

The Importance of LDTs

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What are LDTs?

- Mildly modified FDA-approved tests
 - Subtle changes in sample collection, sample type, patient population, measuring range, interference profile
- Cooking from scratch
 - Buffers, primers, standards, enzymes, instrumentation, supply chains
- How do we know it works?
 - Precision, accuracy, reportable range, reference range, sample integrity
- Performing lab documents/maintains performance for local use.



The Role of LDTs in Clinical Care

- Unmet physician/clinical needs
 - Rare conditions, new knowledge
- Lab/physician collaboration
 - May be initiated by the lab or provider
- Patient diagnosis/prognosis/precision therapy
- Seldom used as a stand alone tool - One of multiple diagnostic tools available to physicians

Who Develops LDTs

- Highly qualified/trained MDs & PhDs
- Limited to high complexity labs
- Approximately 4% of labs eligible
- Considerable monetary, time investment

Bachelor's Degree

MD
PhD

Residency
Fellowship

Board Certification

Maintenance of Certification



Why do lab develop LDTs

- No tests available (too new/too rare)
 - Inborn errors of metabolism (PKU, MCAD deficiency, Cystic Fibrosis)
- Current test insufficient/flawed
 - Drug screening immunoassays
 - Inappropriate target population
- Immediate patient need
 - Emerging infectious agents (e.g. COVID)
 - Emerging toxins (e.g., xylazine, brodifacoum-laced cannabinoids)

Importance of LDTs to Patients

- Rare, complex disorders (diagnosis and monitoring)
- No test available to diagnose
- Failure to diagnose can lead to suffering
- Unnecessary, costly testing
- Unnecessary, inappropriate, costly care

Importance of LDTs to Patients



Definitive LDT → Specific Treatment → LDT monitoring → Positive Outcome

Rare/Complex Disorder

Inconclusive Testing

Trial Therapeutics

Progressive clinical deterioration

Lifelong Complications



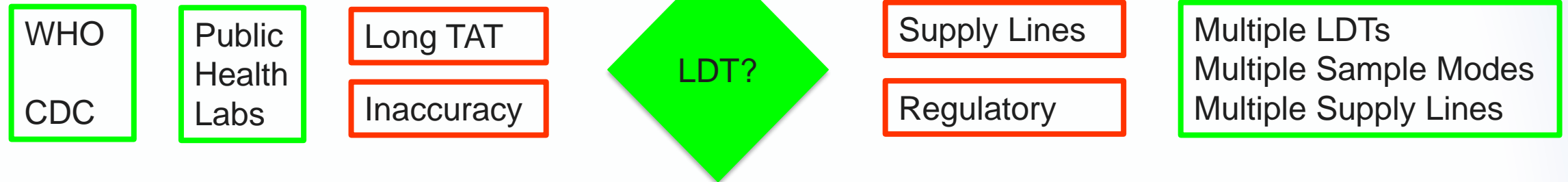
COVID-19 and LDTs

- Problems with initial CDC tests
- EUA process hindered introduction of LDTs
- Labs ready to introduce, FDA became barrier

Asymptomatic
Transmission

Isolation

Contact Tracing



COVID-19 Lessons Learned

- LDTs can meet immediate public health needs
- Regulations (even well-intentioned) may be a barrier to clinical and patient care
- Rapid development of LDTs was critical to flattening the curve
- Additional regulatory burdens unnecessary, hindrance