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28 November 2013

QIAGEN's perspective in HAI testing

QIAGEN – Sample and Assay Technologies

1. Nosocomial Infections – current trends
2. Epidemiology in Europe
3. *artus* QS-RGQ Menu
4. QIAGEN positioning
5. Questions

HAIs: a constant media presence

Source: Sued Deutsche Zeitung 2013 , The Metro, The Guardian, Evening Standard

Clostridium difficile

Overview

- Gram positive, toxin producing (A and B) bacterium
- The most frequent cause of bacterial healthcare-associated diarrhea
- *C. difficile* spores are easily transmitted via direct contact and aerosols.
- Occurs in **1/436 hospital admissions** in Europe
- *C. difficile* infections adds **2,500-14,000 euro** per hospital stay and extends hospitalisation from **6-21 days**
- Total cost in Europe of **3 billion euro**

Diagnosis

- Symptomatic patients tested
- Lab evidence of **toxin-producing** *C. difficile* in stool
- Lab diagnosis is varied across Europe
- Only **1/3 of countries** have standard national screening algorithmns
- ELISA, cell cytotoxicity neutralization assay/ toxigenic culture and PCR can all identify toxin-producing *C. difficile*.
- Many labs employ a **2 step algorithm**
- Best standard laboratory test has not yet been established

Source: Annual Epidemiological Report, ECDC, 2012

Methicillin Resistant *Staphylococcus aureus*

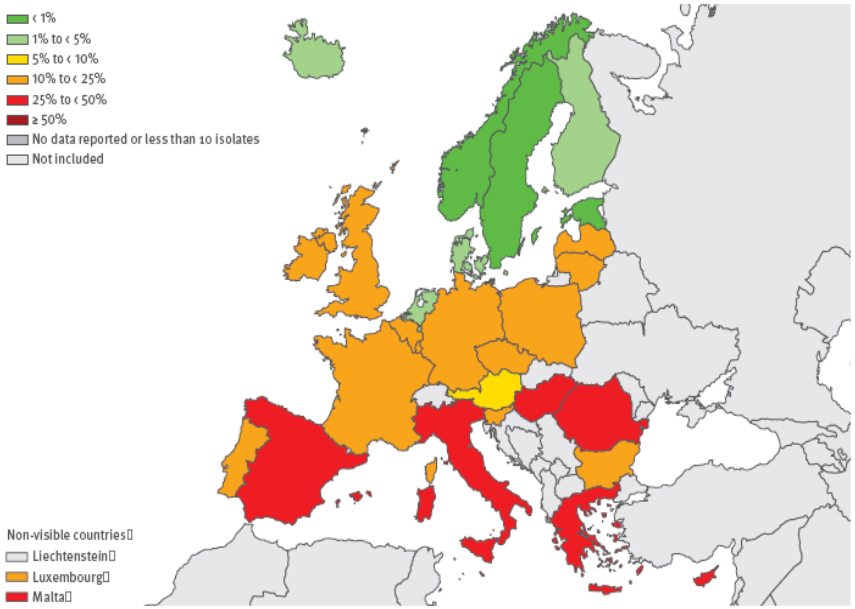
Overview and Diagnosis

- *Staphylococci spp* are ubiquitous colonisers of the skin and mucous membranes.
- MRSA has been a growing threat since the 1960s and is a major cause of HAIs.
- Acquisition of resistance involves transfer of the staphylococcal cassette chromosome (SCCmec) from other organisms
- Traditional diagnostics: culture, chromogenic agar and other biochemical tests.
- Molecular methods have several advantages; they are more sensitive, less subjective and give a much quicker time from sample to result.
- Screening of high risk patients for MRSA carriage is mandatory in some EU countries

Source: Annual Epidemiological Report, ECDC, 2012

Epidemiology

Figure 2.6.4. *Staphylococcus aureus*: percentage of invasive (blood and cerebrospinal fluid) isolates resistant to meticillin, 2010



Source: EARS-Net. Only data from countries reporting more than 10 isolates are shown.

- Some countries have significantly reduced the MRSA rates due to national screening.
- Remains a public health priority
- Prevalence is still >25% in 8 countries
- Mainly in southern and eastern Europe

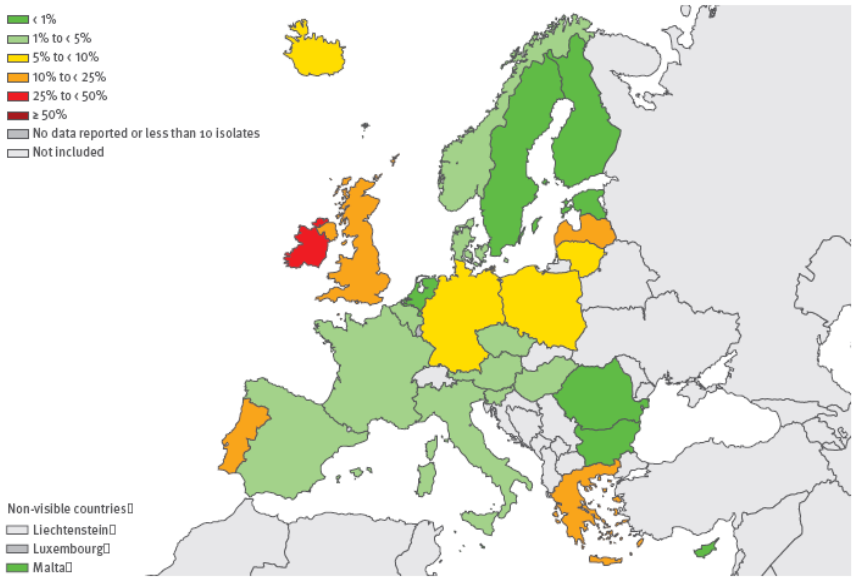
Vancomycin Resistant Enterococci

Overview and Diagnosis

- Enterococci belong to the normal bacterial flora of the GI tract of humans
- The third most common cause of bacterial HAIs
- Easily transmitted via direct contact with contaminated people or objects
- Diagnosis by conventional culture and antibiotic sensitivity methods
- Screening is not widespread across Europe
- Majority of screening is performed when an increase in resistance is observed
- Screening from anal/peri-anal swabs to determine carriage

Epidemiology

Figure 2.6.5. *Enterococcus faecium*: percentage of invasive (blood and cerebrospinal fluid) isolates resistant to vancomycin, 2010



Source: EARS-Net. Only data from countries reporting more than 10 isolates are shown.

Source: Annual Epidemiological Report, ECDC, 2012

artus HAI portfolio on the QS-RGQ platform

artus C. difficile QS-RGQ Kit

- Toxin A and B detection
- Sample type: stool
- 72 (3x24) reactions

artus VanR QS-RGQ Kit

- vanA and vanB detection
- Sample type: perirectal or rectal swabs
- 72 (3x24) reactions

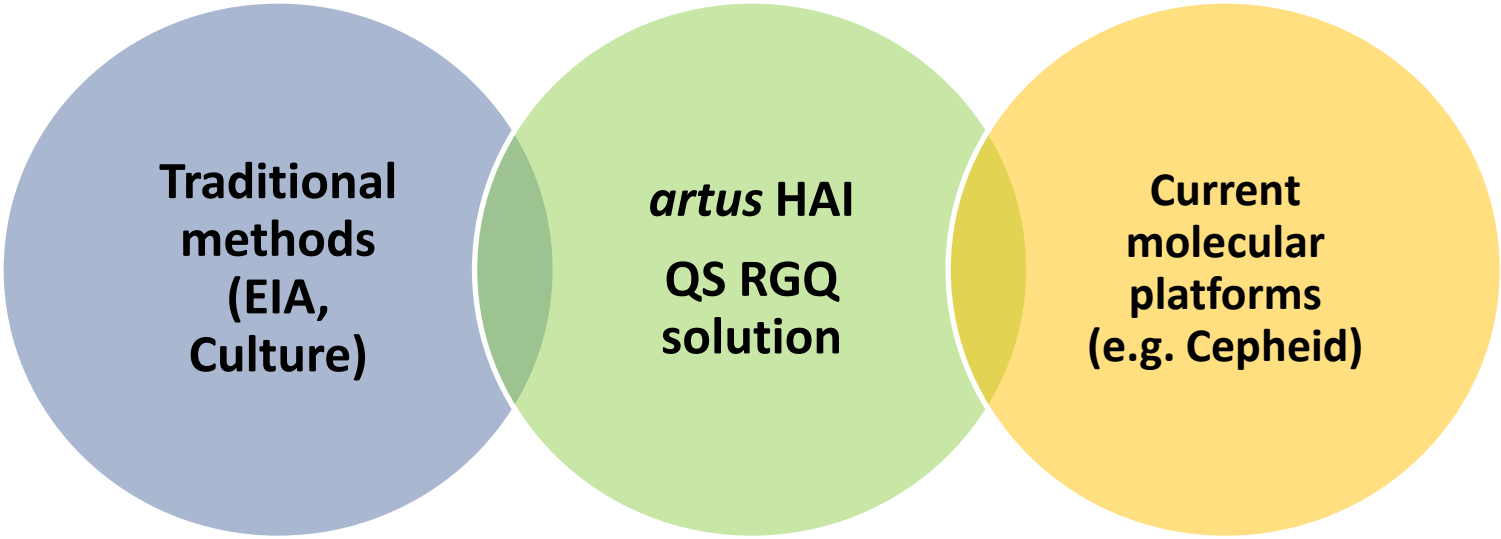
artus MRSA/MSSA QS-RGQ Kit

- MSSA, and MRSA (mecA and mecC) detection
- Sample type: nasal swab
- 72 (3x24) reactions

Launch dates	Q1 2013	Q2 2013	Q3 2013	Q4 2013	Q1 2014	Q2 2014	Q3 2014	Q4 2014	Remarks
artus C. difficile									CE: Q4/2013
artus VanR									CE: Q4/2013
artus MRSA/MSSA									CE: Q1/2014

Positioning of QIAGEN HAI offer

Time-to-result



- Core lab
- Slow to result (48h-92h)
- Manual technique = labour intensive
- Low cost

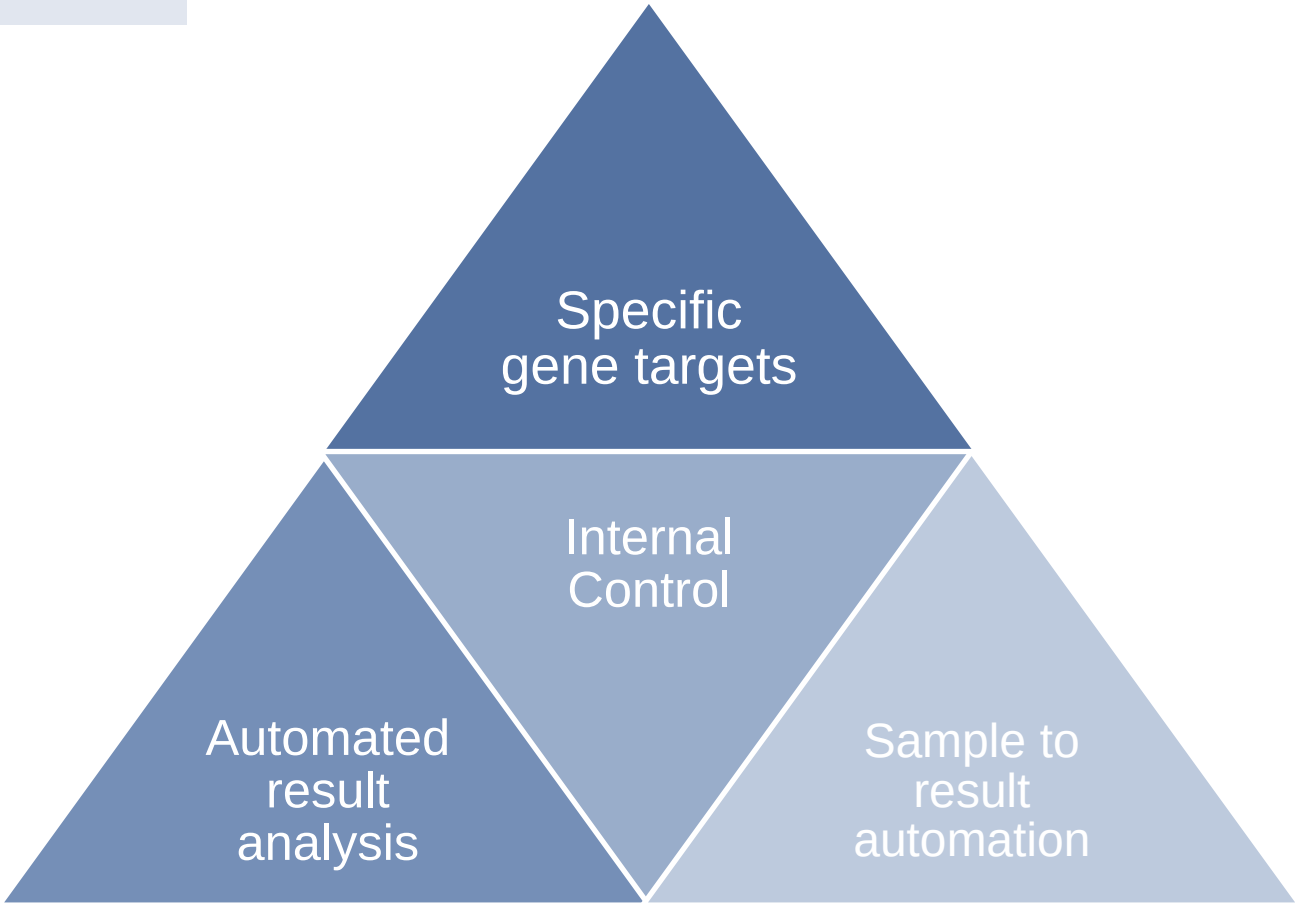
- Workflow harmonisation
- Fast time to result (<4 hrs)
- Fully automated
- Batch possibility
- Cost effective

- "Point of Need" concept
- Very fast time to result (~2hrs)
- Single sample processing = labour intensive
- Very high cost

Cost

artus HAI assays meet the customers' need for fast and cost effective diagnostics

artus HAI portfolio



Fast and reliable results for better patient management

Questions