# Overview of Food and Drug Administration's Technical Assistance on the Diagnostic Accuracy and Innovation Act

The FDA supports the goal of legislation to create a predictable path to market for all in vitro clinical tests (IVCTs) that is a risk-based approach consistent with the least burdensome principle for regulation and assuring necessary safeguards for consumers.

Patients and health care providers need accurate, reliable, and clinically valid tests to make good health care decisions. Inaccurate or false test results, or accurate measurements with an invalid claim regarding the test results' relationship to a disease, can lead to patient harm. While excessive oversight can discourage innovation, inadequate and inconsistent oversight in which different test developers are treated differently can also discourage innovation by making it difficult for high-quality test developers to compete with poorer performing counterparts.

For these reasons, it is important to strike a balance that provides for an efficient pathway to bring new tests to patients without sacrificing the assurances provided by FDA oversight, in a manner that both leverages and avoids duplication with CLIA. To achieve this goal, FDA believes it is necessary to create pathways that are efficient and achieve reasonable assurance of analytical and clinical validity, without imposing unnecessary burdens.

While this technical assistance provides the agency's feedback on many provisions of the legislation, below are several key concepts that demonstrate the agency's thinking:

- ***Establish a balanced regulatory approach:*** FDA believes there should be a balanced, risk-based regulatory approach that applies least burdensome principles not only for monitoring currently marketed IVCTs but also ensuring future IVCTs have a flexible and efficient path to market, all while assuring patients and providers that IVCTs are accurate, reliable, and clinically valid.
- ***Encourage Innovation:*** FDA believes an optional precertification program for certain eligible test developers and categories of IVCTs can encourage innovation and quality. After an entity has been precertified, IVCTs within the specified precertification category would not be subject to premarket review. Ultimately, this would create an efficient, least burdensome pathway for products for two years, at which time precertification would be reviewed to provide continuing assurance that the IVCTs meet statutory standards.

- ***Protect patients***
  - Comprehensive regulatory approach: FDA believes that all IVCTs should be subject to oversight for analytical and clinical validity.
  - Transparency: FDA believes that an approach to IVCTs should build in transparency for patients, providers, payors and competitors, including public availability of information about IVCTs, efficient and effective approaches to reviewing IVCTs and updating or modifying tests, and mechanisms to protect patients when FDA discovers problems relating to IVCTs.
  - Patient Access: FDA believes there should be appropriate mechanisms for grandfathering IVCTs already on the market and for assuring access to tests for small patient populations and rare diseases or conditions, while assuring that FDA can address IVCTs of concern, including an ability, when appropriate, to remove an IVCT from the market.

| | Notification to FDA | Pre-market review | Adverse Event Reports to FDA | QS elements* | FDA-required Labeling | |
|---|---|---|---|---|---|---|
| **Grandfathered Tests** | | Exempt | | Exempt | Exempt | |
| **Tests from Precertified laboratories** | | Exempt from individual premarket review | | | | |
| **Exempt pre-enactment** | | Exempt | | | | |
| **High Risk Tests**** | | | | | | |
| **Low Risk Tests** | | Exempt | | | | |
| **Manual Tests***** | Exempt | Exempt | Exempt | Exempt | Exempt | |
| **Rare Tests (<8,000/year)** | | Exempt | | | | |
| **Public Health Surveillance** | Exempt | Exempt | Exempt | Exempt | Exempt | |
| **Law Enforcement** | Exempt | Exempt | Exempt | Exempt | Exempt | |
| **Custom** | Exempt**** | Exempt | | Exempt | | |
| **Low Volume (<5/year)** | Exempt**** | Exempt | | Exempt | | |
| **Investigational** | Exempt | Exempt | Exempt | Exempt | Exempt | |

*design controls, purchasing controls (including supplier controls), acceptance activities, corrective and preventative action (CAPA), and records

** first of a kind, screening, cross-labeled

*** Done in CLIA high-complexity lab; If not high-risk, which would include HIV, blood donor, fetal/newborn, others

****Annual report required