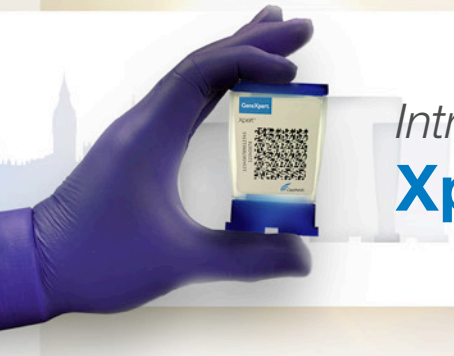

Introducing

Xpert® Carba-R*

Projected Release (CE-IVD) Q1 2014:

Situation/Introduction

- The emergence and global spread of carbapenemase-producing Enterobacteriaceae is of great concern to health services worldwide.
- These bacteria are often resistant to all beta-lactam antibiotics and frequently co-resistant to most other antibiotics, leaving very few treatment options.
- The epidemiology is compounded by the diversity of carbapenem-hydrolysing enzymes and the ability of their genes to spread between different bacterial species.[1]
- Difficulties are also encountered by laboratories when trying to detect carbapenemase production during routine diagnostic procedures due to an often heterogeneous expression of resistance and long turn-around time.

Unmet Need

- Infections caused by CRE (carbapenem-resistant Enterobacteriaceae) have limited treatment options and have been associated with high mortality rates.[2]
- Traditional enriched culture methods offer low sensitivity and are laborious taking up to 72 hours for a result.
- To address this infection control challenge, it is desirable to have a rapid, accurate and easy to use PCR test available.

Preliminary Intended Use

- The Cepheid Xpert Carba-R Assay, performed on the GeneXpert® Systems, is a qualitative in vitro diagnostic test designed for rapid detection and differentiation of the bla_{KPC}, bla_{NDM}, bla_{VIM}, bla_{OXA-48}, and bla_{IMP-1} gene sequences associated with carbapenem-non-susceptibility in gram-negative bacteria obtained from rectal swab specimens from patients at risk for intestinal colonization with carbapenem-non-susceptible bacteria.
- The test utilizes automated real-time polymerase chain reaction (RT-PCR) to detect KPC, VIM, NDM, IMP-1 and OXA-48 genes in about an hour.
- The Xpert Carba-R Assay is intended to aid in the detection of carbapenem-non-susceptible bacteria that colonize patients in healthcare settings.

* Pending CE-IVD approval. Product distribution outside the United States.

Introducing

Xpert® Carba-R*

Cepheid Molecular Testing Delivers:

- RT-PCR improves sensitivity and time to results compared to standard culture methods.
- Accurate detection of CRE provides information to help prevent widespread outbreaks.
- Detection of bacteria associated with carbapenem resistance in a healthcare facility.

Why GeneXpert®?

- A qualitative diagnostic test for accurate detection of carbapenem-resistant Enterobacteriaceae.
- On-demand RT-PCR provides real-time actionable results.
- One platform provides the flexibility to perform a broad menu of on-demand assays.

Impact:

- Identify patients with CRE quickly and efficiently.
  - Aid in reducing widespread outbreaks.
  - Allow healthcare providers to make important isolation decisions that prevent further transmission to other susceptible patients.
- Outbreaks screening of patients who have been in contact with an index case
- Active screening of patients transferred
  - Across borders between healthcare systems
  - From another healthcare facility/Rehospitalization of previously known carrier
- Active screening of high risk patients admitted from long term care facilities.
- Active screening of patients admitted to high risk settings (ICU, ventilator unit).
- Active screening on admission.
- Repeat screening to evaluate the efficacy of isolation measures employed.

Xpert Carba-R: Cepheid's on-demand Xpert test for accurate detection of KPC, VIM, NDM, IMP-1 and OXA-48 genes in about an hour.

* Pending CE-IVD approval. Product distribution outside the United States.

References:

1. Grundmann H, Carbapenem-non-susceptible Enterobacteriaceae in Europe: conclusions from a meeting of national experts. Euro Surveill. 2010;15(46):pii=19711.
2. Gupta N., Carbapenem-Resistant Enterobacteriaceae: Epidemiology and Prevention Clin Infect Dis. (2011) 53(1): 60-67 doi:10.1093/cid/cir202

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