

Xpert® vanA/vanB

The European Antimicrobial Resistance Surveillance System indicates that infection rates with vancomycin-resistant enterococci (VRE) are increasing, particularly in countries with high MRSA prevalence.² CDC, SHEA and WHO have put forward the following guidelines on how to reduce VRE infections:^{3, 4, 5}

- Comprehensive surveillance for targeted Multi-Drug Resistant Organisms; especially for those at high risk⁵
- Judicious use of antibiotics
- Application of infection control precautions during patient care
- Education and training of healthcare personnel
- Environmental cleanliness
- Decolonization therapy when appropriate

The Solution

Xpert® vanA/vanB:

- Allows for an immediate identification of VRE carriers from non-carriers
- Rapid implementation of barrier precautions
- Early identification improves patient bed management

Ordering Information

Xpert® vanA/vanB (10 Cartridges with reagents)

Catalog Number: **GXVANA/B-CE-10**

Materials Required but Not Provided

Use of this assay requires the following materials:

- Cepheid Sample Collection Device (900-0370) or Copan (139CFM LQ STUART)
- Vortex mixer
- Disposable gloves and appropriate Personal Protective Equipment (PPE)
- Disposable sterile transfer pipettes (VWR 14670-331, Samco 2S-PL-232-1S) or equivalent
- Kim Wipes, sterile gauze (VWR 82030-638), or equivalent

References

1. Montecalvo et al (2001) *Infect Control Hosp Epidemiol* 22:437-442.
2. European Antimicrobial Resistance Surveillance System, <http://www.rivm.nl/earss>. 17 July 2009.
3. Siegel et al (2007) *Am J Infect Control* 35 (10 Suppl 2):S165-93.
4. Muto et al (2003) *Inf Control Hosp Epidemiol* 24:362-386.
5. WHO 2004. *Practical Guidelines for Infection Control in Healthcare facilities*. SEARO Regional Publication No. 41.

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Xpert® vanA/vanB

Sample Collection

Sample Collection and Transport

For rectal specimens:

1. Collect the swab specimen using the Cepheid sample Collection Device (Cepheid Part Number 900-0370).
2. Carefully insert the swab approximately 2.5 cm beyond the anal sphincter (so that the cotton tip is no longer visible) and gently rotate 3 times to ensure uniform sample on both swabs.
3. Place the swabs back in the sample container.
4. Label with Sample ID and send to the laboratory.
5. Store swab specimen at 2 – 8 °C. The swab specimen is stable up to 5 days when stored at 2 – 8 °C.

For perianal specimens:

1. Collect the swab specimen using the Cepheid sample Collection Device (Cepheid Part Number 900-0370).
2. Press the buttocks apart to expose the perianal region, then using both of the swabs, fully swab around the perianal surface making sure to swab as much of the surface as possible.
3. Place the swabs back in the sample container.
4. Label with Sample ID and send to the laboratory.
5. Store swab specimen at 2 – 8 °C. The swab specimen is stable up to 5 days when stored at 2 – 8 °C.

Note: Procedures in the current package insert supersede these procedures.

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Xpert Cartridge Preparation

- Xpert MRSA
- Xpert MRSA/SA SSTI
- Xpert C. difficile
- Xpert SA Nasal Complete
- Xpert vanA/vanB

Refer to the package insert for detailed instructions, precautions, and warnings. For a copy of the MSDS, visit www.cephheid.com or www.cephheidinternational.com

Cepheid Technical Support
US office
(888) 838-3222, Option 2
techsupport@cephheid.com
European office
+33 563 82 53 19
support@cephheidurope.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 all of the Sample Reagent vial contents with a disposable transfer 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.

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Retest Procedure

Reasons to Retest

If the instrument returns any of the following indeterminate results, repeat the test:

- **INVALID:** This result indicates that the internal SPC failed. The sample was not properly processed or PCR was inhibited. An invalid result can also be caused by air bubbles in the reaction tube.
- **ERROR:** This result indicates that the assay was aborted. Possible causes include: the reaction tube was filled improperly; a reagent probe integrity problem was detected; the maximum pressure limit was exceeded; a system component failed.
- **NO RESULT:** this result indicates that insufficient data were collected. For example, the operator stopped a test that was in progress, a load error occurred, the software was closed prematurely, or a power failure occurred.

If an External QC fails to perform as expected, repeat external control test and/or contact Cepheid for assistance.

Retest Procedure

To retest within 3 hours, use a new cartridge (do not re-use the cartridge) and a new reagent.

To retest after 3 hours, you can repeat the test using a new cartridge and new reagent with the second swab or a new swab sample.

Note: Procedures in the package insert supersede these procedures.

Xpert® *vanA/vanB*

Laboratory User Training

Laboratory users can be trained with the slides in this chapter. A copy of this presentation is on the Xpert Assay Training CD.



Training Agenda

- **GeneXpert Technology Review**
- **Xpert *vanA/vanB* Training**
 - Clinical utility
 - Kit storage and handling
 - Specimen collection, transport, and storage
 - Preparing cartridge
 - Assay targets
 - Result analysis
- **Clinical Performance**
- **Quality Control**
- **Discussion and Q&A**

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Training Objectives

You will be able to correctly:

- **Store and handle the Xpert *vanA/vanB* materials**
- **Clean and prepare the lab area for the assay**
- **Wear appropriate Personal Protective Equipment (PPE) for this assay**
- **Tell someone how to collect a specimen**
- **Transport and store a specimen**
- **Prepare a cartridge**
- **Perform the assay**
- **Read the software-generated results**
- **Discard the used materials**

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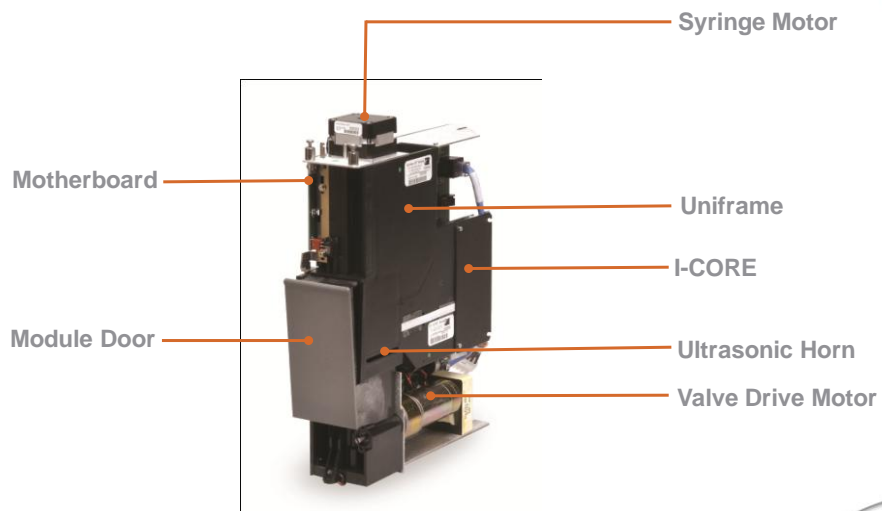
Platform Design



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GeneXpert Module



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GeneXpert Cartridge



- **Universal Medical & Market Utility**
 - Infectious Disease
 - Oncology
 - Genetic Disease
- **All Testing Done Within Cartridge**
 - Sample Prep
 - Amplification
 - Detection
- **Same Basic Cartridge Works With all Tests and GeneXpert® Systems**

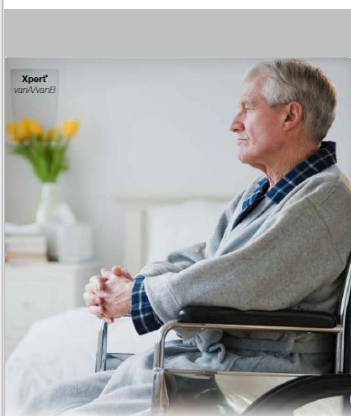
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Xpert *vanA/vanB* Assay



vanA/vanB



Identify Patients in Need of Contact Precautions

* American Journal of Infection Control. 2004; 32: 470-85

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CHALLENGES

- Patients colonized with VRE not accurately identified create opportunities for additional infection
- 28.5% of enterococci causing HAI in intensive care units (ICU) were VRE*
- Current VRE surveillance tests are based on culture method requiring 24-48 hours to generate a result

~ 45 MINUTES WITH Xpert® vanA/vanB

- Rapid identification of patients requiring contact precautions
- Improve resource utilization and reduce IC costs
- Detect breakdown in infection control sooner and reduce the risk of potential outbreak
- Patient counseling to reduce transmission to family and community



The Cepheid Solution



CE-IVD Marked kit

- Highly sensitive and specific
- Results in ~ 45 minutes
- On-demand results: 24/7
- Random access
- Minimal “hands-on” time
- Closed system to minimize the risk of contamination

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Intended Use

The Cepheid Xpert *vanA/vanB* Assay performed in the GeneXpert® DX System is a **qualitative in vitro diagnostic test designed for rapid detection of vancomycin-resistance (*vanA/vanB*) genes from rectal and perianal swab specimens** in patients at risk for intestinal colonization of vancomycin-resistant bacteria.

The test utilizes **automated real-time polymerase chain reaction (PCR)** to detect the *vanA* and *vanB* genes that can be associated with vancomycin-resistant enterococci (VRE).

The Xpert *vanA/vanB* Assay is intended to aid in the recognition, prevention and control of vancomycin-resistant organism colonization in healthcare settings. The Xpert *vanA/vanB* Assay is not intended to diagnose VRE nor to guide or monitor treatment for VRE infections.

Concomitant cultures are necessary only to recover organisms for epidemiological typing, susceptibility testing and for further confirmatory identification of VRE.

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Good Laboratory Practice

- **PCR laboratory setup**
Cartridge/reagent preparation → Sample/reagent addition → Detection
- **Specimen and reagent storage**
Store specimens separately from reagents to prevent reagent contamination.
- **Equipment**
 - Use filtered pipette tips, when needed, for QC dilutions.
 - Follow the manufacturer's recommendation for calibration and maintenance of the lab equipment.
- **Housekeeping**
 - Clean work surfaces with a final concentration of 10% sodium hypochlorite solution and then a 70% ethanol or 70% isopropyl alcohol solution.
 - 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.

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Assay Kit Storage and Handling

- Store the Xpert *vanA/vanB* cartridges and reagents at 2 °C to 28 °C.
- Do not use cartridges or reagents that have passed the expiration date.
- Do not open the cartridge until you are ready to perform testing.
- Do not use any reagents that are cloudy or have changed color.
- Use the cartridge and reagents within 30 minutes after opening the package.

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Warnings and Precautions

- The Xpert *vanA/vanB* Assay does not give susceptibility results. Additional time is required to culture and perform susceptibility testing.
- Do not substitute Xpert *vanA/vanB* reagents with other reagents.
- Do not load a Xpert *vanA/vanB* cartridge that has been dropped or shaken after you have added the sample.
- Do not load a cartridge that has a damaged reaction tube.
- Each single-use Xpert *vanA/vanB* cartridge is used to process one test. Do not recycle cartridges.

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Cepheid Sample Collection Device



Use the Cepheid Sample Collection Device (P/N 900-0370)

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Specimen Collection, Transport, and Storage

For Rectal specimens:

1. Open the Cepheid Collection Device by peeling back the outer packaging.
2. Carefully insert the swab approximately 2.5 cm beyond the anal sphincter (so that the cotton tip is no longer visible) and gently rotate 3 times to ensure uniform sample on both swabs.
3. Place the swabs back in the sample container
4. Label with sample ID and send to the laboratory
5. Store swab specimen at 2-8° C. The swab specimen is stable up to 5 days when stored at 2-8° C


For Perianal specimens:

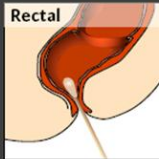

1. Open the Cepheid Collection Device by peeling back the outer packaging.
2. Press the buttocks apart to expose the perianal region, then using both of the swabs, fully swab around the perianal surface making sure to swab as much of the surface as possible.
3. Place the swabs back in the sample container
4. Label with patient ID and send to the laboratory
5. Store swab specimen at 2-8° C. The swab specimen is stable up to 5 days when stored at 2-8° C


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Specimen Collection, Transport, and Storage

1  A Copan Venturi Transystem double swab must be used to collect the specimen. Cepheid Collection Device # 900-0370

2 **Rectal**  OR **Perianal**  Carefully insert the swab approximately 2.5 cm beyond the anal sphincter (so that the cotton tip is no longer visible) and gently rotate 3 times to ensure uniform sample on both swabs. Press the buttocks apart to expose the perianal region then fully swab around the perianal surface making sure to swab as much of the surface as possible.

3  Place the swabs back in the tube.

4  Specimens that can be tested within 24 hours can be kept at room temperature; if not, it is recommended that they be refrigerated. Specimens stored at 2-8°C are stable for up to 5 days.

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Xpert vanA/vanB Assay Testing Protocol

Xpert Cartridge Preparation

- Xpert MRSA
- Xpert MRSA/SA SSTI
- Xpert C. difficile
- Xpert SA Nucleo Complete
- Xpert vanA/vanB

Refer to the package insert for detailed instructions, precautions, and warnings. For a copy of the MSDS, visit www.cephheid.com or www.cephheidinternational.com

Cepheid Technical Support
US office
(866) 838-3222, Option 2
techsupport@cephheid.com
European office
+33 (0) 492 53 19
support@cephheid.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 all of the Sample Reagent vial contents with a disposable transfer 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 swabs below the score mark. Use gauze or its equivalent to minimize the risk of contamination.

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Automated Xpert *vanA/vanB* Protocol



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Discarding cartridges and reagents

To discard used/expired cartridges and reagents, follow your institution's standard operating procedure for biological and chemical waste.

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Xpert *vanA/vanB* Overview

Qualitative, Multiplex, real-time PCR assay

- Rectal or Perianal specimen
- 3 targets detected with TaqMan® probes
 - o *vanA* gene: Resistance to Vancomycin and Teicoplanin (plasmid-mediated)
 - o *vanB* gene: Resistance to Vancomycin (transposon)
 - o Sample Prep Control (SPC): *B. globigii* spores

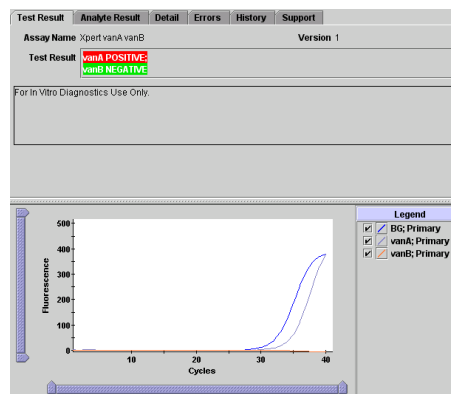
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vanA Positive

vanA POSITIVE

- *vanA* target DNA is detected.
- *vanA* POSITIVE: *vanA* target has a valid Ct.
- SPC: NA (not applicable)
SPC is ignored because *vanA* amplification can compete with this control.
- Probe Check: PASS
All probe check results pass.



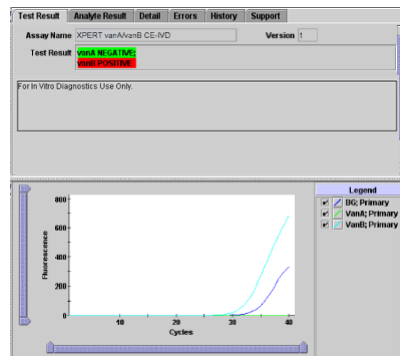
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vanB Positive

vanB POSITIVE

- **vanB target DNA is detected.**
- **vanB POSITIVE: vanB target has a valid Ct.**
- **SPC: NA (not applicable)**
SPC is ignored because vanB amplification can compete with this control.
- **Probe Check: PASS**
All probe check results pass.



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vanA POSITIVE, vanB POSITIVE

vanA POSITIVE, vanB POSITIVE

- **vanA and vanB target DNA sequence are detected.**
- **vanA POSITIVE: vanB target has a valid Ct**
- **vanB POSITIVE: vanB target has a valid Ct**
- **SPC: NA (not applicable)**
SPC is ignored because vanA and/or vanB amplification can compete with this control.
- **Probe Check: PASS**
All probe check results pass.

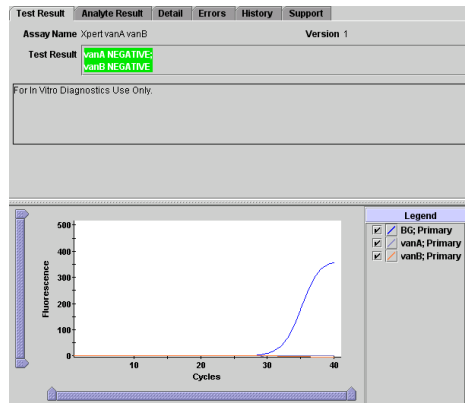
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NEGATIVE

NEGATIVE

- *vanA* and *vanB* target DNA sequence are not detected. SPC meets acceptance criteria.
- **NEGATIVE:** no *vanA* or *vanB* target DNA are detected.
- **SPC: PASS**
SPC has a valid Ct value
- **Probe Check: PASS**
All probe check results pass.



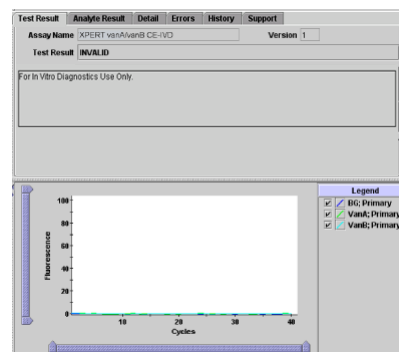
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Invalid

INVALID

- Presence or absence of *vanA/vanB* target sequences cannot be determined. Repeat the test according to the instruction in the Retest Procedure section. The SPC does not meet the acceptance criteria, the sample was not properly processed, or PCR was inhibited.
- **INVALID:** Presence or absence of *vanA* or *vanB* DNA cannot be determined.
- **SPC: FAIL**
SPC target result is negative, and the SPC is not valid.
- **Probe Check: PASS**
All probe check results pass.



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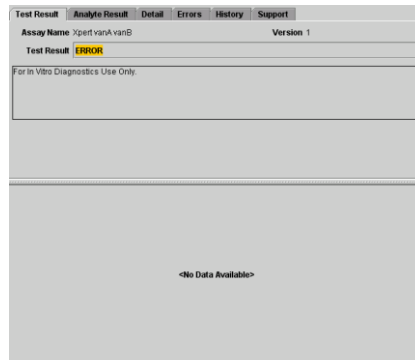


Error

ERROR

- Presence or absence of *vanA/vanB* target DNA cannot be determined. Repeat the test according to the instruction in the Retest Procedure section.
- *vanA*: NO RESULT
- *vanB*: NO RESULT
- SPC: NO RESULT
- Probe Check: FAIL*
All or one of the probe check results fail.

* If the probe check is NA, the error is caused by the maximum pressure limit exceeding the acceptable range.



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No Result

NO RESULT

Presence or absence of *vanA/vanB* target DNA cannot be determined. Repeat the test according to the instructions in the Retest Procedure section.

- *vanA* — NO RESULT
- *vanB* — NO RESULT
- SPC — NO RESULT
- Probe Check — NA (not applicable)

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Factors That Negatively Affect Results

- **Improper specimen collection**
 - Incorrect swabbing may lead to errors or invalid test results
 - Excess of stool on the swabs can result in errors
- **Use of unapproved swabs**
 - Always use these approved swabs: Cepheid Sample Collection Device (P/N 900-0370)
 - Swab should be cut at score mark to prevent errors or invalid results
- **Improper handling and storage of collected specimen**
 - If you must process the specimen on a different day from collection, keep the specimen between 2 °C to 8 °C. The specimen is stable for up to 5 days when kept at 2 °C to 8 °C.
 - Storage in other conditions can result in errors or invalid test results.
 - Two or more freeze/thaw cycles can cause errors (Specimens may be tested after one freeze / thaw cycle).

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Reasons to Repeat the Assay

- An **INVALID** result indicates that the internal SPC failed. The sample was not properly processed or PCR was inhibited. An invalid result can also be caused by air bubbles in the reaction tube
- An **ERROR** result indicates that the assay was aborted. Possible causes include: the reaction tube was filled improperly; a reagent probe integrity problem was detected; the maximum pressure limit was exceeded; a system component failed.
- A **NO RESULT** indicates that insufficient data were collected. For example, the operator stopped a test that was in progress, a load error occurred, the software was closed prematurely, or a power failure occurred.

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Retest Procedure

- To retest within 3 hours of an indeterminate result, use a new cartridge (do not re-use the old cartridge) and new reagent:
 1. Transfer the remaining contents from Chamber S to a new Sample Reagent vial using a disposable transfer pipette.
 2. Vortex, and then add the entire contents of the Sample Reagent to Chamber S of a new Xpert® *vanA/vanB* Assay cartridge.
 3. Close the cartridge lid.
 4. Start the new test.
- Alternatively, you can retest using the second swab with a new cartridge and new reagent.

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Interfering Substances

- Potential inhibitory substances tested include:
 - blood,
 - faeces, and
 - mucus.
- Substances were tested in replicate of three with VRE bacteria spiked near the analytical Limit of Detection (~3x LoD) and higher (~100x LoD).
- Excess faeces material was evaluated with real clinical samples in a multi-site investigation study.
- Inhibitory effect is occasionally seen in the presence of excess faeces on the swab.
- No significant inhibitory effects were observed in the presence of blood or mucus.

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Xpert *vanA/vanB*: Clinical Performance

Please refer to package Insert for more details



Xpert *vanA/vanB* vs Direct Culture

Xpert *vanA/vanB* Assay Performance versus Direct Culture method

	Sensitivity	Specificity	PPV	NPV
PERIANAL	92.5% (52/56)	88.7% (331/373)	55.3% (52/94)	98.8% (331/335)
RECTAL	98.9% (86/87)	80.5% (528/656)	40.2% (86/214)	99.8% (528/529)
TOTAL	96.5% (138/143)	83.5% (859/1029)	44.8% (138/308)	99.4% (859/864)

Xpert *vanA/vanB* vs Enriched Culture

Xpert *vanA/vanB* Assay Performance versus Enriched Culture

	Sensitivity	Specificity	PPV	NPV
PERIANAL	86.8% (59/68)	90.3% (327/362)	62.8% (59/94)	97.3% (327/336)
RECTAL	94.2% (114/121)	81.2% (614/756)	44.5% (114/256)	98.9% (614/621)
TOTAL	91.5% (173/189)	84.2% (941/1118)	49.4% (173/350)	98.3% (941/957)

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Xpert *vanA/vanB*: Analytical Sensitivity

- The limit of detection (LoD) for the Xpert *vanA* Assay on a simulated rectal swab specimen is **32 CFU/sample**.
- The limit of detection (LoD) for the Xpert *vanB* Assay on a simulated rectal swab specimen is **67 CFU/sample**
- The LoD is defined as the lowest number of colony forming units (CFU) per swab that can be reproducibly distinguished from negative samples with 95% confidence.
- The LoD was confirmed by running a total of 20 replicates at the estimated LoD concentration.

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Xpert *vanA/vanB*: Analytical Specificity

- **Strain origins**
 - American Type Culture Collection (ATCC)
 - Culture Collection University of Goteborg (CCUG)
- **Organisms**
 - closely related to enterococci as well as normal and pathogenic rectal/perianal flora
- **Organisms classifications**
 - aerobic (24)
 - anaerobic (14)
 - microaerophilic (2)
- 4 strains of vancomycin/teicoplanin-sensitive enterococci were tested
- Each strain was tested in duplicate at concentrations of at least 10⁹ CFU/swab. Under the conditions of the study, all isolates were reported *vanA* and *vanB* NEGATIVE.
- Positive and Negative controls were included in the study
- The analytical specificity was 100%.

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Cepheid Assay Control Strategy



Cepheid Assay Control Strategy

- **Each GeneXpert cartridge is a self-contained test device**
 - External controls have limited use in assuring proper assay performance
 - Cepheid designed specific molecular methods to include internal controls that enable the system to detect specific failure modes
- **Molecular design was created to address all the key failure modes that could result in a false negative result**
 - Probe Check
 - Specimen Processing Control / Internal Control

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Probe Check

- **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 feature controls for**
 - Missing Target Specific Reagent (TSR) beads which contain all primers, probes, and internal control template
 - Incomplete reagent reconstitution
 - Incomplete reaction tube fill
 - Taqman probe degradation

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Specimen Processing Control (SPC)

- The SPC assesses the effectiveness of the sample preparation steps, including reaction tube filling
- The SPC controls for:
 - Missing primer/probe or enzyme beads
 - Incomplete reagent reconstitution
 - Incomplete reaction tube fill
 - Enzyme degradation
 - Specimen processing
 - Sample inhibition

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Control Material

- KWIK-STIKs™ (MicroBioLogics)
 - Catalog # 01000, *E. faecium*, vanco-resistant a vanA positive control
 - Catalog # 0366, *E. faecium*, as a vanco-sensitive control
- Known patient samples
- QC organisms, such ATCC strains
 - catalog # ATCC 700221, *E. faecium*
 - catalog # ATCC 25922, *E. coli*
- Other vendor: Zeptomatrix

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

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Technical Support

- **North America, South America, Oceania, Asia:**

Monday to Friday 5:00 AM to 5:00 PM (PST)

Saturday 7:00AM to 12:00PM (PST)

Sunday On Call

- Phone: +1 (888) 838-3222 (option 2)
- Fax: +1 (408) 542-8575
- techsupport@cepheid.com

- **Europe, Africa, Middle-East, Indian Peninsula:**

Monday to Friday 8 AM to 6 PM (GMT+1)

- Phone: +33 563 825 319

- Fax: +33 563 825 301

- support@cepheideurope.com

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Discussion and Questions

- **GeneXpert Technology Review**
- **Xpert *vanA/vanB* Training**
- **Clinical Performance**
- **Assay Control Strategy**

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Xpert *vanA/vanB* Hands On Checklist

Note to instructor: Check or initial box(es) upon correct demonstration of skills.

Name of institution:

Date:

Overview of GeneXpert

- Log onto system using windows password (cphd).
- Locate the GeneXpert instrument serial number ().

Clean area and decontaminate

- Clean the work area (hood and sample prep area) with a final concentration of 10% sodium hypochlorite solution and then a 70% ethanol or 70% isopropyl alcohol solution.
- Change gloves between samples.
- Change or take off gloves before using computer.

Specimen and reagent storage and handling

- Verify approved swab was used for stool sampling.
- Verbalize correct stool storage: up to 24 hours at room temperature and for up to 5 days at 2 to 8°C.
- Verbalize that specimens can be frozen and thawed one time.
- Verbalize that Xpert *vanA/vanB* reagents stored at 2 to 28 °C.

Preparation of Xpert *vanA/vanB* cartridge

1. Obtain one cartridge and Elution Vial per specimen. Handle the cartridge without touching the reaction tube.
2. Visually inspect the cartridge, reaction tube, and Elution Vial.
3. Label the cartridge and Elution Vial.
4. Use a KimWipe or gauze to remove one swab.
5. Break the swab off into the Elution Vial.

Important: you can use a KimWipe or gauze over the mouth of the Elution Vial to prevent splash/spill/ aerosol formation.

6. Immediately discard the used KimWipe and swab shaft into the waste container.
7. Vortex the Elution Vial for 10 seconds. Hold the vial and not the cap when placing the vial into the mixer.
8. Transfer all contents of the Elution Vial into the “S” chamber using a sterile transfer pipette.

Important: Minimize bubble formation by touching the pipette or ampoule tip against the cartridge chamber wall.

9. Close the cartridge lid. Do not shake or tilt the cartridge and start the test within 30 minutes of adding the reagents.

Cartridge processing

1. Start the GeneXpert software.
 2. Click Create Test.
 3. Enter or scan the sample ID and the cartridge barcode.
 4. Click Start Test (enter user ID and password if prompted).
 5. Place the cartridge in the blinking module and close the door completely.
 6. Remove the cartridge after the test completes.
 7. Discard used cartridge in the correct waste container.
- Verbalize the completion time for the assay (x minutes).

Xpert *vanA/vanB* results

- Retrieve the automatically printed Test Report (if applicable)
- View the results under Check Status > Tests Since Launch.
- Verbalize or demonstrate the retest procedure

Cepheid Technical Support

Explain how to contact technical support

Signature of Technician:

Signature of Trainer:

Cepheid Xpert *vanA/vanB* Assay Quality Control Log

Old Lot Number	Expiration Date	Positive Control	Negative Control	New Lot Number	Expiration Date	Positive Control	Negative Control	Pass/Fail	Technician	Date

Reviewed by:
Date:

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