# FDA issues warning as women abort healthy babies due to false positives on prenatal genetic screening tests

## Description

USA: The FDA is warning that certain prenatal screening tests used to detect genetic abnormalities have a high chance of returning a false positive, and the stakes could not be higher as the results of these tests lead some women to get abortions.

At the heart of the concern are Noninvasive Prenatal Screening (NIPS) tests, which are used to assess a baby's risk of having a genetic abnormality rather than definitively confirming one or ruling one out. However, labs often claim that they are highly accurate and reliable, and women are making life-and-death decisions based on their results.

The FDA said that it "is concerned that these claims may not be supported with sound scientific evidence" and that there is a particularly high chance of getting a false positive when screening for rare disorders such as microdeletions.

The agency also noted that it was aware that women have been getting abortions based solely on the results of these tests. They warned that there is no way to know if a baby actually has a genetic abnormality indicated by the screening without getting a confirmatory diagnostic test. In some cases, a screening test may indicate the presence of a genetic abnormality only for a diagnostic test to later find it does not exist.

## Women are not being told that positive results aren't very accurate

Part of the problem is that NIPS tests results are indeed accurate when they are negative. In fact, they enjoy a 99.9% chance of accuracy on negative results. However, when the results come back positive, the rate of accuracy is considerably lower depending on the abnormality in question – and many women aren't aware of this fact.

Of all the abnormalities, the tests' reliability for the detection of Down syndrome in positive results was the highest at 90 percent, which means there is still a notable 10 percent chance of getting a false positive. The numbers are much worse for other disorders. For example, for microdeletion disorder such as Di George Syndrome, which causes delayed language acquisition and heart defects, the FDA notes that the positive predictive value ranges from 2 to 30 percent. Therefore, the American College of Obstetricians and Gynecologists does not recommend using these tests for detecting microdeletions.

According to the FDA, the notice was prompted by an increase in the use of NIPS tests and "concerns raised in recent media reports."

They may be referring, at least in part, to a *New York Times* report on January 1 that revealed microdeletion tests yield 85 percent false positives. A geneticist quoted in the story said they knew of a woman who had aborted her baby over the results only to discover when follow-up test results came in later that the baby had actually been healthy.

In interviews with 14 patients who were given false positives for genetic disorders, the publication found that more than half of them said they were never given any information about the possibility of false positives, and five of them characterized their doctors' treatment of the test results as "definitive."

Another story in the *Boston Globe* quoted a doctor discussing three abortions after unconfirmed positive results in these tests.

The *Times* also found that many of the patient and doctor brochures from popular testing companies do not mention the possibility of false positives occurring, and only one indicated how often each test gets a positive result wrong.

With a third of all pregnant women in the U.S. taking these tests every year and many women basing decisions about whether to terminate on the results, this deception needs to stop, and companies and healthcare providers need to be more up front about the limitations of these tests.

**Sources for this article include:**

LifeSiteNews.com

NYTimes.com

FDA.gov

by: Cassie B.

**Category**

1. Health-Wellness-Healing-Nutrition & Fitness
2. Main
3. Politics-Geopolitics-Gov.-Events
4. Science-Tech-AI-Medical & Gen. Research

**Date Created**

04/28/2022