

FDA warns about genetic noninvasive prenatal screening tests

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Noninvasive prenatal screening (NIPS) tests may yield false results or

inappropriate interpretations of results, according to a safety communication issued by the U.S. Food and Drug Administration.

NIPS tests, the FDA warns, are not authorized, cleared, or approved, and the accuracy and performance of these tests have not been evaluated by the FDA. The FDA says it is aware of cases where a screening test reported a [genetic abnormality](#) and a confirmatory diagnostic test later found that the fetus was healthy.

The FDA issued the following recommendations: (1) patients should discuss the benefits and risks of NIPS tests with a genetic counselor or other health care provider before deciding to get these tests; (2) [patients](#) should discuss NIPS test results with a genetic counselor or other [health care provider](#) before making any decisions about their pregnancy; and (3) [health care providers](#) should be aware of the risks and limitations of using these screening tests. Results from NIPS tests alone should not be used to diagnose fetal chromosomal (genetic) abnormalities or disorders, the FDA says.

"While genetic NIPS tests are widely used today, these tests have not been reviewed by the FDA and may be making claims about their performance and use that are not based on sound science," Jeff Shuren, M.D., J.D., director of the FDA Center for Devices and Radiological Health, said in a statement. "Without proper understanding of how these tests should be used, people may make inappropriate health care decisions regarding their pregnancy."

More information: [More Information](#)

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