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March 14, 2014

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By a GenomeWeb staff reporter

NEW YORK (GenomeWeb News) – BGI said this week that it is working with its collaborators to suspend the clinical application of its non-invasive fetal trisomy test in mainland China following a recent announcement from Chinese officials that genetic tests should be regulated.

The China Food and Drug Administration and the National Health and Family Planning Commission made the announcement last month. The statement specifically noted prenatal genetic testing, including sequencing-based tests, and said that regulating the use of such products is being done to "ensure the public safety of gene sequencing diagnostic products," according to an English translation of the document.

It also noted that the National Health and Family Planning Commission is responsible for managing the clinical application of sequencing-based diagnostics.

In its statement BGI said that it "fully acknowledges the necessity to regulate [the] genetic testing industry." It added that non-invasive fetal trisomy testing "is a reliable technology verified with massive samples, which has enormous clinical demands and with great social benefits."

BGI said that it is in the process of registering its test according to the new regulations.

Other providers of sequencing-based trisomy testing products, including Life Technologies and Illumina, declined to comment on the regulation notice.

An Illumina official said during a webcast of the firm's investor day in January that the company would seek US Food and Drug Administration and Chinese Food and Drug Administration clearance of its HiSeq2500-based NIPT assay later this year.

Another competitor in the market, China's Berry Genomics, told *Clinical Sequencing News* in January that it had evaluated more than 150,000 of its noninvasive prenatal tests, called Bambni, since its launch in late 2011. The test was validated on Illumina's HiSeq 2000, but a company official said the firm is in the process of switching to the HiSeq 2500.