CapitalBio® Non-Invasive Prenatal Testing (NIPT) for Fetal Chromosomal Aneuploidies

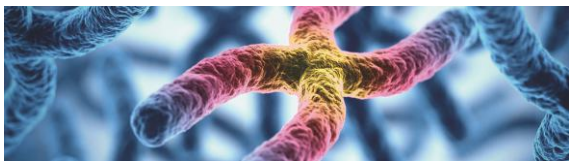


CapitalBio®BioelectronSeq 4000

Symptoms of Chromosomal Abnormalities

Chromosomal diseases are diseases caused by abnormal number or structure of chromosomes. In clinic, 21–trisomy syndrome, 18–trisomy syndrome, and 13–trisomy syndrome are common.

Most of these children have mental retardation, slow growth, underdevelopment, multiple malformations, and fertility problems in adulthood. And Most of them cannot take care of themselves. So far, there is no cure for chromosomal abnormalities.



Product Introduction

By extracting fetal free DNA from maternal peripheral blood, with a new generation of high–throughput sequencing technology, and combined with bioinformation analysis, Chromosome abnormalities, such as trisomy 21, 13 and 18, can be detected simultaneously.

A validation study of 10,818 clinical trials has been completed. Compared with the results of chromosome karyotype analysis and birth follow–up results, the sensitivity is 100%, the specificity is 99.91%, and the total coincidence rate is 99.91%. The kit has obtained CFDA in August 2020.

Fetal Cell–Free DNA enrichment

Increase the fetal free DNA concentration from 11.3% to 22.6% through innovative experiment technology.

Determination of fetal free DNA concentration

Accurate determination of fetal DNA concentration through innovative bioinformatics methods.

99.9% Accurate result

The detection accuracy is more than 99.9% through the verification of more than 2,500,000 clinical trials.

Applicable Population



01 Pregnant women whose serological screening shows that the critical risk value of common fetal chromosomal aneuploidy is between the high-risk cut value and 1/1000.

02 Those with contraindications for interventional prenatal diagnosis, such as threatened abortion, fever, bleeding tendency, the active period of chronic pathogen infection, Rh-negative blood group pregnant women, etc.

03 At the time of treatment, patients who were more than 20+6 weeks pregnant, missed the best time for serological screening, but required to assess the risk of 21-trisomy syndrome, 18-trisomy syndrome, and 13-trisomy syndrome

Please use with caution when in any of the following situations

- High risk of prenatal screening in the first and second trimester
- Advanced maternal age (AMA)
- Obese mothers (BMI ⩾40)
- Conception through in vitro fertilization
- Childbirth history of fetuses with chromosomal abnormalities, but does not include the case of couples with chromosomal abnormalities
- Fetal reduction and abortion during twin pregnancy
- Other situations that significantly affect the accuracy of the results



Applications

Through cooperation with Chongqing Xinqiao Hospital, University of California San Diego and other units, analysis of plasma samples from 190,277 pregnant women from 2015 to 2016 showed that the sensitivity and specificity were 99.61% and 99.91%, respectively. Overall positive predictive value (PPV) and overall negative predictive value (NPV) were 89.74% and 99.99%, respectively. This is the first large-scale clinical study of semiconductor sequencing technology in the application of fetal cell-free DNA.

Test Type	Sensitivity	Specificity	Positive predictive value	Negative predictive value
21-trisomy	99.80%	99.98%	96.42%	100.00%
18-trisomy	98.84%	99.98%	87.08%	100.00%
13-trisomy	100%	99.96%	32.08%	100%
Total	99.61%	99.91%	89.74%	100.00%

Reference

Hu H, Liu H, Peng C, et al. Clinical Experience of Non-Invasive Prenatal Chromosomal Aneuploidy Testing in 190,277 Patient Samples[J]. Current Molecular Medicine, 2016, 16(8): 759-766.

Performance parameters

Sequencing sample size	Sequencing time	Average read length	NO. of specific fragments	Accuracy rate
PI: 20-22 Samples/run PII: 40-50 Samples/run	2-4 times/day	>100 bp	4.5M±20%/sample	>99.9%

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