Leveraging Clinical Laboratory Analytics

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Learning Objectives

At the end of this activity, participants will be able to:

- 1. Provide examples of common clinical laboratory data elements
- 2. Explain common pitfalls in clinical laboratory data analysis
- 3. Describe the value of mapping lab data to LOINC and SNOMED CT
- 4. Provide examples of data wrangling



Leveraging Clinical Laboratory Analytics

Agenda

Data elements, architecture, and data wrangling

Example 1 – Frequency of LDT Orders

Example 2 – Ordering the Right Testosterone Test

Example 3 – Positivity Dashboard





Clinical Laboratory Testing: Data elements, architecture, and data wrangling



Structure of Laboratory Tests

Coccidioides Antibody Panel

Cocci IgM by EIA

Cocci IgG by EIA

Cocci Ab by Immunodiffusion

Cocci Ab by Complement Fixation

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500 Chipeta Way, Salt Lake City, Utah 84108-1221 phone: 801-583-2787, toll free: 800-522-2787

Jonathan R. Genzen, MD, PhD, Chief Medical Officer

PATIENT REPORT

Patient: Patient, Example

Patient Age/Sex: 46 years Male

Specimen Collected: 11-Dec-23 13:02

Coccidioides Antibody Panel Report/Verified: 11-Dec-23 13:17 |Received: 11-Dec-23 13:05 Procedure Result Units Reference Interval 1.7 H Cocci IgM by EIA ΙV [<=0.9] Cocci IgG by EIA 0.9 ΙV [<=0.9]Cocci Ab by ID Detected * [Not Detected] 1:16 * Cocci Ab by CF [<1:2]

*=Abnormal, #=Corrected, C=Critical, f=Result Footnote, H-High, i-Test Information, L-Low, t-Interpretive Text, @=Performing lab

Unless otherwise indicated, testing performed at:

ARUP Laboratories

500 Chipeta Way, Salt Lake City, UT 84108

Laboratory Director: Jonathan R. Genzen, MD, PhD

ARUP Accession: 23-345-xxxxx

Report Request ID:

Printed: 12-Dec-23 07:43

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Common Data Elements

Common Lab Data Elements

Patient Demographics

Dates

Order, collection, receipt, reported

Order and component names

Results

Units of Measure

Reference Interval

Abnormal flag(s)

Interpretive comments

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Specimen Collected: 11-Dec-23 13:02

Coccidioides Antibody Panel	Received:	11-Dec-23 13:05	Report/Verified: 11-Dec-23 13:17
Procedure	Result	Units	Reference Interval
Cocci IgM by EIA	1.7 H	IV	[<=0.9]
Cocci IgG by EIA	0.9	IV	[<=0.9]
Cocci Ab by ID	Detected *	•	[Not Detected]
Cocci Ab by CF	1:16 *		[<1:2]

*=Abnormal, #=Corrected, C=Critical, f=Result Footnote, H-High, i-Test Information, L-Low, t-Interpretive Text, @=Performing lab

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23-345-хохох

Report Request ID: XXXXXXX

Printed:

12-Dec-23 07:43

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Common Data Elements

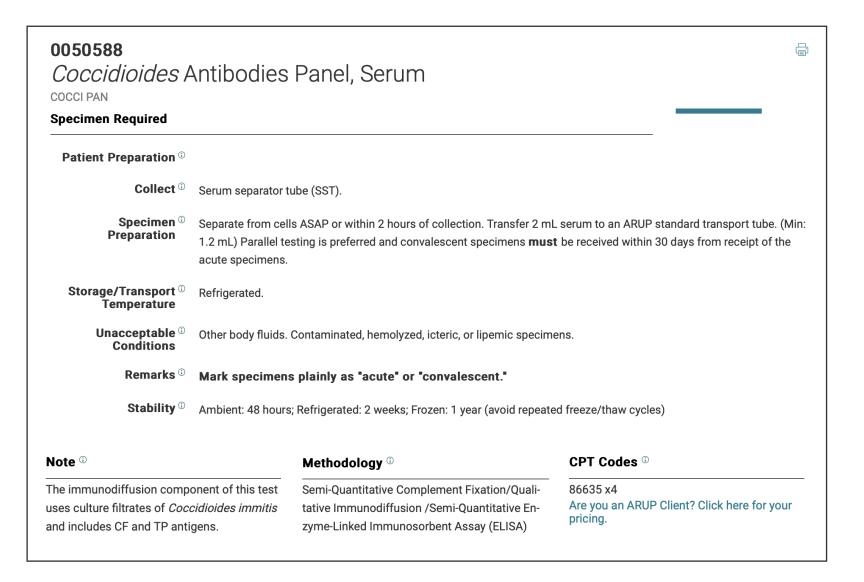
Common Lab Data Elements

Specimen Information

Method

CPT Codes

Regulatory Status (FDA vs LDT)







Common data elements for lab testing based on USCDI

Patient Demographics/Information

Data used to categorize individuals for identification, records matching, and other purposes.

First Name

Last Name

Middle Name (including middle initial)

Name Suffix

Previous Name

Name To Use

Pronouns

Date of Birth

Date of Death

Race

Ethnicity

Tribal Affiliation

Sex

Sexual Orientation

Gender Identity

Preferred Language

Interpreter Needed

Current Address

Previous Address

Phone Number

Phone Number Type

Email Address

Related Person's Name

Relationship Type

Occupation

Occupation Industry

Medications

Pharmacologic agents used in the diagnosis, cure, mitigation, treatment, or prevention of disease.

Medications

Dose

Dose Unit of Measure

Route of Administration

Indication

Fill Status

Medication Instructions

Medication Adherence

Allergies and Intolerances

Harmful or undesired physiological responses associated with exposure to a substance.

Medication Allergy Intolerance

Drug Class Allergy Intolerance

Non-Medication Allergy Intolerance

Reaction

Immunizations

Record of vaccine administration.

Immunizations

Lot Number

Laboratory

Analysis of clinical specimens to obtain information about the health of a patient.

Tests

Values/Results

Specimen Type

Result Status

Result Unit of Measure

Result Reference Range

Result Interpretation

Specimen Source Site

Specimen Identifier

Specimen Condition Acceptability





HL7 V2 Messages are Typically Used to Exchange Data

Segments

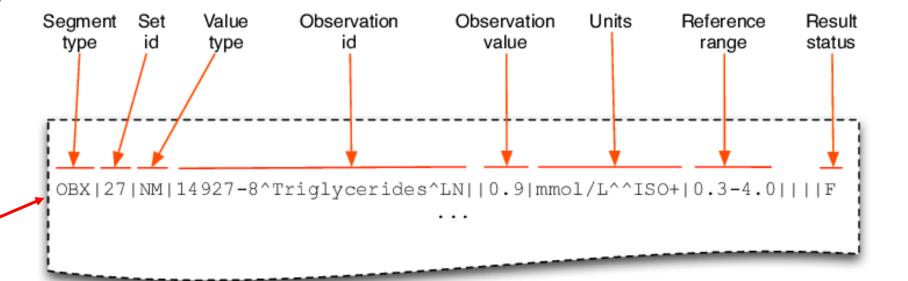
MSH – Message Header

PID – Patient Information

OBR – Observation Request

OBX – Result Segment

NTE – Notes and Comments



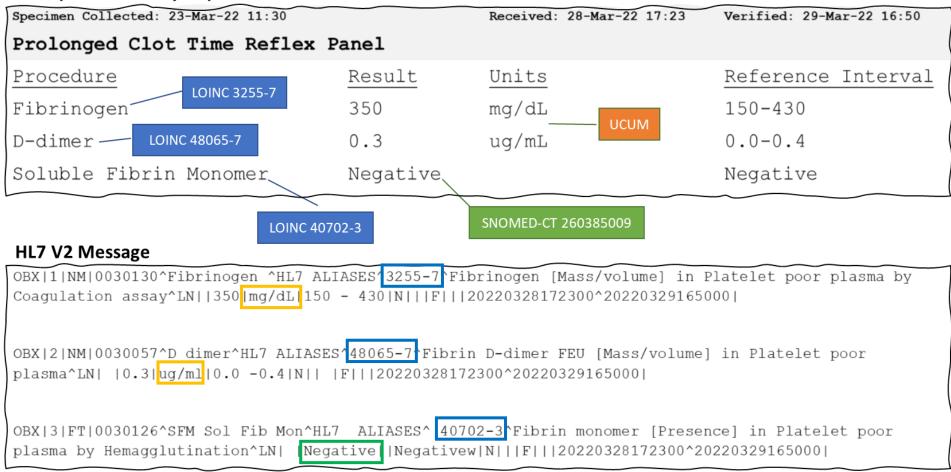
*HL7 messages have been truncated for simplicity





Terminology Standards for USCDI – LOINC, SNOMED, UCUM

Example Laboratory Report



^{*}HL7 messages have been truncated for simplicity





Mapping Lab Tests to LOINC

LOINC 15179-5

Fibrin D-dimer [Presence] in Platelet poor plasma

Dimension	Description
Component	Fibrin D-dimer
Property	Presence or Threshold
Timing	Point in time
System	Platelet Poor Plasma
Scale	Ord
Method	

LOINC 42499-4

Fibrin D-dimer [Presence] in Cerebral spinal fluid

	Dimension	Description
		Fibrin D-dimer
		Presence or Threshold
	Timing	Point in time
I	System	CSF
Ī	Scale	Ord
	Method	

LOINC 48058-2

Fibrin D-dimer DDU [Mass/volume] in Platelet poor plasma by Immunoassay

Description
Fibrin D-dimer
Mass Concentration
Point in time
Platelet Poor Plasma
Quantitative
lmmunoassay





Mapping Errors are the Biggest Limitation for LOINC

LOINC	COMPONENT	PROPERTY	TIME	SYSTEM	SCALE	METHOD	UCUM UNITS
14158-0	Cortisol	MRat	24H	Urine	Qn		ug/(24.h)
15043-3	Cortisol	SCnc	Pt	Urine	Qn		nmol/L
20622-7	Cortisol	MCnc	24H	Urine	Qn		mg/dL
2142-8	Cortisol	MCnc	Pt	Saliva	Qn		ug/dL
2143-6	Cortisol	MCnc	Pt	Ser/Plas	Qn		ug/dL
2144-4	Cortisol	MCnc	Pt	Urine	Qn		ng/mL
2144-4	Cortisol	MCnc	Pt	Urine	Qn		ng/mL
28550-2	Cortisol	PrThr	Pt	Urine	Ord		
32310-5	Cortisol	SRat	24H	Urine	Qn		nmol/(24.h)
33257-7	Cortisol	MCnc	Pt	CSF	Qn		ug/dL
50848-1	Cortisol	SCnc	24H	Urine	Qn		nmol/L
83088-5	Cortisol	MCnc	Pt	Ser/Plas	Qn	IA	ng/mL
83089-3	Cortisol	MCnc	24H	Urine	Qn	IA	ng/mL
83091-9	Cortisol	SCnc	24H	Urine	Qn	IA	nmol/L





Mapping Specimen Source to SNOMED

```
309051001 | Body fluid specimen (specimen) |
   119341000 | Bile specimen (specimen) |
 ▶ 119343002 | Pancreatic fluid specimen (specimen)
 418564007 | Pleural fluid specimen (specimen)

    33511000087108 | Fluid specimen from abdominopelvic cavity (specimen) |

       168139001 | Peritoneal fluid specimen (specimen) |
            309201001 | Ascitic fluid specimen (specimen)
  119332005 | Synovial fluid specimen (specimen)
      167874004 | Knee joint synovial fluid (specimen) |
```

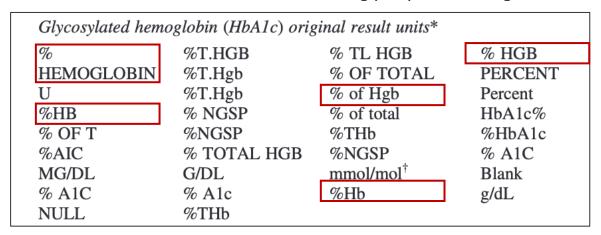




Assigning Units of Measure that Conform to UCUM

Based on a database of 385,516,239 laboratory test results from 12 data partners

34 variations in the units of measure for glycosylated Hemoglobin



68 variations in the units of measure for Platelet Count

Platelet count original result units [‡]						
Blank	FL	TH/UL	X10(3)			
%	K/CMM	THOU/CMM	1000/UL			
/100 W	k/cmm	thou/cmm	X10(3)/MCL			
/CMM	K/CU MM	thou/mm3	X10(3)/UL			
CMM	K/CUMM	THOU/UL	X10(6)/MCL			
10 3 L	K/MCL	THOUS/CU.MM	X10*9/L			
10X3UL	K/mcL	THOUS/MCL	X10E3/UL			
10^3/UL	K/UL	THOU/mcL	X1000			
10*3/uL	k/uL	THOUS/UL	X10X3			
10?3/uL	KU/L	Thou/uL	X10^3/UL			
10E3/uL	K/MM3	THOUSA	x10			
10e3/uL	K/mm3	THOUSAND	X10?3/ul			
10e9/L	LB	THOUSAND/UL	X10E3/UL			
E9/L	PLATELET CO	U	X10E3			
BIL/L	T/CMM	X 10-3/UL	K/A?L			
bil/L	TH/MM3	X 10(3)/UL	K/B5L			
CU MM	th/mm3	X10 3				

Raebel MA, Haynes K, Woodworth TS, Saylor G, Cavagnaro E, Coughlin KO, Curtis LH, Weiner MG, Archdeacon P, Brown JS. Electronic clinical laboratory test results data tables: lessons from Mini-Sentinel. Pharmacoepidemiol Drug Saf. 2014 Jun;23(6):609-18.





Steps of Data Wrangling

Discovery – get familiar with the data

Structuring – format for analysis

01/01/2024 13:42:15 vs. Jan 2024

Cleaning – remove for inherent errors

duplicates, invalid data

Enriching – add additional data

respiratory = sputum, BAL, Bronch

Verifying – ensure consistency, identify outliers





Potential Pitfalls with Lab Data

ACCESSION	PATIENT NAME	AGE	SEX	IN LAB WHEN	COLLECTION WHEN	VERIFIED WHEN	GENERAL SOURCE	ORGANISM MNEMONIC	RESULT LONG TEXT
2413513790	xxxxxx	43	M	3/17/2024	3/17/2024	8/18/2024	*	Myctub	Culture POSITIVE for M. tuberculosis. Supplemental information provided in this final report.
2426310883	уууууу	52	F	6/23/2024	6/22/2024	8/17/2024	Paracentesis FI	*	Culture negative for acid fast bacilli
2426310883	уууууу	52	F	6/23/2024	6/22/2024	8/17/2024	Paracentesis FI	*	Culture negative for acid fast bacilli
2433014448	TESTING, ARUP	68	F	8/29/2024	8/28/2024	8/29/2024	Respiratory	*	Negative for Acid Fast Bacteria.







Data Elements, Architecture, Data Wrangling – Summary

- Orderable lab tests can be made up of multiple components, each representing a single assay
- Lab results typically include the result, unit of measure, reference interval, abnormal flag, and date of order, collection, and verification
 - These data elements are required for electronic exchange by the ONC as part of USCDI
- Lab results are exchanged using a standardized format called HL7
- Within the HL7 message, the lab test is
 - coded by LOINC,
 - Unit of Measure is standardized to UCUM
 - organisms, specimen sources, and qualifiers are mapped to SNOMED CT codes
- LOINC, SNOMED CT, and UCUM help to standardize electronic lab results, but they are imperfect



Lab Developed Tests:

How frequently are they ordered?





Lab Developed Tests – How Frequently are they Ordered

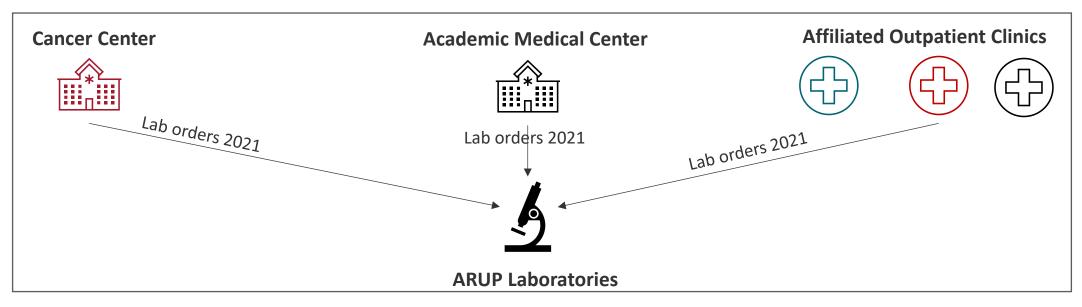
	A SNAPSHOT OF LAB-DEVELOPED TEST REGULATIONS
2003	Amendments to CLIA '88 introduce new requirements for LDTs but deem them outside the FDA's purview.
2014	The FDA releases draft guidance declaring that LDTs should be held to the same standards as IVDs.
2016	The House Committee on Appropriations directs the FDA to suspend efforts to regulate LDTs.
2020	The VALID Act is introduced in Congress outlining the FDA's intent to regulate all <i>in vitro</i> clinical tests, including LDTs, but it is never passed.
2023	The FDA announces proposed rule to regulate all IVDs and phase out its discretionary approach to LDTs.
2024	The FDA publishes final rule on LDTs and two draft guidance documents: enforcement discretion in declared emergency situations and in the absence of a declared emergency.

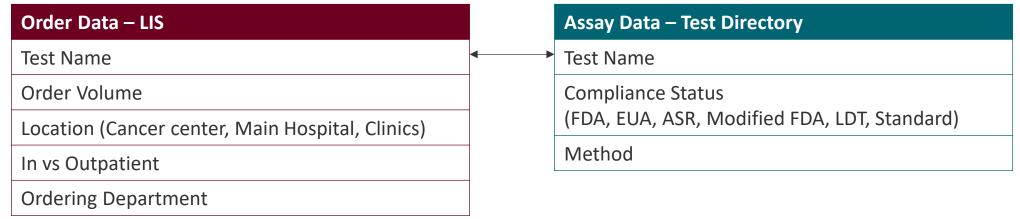




Lab Developed Tests – Data Wrangling

Step 1 - Merge multiple data sources into a single dataset for analysis







Lab Developed Tests - Transformation

Step 2 – Assign Specialty Field

Department Name	Assigned Specialty
Cardiovascular Medical UH CARDIOVASCULAR ICU	Cardiology
MIDVALLEY GENERAL DERMATOLOGY UH DERMATOLOGY	Dermatology
HUNTSMAN INTENSIVE CARE UH EMERGENCY DEPT Neuro Acute Care	Emergency Medicine/Intensive Care
UH INFECTIOUS DISEASE	Infectious Disease
Acute Internal Medicine ARUP HEALTH AND WELLNESS SHC ENDOCRINOLOGY	Internal/Family Medicine





Lab Developed Tests - Analysis

TABLE 1 Categorization of Tests by Regulatory Status					
Characteristic	Volume of Tests Ordered, No. (%)	Distinct Assays, No. (%)			
FDA assays	2,831,489 (93.9)	983 (50.3)			
FDA	2,807,104 (93.0)	979 (50.1)			
EUA	24,385 (0.8)	4 (0.2)			
LDT assays	116,583 (3.9)	880 (45.0)			
LDT	110,282 (3.7)	831 (42.5)			
Modified FDA	6,301 (0.2)	49 (2.5)			
Standard methods	68,856 (2.3)	91 (4.7)			
Total	3,016,928	1,954			

EUA, emergency use authorization; FDA, Food and Drug Administration; LDT, laboratory-developed test.



Lab Developed Tests – Analysis

Test Name	Specimen	Method	Test Volume, No.	% LDT Volume
Tacrolimus	WB	MS	12,662	10.9
Cytomegalovirus, viral load	Р	RT-PCR	5,226	4.5
Estradiol	S, P	MS	4,527	3.9
Leukemia/lymphoma phenotyping	WB	FC	4,410	3.8
Targeted drug profile	U	EIA, MS	3,394	2.9
CD4 lymphocyte subset	WB	FC	3,373	2.9
Vitamin B₁	WB	MS	3,222	2.8
Zinc	S, P	MS	2,858	2.5
Copper	S, P	MS	2,635	2.3
Epstein-Barr virus, viral load	S, P	RT-PCR	2,584	2.2
Progesterone	S, P	MS	2,279	2.0
Vitamin A	S, P	HPLC/UV	2,144	1.8
Chromosome analysis	BM	GB	1,954	1.7
Testosterone, total	S, P	MS	1,822	1.6
Vitamin B6	S, P	MS	1,784	1.5
Selenium	S, P	MS	1,618	1.4
BK virus, viral load	WB, S, P	RT-PCR	1,546	1.3
Everolimus	WB	MS	1,445	1.2
Albumin, body fluid	BF	IT/SPEC	1,342	1.2
Cyclosporin A	WB	MS	1,270	1.1

BF, body fluid; BM, bone marrow; EIA, enzyme immunoassay; FC, flow cytometry; GB, Giemsa band; HPLC/UV, high-performance liquid chromatography/ultraviolet absorbance; IT/ SPEC, immunoturbidimetry and spectrophotometry; LDT, laboratory-developed test; MS, mass spectrometry; P, plasma; RT-PCR, real-time polymerase chain reaction; S, serum; U, urine; WB, whole blood.

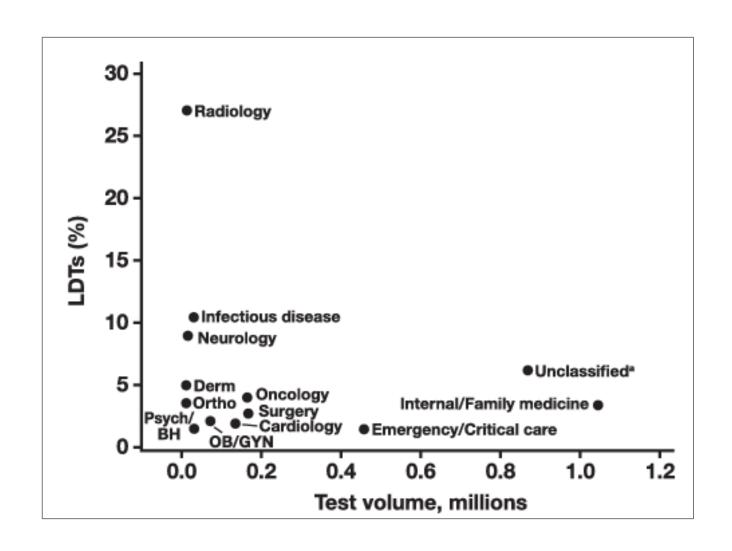
Common Themes

- Mass Spectrometry
- Tests used in Transplant Medicine





Lab Developed Tests – Analysis







Lab Developed Tests - Summary

- Given the FDA interest in regulating LDT, we were interested in how frequently LDTs were ordered within our health system
- We merged test volume data out of our LIS with test information from our test directory to create the data set
- We had to transform the ordering department data into clinical specialty for this data element to be meaningful
- Laboratory Developed Tests represented 3.9% of the test volume ordered within our health system
- This test volume involved 880 unique assays
- Radiology was an outlier, with more than 25% of ordered tests being LDTs





Testosterone Testing: *Make it easier to order the right test*



Testosterone Testing – Make it Easier to Order the Right Test

Test Order/Result

Testosterone, Adult Male Testosterone 102 ng/dL L (Ref Interval: 300-890) INTERPRETIVE INFORMATION: Testosterone by Immunoassay

Testosterone immunoassays are both imprecise and inaccurate at low testosterone concentrations, such as those found in children and cisgender females. For these individuals, testing by mass spectrometry is recommended; refer to Testosterone (Adult Females, Children, or Individuals on Testosterone-Suppressing Hormone Therapy) (ARUP test code 0081058). Free or bioavailable testosterone measurements may provide supportive information.

For individuals on testosterone hormone therapy, refer to cisgender male reference intervals. No reference intervals have been established for males younger than 14 years or for cisgender females. For a complete set of all established reference intervals, refer to ltd.aruplab.com/Tests/Pub/0070130.

Clarify patient demographics

Except TT

Order Comment

AUTO SEND Testing for Testosterone Free and Total by ED/LC-MS/MS (Free) and LC-MS/MS (Total), Adult Males is intended for an adult male. Patient is not registered as an adult male. Please clarify whether we should run testing with a disclaimer, or cancel test and order Testosterone, Free and Total (Includes Sex Hormone Binding Globulin), Females or Children (0081056). *AUTO SEND END*





Testosterone Testing – Make it Easier to Order the Right Test

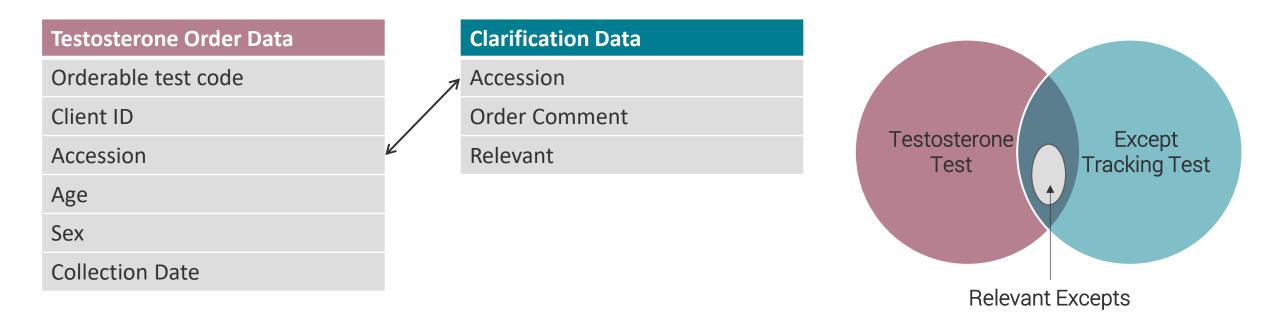
Previous Test Name	Updated Test Name	Previous Clarification Rules	Updated Clarification Rules	
Testosterone, Adult Male	Testosterone (Adult Males or Individuals on Testosterone Hormone Therapy)			
Testosterone, Females and Children	Testosterone (Adult Females, Children, or Individuals on Testosterone- Suppressing Hormone Therapy)		Males < 14 yo, Females < 18 yo, Unknown sex < 18 yo	
Testosterone, Free Adult Males by ED/LC-MS/MS	Testosterone, Free by Dialysis and Mass Spectrometry (Adult Males or Individuals on Testosterone Hormone Therapy)	Males < 14 yo		
Testosterone, Free and Total (Includes Sex Hormone Binding Globulin), Adult Male	Testosterone, Free and Total, Includes Sex Hormone Binding Globulin (Adult Males or Individuals on Testosterone Hormone Therapy)	All Females All Unknown sex		
Testosterone, Free and Total (Includes Sex Hormone Binding Globulin), Females and Children	Testosterone, Free and Total, Includes Sex Hormone Binding Globulin (Adult Females, Children, or Individuals on Testosterone- Suppressing Hormone Therapy)			
Testosterone Free and Total by ED/LC-Ms/MS (Free) and LC-MS/MS (Total), Adult Males	Testosterone Free and Total by Dialysis and Mass Spectrometry			





Testosterone Testing - Data Wrangling

Step 1 - Merge multiple data sources into a single dataset for analysis



Testosterone Data Set = all testosterone orders 1 year prior to the change, the year immediately following the change, and 2 years immediately following the change

Clarification Data Set = all orders for 'except tracking' over these same time periods.

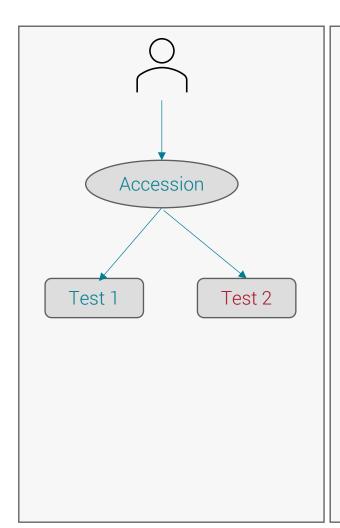
Merged Data Set = For each accession in the testosterone data, show all the order data and the linked order comment for the clarification data, if it exists

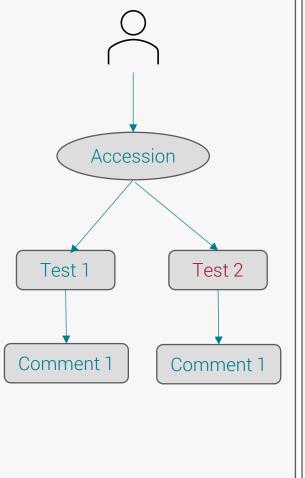


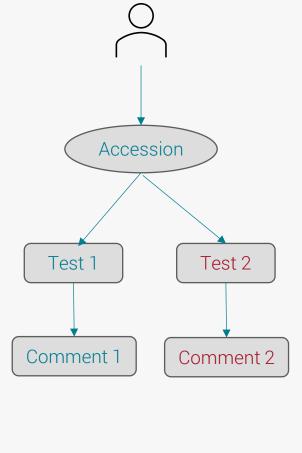


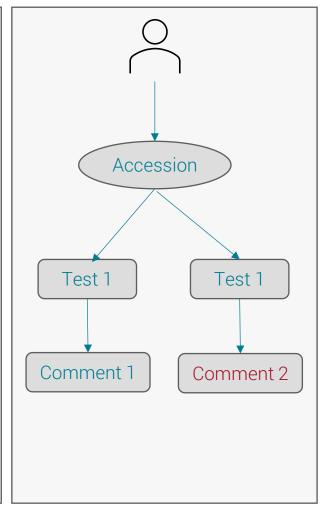
Testosterone Testing - Data Wrangling

Step 2 – Assess and remove duplicates









Testosterone Testing - Data Wrangling

Step 3 – Code each record as Null, Not Relevant, or Relevant

NULL

NOT RELEVANT

Specimen quantity was insufficient to repeat FREE T TMS portion of TE F&T ED testing. Specimen is in the frozen hold rack in the Mass Spec 1 dept.

Clarify DDT for FREE T2. DDT on spec: not provided. DDT on ppwk and in LIS: 1/XX/2021.

AUTO SEND Please clarify the collection date and time for Testosterone Free, Adult Male. Specimen did not provide the collection date and time and paperwork/LIS states 1/21/2021. *AUTO SEND END*

RELEVANT

AUTO SEND Testing for Testosterone, Adult Male is intended for an adult male. Patient is not registered as an adult male. Please clarify whether we should run testing with a disclaimer, or cancel test and order Testosterone, Females or Children (0081058).
AUTO SEND END

Clarify GENDER for TESTOS. DOB/Age on spec: NOT ARRIVED. DOB/Age on ppwk and LIS: UNKNOWN. *AUTO SEND* Please clarify patient's gender for Testosterone, Adult Male. LIS states: Unknown. *AUTO SEND END*





Testosterone Data – Analysis

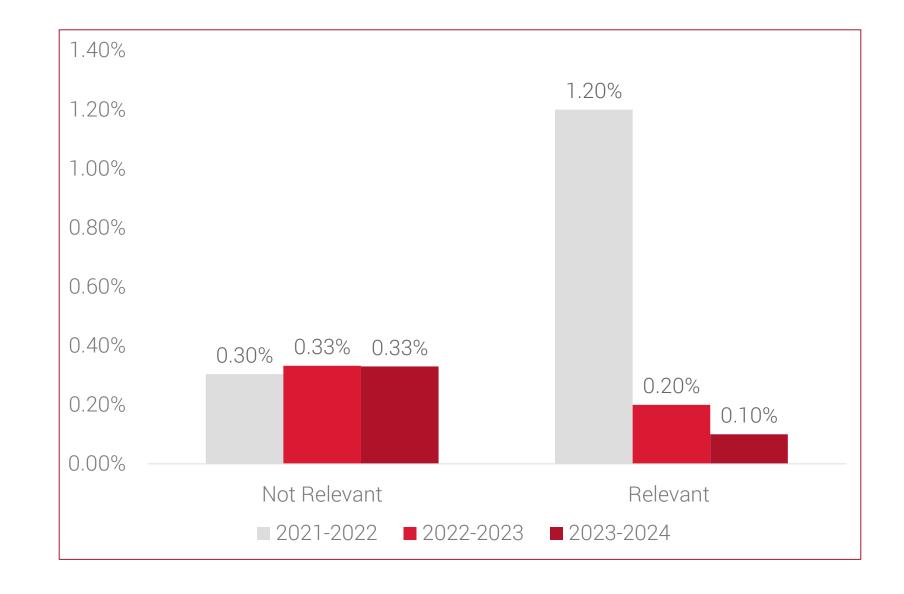
Clarification Rules

2021-2022 (before):

- Males < 14 yo
- All Females,
- All Unknown Sex

2022-2024 (after):

- Males < 14 yo
- Females <18 yo
- Unknown sex <18 yo







Testosterone Data – Analysis

Clarification Rules Before

- Males < 14 yo
- All Females
- All Unknown Sex

Clarification Rules After

- Males < 14 yo
- Females <18 yo
- Unknown sex <18 yo

	Before			After		
	Pediatric	Adult	Age Unknown	Pediatric	Adult	Age Unknown
Female	8.36%	77.71 %	0.00%	30.97%	12.74%	0.16%
Male	0.78%	10.31%	0.29%	5.16%	45.16%	0.00%
Unknown sex	0.05%	1.91%	0.59%	0.97%	4.35%	0.48%





Testosterone Data Wrangling - Summary

- Testosterone test names were confusing resulting in a significant effort to clarify the testing that was indicated
- Multiple data sets were joined together to get the data set for analysis, resulting in a large data set that was best analyzed via Python (not Excel)
- Utilized a simple clustering algorithm on the comments to identify the words that differentiated relevant from non-relevant comments
- There was a significant reduction in the percent of orders that required clarification after the test names were changed
- Prior to the change, the majority of clarifications were for patients registered as adult females
- After the change, a large proportion were for orders where the patient sex was initially transmitted as unknown but then clarified to adult male





Positivity Dashboard: *Many uses of dashboards*

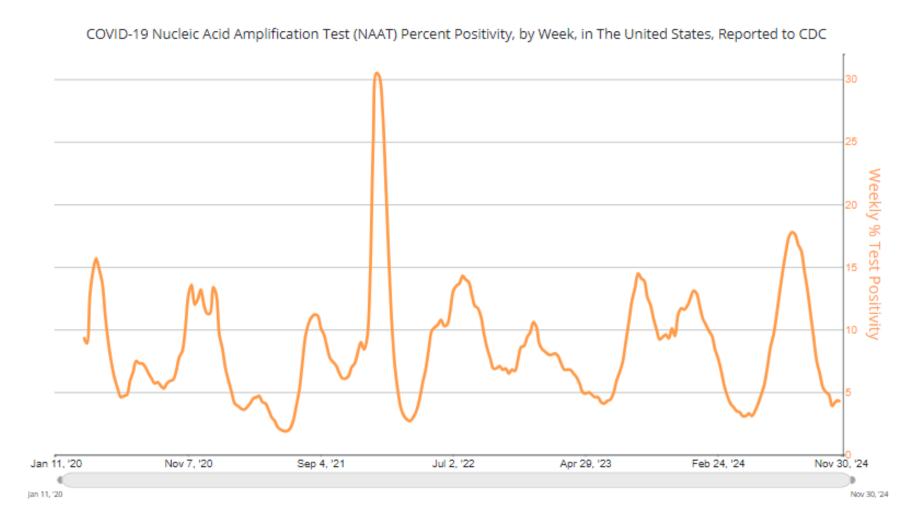




Positivity Dashboards – COVID Data Tracker



- NREVSS Participating laboratories voluntarily report diagnostic testing data weekly
- Includes NAAT
- Excludes Antigen, Antibody testing

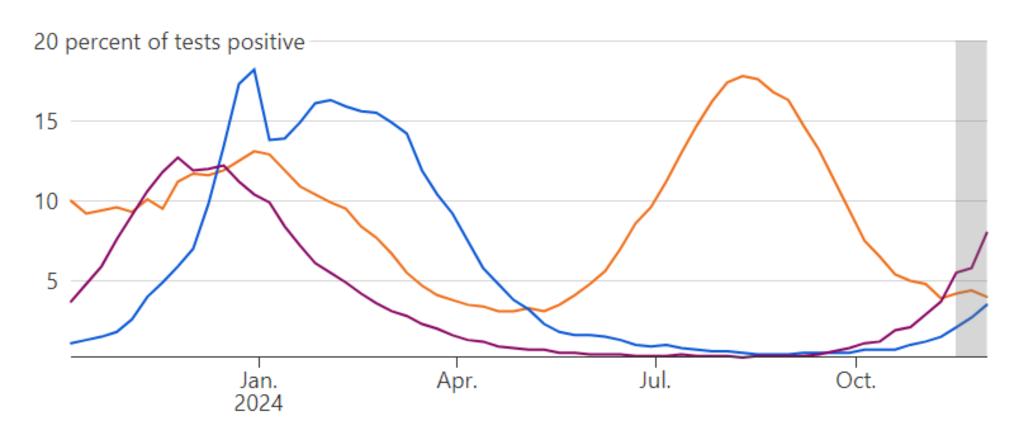


National Respiratory and Enteric Virus Surveillance System (NREVSS)





Positivity Dashboards – COVID Data Tracker



Respiratory Virus



Influenza



Sources: COVID-19 and RSV: National Respiratory and Enteric Virus Surveillance System (NREVSS), Influenza: Clinical laboratory test results from NREVSS and U.S. World Health Organization collaborating laboratories





Positivity Dashboards – COVID Data Tracker

LOINC	Description
105749-6	SARS-CoV-2 RNA in Bronchoalveolar lavage by NAA with probe detection
95406-5	SARS-CoV-2 RNA in Nose by NAA with probe detection
94759-8	SARS-CoV-2 RNA in Nasopharynx by NAA with probe detection
96797-6	SARS-CoV-2 RNA in Oropharyngeal wash by NAA with probe detection
94500-6	SARS-CoV-2 RNA in Respiratory system specimen by NAA with probe detection
94845-5	SARS-CoV-2 RNA in Saliva (oral fluid) by NAA with probe detection
94660-8	SARS-CoV-2 RNA in Serum or Plasma by NAA with probe detection
105748-8	SARS-CoV-2 RNA in Tracheal aspirate by NAA with probe detection
94309-2	SARS-CoV-2 RNA in Specimen by NAA with probe detection

SNOMED CT	Qualifier Value
260373001	Detected
260415000	Not Detected
10828004	Positive
260385009	Negative
419984006	Inconclusive

% Positivity

Sum the number of tests with these LOINC where the result is one of the following SNOMED CT (260373001, 10828004)

Sum the number of tests with the these LOINC

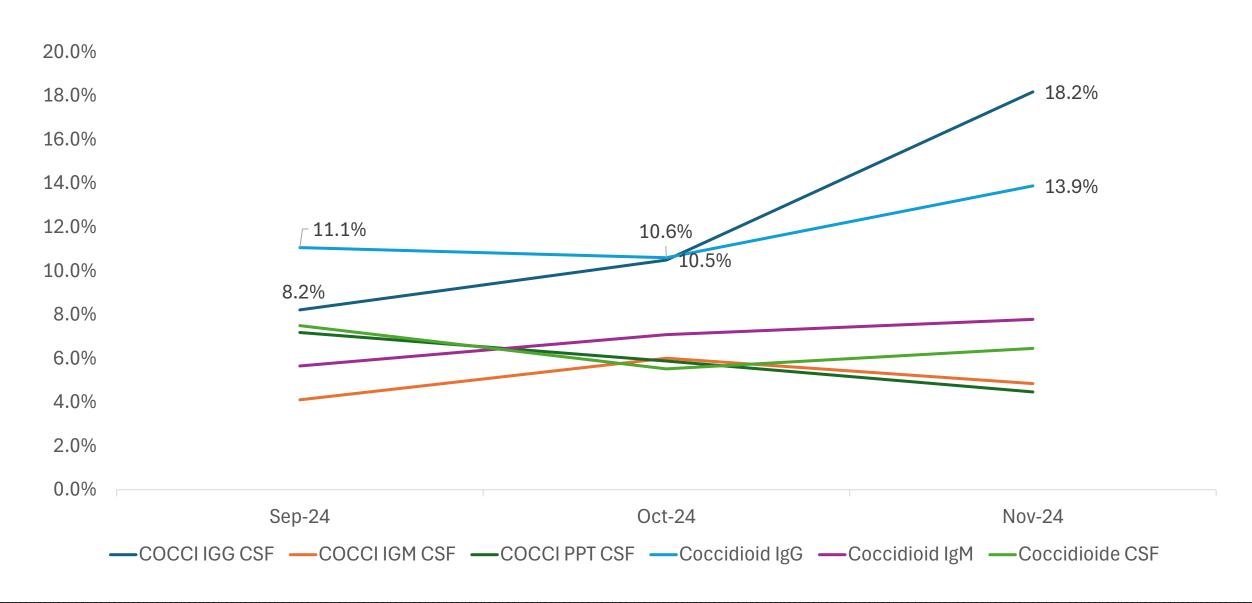












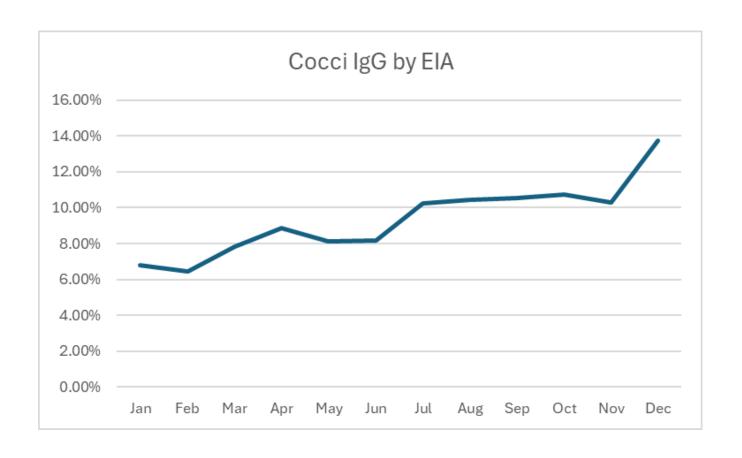


Email from an outside colleague

We are starting to see a higher-than-average positivity rate for our Coccidioides IgG EIA

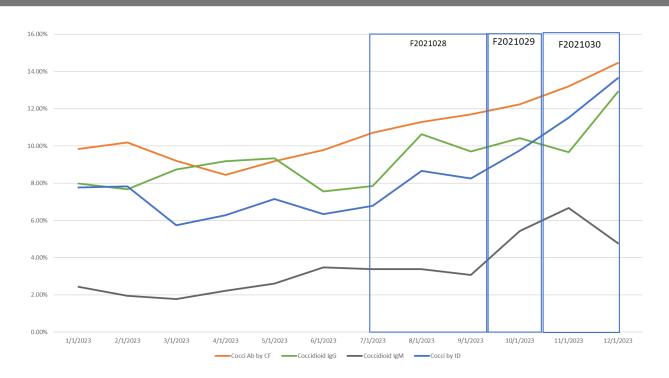
We have identified specific lots that are associated with the trend.

Are you seeing a similar trend?



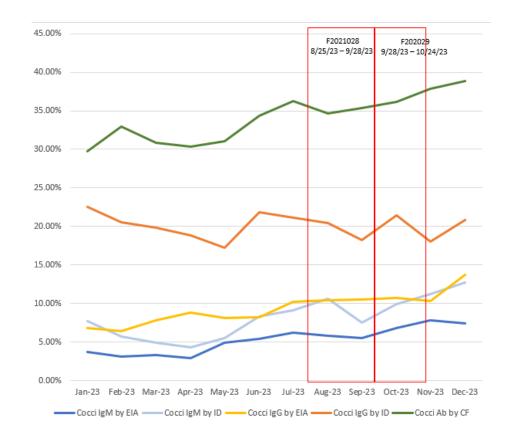








- See a similar trend in positivity across methods (EIA, CF, ID)
- Did not see much of a bias in our lot-to-lot comparisons
- I was assuming this was a seasonality issue.



- See a similar pattern as well (the exception being ID)
- Perhaps associated with recent influx of people recently in the Southwest





Positivity Dashboards - Summary

- For qualitative testing, real time positivity dashboards can be helpful for public health and for monitoring testing within the lab
- We use a Tableau dashboard to visualize positivity data in real time.
 - Filter based on time frame and test
 - Set up monthly subscription for notification via email
- Tableau has a feature for exporting the data for additional analysis in Excel
- Positivity dashboard helps to identify assay issues that may have not been caught using typical run QC
- Real time access made it easy to collaborate with colleagues









ARUP is a nonprofit enterprise of the University of Utah and its Department of Pathology.