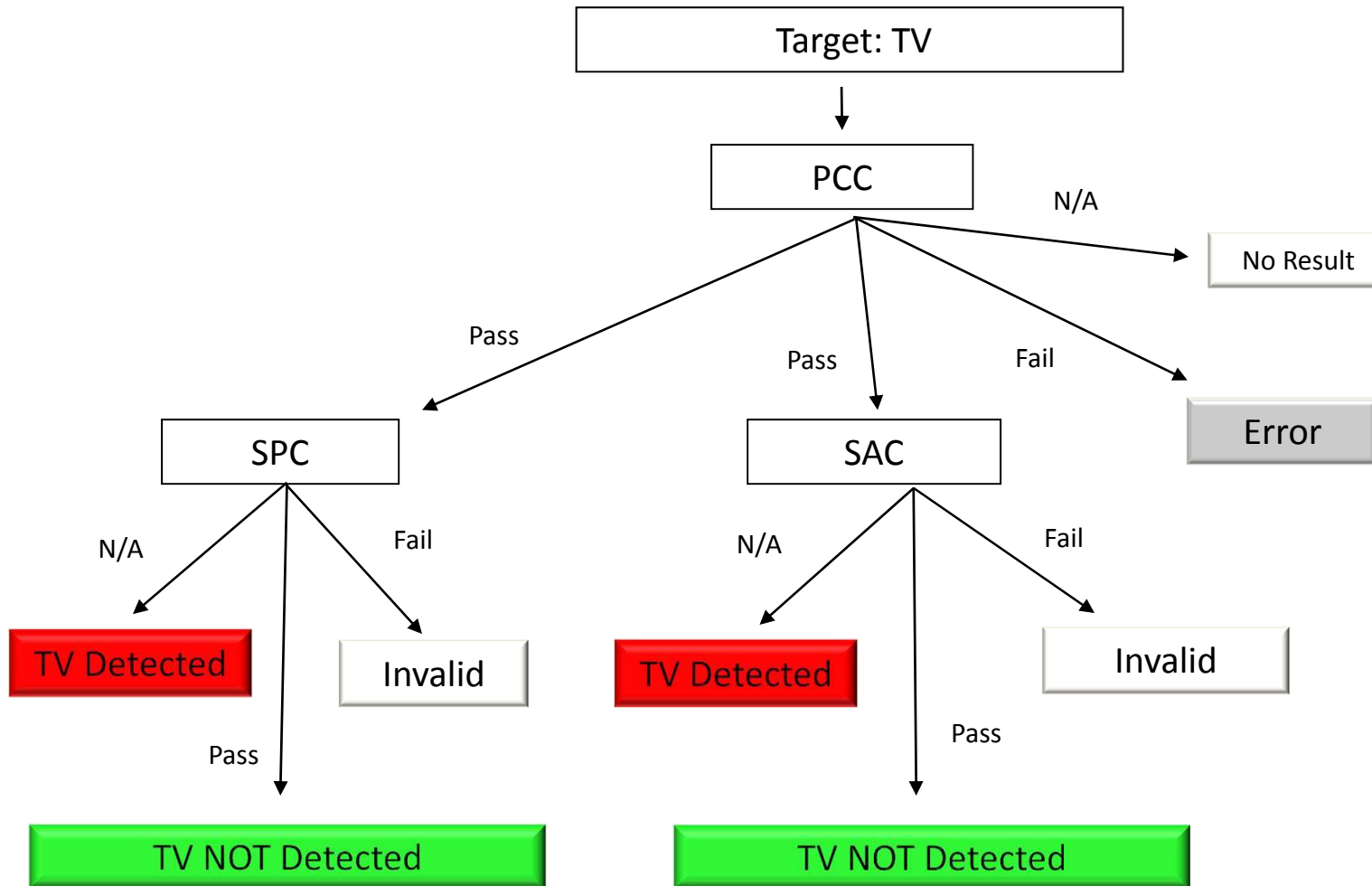
These products are intended for research, product development, quality assurance or manufacturing use. These products are NOT intended for use in the manufacture or processing of injectable products subject to licensure under section 351 of the Public Health Service Act or for any other product intended for administration to humans.

Results Analysis

Refer to the Package Insert for complete details



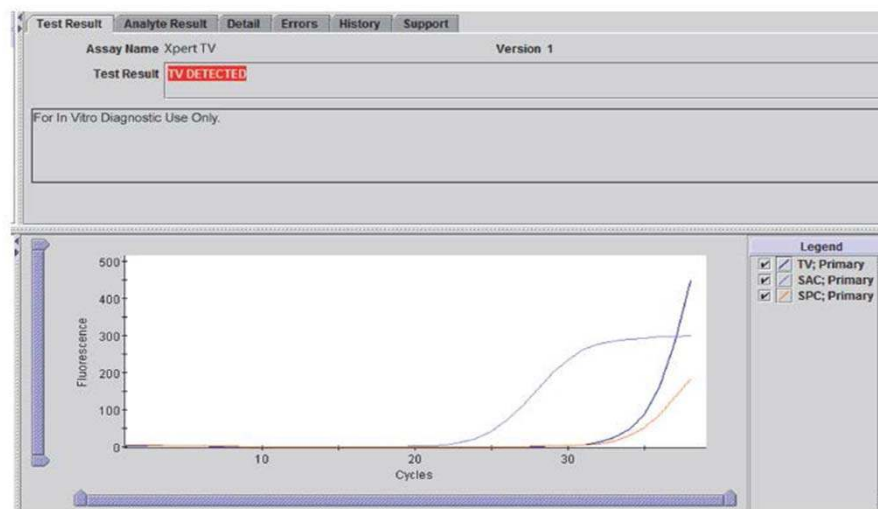
Algorithm



TV DETECTED

Trichomonas target DNA is detected.

- The *Trichomonas* target has a Ct within the valid range and a fluorescence endpoint above the threshold setting.
- SAC: Not applicable. The SAC is ignored because the TV target amplification may compete with this control.
- SAC: Not applicable: The SAC is ignored because the TV target may compete with this control.
- PCC: PASS. All probe check results pass

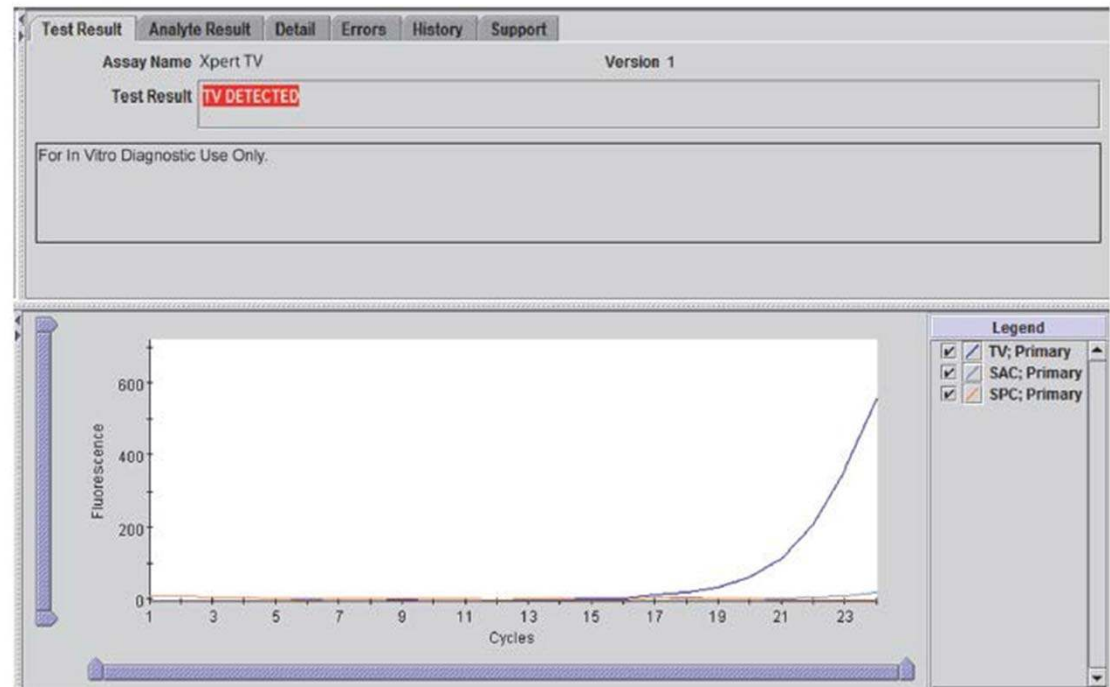


Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result
TV	33.2	529	POS	PASS
SAC	28.3	288	NA	PASS
SPC	36.3	86	NA	PASS

TV DETECTED (Early Assay Termination)

Trichomonas target DNA is detected.

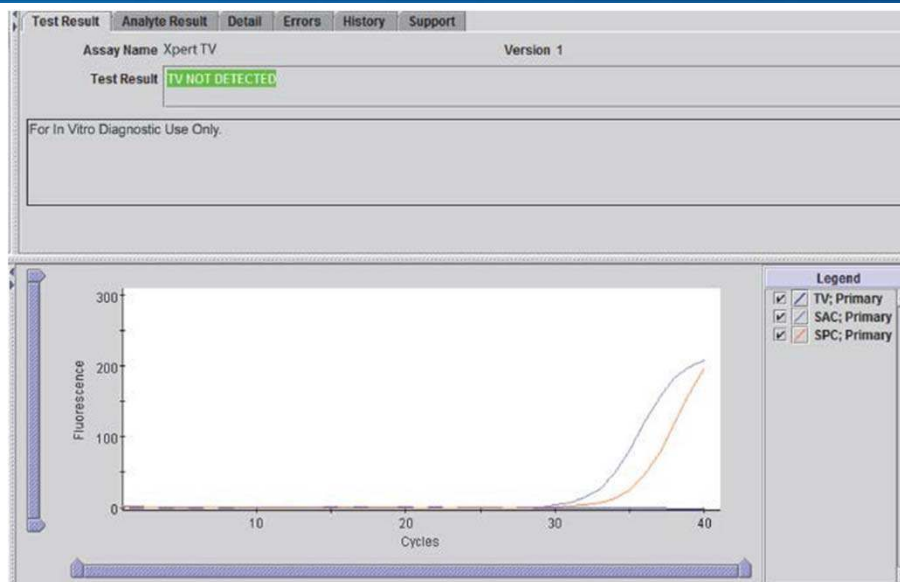
- The *Trichomonas* target has a Ct within the valid range and a fluorescence endpoint above the threshold setting.
- SPC: Not applicable. The SPC is ignored because the TV target amplification may compete with this control.
- SAC: Not applicable: The SAC is ignored because the TV target may compete with this control.
- PCC: PASS. All probe check results pass



TV NOT DETECTED

Trichomonas target DNA is not detected.

- SPC – PASS; SPC has a Ct within the valid range and fluorescence endpoint above the minimum setting.
- SAC – PASS; SAC has a Ct within the valid range and a fluorescence endpoint above the minimum setting.
- PCC – PASS; all probe check results pass



Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result
TV	0.0	0	NEG	PASS
SAC	37.7	114	PASS	PASS
SPC	36.2	210	PASS	PASS

Reasons to Repeat the Assay

- An **INVALID** result indicates that the controls, either SPC and/or SAC failed. The sample was not properly processed or PCR was inhibited.
- An **ERROR** result indicates that the Probe Check control failed and the assay was aborted possibly due to the reaction tube being filled improperly, a reagent probe integrity problem was detected, or because the maximum pressure limits were exceeded.
- A **NO RESULT** indicates that insufficient data were collected. For example, the operator stopped a test that was in progress.

INVALID

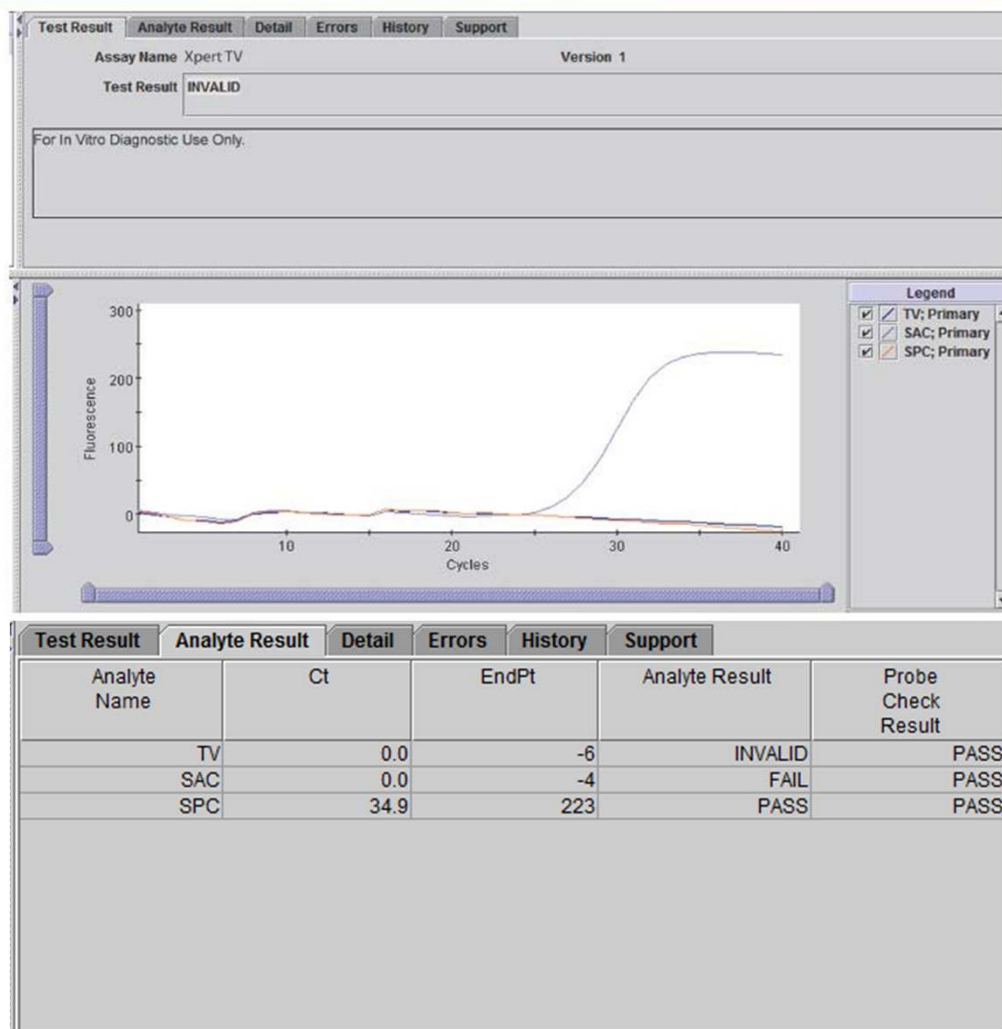
- Presence or absence of *Trichomonas* target DNA cannot be determined.

Repeat the test according to the instructions in Section 11.2 of the Package Insert, Retest Procedure to repeat the test.

- SPC: FAIL; SPC target result is negative. The SPC Ct is not within valid range and fluorescence endpoint is below the minimum setting.

AND/OR

- SAC – FAIL. SAC Ct is not within valid range and fluorescence endpoint is below the threshold setting.
- PCC: PASS; all probe check results pass.



ERROR

Presence or absence of *Trichomonas* target DNA cannot be determined. Repeat the test according to the instructions in the Package Insert, Retest Procedure to repeat the test.

- TRICHOMONAS – NO RESULT
- SPC – NO RESULT
- SAC – NO RESULT
- PCC – FAIL.* All or one of the probe check results fail.

* If the probe check passed, the error is caused by the maximum pressure limit exceeding the acceptable range or by a system component failure.

Test Result	Analyte Result	Detail	Errors	History	Messages	Support
Troubleshoot						
#	Description	Detail			Time	
1	Post-run analysis error	Error 5007: [TV] probe check failed. Probe check value of 0.0 for reading number 2 was below the minimum of 250.0			06/06/14 12:14:32	





Test Result	Analyte Result	Detail	Errors	History	Support
Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result	
TV	0.0	0	NO RESULT	FAIL	
SAC	0.0	0	NO RESULT	FAIL	
SPC	0.0	0	NO RESULT	FAIL	

NO RESULT

- NO RESULT indicates that insufficient data were collected. For example, the operator stopped a test that was in progress.
- The presence or absence of Trichomonas target DNA cannot be determined. Repeat the test.
- Trichomonas – NO RESULT
- SPC – NO RESULT
- SAC – NO RESULT
- PCC – Not Applicable

The screenshot shows a software interface for a test result. At the top, there is a header bar with the text "Test Result" followed by a box containing "NO RESULT". Below this is a large rectangular area with a light gray background and a thin black border, containing the text "For In Vitro Diagnostics Use Only." Below this area is a horizontal dashed line. At the bottom of the interface, centered, is the text "<No Data Available>".

TV Retest Procedure

1	Discard used cartridge.	 A blue diamond-shaped icon with a white trash can symbol inside, indicating disposal.
2	Obtain the leftover sample from the Transport Reagent tube. If the leftover sample volume is insufficient, or the retest continues to return an INVALID , ERROR , or NO RESULT , collect a new sample.	 Two vertical transport reagent tubes. The one on the left has a red cap and the one on the right has a yellow cap. Both have labels with 'Gen' visible.
3	Repeat the test with a new cartridge.	 A blue and white cartridge with a QR code on the front, representing a new test cartridge.
4	Follow the Package Insert on how to run a test.	 A yellow smiley face wearing black-rimmed glasses and holding an open red book, symbolizing reading instructions.

Factors That Negatively Affect Results

- **Improper specimen collection**
 - Performance with other collection devices and specimen types has not been assessed.
 - For assays that contain the SAC control, a specimen that does not contain human cells will result in an invalid test result.
- **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.
 - Technical error or sample mix-up can impact test results.
 - Careful compliance with the Package Insert is necessary to avoid erroneous results.
- **Interfering substance**
 - False negative test results or invalid results may be observed in the presence of interfering substance.
- **The number of organisms in the specimen is below the detection limit of the test**

Limitations

- ***Trichomonas tenax* was found to cross-react with the Xpert TV Assay at levels above 1.0×10^2 cells/mL. *T. tenax* is a commensal of the oral cavity. See Xpert TV Analytical Specificity for details.**
- **With endocervical and patient-collected vaginal specimens, assay interference may be observed in the presence of blood (>50% v/v).**
- **Xpert TV Assay performance has not been evaluated in pregnant women, or in patients with a history of hysterectomy.**
- **Xpert TV Assay performance has not been evaluated in patients less than 18 years of age or older than 78 years of age.**
- **Please refer to Package Insert for a complete list of limitations.**

Technical Support

- Cepheid provides technical support in the field, on the phone, by fax, and by email.
- Contact information for other Cepheid offices is available on our website at:

www.cepheid.com or www.cepheidinternational.com

under the SUPPORT tab. Select the Contact Us option.

Discussion and Q&A





Thank You.

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