



# HITAC Adopted Standards Task Force

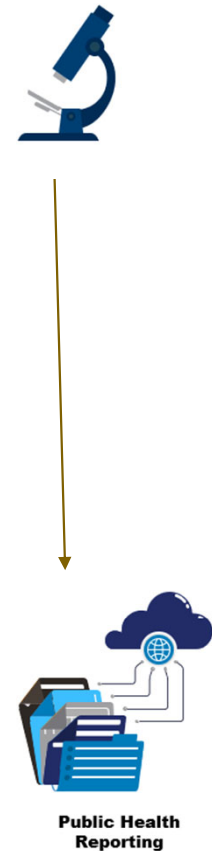
*Tuesday, July 26*

# Lab Standards

- ISO/IEC 17025:2017(E)—General Requirements for the Competence of Testing and Calibration Laboratories, (Third Edition), November 2017
  - From the food safety program at APHL:
    - APHL food program helped FDA labs get accredited to this standard about 7 years ago – success stories are described here: [https://www.aphl.org/programs/food\\_safety/Pages/APHL-Food-Safety.aspx](https://www.aphl.org/programs/food_safety/Pages/APHL-Food-Safety.aspx)
    - Latest version is 2017
    - Details about accreditation work: [https://www.aphl.org/programs/food\\_safety/human-and-animal-food-testing/Pages/Quality-Management-Systems-and-Accreditation.aspx](https://www.aphl.org/programs/food_safety/human-and-animal-food-testing/Pages/Quality-Management-Systems-and-Accreditation.aspx)
    - See resource links on right hand column on this page: [https://www.aphl.org/programs/food\\_safety/human-and-animal-food-testing/Pages/default.aspx](https://www.aphl.org/programs/food_safety/human-and-animal-food-testing/Pages/default.aspx)

# Electronic Lab Reporting Standards

- ELR = results of lab tests for reportable conditions sent to Public Health
- No national standard established, but various state specific ELR IGs in V2.3, V2.3.1
  - Some still in use
- [HL7® Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1 \(US Realm\)](#) = ELR R1 (2010)
  - Needs to be used in conjunction with [Electronic Laboratory Reporting \(ELR\) 2.5.1 Clarification Document for EHR Technology Certification](#)
  - created by NIST when developing the tooling
  - named in Promoting Interoperability
  - widely implemented and in use in labs and PHAs
  - Implementations were adapted to support HHS reporting elements for SARS-CoV-2



# Electronic Lab Reporting Standards (cont.)

- [ELR Release 2, DSTU R1.1 2014](#)
  - ELR data elements (PH\_Component) added to lab result reporting to ordering provider use case (LRI DSTU1 R1)
  - LRI supports all CLIA elements and AOE
  - published as separate document on demand
  - unsure if implemented at PHA
- PH\_Component in LRI STU 1 R2 (Sept 2015) and [R3](#) (Sept 2018)
  - published in single document with [separate vocabulary for all lab standards](#)
  - LRI supports all CLIA elements and AOE
  - First R2 has [EHR-S Functional Requirements](#) document for EHR-s certification
  - R3 has some implementation with Newborn Dried Bloodspot component –  
• unsure about PH\_Component



Provider Electronic Health Records (EHRs)



Public Health Reporting

# Electronic Lab Reporting Standards (future)

- PH\_Component in LRI STU 1 R5 (Aug 2022)
  - To be published in single document with updated separate vocabulary for all lab standards
  - LRI supports all CLIA elements and AOE's
  - Incorporates all HHS required elements for SARS-CoV-2 reporting
  - Relaxes some OID use rules for PH\_Component to adjust to real world implementations of ELR R1
  - Still supports all other use case components
  - Beneficial to support for NEW implementations, if PHA can support
  - Consider ROI for existing implementations to update

