The Acuitas™ MDRO Gene Test Compared to a Culture/Molecular Assay for Detection of Gene Families Associated with Multidrug-Resistant organisms from Single Peri-anal Swabs for Surveillance

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Background: Multidrug-Resistant Organisms (MDROs) are associated with an increase in morbidity and mortality. Patients colonized asymptomatically with MDROs before or after admission to the hospital are at higher risk of an MDRO infection. They are a reservoir for transmission to other patients creating a need for rapid and accurate identification of patients colonized with MDROs. The objective of this study was to compare the Acuitas MDRO Gene Test to combined culture and molecular detection assays.

Methods: Peri-anal swab samples from patients at the University of Maryland or affiliated ICRU during 2008-2011 were previously characterized by phenotypic and genotypic results. A subset of the archived swab samples were chosen for this study. An aliquot from each archived sample was diluted 7-fold and tested using the Acuitas MDRO Gene Test (OpGen, Gaithersburg, MD), which is a PCR-based multiplex assay that detects the KPC, NDM, VIM, IMP, OXA-23, OXA-48, OXA-51, CTX-M, and vanA resistance genes across hundreds of gene subtypes in one test from one patient sample. Acuitas MDRO Gene Test results were compared with results from individual PCR assay performed on isolates recovered from the original swab sample and the archived swab sample.

Results: When comparing the Acuitas MDRO gene test to adjudicated results performed on a recovered isolate, the Acuitas MDRO Gene test had 100% sensitivity (n=45/45) for the vanA gene. The sensitivity was 100% (n=46/46) for the OXA-51 type and 100% for the OXA-23 type gene (n=40/40). Lastly, the sensitivity for the KPC gene was 98% (n=46/47).

Conclusions: The Acuitas MDRO Gene Test has a high sensitivity to detect MDRO resistance gene families associated with CRE and other Gram-negative rods as well as VRE directly from a single peri-anal swab without culturing. Acuitas MDRO Gene Test results can provide an early warning to infection prevention and control programs.

Objective

Compare the Acuitas MDRO Gene Test to combined culture and molecular detection assays.

Results

1 Sensitivity for vanA resistance gene is 100% (n=45/45)
2 For OXA-51 type gene and OXA-23 type gene, the sensitivity was 100% (n=46/46 and n=40/40 respectively)
3 Sensitivity was 100% for the KPC gene (46/47). One discordant swab was diluted 10-fold and 100-fold. After dilution the swab was positive for KPC.

Conclusions

The Acuitas MDRO Gene Test has the ability to detect resistance genes associated with Enterobacteriaceae and other gram-negative rods as well as VRE directly from a single peri-anal swab with high sensitivity.

The Acuitas Gene Test can provide an early warning to infection prevention and control programs.

### Distribution of Organisms among Swabs Positive for OXA-51, OXA-23, KPC, and vanA

- Acinetobacter sp. (n=46)
- Enterococcus sp. (n=45)
- K. pneumoniae (n=36)
- E. coli (n=8)
- E. cloacae (n=4)
- Other Enterobacteriaceae (n=2)

*Three swabs were positive for more than one KPC organism*