Genetic Testing Oversight Map

* LDTs that are IVD/IVDMIAs are subject to FDA and CLIA oversight

** Functions of FDA Quality System Regulation

CLIA-Exempt State Regulation (e.g., NY)

- Proficiency Testing
- Quality Assurance
- Quality Control
- Personnel Standards
- Reagent & Equipment Inspection

G9-11 Biennial Inspection

NY State Licensed/CLIA Exempt

NY Lab Approval of non-FDA Approved Tests

Analytical & Clinical Validity Review

G12

G2

LDTs
*

(DTC tests by non-CLIA certified labs)

G15-16   G17   Outcomes Research

Available for Use

Guideline Development

G13

Gene

Disease

NIH CDC NIST

Basic Research

G1

Test Clinical Development

CMS Approved Organizations

G3-8

CLIA Regulation

- Personnel Standards
- Quality Assurance
- Quality Control
- Analytical Validity
- Proficiency Testing

CMS or Agent

Inspection & Survey Requirements

CLIA Accreditation

CDC FDA FTC State Courts, Legislatures Prof. Orgs. Con. Adv. Grps. Other Laws, Guidelines & Standards (ERISA, HIPAA, GINA?)

DTC
G18-19

DAT

Clinician
G20-21

Lab

G22-30

CMS PT Prov. CDC

G9-11

Biennial Inspection Review of validation data for all tests

Prototype/Design

FDA Design Control **

Preclinical Development

Apply for IDE (PMA, select 510(k), other)

Apply for IND (selected therapeutics)

Co-developed Therapeutic Clinical Development

IVD/IVDMIA

Class Designation (I, II, III)

FDA Postapproval Inspections **

FDA Approval/Clearance

Clinical Utility Review (selected tests)

USPSTF EGAPP

G14 & 31

Phase I

Phase II

Phase III

Application for FDA Approval/Clearance

FDA Manufacturing Control **

FDA Preapproval Inspection **

513(f)(2)

PMA

PMA

de novo 510(k)

510(k)

BLA

NDA

Analytical Validity Safety and Effectiveness

G6 & 14

Application Review

FDA

Postmarket Surveillance

Medicare (CMS) Medicaid (CMS & States) Private Insurance VA, DoD, Other

Reimbursement

G32-33

Lewin 2-12-08

Federal Courts