CT/NG molecular tests, 2/13:109

Meridian Bioscience has completed beta trials for two new Illumigene molecular amplification tests specifically designed to detect the DNA of Chlamydia trachoma-tis and Neisseria gonorrhoeae, respectively, from swab and urine specimens.

The assays will also incorporate Meridian's new nucleic acid preparation device, which further simplifies the Illumigene test procedure. This novel sample preparation device does not require excessive sample manipulation steps and takes only five minutes to process a clinical specimen.

In the beta trial, performance of the new Illumigene assays was assessed against two molecular platforms on a statistically significant cohort of symptomatic patients. The trials were successful and satisfied the design criteria for both assays. Total test time, from specimen to results, for the new molecular tests was about one hour on the Illumipro-10 integrated incubator/reader. It is expected that the clinical trials for regulatory submission will begin in the second quarter and should be completed in the third quarter of the year.

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