The Diagnostic Accuracy and Innovation Act

Section-by-Section Overview

SEC. 590. REGULATION OF IN VITRO CLINICAL TEST DEVELOPMENT ACTIVITIES.	
Page 5-13	• Sets forth clear lines of jurisdiction (in conjunction with other sections). • Establishes FDA authority to review the design, development, validation, production, manufacture, preparation, propagation, assembly, and modification of an in vitro clinical test (IVCTs). • Creates a new Center at FDA for IVCT regulation. • Establishes "reasonable assurance of analytical validity and clinical validity" as the IVCT standard for review and defines those terms. • Defines key terms including "valid scientific evidence" and "reasonable assurance".
"SEC. 590A. CLASSIFICATION OF IN VITRO CLINICAL TESTS.	
Page 13-35	• Sets up three risk classifications: High-risk, Moderate-risk, and Low-risk. o High-risk tests are those that would cause serious or irreversible harm, prolonged disability, or death, to the patient or public based on an inaccurate result, have no mitigating factors and the chance of the risk is not remote. o Moderate-risk tests are those that have mitigating factors for an otherwise high risk-test, a reversible risk to a patient, or a delay in treatment based on an inaccurate result and that the chance of the risk is not remote. o Low-risk tests are those that have mitigating factors for an otherwise moderate-risk test, or those that have minimal or no harm from an inaccurate result or if the risk to patients is remote. • Establishes a risk classification process in which developers propose to FDA the appropriate classification of new IVCTs. o FDA has 60 days to agree or object to the developer's proposed classification. If FDA does not act within this period, the developer's proposed classification will be the final classification. o A reclassification process (including a streamlined down-classification process) may be initiated by any person (including the developer or FDA). o Advisory panels are available for complex classification and reclassification issues.
"SEC. 590B. PREMARKET REVIEW.	
Page 35-104	• Establishes process for developers to request a pre-submission meeting with FDA. • Sets up premarket requirements that vary according to risk: o High-Risk IVCTs ▪ Prior to offering, requires submission of evidence to demonstrate reasonable assurance of analytical and clinical validity. Content for the submission is set forth in this section.

	▪ Requires an FDA decision within 120 calendar days. ▪ Does not require a mandatory premarket inspection or detailed manufacturing information (summary manufacturing will be submitted, as applicable) to be submitted. ▪ Requires a declaration of conformity to quality requirements. ▪ Allows for FDA to require the submission of raw data from any studies performed if, pursuant to regulation, FDA determines the raw data is necessary to address one or more questions directly related to the analytical and clinical validity. o Moderate-Risk IVCTs (Except as below) ▪ Prior to offering, requires submission of summary evidence to demonstrate reasonable assurance of analytical and clinical validity. Content for the submission is set forth in this section. ▪ Requires an FDA decision within 75 calendar days. ▪ Sets for that an IVCT can be legally marketed if no FDA decision within 75day period. ▪ Allows for submissions to use summary reports of evidence. ▪ Does not allow for mandatory prospective clinical trials. ▪ Does not require the raw data from any studies performed to be submitted except in specific circumstances in which determined by the Secretary that the raw data is necessary to address one or more questions directly related to the clinical validity of an IVCT with a new intended use or utilizing a new technology. o Low-Risks IVCTs ▪ Requires notification to FDA of IVCT name and intended use within 10 days after first offering. o Unmet Need IVCTs, and Moderate-Risk IVCTs that offer a Clinically Significant Advantage ▪ Prior to offering, requires submission of approval summary evidence to demonstrate a reasonable assurance of analytical validity and either (i) a reasonable assurance of clinical validity, or (ii) probable clinical validity. ▪ Requires FDA to approve or disapprove unmet need IVCTs within 30 calendar days. ▪ Requires FDA to approve or disapprove moderate-risk IVCTs within75 calendar days. ▪ In cases where evidence only demonstrates probable clinical validity, post-market evidence is required to be collected over a three-year period to demonstrate a reasonable assurance of clinical validity and thereby authorizing continued offering. o Rare Disease IVCTs ▪ Requires notification to FDA of IVCT name and intended use within 10 days after first offering, no premarket submission required. • Grandfathers all IVCTs that are first offered on a date that is 90 calendar days

	or more prior to enactment and considers them legally marketed. o Requires the listing of grandfathered tests with FDA within 180 calendar days of enactment. • Sets up conditions in which modifications must be submitted for approval if the modification: o Changes the intended use of the IVCT (to a high- or moderate-risk use); o Is demonstrated (post-verification and -validation) to change the analytical or performance specifications of the IVCT as compared to the approved specifications; or o The risk assessment for the modification to the IVCT (post-verification and -validation) demonstrates that the modification creates a meaningful, and not remote, increase in risk. ▪ A simple notification (not subject to affirmative approval) is required if the validation and verification demonstrates that any meaningful risks have been mitigated. • Submission is not required if the modification complies with a recognized standard (e.g., CLSI) or FDA guidance. • Specimen-related changes are not required to be submitted if validated pursuant to protocols reviewed and approved by FDA, or if made solely for extending specimen stability. • Does not require premarket submission for custom IVCTs. • Established standards for IVCT approval based upon analytical validity, clinical validity and adequate labeling.
"SEC. 590C. INVESTIGATIONAL AND RESEARCH USE IN VITRO CLINICAL TESTS.	
Page 104-125	• Requires an agency approved investigational plan and exemption for investigational IVCTs that pose a significant risk to public health. • To qualify for this exemption, an application must be submitted. o FDA must review the application within 30 calendar days. • Creates an exemption from approval for true "research use only" IVCTs.
"SEC. 590D. QUALITY REQUIREMENTS; UNIQUE IDENTIFIERS.	
Page 126-128	• Establishes quality requirements for test development activities including: o Finished products and laboratory test protocols are subject to design controls. o Production of finished products for distribution to other facilities and third parties are subject to updated FDA quality requirements. o Component (including reagent) and raw material suppliers will not be directly regulated under the IVCT construct, but will, to the extent applicable, be subject to the IVCT developer's supplier controls and related quality requirements. • The Secretary shall promulgate regulations to establish a unique identification system for finished products. o This UDI system will utilize, as much as possible, the existing UDI system.

"SEC. 590E. POSTMARKET REQUIREMENTS.	
Page 128-145	• Adverse event reporting for IVCTs will (1) limit individual submissions to those events that involve death or imminent threat to public health, and (2) use quarterly summary and trend reporting for all other adverse events, including malfunctions. • Allows developers to initiate a correction or removal action and requires them to notify FDA within 7 calendar days of the action. • Establishes FDA authority to withdraw from the market IVCTs which present an unreasonable and substantial risk of illness or injury when used as intended. • Establishes the ability for postmarket surveillance to be mandated for high risk IVCTs and certain other IVCTs if necessary to avoid serious health consequences. • Does not allow FDA to mandate postmarket studies to assess clinical utility.
"SEC. 590F. APPEALS.	
Page 145- 146	• Establishes an appeals process for the review of classifications and reclassifications, premarket determinations, and other decisions.
"SEC. 590G. PREEMPTION.	
Page 146-147	• Consistent with current law, preempts all State requirements different from, or in addition to, FDA IVCT requirements.
"SEC. 590H. APPLICABILITY OF CERTAIN PROVISIONS.	
Page 147-156	• Establishes authority for inspections of establishments engaged in the design, development, validation, production, manufacture, preparation, propagation, or assembly of an IVCT. o Establishes inspection processes by FDA accredited bodies • Provides for the emergency use authorization of IVCTs, including for state or regional public health emergencies. • Requires FDA to promulgate final regulations within three years. Those regulations will be effective two years after finalization, except the new submission process will be available one year after finalization. • Requires FDA to develop education and training for staff within two years.
SEC. 4. FDA FEES.	
Page156-160	• Sets forth a process for the development of IVCT user fees. Beginning no later than October 1, 2018, FDA shall develop recommendations for IVCT user fees. • Caps user fees at 30% of the funding for the new regulatory structure.
SEC. 5. CERTIFICATION OF LABORATORIES (CLIA).	
"SEC. 353. CERTIFICATION OF LABORATORIES.	
Page 161-206	• Establishes exclusive CLIA authority to regulate laboratory operations. • Modernizes applicable requirements and regulations by adding appropriate references to the new framework. • Clarifies that modifications of IVCTs will be regulated by FDA. • Establishes process to issue updated standards for laboratory certification. Current CLIA standards will be updated to align, as appropriate, with more

	stringent accreditation standards such as those from third party organizations. • Preempts all State requirements different from, or in addition to, CLIA requirements. • Establishes ability for inspections of facilities with or without notice. • Enhances the CLIA standards for laboratory computer systems, including security standards, data integrity, auto-verification standards, and standards for internal controls of software modifications.
SEC. 6. TRANSITIONAL PROVISIONS.	
Page 206-215	• Provides for the transition from the old regulatory system to the new system over a 4-5-year time frame, including transition timeframes and processes for both submissions and quality systems.