

A photograph of two scientists in a laboratory setting. They are both wearing white lab coats and safety glasses. The scientist on the left is pointing at a computer monitor, while the scientist on the right is looking at the screen. The monitor displays a complex data visualization with various charts and graphs. The background is slightly blurred, showing other lab equipment and a clean, professional environment. The overall color palette is dominated by cool blues and whites.

COVID-19 Lab Working Group

Topics



- I. COVID-19 Knowledge Updates
- II. COVID-19 Autoverification Rule Set
- III. Understanding Test Code Mapping
- IV. Troubleshooting Resources
- V. Q&A

COVID-19 Resources from Data Innovations



- COVID-19 Driver Listing
- News Blog
- Recurring webinar series

Upcoming Webinars

**New Release Update: IM
2020 Edition, Version 8.17**

Wed., June 3rd

10:00 AM PT /1:00 PM ET

**IM Customer Case Study with
Sentara Healthcare**

Mon., June 22nd

10:00 AM PT /1:00 PM ET



COVID-19 Knowledge Updates

Testing Update and Meeting Challenges with DI Solutions

Selecting the right test



Based on clinical need/demand



Decision-making



Sensitivity and specificity



Reimbursement



Decision made

Future COVID-19 Considerations



Watch for changes in incident rates



Watch for changes in FDA approval



Will the lab be thrown a lifeline? \$\$\$



Critically analyze challenges and successes

COVID-19 Testing Update

Selecting the right test

- On May 4th the FDA provided new guidance for COVID-19 test data submission
- Tests must have 90% sensitivity and 95% specificity
- As of 5/22/20 there are 13 approved tests per the [FDA website](#)
- Keep an eye on this list

Test	Sensitivity PPA	PPA n	Specificity NPA	NPA n	PASS FDA 90-95?	Source
Abbott Alinity I IgG	100	34/34	99	99/100	YES	FDA/IFU
Abbott ARCHITECT IgG	100	88/88	99.6	1066/1070	YES	FDA/IFU
	96.9		99.9	1012/1020	YES	Pre-print UW, Idaho
	93.8		"	"	YES	Pre-print UW-St Louis
Bio-Rad Patelia Total Ab	92.2	47/51	99.6	684/687	YES	FDA/IFU
Diasorin Liaison S1/S2 IgG	97.6	40/41	99.3	1082/1090	YES	FDA/IFU
Mount Sinai ELISA Ab	92.5	37/40	100	74/74	YES	FDA/IFU
Ortho-Clinical VITROS Total	100	49/49	100	400/400	YES	FDA/IFU
Roche Elecsys	100	29/29	99.8	5262/5272	YES	FDA/IFU

Meeting Challenges with EP Evaluator



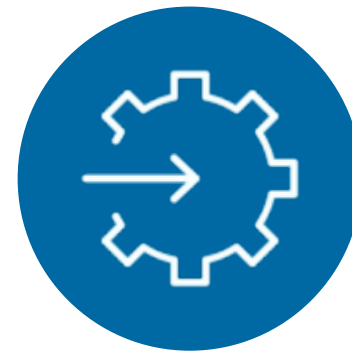
The challenges of performance verification studies



Complicated, manual statistical computations can result in errors and create risk



Automate statistical calculations with accuracy



Direct integration with Instrument Manager

www.datainnovations.com/ep-evaluator

Meeting Challenges with Instrument Manager

Use what you may already have!



Connectivity



Specimen Management (SM)
Workspaces and Autoverification



Lab Intelligence



Moving Averages



Open Data Exchange
Connectivity



Sales Engineering

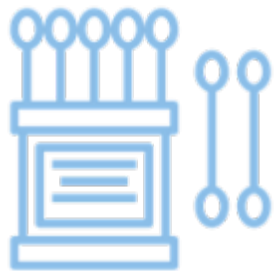
Autoverification Rules for COVID-19

Topics

- I. RT-PCR vs. Serology
- II. Serology Rules
- III. Molecular Biology Rules
- IV. Example of Molecular Biology Rules

RT-PCR Tests

Understanding the difference between RT-PCR and Serology tests



- Molecular biology test to identify virus' RNA
- Preferred laboratory test for diagnosis in symptomatic patients in disease's acute phase
- Collection made with a swab from a sample of respiratory secretion

Serology Tests

Understanding the difference between RT-PCR and Serology tests



- Verifies the body's immune response to the virus by detecting antibodies (IgG and IgM).
- Blood sample is collected from the patient

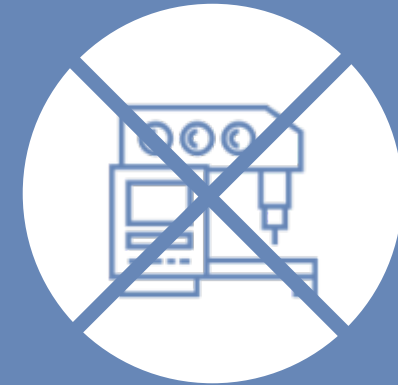
Molecular Biology Rules



More complex



Verify different test results (numeric and alphanumeric) to provide an interpreted result (Detected, Undetected, Undetermined)



Analyzer does not provide the final interpreted result

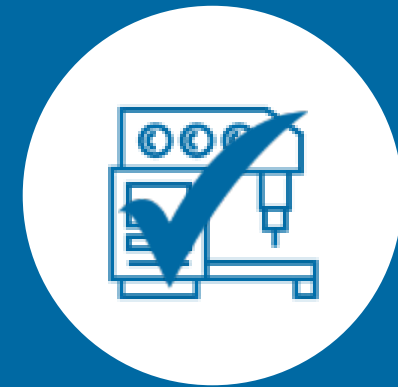
Serology Rules



Less complex



Verify the result range to provide an interpreted result (negative, gray zone, positive)



Analyzer can provide the interpreted result for IgG and IgM

Example of Target for RT-PCR Rules

**Analyzer:
ABI7500 with XGen
kit**

Test Code	Result Received	Interpreted Result
Gene_N	CT < 38	Detected
ORF1ab	CT < 38	
CI_XGen	CT < 38	
Gene_N	CT < 38	Undetermined
ORF1ab	Undetermined	
CI_XGen	CT < 38	
Gene_N	Undetermined	Undetermined
ORF1ab	CT < 38	
CI_XGen	CT < 38	
Gene_N	CT < 38	Detected
ORF1ab	CT < 38	
CI_XGen	Undetermined	
Gene_N	Undetermined	Not Detected
ORF1ab	Undetermined	
CI_XGen	CT < 38	
Gene_N	Undetermined	Undetermined
ORF1ab	Undetermined	
CI_XGen	Undetermined	

Why use Autoverification Rules with ABI7500?

Analyzer exports all results in one result file

IM uses an Advanced Configurable Delimited Instrument driver

Each Test Result comes as a separate result message

Example of RT-PCR Rules Analyzer: ABI7500 with XGen kit

Instrument Manager by Data Innovations LLC - [Rules Setup - Specimen Management]

System Configuration Diagnostics Security Specimen Management SSR QC SR MM MA Laboratory Intelligence Reports Window Help

Specimen Management Panes

Tree View

- [7] Test / In Validation (Compatibility)
 - [7] Incoming result
 - [7] After Data Added to Specimen Management Database
 - [0] Do not process QC samples
 - If: {Specimen ID} {NOT} {Matches Pattern of} "1.10N1A"
 - [0] Then: {Stop Processing Rules}
 - [0] Else:
 - [0] Corona AB7500 Kit XGen - Case 1 Detected
 - If: ({Interpreted Result} {On SM Test} "COV-GEN" {On Inst} "AB7500" {Is Numeric}) {AND} ({Interpreted Result} {On SM Test} "COV-GEN" {On Inst} "AB7500" < "38") {AND} ({Interpreted Result} {On SM Test} "COV-GORF" {On Inst} "AB7500" {Is Numeric}) {AND} ({Interpreted Result} {On SM Test} "COV-GORF" {On Inst} "AB7500" < "38") {AND} ({Interpreted Result} {On SM Test} "COV-GCI" {On Inst} "AB7500" {Is Numeric}) {AND} ({Interpreted Result} {On SM Test} "COV-GCI" {On Inst} "AB7500" < "38")
 - Then: {Add Test} "COV-INT" {On Inst} "AB7500" {AND} {Set} {Result} {On SM Test} "COV-INT" {On Inst} "AB7500" = "Detected" {AND} {Set} {Instrument ID} = "AB7500"
 - Else:
 - [0] Corona AB7500 Kit XGen - Case 2 Suppress on LIS
 - [0] Corona AB7500 Kit XGen - Case 3 Suppress on LIS
 - [0] Corona AB7500 Kit XGen - Case 4 Detected
 - [0] Corona AB7500 Kit XGen - Case 5 Not Detected
 - [0] Corona AB7500 Kit XGen - Case 6 Suppress on LIS
- [7] Live (Compatibility)

Value List Items

Enter Find Text

Load From * Copy Values to New Row

* |

Rules Testing

Tree View Grid View

```
If: ( {Interpreted Result} {On SM Test} "COV-GEN" {On Inst} "AB7500" {Is Numeric} ) {AND} ( {Interpreted Result} {On SM Test} "COV-GEN" {On Inst} "AB7500" < "38" ) {AND} ( {Interpreted Result} {On SM Test} "COV-GORF" {On Inst} "AB7500" {Is Numeric} ) {AND} ( {Interpreted Result} {On SM Test} "COV-GORF" {On Inst} "AB7500" < "38" ) {AND} ( {Interpreted Result} {On SM Test} "COV-GCI" {On Inst} "AB7500" {Is Numeric} ) {AND} ( {Interpreted Result} {On SM Test} "COV-GCI" {On Inst} "AB7500" < "38" )
Then: {Add Test} "COV-INT" {On Inst} "AB7500" {AND} {Set} {Result} {On SM Test} "COV-INT" {On Inst} "AB7500" = "Detected" {AND} {Set} {Instrument ID} = "AB7500"
Else:
```

Status and Warnings Properties

Logged On User: IM_NT Locale: Default License #: IM-999999 Customer Name: Data Innovations LLC

CAPS NUM INS

13/05/2020 17:11

Example of RT-PCR Rules Analyzer: ABI7500 with XGen kit

SM Rule detailed

<u>Test Code</u>	<u>Result Received</u>	<u>Interpreted Result</u>
<u>Gene N</u>	CT < 38	<u>Detected</u>
ORF1ab	CT < 38	
<u>CI XGen</u>	CT < 38	

If: ({Interpreted Result} {On SM Test} "COV-GEN" {On Inst} "AB7500" {Is Numeric}) {AND} ({Interpreted Result} {On SM Test} "COV-GEN" {On Inst} "AB7500" < "38") {AND} ({Interpreted Result} {On SM Test} "COV-GORF" {On Inst} "AB7500" {Is Numeric}) {AND} ({Interpreted Result} {On SM Test} "COV-GORF" {On Inst} "AB7500" < "38") {AND} ({Interpreted Result} {On SM Test} "COV-GCI" {On Inst} "AB7500" {Is Numeric}) {AND} ({Interpreted Result} {On SM Test} "COV-GCI" {On Inst} "AB7500" < "38")

Then: {Add Test} "COV-INT" {On Inst} "AB7500" {AND} {Set} {Result} {On SM Test} "COV-INT" {On Inst} "AB7500" = "Detected" {AND} {Set} {Instrument ID} = "AB7500"

Else:

Some things to evaluate prior to writing rules

1. Check how the instrument driver manages results (many test results per record or one test result per record).
2. Check the data element of the result to be evaluated.
3. Check the result type (use {Is Numeric} operator every time you need to evaluate a numeric result).
4. The rules must cover all conditions provided by the analyzer (avoid 'holes').



Tools for Troubleshooting

Topics

- I. Tools used in troubleshooting
- II. Walkthrough of a tricky Test Code Mapping scenario

Tools of my trade



System Log

Shows events that occurred on a system level within IM



Communication Trace

Shows raw data being transmitted to and from a connection



Specimen Event Log

A record of what events occurred for a Specimen within IM

System Log



- Contains date/time, user, PC name, IP address and event records on a system level.
- Can see backup events, purge, logins, rule changes, and configuration changes
- Useful to piece together historically what may have changed on the system and by who

Communication Trace

- View into the data transmitted between IM and something outside of IM
- Can use this to see orders/results/queries/status
- Lower level protocol communication (ack, nak, eot, stx)
- Debug/error messages IM posted about that communication
- The actual data transmitted allowing troubleshooting of the communication between IM and others



Specimen Event Log



- Record of events within IM for a specific Specimen ID
 - Audit/rules
 - Mapping: Fluid/Error/Test/Instrument
 - Order in Orders database
 - Specimen Management information updates
- Able to see what was parsed into Data Elements in IM and correlate it to what was in the comm trace
- Gives you an inside look into troubleshooting what happened to the Specimen as it flowed through IM

For more information



- <https://datainnovations.com/webinars>
 - IT Webinar Series – Diagnostics Tools and RDWeb
 - Same spot for Covid19 webinar recording from 5/13/20
- Quick Start manual: Chapter 8
- Contact Support!

North America

[DINA Customer Web Portal](#)

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09:00 - 20:00 EST/EDT
Monday - Friday

Introduction to Test Code Mapping

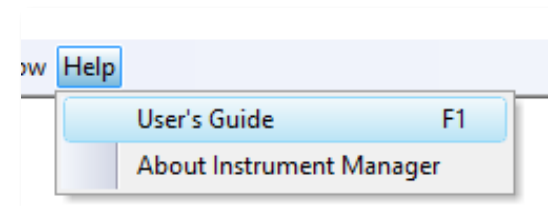
IM allows communication between LIS and Instruments using mapping

Communication handled by our drivers based on instrument specifications

Once Message is "read"/parsed, IM translates using Mapping

Mapping can be applied to 4 buckets of information: tests, fluid, error, instrument

For more information: The Getting Started User Guide has a chapter on "Mapping"



Test Code

Select Instrument Test Code

TEST (ExTestCode)

Mapping For All Tests

Learning Mode

LIS/Host to Instrument Manager to Instrument (Orders)

Select or Add IM Test Code

LISSentTest

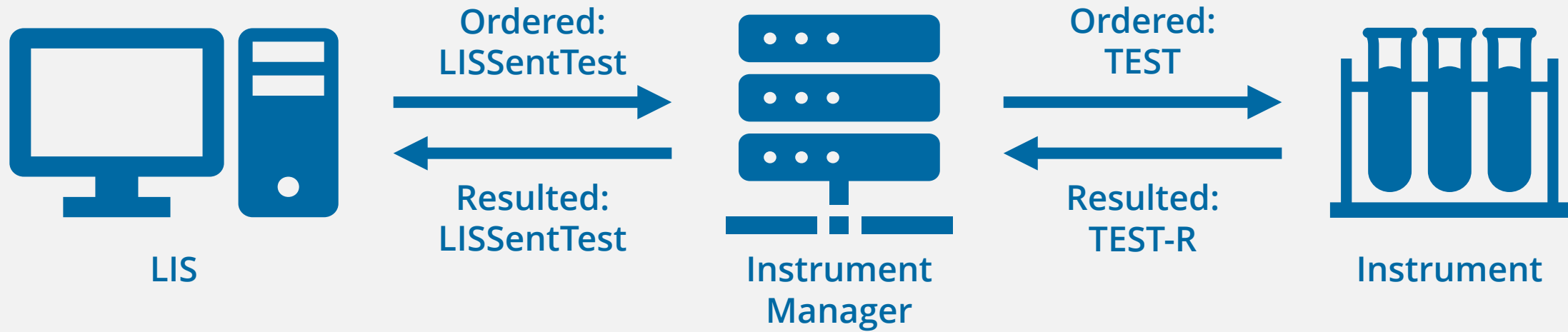
Select Fluid Type

N/A

Select or Add Display Name

ExTestCode

IM Test Code	Instrument Test Code	Fluid	Display Name	LOINC
LISSentTest	TEST (ExTestCode)	N/A	ExTestCode	



Instrument to Instrument Manager to LIS/Host (Results)

Select or Add IM Test Code

LISSentTest

Select Fluid Type

N/A

Select Test Resulting Option

Ordered or Default (OD)

Select or Add Display Name

ResultTestCode

Instrument Test Code	IM Test Code	Fluid	Option	Display Name
✓ TEST-R (ResultTestCode)	LISSentTest	N/A	OD	ResultTestCode
TEST-R (ResultTestCode)	TEST-R	N/A	OD	ResultTestCode

Lab Q&A

Tania Hong, Director of Pathology and
Laboratory Medicine

- University of Vermont Medical Center



Questions?

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