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ePoster Viewing

Molecular bacteriology

Evaluation of nasal swab specimens with the cobas® MRSA/SA test for the detection of *Staphylococcus aureus* and MRSA compared with direct and enrichment culture

L. Peterson[1], S. Young[1], T. Davis[1], Z. Wang[1], C. Woods[1], K. Lu[2], J. Duncan[2], O. Liesenfeld[2], J. Osiecki[3], M. Lewinski[2]

[1]*Northshore University Health System, Evanston- IL, USA*

[2]*Roche Molecular Systems, Pleasanton- CA, USA*

[3]*Roche Molecular Systems, Pleasanton CA, USA*

Objectives: Nucleic acid amplification tests have proven to be reliable, rapid and sensitive tools for the detection of *Staphylococcus aureus* (SA) and methicillin-resistant *S. aureus* (MRSA) DNA from nasal specimens. SA is an opportunistic pathogen carried on the skin and nares of approximately 30% of the normal population and is capable of causing a broad spectrum of diseases. SA and MRSA are a major source of healthcare-acquired infections responsible for bacterial outbreaks in healthcare settings worldwide. The objective of this study was to evaluate the newly developed **cobas**® MRSA/SA Test performed on the **cobas**® 4800 system using nasal swabs from patients representative of the United States as part of a large, multicenter clinical trial.

Methods: Eligible male and female subjects screened for MRSA and SA were selected for participation. Specimens were collected at 6 geographically diverse sites across the United States. An MSwab specimen (Copan, Brescia, Italy) was collected for the **cobas**® MRSA/SA Test and direct chromogenic and enrichment culture. The **cobas**® MRSA/SA Test was performed at 3 sites and the culture was performed at a reference laboratory. Sensitivity, specificity, PPV and NPV values were calculated by comparing **cobas**® MRSA/SA Test results with direct chromogenic culture combined with enrichment culture. Discrepant analysis was performed on all discordant samples using the Cepheid Xpert™ SA Nasal Complete test, a second FDA-cleared nucleic acid amplification test (NAAT), and a non-selective direct and non-selective enrichment culture.

Results: A total of 2,528 subjects were enrolled in the study with 2,504 (99.1%) evaluable results from 1,372 males (54.8%) and 1,132 (45.2%) female subjects. There were a total of 160 MRSA-positive and 660 SA-positive specimens. The sensitivity, specificity, prevalence, PPV and NPV for the **cobas**® MRSA/SA Test compared to direct chromogenic culture combined with enrichment culture was determined from 2,500 evaluable results for MRSA and 2,501 evaluable results for SA. Sensitivity and specificity for MRSA compared to combined direct and enrichment culture was 93.1% (149/160) and 97.5% (2281/2340), respectively, with a prevalence, PPV and NPV of 6.4%, 71.6% and 99.5%, respectively. The sensitivity and specificity for SA compared to combined direct and enrichment culture was 93.9% (620/660) and 94.2% (1734/1841), respectively, and the prevalence, PPV and NPV for SA compared to combined direct and enrichment culture was 26.4%, 85.3% and 97.7%, respectively. Discrepant analysis corroborated the **cobas**® MRSA/SA Test results for 5 of 11 MRSA false negative samples, 20 of 59 MRSA false positive samples, 31 of 40 SA false negative samples and 24 of 107 SA false positive samples.

Conclusion: The **cobas**® MRSA/SA Test, performed on the automated **cobas**® 4800 system, displayed excellent performance compared to direct chromogenic and enrichment culture for the detection of *Staphylococcus aureus* and MRSA from clinical samples.