

**Background:** Multidrug-Resistant Organisms (MDROs) are associated with an increase in morbidity and mortality. Patients colonized asymptotically 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 resistance. The swab samples were archived at -80° C in the presence of tryptic soy broth and 15% glycerol. 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 gene families 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.

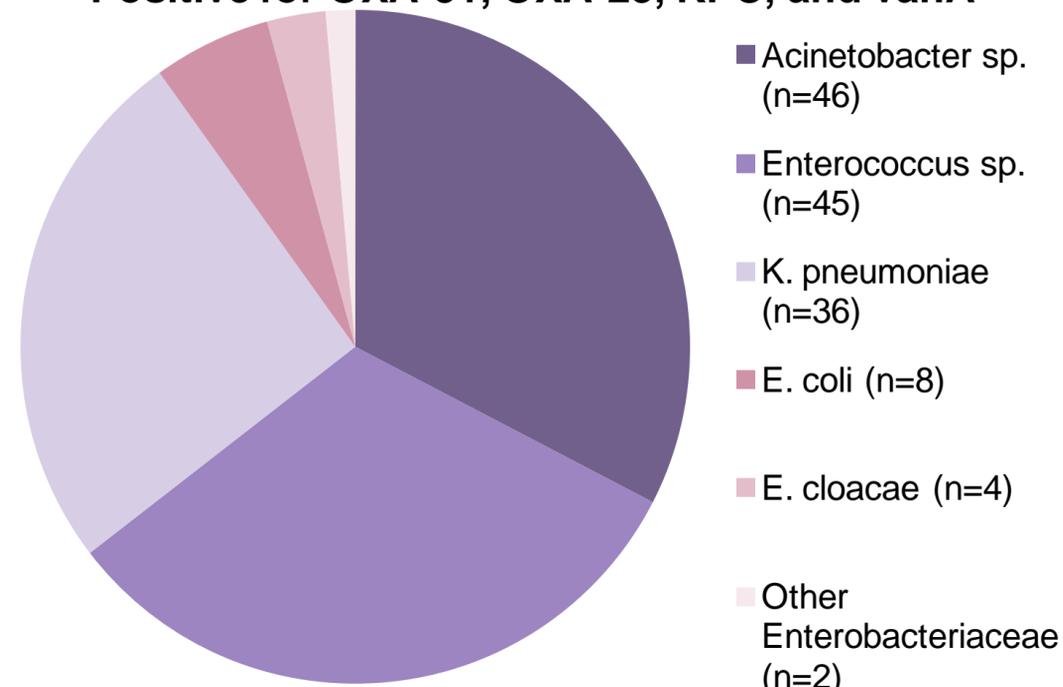
### Objective

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

### Background

- ❖ Multidrug-Resistant Organisms (MDROs) are an increasing threat and are associated with an increase in morbidity and mortality.
- ❖ Patients that are colonized asymptotically with MDROs in the hospital are at higher risk for an MDRO infection and are a potential reservoir for transmission to other patients.
- ❖ Rapid and accurate detection can aid in better management of these patients to lower infection rates, decrease patient length of stay, and proactively stop outbreaks before they occur.
- ❖ Acuitas MDRO gene test 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 in one patient sample.

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



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

### Results

- ❖ Sensitivity for *vanA* resistance gene is 100% (n=45/45)
- ❖ For *OXA-51* type gene and *OXA-23* type gene, the sensitivity was 100% (n=46/46 and n=40/40 respectively)
- ❖ 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*.

### Methods

- ❖ Peri-anal swab samples from patients at the University of Maryland, previously characterized genotypically and phenotypically, were frozen at -80° C in tryptic soy broth with 15% glycerol.
- ❖ A subset of the archived swabs 50 *KPC*, 42 *OXA-23*, 48 *OXA-51*, and 45 *vanA* were chosen based on their phenotypic and genotypic results.
- ❖ Archived swabs were cultured again and organisms recovered were tested with individual PCR assays for *KPC*, *OXA-23*, *OXA-51*, and *vanA*.
- ❖ Archived swabs were also tested using the Acuitas MDRO Gene Test.

		UMB <i>KPC</i> Result	
		+	-
Acuitas <i>KPC</i> Result	+	47	0
	-	0	3

		UMB <i>vanA</i> Result	
		+	-
Acuitas <i>vanA</i> Result	+	45	0
	-	0	0

		UMB <i>OXA-51</i> Result	
		+	-
Acuitas <i>OXA-51</i> Result	+	46	0
	-	0	2

		UMB <i>OXA-23</i> Result	
		+	-
Acuitas <i>OXA-23</i> Result	+	40	0
	-	0	2

### 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.