

Xpert[®]
vanA



45-minutes. No compromises.

 **Xpert[®] vanA**

The first rapid & accurate test to assist
with VRE surveillance.

 **Cepheid[®]**
A better way.

Xpert® vanA empowers clinicians to make critical decisions at the time it is needed most, thereby improving the quality of patient care while reducing cost.



THE NEED

According to the Centers for Disease Control and Prevention (CDC), *Enterococci* cause about 1 of every 8 hospital infections with 30% of those infections, caused by Vancomycin-Resistant Enterococci (VRE)¹. However, VRE can be even more prevalent in high risk groups, such as immunocompromized and ICU patients.

The human and financial impact of VRE is high²:

- Attributable mortality: 10%
- Extended length of stay: 6.2 days
- Incremental cost: \$12,800



THE SOLUTION

The CDC and SHEA have both published guidelines on how to reduce or eliminate healthcare associated infections^{3,4}. As a part of a quality infection control program, Cepheid's Xpert® *vanA* provides:

- Immediate and accurate detection of the *vanA* gene most closely associated with VRE colonization
- Superior NPV required in a surveillance test
- Easy-to-use test with less than 1 minute hands-on-time



PERFORMANCE

Performance characteristics of Xpert® *vanA* were determined in a multi-site prospective investigation study by comparing Xpert *vanA* run on the GeneXpert® System with direct culture with bi-directional sequencing.

Xpert *vanA* Performance vs. Direct Culture with Bi-directional Sequencing

	POSITIVE	NEGATIVE	TOTAL	
Xpert <i>vanA</i> POSITIVE	126	85	210	% POS Agreement: 98.4%
Xpert <i>vanA</i> NEGATIVE	2	1019	1021	% NEG Agreement: 92.4%
Xpert <i>vanA</i> TOTAL	128	1103	1231	Accuracy: 93.0%
				PPV*: 60.0%
				NPV*: 99.8%
				Prevalence: 94.0%

* Positive predictive value; Negative predictive value



REPRODUCIBILITY

A panel of four specimens with varying concentrations of *vanA* were tested on 10 different days by two different operators at each of three sites (4 specimens x 2 operators/day x 10 days x 3 sites).

Summary of Reproducibility Results (% Agreement)

SPECIMEN ID	SITE 1	SITE 2	SITE 3	% TOTAL AGREEMENT BY SAMPLE
Negative	100% (20/20)	90% (18/20)	100% (20/20)	96.7% (58/60)
<i>vanA</i> High Negative	100% (20/20)	100% (20/20)	95% (19/20)	98.3% (59/60)
<i>vanA</i> Low Positive	100% (20/20)	100% (20/20)	100% (20/20)	100% (60/60)
<i>vanA</i> Moderate Positive	100% (20/20)	95% (19/20)	100% (20/20)	98.3% (59/60)
% Total Agreement by Site	100% (80/80)	96.3% (77/80)	98.8% (79/80)	98.3% (236/240)



ANSWER YOU NEED IN 90 MINUTES OR LESS

Xpert *vanA* provides useful and timely information to clinicians for improved patient management.

Min

00'

15'

60'

70'

90'



Patient Suspected of VRE Colonization



Specimen Taken and Sent for Hospital Near Patient Testing



Specimen Run on GeneXpert® System With Results in Less Than 1 Hour



Floor Receives Results Indicating:
• *vanA* Positive
• Negative



Optimal Patient Management Decision



WORKFLOW:

3 EASY STEPS

Total hands-on time: <1 Minute

1

Insert swab into Sample Reagent vial and break



2

Vortex and dispense Sample into Port S



3

Insert Cartridge and start assay



> Ordering Information

CATALOG INFORMATION

Xpert *vanA* (10 tests) Catalog No. GXVANA-10

References:

1. http://www.cdc.gov/ncidod/dhqp/ar_VRE_publicFAQ.html
2. Carmeli et al., "Health and Economic Outcomes of Vancomycin-Resistant *Enterococci*". Archives of Internal Medicine 2002; 162:2223-2228.
3. Siegel, Jane, et al. "Management of Multidrug-Resistant Organisms In Healthcare Settings, 2007," Center for Disease Control, 2007.
4. Muto, Carlene, et al. "SHEA Guideline for Preventing Nosocomial Transmission of Multidrug-Resistant Strains of *Staphylococcus aureus* and *Enterococcus*", Infect Control Hosp Epidemiol 2003; 24:362-386.

For In Vitro Diagnostic Use.

CORPORATE HEADQUARTERS

904 Caribbean Drive
Sunnyvale, CA 94089 USA

TOLL FREE 1.888.336.2743
PHONE 1.408.541.4191
FAX 1.408.541.4192

EUROPEAN HEADQUARTERS

Vira Solelh
81470 Maurens-Scopont France

PHONE 33.563.82.53.00
FAX 33.563.82.53.01

www.Cepheid.com