Timeline for FDA's Regulation of Laboratory Developed Tests ("LDTs") and *In Vitro* Diagnostic Devices ("IVDs") Marketed as LDTs by CLIA-Certified Laboratories[1]

Date or Time Frame	FDA Action or Requirement
Already in effect and will remain in effect	• LDTs for infectious agents and cleared or approved LDTs must comply with all device requirements. • Laboratories that use LDTs must comply with the user facilities' medical device reporting ("MDR") requirements in 21 C.F.R. Part 803, Subpart C.
July 31, 2014	• FDA delivered its preliminary plan for regulating LDTs to Congress as required by Section 1143 of the Food and Drug Administration Safety and Improvement Act of 2012 ("FDASIA"). FDA set forth the plan in: (i) "Anticipated Details of the *Draft Guidance for Industry, Food and Drug Administration Staff and Clinical Laboratories: Framework for Oversight of Laboratory Developed Tests*" and (ii) "Anticipated Details of the *Draft Guidance for Industry, Food and Drug Administration Staff and Clinical Laboratories: FDA Notification and Medical Device Reporting for Laboratory Developed Tests.*"
October 3, 2014	• FDA publishes *Draft Guidance for Industry, Food and Drug Administration Staff and Clinical Laboratories: Framework for Oversight of Laboratory Developed Tests (LDTs)* ("*draft Framework*") and *Draft Guidance for Industry, Food and Drug Administration Staff and Clinical Laboratories: FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)* ("draft *Notification Guidance*") in the *Federal Register*. • FDA establishes a 120-day deadline for comments to the draft guidance documents.
Between October 3, 2014, and January 30, 2015	• FDA intends to hold a public hearing about the draft guidance documents during the comment period.
January 30, 2015	• Deadline for comments on the draft guidance documents.[2]
No specified time frame	• FDA reviews the comments and revises the draft guidance documents as necessary.
At least 60 days before the publication of the final guidance documents	• FDA must inform Congress of its intent to finalize the *Framework* and *Notification Guidance* documents and, at a minimum, summarize their contents.
Dependent on the duration of the comment period, FDA's review of the comments, the preparation and delivery of the notification, and Congress's response/actions, if any	• FDA plans to finalize and publish the final *Framework* and *Notifications Guidance* documents.
6 months after publication of the final *Framework* guidance document ("the Final *Framework*")	• Laboratories must submit LDT notifications for all LDTs marketed as of the date of publication ("existing LDTs") OR register as device establishments and list each existing LDT.[3] • Laboratories must comply with the MDR Requirements for Manufacturers in 21 C.F.R. Part 803, Subpart E for LDTs they manufacture.

12 months after publication of the Final *Framework*	• FDA must receive premarket submissions, e.g., 510(k) premarket notifications or premarket approval applications for existing highest-risk LDTs, i.e., LDTs with the same intended use as cleared or approved companion diagnostics or approved Class III medical devices and certain LDTs used to determine the safety/efficacy of blood or blood products.[4] • Laboratories with at least one existing Highest-Risk LDT that requires PMA approval would have to comply with Quality Systems Regulations within that period.[5]
18 months after publication of the Final *Framework*	• FDA plans to issue a draft guidance classifying LDTs into Class I, Class II, or Class III.[6]
24 months after publication of the Final *Framework*	• FDA expects to issue a list of the order and time frames of the sequential review of PMAs for all types of Class III LDTs ("Class III LDT Priority List").
36 months after the publication of the Final *Framework* if the Class III LDT Priority List as above (12 months after publication of the Class III LDTs priority list)	• FDA would begin requiring PMAs for the highest-priority types of existing Class III LDTs, which FDA indicated are likely to be: (i) devices that act like companions diagnostics; (ii) screening devices for serious diseases and/or conditions without any available confirmatory diagnostic product or procedure; and (iii) diagnostic devices for certain infectious diseases with high-risk intended uses. • Laboratories would submit PMAs for other types of existing Class III LDTs sequentially in descending order of priority based on the Class III LDT Priority List.
48 months after publication of the Final *Framework*	• FDA plans to issue its priority list for 510(k) submissions for Class II LDTs ("Class II LDT Priority List").
60 months after publication of the Final *Framework*	• FDA expects to complete review of PMAs for all existing Class III LDTs. • FDA intends to begin its sequential review of 510(k) notices for Class II LDTs based on the Class II LDT Priority List.
108 months after publication of the Final *Framework*	• FDA expects to complete review of 510(k) notices for Class II LDTs.

1 IVDs are tests that can detect diseases, conditions, or infections. Some tests are used in laboratory or other health professional settings, and other tests are for consumers to use at home. As described by FDA, an LDT is a type of *in vitro* diagnostic test that is intended for clinical use and designed, manufactured, and used within a single laboratory. LDTs do not include devices designed or manufactured completely, or partly, outside of the laboratory that offers and uses them. LDTs were formerly called "home brews" and/or "in-house devices." Neither draft guidance document applies to direct-to-consumer LDTs.

2 FDA may extend the comment period.

3 For each LDT first marketed six months after the date of publication ("new LDTs"), laboratories must submit LDT notifications or comply with the establishment registration and listing requirements before initial clinical use.

4 A premarket submission is required before first clinical use of a new Highest-Risk LDT.

5 Existing and new Highest-Risk LDTs that require 510(k) clearance would have to comply with QSRs upon clearance.

6 FDA intends to obtain Advisory Committee input on the classification of LDTs. However, the plan does not indicate whether the Advisory Committee would meet to discuss the guidance or provide written comments and whether it would provide feedback before and/or after FDA publishes the draft *Framework Guidance*. Those factors could affect the timing of FDA's publication of the draft and/or final guidance documents.