COVID-19 Laboratory Reporting Challenges and Opportunities

Duke University Health System

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Public health lab reporting depends on *everything* that comes before it…

Outline

- It all starts with the clinical order, and names are important…
- Increasing testing capacity to meet demand in a setting of supply chain shortages
- Confusion and communications
- Reporting and data element challenges
- Optimizations and opportunities for the future

Key Elements of a COVID-19 Order

- Standard naming convention
  - Should convey exactly what is being tested for
    - Organism SARS-COV2 (vs other coronaviruses, flu viruses, etc)
    - Disease COVID-19
    - Type of test: PCR (nucleic acid vs antibody or antigen)
  - Should convey the proper setting for the test
    - Inpatient
    - Outpatient
  - Should convey the expected turnaround time
    - Rapid
    - Routine
  - Should convey performing lab
    - In house vs reference lab
  - Certain orders are designed to trip EHR “flags” that trigger various patient “statuses”, e.g. isolation, no isolation, r/o COVID-19 (symptomatic vs asymptomatic), COVID19+
- Order guidance is needed!

Inpatient COVID-19 Order Guidance

Coronavirus (COVID-19) SARS-CoV-2 ED & Inpatient Testing

Review latest Duke testing guidelines (links below) before placing order or calling Infection Control or ID.

Questions about whether to test an inpatient (current or being admitted)? DUH: 970-5050. DRAH/DRH: contact ID consult.

Symptoms?	*COVID / SARS-CoV-2 Test*	*Setting / Context*	*Infection Status & Isolation*
Symptomatic	Inpatient Only	• Inpatient or ED, expected to require admission	(*Symptomatic*) • Automatic "Rule-Out COVID-19" Status • Pre-checked Special Airborne Contact Isolation
	Outpatient	• Outpatient or ED, **not** expected to required admission • Preferentially run by Duke but may be diverted to LabCorp	
	Rapid / POC (Point-of-Care)	• Limited capacity – Use only in locations where POC testing devices deployed. • Need for rapid results to influence management disposition	(*Symptomatic Rapid/POC*) • **Order** Special Airborne Contact Isolation
Asymptomatic	Preoperative Screen	• Inpatient or outpatient • Level 5 or non-leveled surgical cases or other procedures requiring testing	(*Asymptomatic*) • No isolation required
	Administrative	• Inpatient or outpatient • Screening for administrative reason (e.g., clearance for SNF or dialysis) • Screening recovering patient for clearance of COVID-19	

Links to hospital-specific patient use cases:

Testing Guidance DRH
Testing Guidance DUH
Document Library > Periop & Pre-procedural

- ◯ COVID-19 POC RAPID (Periprocedural & OB Nurse Collect) + optional Isolation
- ◯ COVID-19 INPATIENT Only + Isolation
- ◯ COVID-19 OUTPATIENT + Isolation
- ◯ COVID-19 PRE-PROCEDURE Screen, No Isolation
  Nasopharyngeal Swab
- ◯ COVID-19 Administrative Testing Only, No Isolation

Ambulatory COVID-19 Order Guidance

Symptoms?	*COVID/SARS-CoV-2 Test*	*Setting/Context*	*Infection Status*
Symptomatic	**Outpatient**	• Outpatient or ED, **not** expected to require admission • Preferentially run by Duke but may be diverted to LabCorp	• **Automatic 'Rule Out COV' Infection Status** • 'COVID-19' Infection Status only if positive
	LabCorp	• Outpatient • Available only to select locations who use that vendor	
	Employee Screen (EOHW staff only)	• Available only to EOHW staff • Duke employees who need urgent testing to return to direct patient care	• 'COVID-19' Infection Status only if positive
	Rapid / POC (Point-of-Care)	• **Very limited capacity – Use only in locations where POC testing devices deployed. See also CMO-approved use cases.** • Need for rapid results to influence management and disposition	
Asymptomatic		• Outpatients undergoing procedure either urgently or from out of town.	
	Preoperative screen	• Outpatient or inpatient • Undergoing planned surgical or other procedures	

COVID-19 Orders/Results -> Downstream Actions

- What can be made to happen…
  - Set COVID-19 infection status with informative banner on EHR
  - Text page (to one or more key individuals / roles)
  - Linked order for patient isolation
    - BPA alert if proper isolation order is not present and should be based on result
- When should something happen…
  - Order signed (e.g. page appropriate administrator)
  - Positive result posted (e.g. set infection status/banner)
  - Negative result posted (e.g. clear infection status)

Duke Health COVID-19 Diagnostic Test Orders

Order Display Name	Abbreviation for Labels (12 char max)	Performing Lab	Result Component External Name (LRR)	Base Name	Common Name
Coronavirus (COVID-19) SARS-CoV-2 PCR - Inpatient Only	SARCOVID IPT	Duke Microbiology	Coronavirus (COVID-19) SARS-CoV-2 PCR	SARSCOV2	CORONAVIRUS SARS-COV-2
Coronavirus (COVID-19) SARS-CoV-2 PCR – VIRACOR	SARCOVID VIR	Viracor	Coronavirus (COVID-19) SARS-CoV-2 PCR – VIRACOR	SARSCOV2	CORONAVIRUS SARS-COV-2
Coronavirus (COVID-19) SARS-CoV-2 PCR – LABCORP	SARCOVID LCP	DUH Ref Lab LabCorp	Coronavirus (COVID-19) SARS-CoV-2 PCR – LABCORP	SARSCOV2	CORONAVIRUS SARS-COV-2
Coronavirus (COVID-19) SARS-CoV-2 PCR – QUEST	SARCOVID QST	Quest Diagnostics	Coronavirus (COVID-19) SARS-CoV-2 PCR	SARSCOV2	CORONAVIRUS SARS-COV-2
Coronavirus (COVID-19) SARS-CoV-2 PCR – MAYO	SARCOVID MYO	Mayo	Coronavirus (COVID-19) SARS-CoV-2 PCR	SARSCOV2	CORONAVIRUS SARS-COV-2
Coronavirus (COVID-19) SARS-CoV-2 PCR -Employee Screen	SARCOVID EMP	Duke Microbiology	Coronavirus (COVID-19) SARS-CoV-2 PCR	SARSCOV2	CORONAVIRUS SARS-COV-2
Coronavirus (COVID-19) SARS-CoV-2 PCR -Preoperative Screen	SARCOVID PRE	Duke Microbiology	Coronavirus (COVID-19) SARS-CoV-2 PCR	SARSCOV2	CORONAVIRUS SARS-COV-2
Coronavirus (COVID-19) SARS-CoV-2 PCR - Administrative (Infection Prevention Use Only)	SARCOVID ADM	Duke Microbiology	Coronavirus (COVID-19) SARS-CoV-2 PCR	SARSCOV2	CORONAVIRUS SARS-COV-2
POC Coronavirus (COVID-19) SARS-Cov-2 Rapid Test	SARCOVID POC	DUH Point of Care (RALS)	POC Coronavirus (COVID-19) SARS-Cov-2 Rapid Test	SARSCOV2	CORONAVIRUS SARS-COV-2
Coronavirus (COVID-19) SARS-Cov-2 Rapid Test (DRH, DRAH)	SARCOVID RPD	DRH CP LAB and DRAH CP LAB	Coronavirus (COVID-19) SARS-CoV-2 Rapid Test	SARSCOV2	CORONAVIRUS SARS-COV-2
CORONAVIRUS (COVID-19) SARS-COV-2 PCR OUTPATIENT	SARCOVID OPT	Duke Microbiology	Coronavirus (COVID-19) SARS-CoV-2 PCR	SARSCOV2	CORONAVIRUS SARS-COV-2

Increasing Testing Capacity in a Setting of Supply Chain Shortages

- Inability to source collection “kits”; must make our own by sourcing:
  - Swabs (direct np swabs have shorter viability but increased sensitivity)
  - Viral transport media (sample has longer viability but decreased sensitivity)
- Reagents limited (esp. Cepheid, Roche platforms)
- Instrument bandwidth also too limited to meet demand
- Instrument testing challenges and characteristics
  - One at a time, synchronous
  - One batch at a time, synchronous
    - Starting a partially empty batch wastes that potential bandwidth
    - Starting a full batch means potentially increasing turnaround time
  - Asynchronous “load sample when ready” is most flexible
  - Need to manually aliquot every sample (changing gloves between samples) before loading limits theoretical bandwidth to what a human can process in sequence to load machines that require aliquots (e.g. Roche 6800, Alinity)
  - PCR tests generally aren’t “load and go”, must be monitored for failures at multiple steps in the process

Transport, Receive, and Triage

- Viral transport media (VTM) or direct swab?
- Transport tracking from tents, clinics, ED
- Triage when reaching microbiology laboratory; when are results needed?
  - ASAP (e.g. inpatient, ED)
  - Next morning (e.g. pre-operative screening)
  - “Soon?” (e.g. discharge planning)
  - Few days ok (e.g. outpatient)
- Specimen placement on which instrument optimizes patient care outcomes?

Duke Health COVID-19 Instruments

- ABI 7500, CDC assay, capacity 20 per run (5 hr run time)
- Diasorin, capacity batch of 8 per device x 3 = 24 samples per run (each run 3 hrs)
- Cepheid Xpert, capacity 48, can load asynchronously (reagent limited to 125/day)
- Abbott m2000, capacity batch of 96 at a time but 8 hr run time per batch
- Abbott IDNow POCT, capacity 1 at sample at a time, 5-15 min/sample
- Alinity, batches of 12x4=48 at a time x # of APUs (3 or 4 working at a time) so 144 samples at once (actual ~1500/day, with 2 devices)
- Roche 6800, capacity batch of 96 at a time but reagent limited < 100 per day

- CDC assay – March 23rd
- DiaSorin Simplexa – March 25th
- Cepheid Xpert – March 31st
- Abbott m2000 RealTime – April 6th
- Abbott ID Now – April 6th
- Abbott Alinity #1 – June 15th
- Roche 6800 – August 18th
- Abbott Alinity #2 – September 22nd

Communications & Confusion

- 3-29-2020 Letter from VP to hospital administrators
  - COVID19 test result reporting by spreadsheet every day at 5 pm ET via email to FEMA
  - Hospitals report via CDC's National Healthcare Safety Network (NHSN)
  - Data Elements:
    - New Diagnostic Tests Ordered/Received
    - Cumulative Diagnostic Tests
    - New Tests Resulted
    - Cumulative Specimens Rejected*
    - Cumulative Tests Performed
    - New Positive COVID-19 Tests
    - Cumulative Positive COVID-19 Tests
    - Percent Positive among Newly Resulted Tests
    - Cumulative Percent Positive among Resulted Tests

- 4-09-2020 Metrics updated to include serology, capacity, utilization data
  - Data Elements
    - State, hospital, county, zip code,
    - # beds (ICU, inpatient, total) w/ occupancy
    - Ventilators, available vs in use
    - Hospitalized, ED COVID-19 patients
    - Supply of N95 masks
    - Previous day's admission with confirmed / suspected COVID-19
  - Submit via TeleTracking, NHSN, directly from HIT vendor, or publish to web in standard format
  - Submit at least daily
  - In house labs should provide directly to their State or authorize their HIT vendor to submit testing data to HHS/CDC.

Communications & Confusion

- 06-04-2020 COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115
  - Data Elements: 18 “must”, 6 more “should”, 7 AOE questions
  - Submit to local, state public health departments and CDC “asap”, but no later than 8-1-2020
  - Use ELR if possible but flat file ok
  - Key data should go back to EHR, ordering provider, and patient
- 07-10-2020 COVID-19 Guidance for Hospital Reporting & FAQs Updated
  - Data Elements: 32 for hospital utilization and capacity
  - Submit to HHS via Teletracking, authorize HIT vendor to share directly with HHS or publish to website in std format
  - STOP reporting to NHSN site of CDC
    - *Why?*
  - You do not need to send data if test performed by commercial labs: labcorp, bioreference, quest, mayo, arup, sonic

Communications & Confusion

- 07-14-2020 HHS Asks Hospitals to Prioritize Certain Data Fields in COVID-19 Daily Reporting Starting Tomorrow, July 15

Following yesterday's announcement of changes to its process for collecting daily COVID-19-related data from hospitals, the Department of Health and Human Services (HHS) today asked hospitals to prioritize the reporting of seven data fields starting tomorrow, July 15:

- Previous day's new adult admissions for confirmed COVID-19
- Previous day's new adult admissions for suspected COVID-19
- Total adults hospitalized for COVID - suspected and confirmed
- Total hospitalized for COVID - confirmed only
- Total adults in ICU with COVID - suspected and confirmed
- Total adults in ICU with COVID - confirmed
- Remdesivir doses (field will be available by July 15)

- 07-18-2020 CDC Updated Guidance on How to Report COVID-19 Laboratory Data
  - Data Elements: 24
  - AOE Questions: 8
  - LOINC codes must be used to represent the "question", test ordered
    - *90 lab test codes exist!?*
  - SNOMED CT codes must be used to represent the "answer", specimen description and test results
- 07-31-2020 CDC Lab Advisory published with detailed technical specifications for data elements

Communications & Confusion

- 08-24-2020 CMS-3401-IFC (CMS CLIA Revision for COVID-19)
  - Mandatory reporting requirements for hospitals and CLIA-certified labs
  - Enforce *penalties* for non-compliance with reporting
  - Must report to state HHS in which laboratory resides
  - Must report all +/- lab results
  - Other data elements not enforced through penalties (huge relief for laboratories!)
- 10-06-2020 HHS Updated Guidance
  - Hospital utilization and capacity data (25 data elements daily, 7 additional weekly, 6 additional flu related elements daily, 8 elements for diagnostic tests reported daily)
  - In house tests should be reported through HHS Protect System
  - Lab test results should be sent to state health departments (which will deidentify and send to CDC)

Reporting Challenges

- Laboratory reporting vs hospital reporting –> incongruent data, different teams
- Reporting to all 50 state health departments based on patient address (as stipulated in CDC guidance) is inefficient; impractical for smaller orgs
  - NC HHS forwards on to other states (not all states do, e.g. GA)
- In the early days of reporting had to send information to local health dept, state health dept, FEMA, and NHSN
- ELR interface represents a vast improvement in efficiency but significant build effort for team of IT experts required by both state HHS and hospital
  - State health departments were not ready to accept data as required by the August 1 due date
- Not all reference labs accept AOE questions for sample testing
- There is no explanation / justification for why data elements are requested or how they will be used to manage the pandemic. *What is the value?*

Data Element Challenges

- The extent to which a data element should be transmitted are classified in *multiple ambiguous ways*: “yes”, “no”, blank (no value), “yes as applicable”, “yes if known”, “requested”, “optional”.
- AOE questions impose a burden on ordering providers at a time when testing demand and need also increasing
- Being proscriptive about how to obtain data (e.g. pregnancy must be asked at order) precludes more efficient data processing (e.g. directly pulling data element from EHR to populate ELR data stream)
- Large HIT vendors more capable to address requirements for customers without “reinventing wheel” at each laboratory / hospital

Data Element Challenges

- Device Identifier follows an algorithm for hobbling together an identifier due to lack of an FDA assigned device ID for EUA platforms
  - Lab information systems may have no place for storing a device ID (but the device ID can be hard-coded into the ELR interface)
- Many laboratories do not store/transmit/have experience with LOINC codes for orders
- LOINC codes are prone to misassignment due to manual mapping errors (CDC technical specifications include a mapping, which helps!)
- Many laboratories do not (or are not capable to) report results with SNOMED CT codes (but this can be hard-coded into the ELR interface)

Optimizations and Opportunities

- Communications should be sent by one central agency after full coordination with other agencies at federal, state, and local levels
- Reporting requirements for laboratories should be clearly defined with test patient examples that reflect real-world scenarios
- The purpose for collecting any specific data element should be documented to ensure laboratory and IT efforts are aligned with achieving the objective
- The burden on small hospitals and labs to fulfill reporting requirements should be recognized and addressed
  - Small organizations do not have the IT or lab staff to meet requirements
  - Small organizations do not have the funds to hire contractors

Optimizations and Opportunities

- Duplicate reporting should be avoided as it is wasteful for transmitter and receiver and may falsely inflate data registries
  - A laboratory should only report to the state HHS in which it is located
  - State HHS should aggregate data centrally (CDC or Federal HHS)
  - Centralized data should be channeled by the central government agency back to the state and local health departments where the patient and ordering provider resides (if outside the state of the performing lab).
- The College of American Pathologists (www.cap.org) represents a resource of laboratory leaders and subject matter experts that can provide critical input, preferably *proactively* as regulations are being drafted for this ongoing pandemic and/or in preparation for the next one…