



Technical billing accuracy analysis. For Research Use Only. Not for clinical use.

The test and lab details in this mock report are fictional yet are modeled after real clinical lab scenarios.

NPI #####

Test Name: PROSPECT NIPT

Laboratory: FETAL TESTING EXPERTS, INC

Date: 21 January 2022

Test Description

Noninvasive prenatal testing/screening. A genetic test using fetal DNA fragments found in the blood from a pregnant person to screen for chromosomal abnormalities.

FINDINGS

BILLING FRAUD: Very Likely

A CPT code for a technology not typically used in this type of genetic testing and not described in the test's technical specifications has been repeatedly used by the laboratory and reimbursed by [the Client]. This anomalous CPT code is 88271 (molecular cytogenetic analysis) and has been used along with legitimate CPT codes. Further investigation is recommended.

CURRENT MARKETING CLAIMS: Possibly Misleading

The test is currently marketed in the U.S. with the tagline "Total confidence in every result for your peace of mind." However, in the instances where the test result is "positive" for a chromosomal anomaly, approximately half the time the result is a false positive (see Results Details on the next page). Therefore, the marketing claim of "total confidence in every result" is likely not a correct representation of this test.

While the technical specifications and website details describe this test as a screen for which positive results should be confirmed through more accurate diagnostic testing, the primary marketing language is possibly misleading to clinicians and patients and may compromise the quality of care for plan members.

## METHODOLOGY & RESULT DETAILS

### Billing Fraud (CPT Code Usage)

[The Client's] Special Investigation Unit searched ICD-10 and CPT codes congruent with noninvasive prenatal testing done at the Fetal Testing Experts, Inc laboratory (NPI #####) from December 2018 through November 2021 (inclusive). The CPT codes and usage counts of reimbursed services were shared with the Center for Genomic Interpretation (CGI). Patient level data and reimbursement details were *not* shared.

The technical specifications for the test under investigation were obtained through CGI contacting the laboratory's Customer Service team. During the time period of investigation, the test's technical specifications had been updated once. The Laboratory's Customer Service team supplied both technical specifications used during the investigated time period to CGI. The laboratory was blinded to the purpose of the request and participation was *not* required for the analysis. The CPT codes used by the laboratory were then compared to these technical specifications. Any CPT code that did not match the technologies described in the technical specifications was flagged.

### Results on CPT Code Usage

CPT code 88271 (molecular cytogenetic analysis) is the only code discovered in this analysis that did not match the test description on the technical specifications. Noninvasive prenatal testing does not typically involve a molecular cytogenetic analysis, nor do the technical specifications of the test indicate the use of DNA probes. This code was used 2,732 times within the dataset [the Client] shared with CGI.

### Current Marketing Claims

The test is marketed in the U.S. with the tagline "Total confidence in every result for your peace of mind," which is presently on display on the landing page for Prospect NIPT at <http://www.fetaltestingexperts.com/prospect-nipt-prenatal-screening/>. This test screens for multiple fetal chromosomal anomalies, with Trisomy 21 (Down syndrome) being the most common chromosomal anomaly being screened for in terms of birth incidence. A review of the test's Technical Specifications indicate a technical sensitivity for Trisomy 21 detection of 99.2% and a specificity of 99.91%. For a woman of typical childbearing age in the U.S. of 26 years, the positive predictive value of this test for a Trisomy 21 positive result at 16 weeks of gestation is 53%. That is, the probability that the positive result is a true positive (the fetus has Trisomy 21) is 53%, and the probability that the positive result is a false positive (the fetus is not affected by Trisomy 21) is 47%. For rarer microdeletions such as DiGeorge syndrome, the positive predictive value of the test is estimated to be between 4% and 9%.

While the technical specifications and website details describe this test as a screen for which positive results should be confirmed through more accurate diagnostic testing, **the primary marketing language is possibly misleading to clinicians and patients.**