

Development of an Adverse Event Reporting Mechanism for Laboratory Developed Tests

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IVDs – Two Regulatory Paths

	LDT	FDA
Research Phase	No	Yes
Registration and listing	No	Yes
Analytical validation	Post hoc sampling	Yes
Clinical validation	No	Yes
Report Adverse Events	No requirement; no system	Yes
Transparent Results	No public information	Published review summary



Postmarket Controls

- Surveillance -- problem identification and correction



Medical Device Reporting (MDR)

- ❑ Ensures the safety and effectiveness of medical devices
- ❑ Prevents re-occurrence of adverse events due to medical device design, malfunction or misuse
- ❑ Identifies problem causes quickly when harm to public does occur
- ❑ Informs stakeholders as effectively as possible



MDR Review

- Reports individually reviewed to identify immediate or potential risk to public health
 - Unrecognized risk
 - Problems uncorrected by manufacturer
 - Problems unknown to manufacturer
 - Problems across device type
 - Systematic user error



Current Surveillance of LDTs

- ❑ MDR reporting not enforced
- ❑ Lack of mechanism to segregate and analyze data
- ❑ Voluntary reporting has not been promoted



MedWatch

For use by health professionals and consumers for voluntary reporting of adverse events, product use errors and product quality problems with FDA-regulated medical products.



MedWatch

For more information on medical device reporting, see the FDA Center for Devices and Radiological Health (CDRH) Reporting page at <http://www.fda.gov/cdrh/mdr/>

For MedWatch go to <http://www.fda.gov/safety/MedWatch/default.htm>