eha Sf(PM)

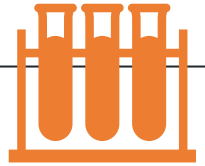
Assay Certification and Investigational Device Exemption for Clinical Trials

Kristine Radomski Crews, Pharm.D.
St. Jude Children's Research Hospital
Department of Pharmacy & Pharmaceutical Sciences
Memphis, TN, USA

In May 2024, the FDA released the final rule to classify LDTs as medical devices and require FDA approval

Clinical Laboratory Improvement Amendments (CLIA)

Clinical laboratories that perform patient testing for diagnostic or treatment purposes require a CLIA certificate.
The College of American Pathologists (CAP) is a "CLIA deemed" organization with responsibility for laboratory accreditation programs



Laboratory Developed Tests (LDTs)

In vitro diagnostic devices (IVDs) require pre-market approval by the FDA. However, laboratories can develop their own tests.
A laboratory developed test (LDT) is a type of IVD that is designed, manufactured and used within a single laboratory
FDA previously practiced “enforcement discretion” with LDTs. Labs must comply with all CLIA regulations when validating an LDT

FDA Final Rule on LDTs Implementation (through 2028)

Requirement	Stage	Date	1976 Type	HLA for Trans.	Foren.	VHA / DoD	NY CLEP	Unmet Need	Curr. Market	Rare RBC Ant.	New LDT	Minor Mod. to Curr. Mark.	Signif. Mod. to Curr. Mark.	Mod. Other's 510(k)	Mod. Other's PMA
MDR, Correction, Removal (§ 803 and § 806)	1	5/6/25	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Complaint Files (§ 820.198)	1	5/6/25	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Registration (§ 807)	2	5/6/26	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Listing (§ 807)	2	5/6/26	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Labeling (§ 809.10)	2	5/6/26	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Investig. Device (§ 812)	2	5/6/26	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Design Controls (§ 820.30)	3	5/6/27	No	No	No	No	Yes	No	No	No	Yes	No?	Yes	Yes	Yes
Purchasing Controls (including supplier controls) (§ 820.50)	3	5/6/27	No	No	No	No	Yes	No	No	No	Yes	No?	Yes	Yes	Yes
Acceptance Activities (receiving, in-process, and finished device acceptance) (§ 820.80 and § 820.86)	3	5/6/27	No	No	No	No	Yes	No	No	No	Yes	No?	Yes	Yes	Yes
CAPA (§ 820.100)	3	5/6/27	No	No	No	No	Yes	No	No	No	Yes	No?	Yes	Yes	Yes
Records (part 820, subpart M)	3	5/6/27	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Premarket Review (high-risk); PMA	4	11/6/27	No	No	No	No	No	No	No	No	Yes	No	Yes	No	Yes
Premarket Review (mod / low-risk); 510(k) & De Novo	5	5/6/28	No	No	No	No	No	No	No	No	Yes	No	Yes	No	N/A (PMA)

ARUP

Please send comments/edits to jonathan.genzen@aruplab.com. See Final Rule for exact requirements.

PM)