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.

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Introduction and 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 (Figure 1) using nasal swabs from patients representative of the United States as part of a large, multicenter clinical trial.

Methods

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 a second FDA-cleared nucleic acid amplification test (NAAT), the Cepheid Xpert™ SA Nasal Complete test, and a non-selective direct and non-selective enrichment culture.

Figure 1. **cobas**® 4800 System (**cobas x** 480 and **cobas z** 480 instruments)

Results

A total of 2,528 subjects were enrolled in the study with 2,504 (99.1%) evaluable results from 1,371 males (54.8%) and 1,133 (45.2%) female subjects. The results comparing the **cobas**® MRSA/SA Test with direct and enrichment culture for MRSA and SA are shown in Tables 1 and 2, respectively.

There were a total of 160 MRSA-positive and 660 SA-positive specimens based on direct and enrichment culture (Reference Method). 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.

Table 1. Comparison of MRSA results from the cobas® MRSA/SA Test with direct and enrichment culture (Reference Method).

MRSA		Direct and Enrichment Culture		
		Pos	Neg	Total
cobas® MRSA/SA Test	Pos	149	59	208
	Neg	11	2281	2292
	Total	160	2340	2500
SEN: 93.1% (95% CI: 88.1-96.1%)				
SPEC: 97.5% (95% CI: 96.8-98.0%)				
PPV: 71.6%				

CI = 95% Confidence Interval

Table 2. Comparison of SA results from the cobas® MRSA/SA Test with direct and enrichment culture (Reference Method).

SA		Direct and Enrichment Culture		
		Pos	Neg	Total
cobas® MRSA/SA Test	Pos	620	107	727
	Neg	40	1734	1774
	Total	660	1841	2501
SEN: 93.9% (95% CI: 91.9-95.5%)				
SPEC: 94.2% (95% CI: 93.0-95.2%)				
PPV: 85.3%				

CI = 95% Confidence Interval

Conclusions

- ❑ 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 nasal swab specimens.
- ❑ The test is highly suitable for the direct detection of MRSA and SA DNA from nasal swabs to aid in the prevention and control of MRSA and SA infections in healthcare settings.

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