



**ASSOCIATION FOR MOLECULAR PATHOLOGY**  
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## **AMP Response to Recent FDA Safety Communication on NIPS Testing**

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Last week, the U.S. Food and Drug Administration (FDA) issued a safety communication on the risk of false results, inappropriate use, and inappropriate interpretation of results of non-invasive prenatal screening (NIPS) tests. While AMP objects to the assertion by the FDA that NIPS tests developed by federally certified laboratories are inaccurate, we support all efforts to educate healthcare providers, patients, and the public on the appropriate use of these screening tools. AMP is committed to ensuring pregnant people have access to recommended screening and diagnostic testing through outreach and educational programs for healthcare providers and patients. As an example, in February, AMP hosted a webinar for patient advocates and the public on NIPS tests, highlighting how the technology is currently used clinically, how patients can benefit, and how screening tests differ from diagnostic tests. AMP also appreciates the FDA's recognition of the importance of professional society practice guidelines in informing proper clinical care as well as the essential role that certified genetic counselors and other qualified healthcare professionals have in pre-screen consenting, educational processes, and follow-up confirmatory diagnostic testing.

When used correctly, NIPS tests can provide valuable information about the risks a fetus might be affected by a severe health condition. They are designed to screen for genetic abnormalities and provide an estimate of risk. These screening tests are not meant to deliver a definitive diagnosis that a fetus has a genetic condition. Pregnant people should undergo confirmatory diagnostic testing and genetic counseling before critical healthcare decisions are made. As with all prenatal genetic screening and testing, it is important for patients and healthcare providers to discuss the benefits and risks before considering such testing or making any decisions about their pregnancy.

Despite what is being miscommunicated in some recent news coverage, NIPS is a highly accurate screening modality supported by practice guidelines from premier genetics and women's health professional organizations. NIPS tests are currently offered as laboratory developed testing procedures (LDPs) and regulated by the Centers for Medicare & Medicaid Services (CMS) under the Clinical Laboratory Improvement Amendments (CLIA) in addition to state-level requirements. LDPs are performed in clinical laboratories by appropriately trained and qualified professionals. As with all LDPs, AMP has long maintained that FDA oversight of LDPs would be duplicative with existing regulations, slow innovation, and could compromise patient access to the tens of thousands of high-quality, validated medical procedures that benefit patients each and every day.