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Development and performance of the QIAGEN artus GBS QS-RGQ kit for detection of group B streptococci using the QIAsymphony RGQ MDx system

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Objectives

Infection with Group B streptococci (GBS) is responsible for most cases of neonatal sepsis, posing a large threat to newborn health. GBS-colonised mothers are the primary risk factor for disease, as they can transmit the bacteria to newborns *in utero* or vaginally during birth. In Europe, GBS vaginal colonisation rates have been reported to range from 6.5 to 36%, with serotypes Ia, II, and III being the most frequently identified. It is critical to screen pregnant women early in order to administer preventative treatment and reduce occurrence of newborn infection. IMDx has employed its proprietary bioinformatics platform to design an *in silico* screened, qualitative, multiplexed, real-time PCR-based assay to detect GBS directly from Lim broth cultures obtained by incubating vaginal/rectal swab specimens from antepartum women, using the QIAsymphony SP/AS and Rotor Gene Q instruments. This study evaluated the initial analytical performance characteristics of the *artus* GBS QS-RGQ Kit.

Methods

To assess initial performance characteristics of the *artus* GBS QS-RGQ Kit, a series of validation studies was conducted. Analytical reactivity was assessed by testing GBS strains representing serotypes Ia, Ib, II, III, VI, V, IV, VII, and VIII. Preliminary limit of detection studies were conducted for serotype Ia and III using Lim broth. The assay was tested for potential interference and cross reactivity using a panel of organisms found in genital and rectal specimens and a panel of potentially interfering substances that may be used on or near the sampling site. A subset of clinical samples (35 known positive and 35 known negative) was tested for reactivity with the *artus* GBS QS-RGQ Kit. Initial studies to establish reagent stability were also conducted.

Results

Preliminary analytical reactivity studies demonstrate that the *artus* GBS QS-RGQ Kit detects a variety of strains of GBS, representing all serotypes tested. Preliminary limit of detection studies demonstrate values of 74.85 (95% CI 40.29-181.06) CFU/mL for serotype Ia and 24.29 (95% CI 16.73-64.57) CFU/mL for serotype III. No interference or cross-reactivity was found when the assay was challenged with a panel of organisms and a panel of substances. When a subset of clinical samples was tested, the assay demonstrated agreement of 100% for positive samples and 91% for negative samples. In addition, samples and reagents were found to be stable on-board the instrument for 60 minutes.

Conclusions

The *artus* GBS QS-RGQ Kit has demonstrated effective analytical performance with good correlation to results obtained from standard culture methods. Combined with a turnaround time of one work shift for up to 70 patient samples, this assay is a desirable option for screening antepartum women at risk for GBS infection. The *artus* GBS QS-RGQ Kit is in development and not available for sale.