Innovations in Use of Auto verification to Improve Med Tech Productivity, Combined with Our Unique Method to Easily, Quickly, and Accurately Validate 100% of Auto verification Rules

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Learning objectives

- Understand the importance of rules verification testing in an IHN environment to ensure quality of patient care
- Learn how an automated rule testing solution can reduce testing efforts, verify proper rule operation and improve patient result outcomes
- Identify how an automated rule testing software solution produces testing documentation that ensures inspection-readiness and rule traceability across testing events

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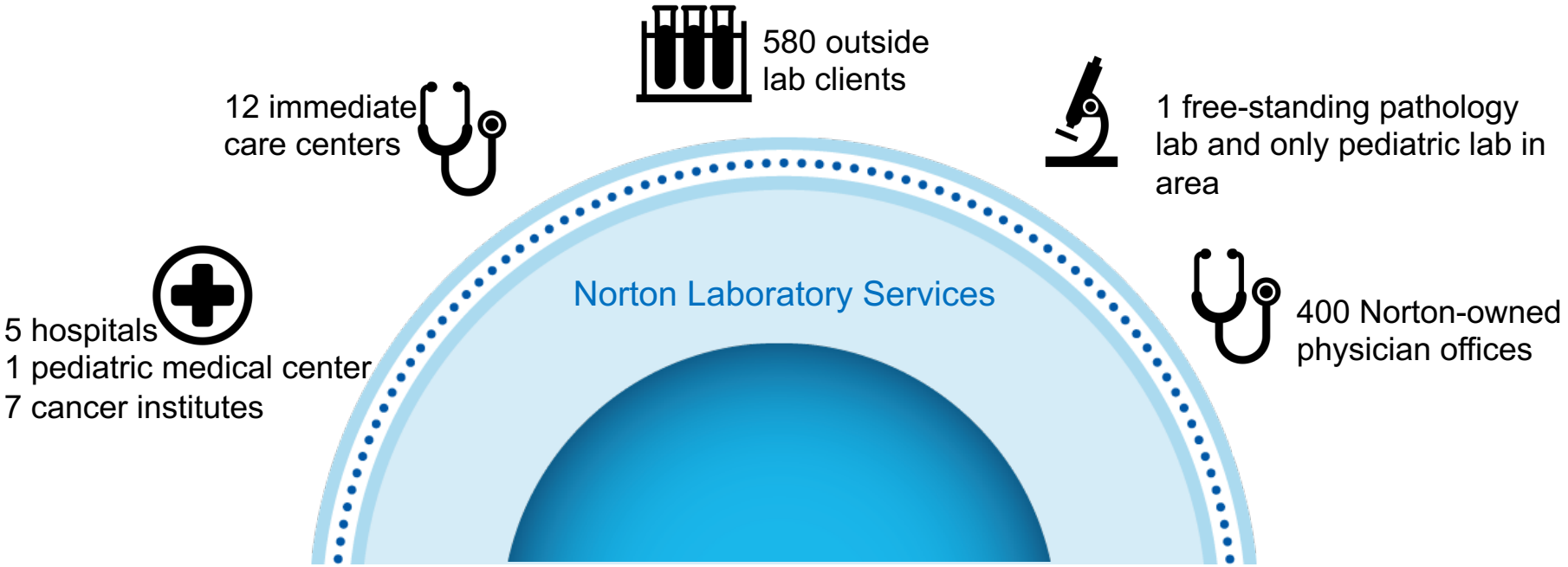

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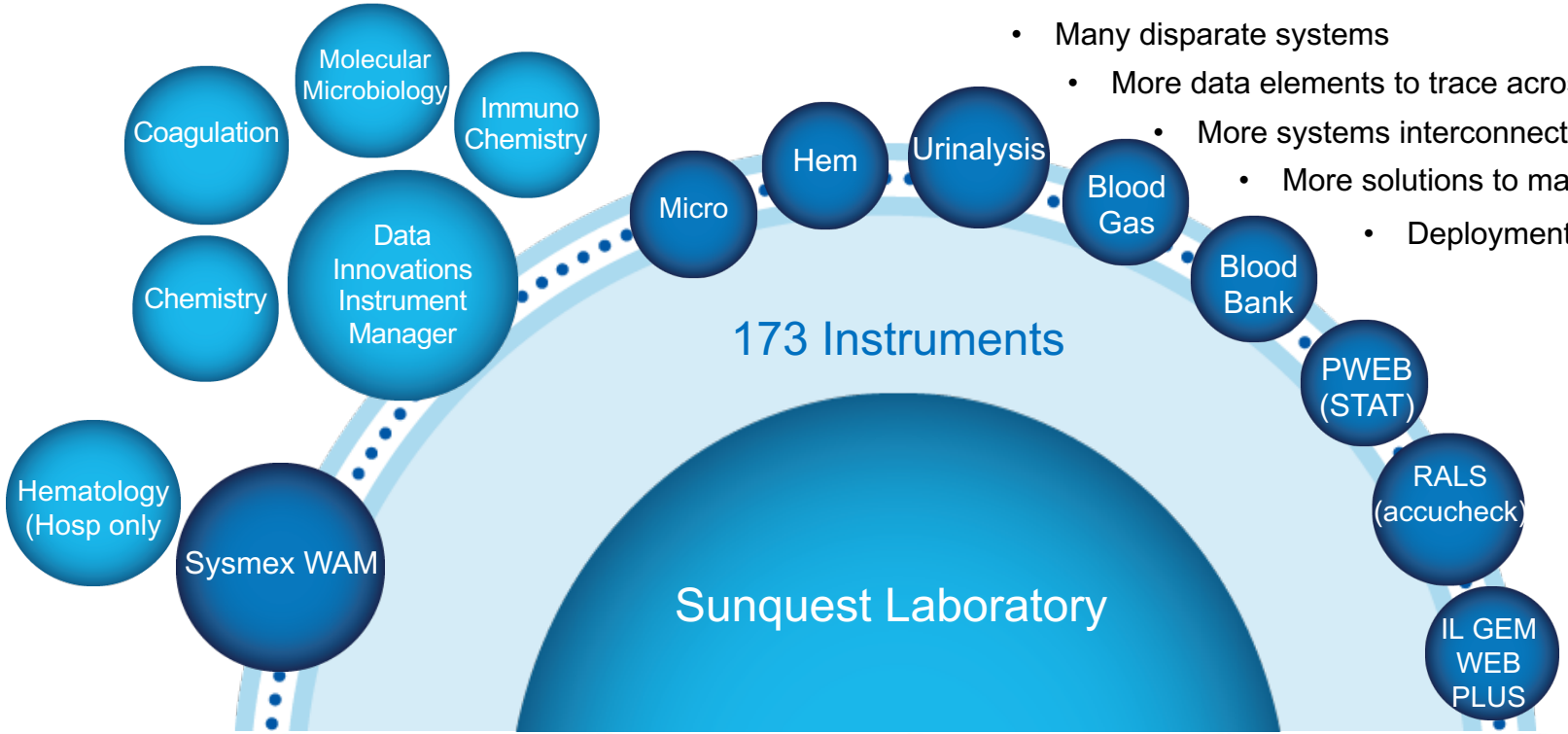
NORTON WOMEN'S & KOSAIR CHILDREN'S HOSPITAL

Norton Healthcare - Laboratory Network



- Many disparate systems
- More data elements to trace across systems
- More systems interconnected that share data
- More solutions to manage and support
- Deployment takes longer

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How to balance our needs

What are Lab's Needs?

Best technology & reliability

Highest Auto-verification rate

Lowest review rate

Highest turnaround time

Conserve valuable staff resources

What are Lab IT's Needs?

Standardized equipment, systems and software

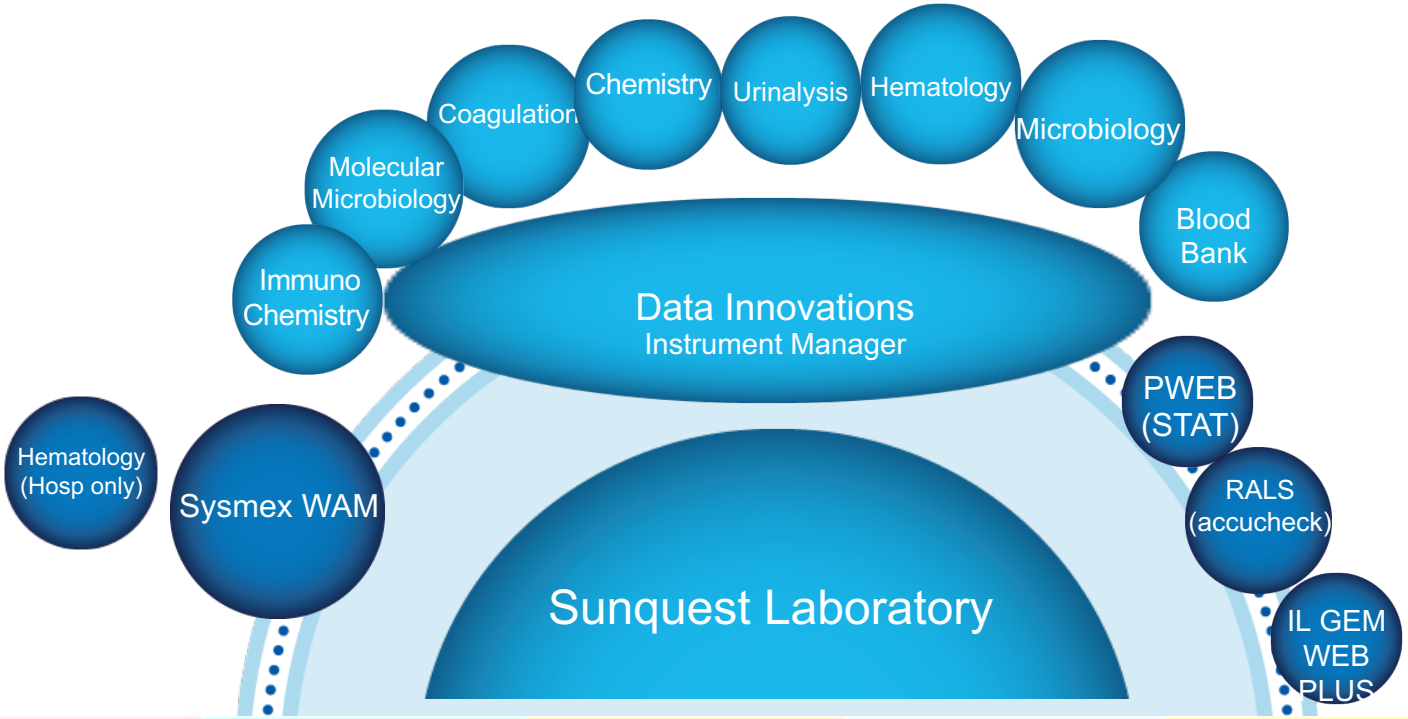
Fewer equipment, systems, software to manage

Solutions that improve speed of deployment

Better visibility -- know data is the best quality

Conserve valuable staff resources

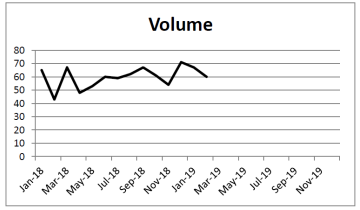
Streamline and standardize lab IT solutions



Go forward strategy – the good news

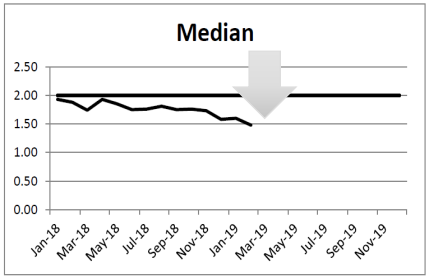
- Centralize and standardize our rules-based software systems
  - Ease deployment burden for LIS Team
  - Reduce support burden on LIS Team
- Increase use of auto-verification rules
  - Reduce manual effort in the lab
  - Improve TAT

Impact of auto-verification on TAT

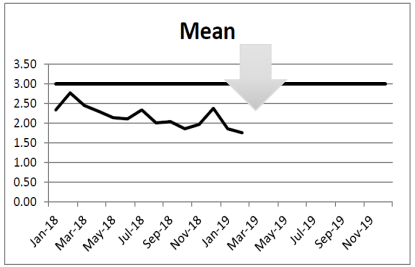


Example: Microbiology CSF Pathogen Panel

Median (Hours)	
Goal	2
Measured	1.48



Mean (Hours)	
Goal	3
Measured	1.76



Significant Reduction In Result TAT!

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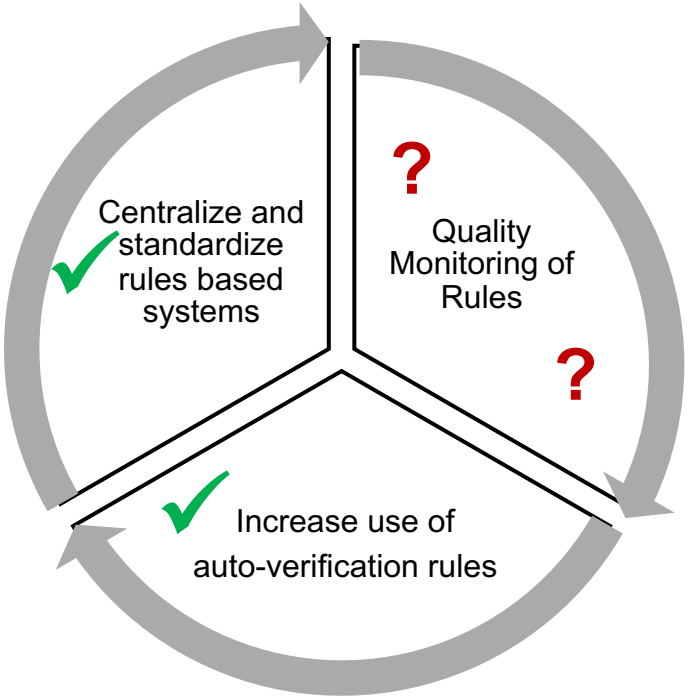


So…

What about the Quality of our Rules?

- How do we know our auto-verification rules are right?
- What is the impact of our rules changes over time?
- How do we give our lab team visibility to our rules?

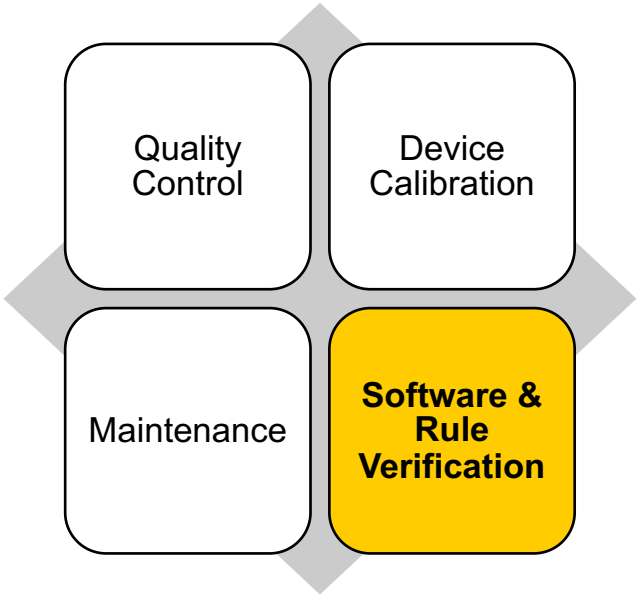
Quality Monitoring Issues

- Poor visibility to our rules
- Lack of traceability
- Inadequate tools for testing rules

More rules = more value + more risk

- Auto-validation rules are complicated to manage
  - ‘mother-daughter’ rules
  - Nested rules
  - Large value lists
- Challenges we face trying to maintain quality
  - Manual, tedious testing, no tools
  - No analysis capability
  - Difficult to understand changes to our rules over time

Quality Assurance Monitoring Program



Lab Quality Program

Our Situation

- Rules database is not ‘human readable’
- Reliant on manual effort to analyze and test rules
- Limited to spot checking rules
- Difficult to document rules testing
- Impossible to be as thorough as we need to be!

Our Challenge

- How do we know are rules are working all the time?
- How do we know they are defined correctly?
- How do we know we are releasing qualified results?
- How can we build a reliable QA program for our rules?

How do we manage the integrity of our rules?

Build a standardized quality approach

Your quality program should include

- Rules Analysis
  - Need to know and explain what rules we have
  - Must be able to engage the clinical lab team
  - Software rules should be easy to review by medical director
- Rules Testing and Verification
  - Must be able to ensure all the rules are correct
  - Must be able to test all variables and values
- Rules Traceability
  - Need to know rules are working continuously
  - Identify insidious or hidden issues
- Rules Testing documentation
  - Inspection-ready and complete

Rules quality – Our Report Card

Rules Quality Measure	Grade	Status / Situation at Norton
Centralized & standardized platforms	A	Data Innovations, Sysmex WAM (hematology)
Standardized instrument interfacing	A	Data Innovations, Sysmex WAM (hematology)
Standardized rules across enterprise	B	Data Innovations, Sysmex WAM (hematology)
Rules visibility, including a mechanism for viewing rules in 'English', easy to understand by all stakeholders	D	Lack of transparency; no tools to helps us work with the clinical team and medical director; to understand what we have
Rules verification testing for rules changes, added rules and CAP verification requirements	C	Manually heavy / tedious and time consuming; not able to thoroughly test all rules / variables / values
Rules comparison capability to see if and how our rules database has changed over time	F	No ability to compare our rule sets over time or as rules are changed
Rules testing documentation for proof of quality monitoring and for inspections	C	Manual process - tedious and time consuming

We need to modernize how we test rules

No Testing Coverage	Manual Testing Minimal Coverage	Semi-Automated Moderate Coverage	Fully Automated Thorough Coverage
No rule verification program	Manual data input Manual result capture	Some automated data input with manual result capture	Full data entry automation with rules verification
Spot checking by cursory review	Test one rule at time with single conditions	Test one rule at a time with 1-2 conditions	All rules, boundaries & conditions
Incomplete or documentation	Time consuming (months) Error prone	Time consuming Fewer errors than manual	Fast and accurate

To err is human

- Rules are improperly set up
- Omission of rules
- Rules are inadvertently changed or removed
- Variables and value lists are not updated
- Loss of LIS & SME expertise

Our objectives

- Improve our rules testing process
  - Find a way to visualize and understand the integrity of our rules base
  - Adopt test automation to establish better rules quality
  - Offload tedious rules testing and documentation to automated testing
- Identify areas of improvement
  - Strengthen our rules
  - Give better visibility of our rules to both the clinical team and lab IT

“Better understanding of our rules Quality, will give us the confidence to Grow our auto-verification rules base.”

Options and goals

- Goals
  - Off-load testing to automation
  - Solution that supports constant rules changes and new rules
  - Support our clinical best practices
  - Longitudinal traceability of rules/values list over time
  - Shared responsibility with technical and clinical teams
- Options
  - No in-house tools available
  - Not practical to develop and maintain ourselves
  - Outside test automation partner

Our selected solution

- Software Testing Solutions (STS)
  - Already a partner for LIS and Blood Bank test automation
- STS Rules Verification Solution on Data Innovations
  - Rules Analysis Tool
  - Test automation that STS would run for us
  - Inspection-ready documentation that STS would produce
  - Comparison Tool that would compare our rule set between changes and testing events

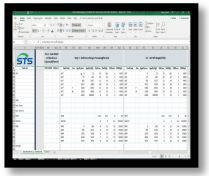
Process overview

01

XML rule export from our DI to STS

02

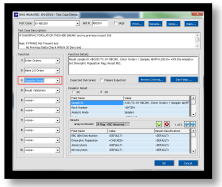
STS created Rules Analysis Tool for our review



Rule Analysis Tool

03

STS created automated test cases



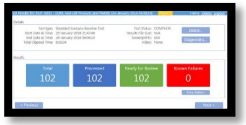
Test Case Creation

04

STS executed the test cases

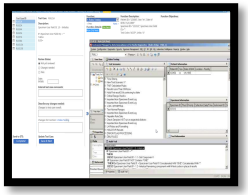
05

We reviewed & approved rules testing results on-line



06

STS created final report with screen prints

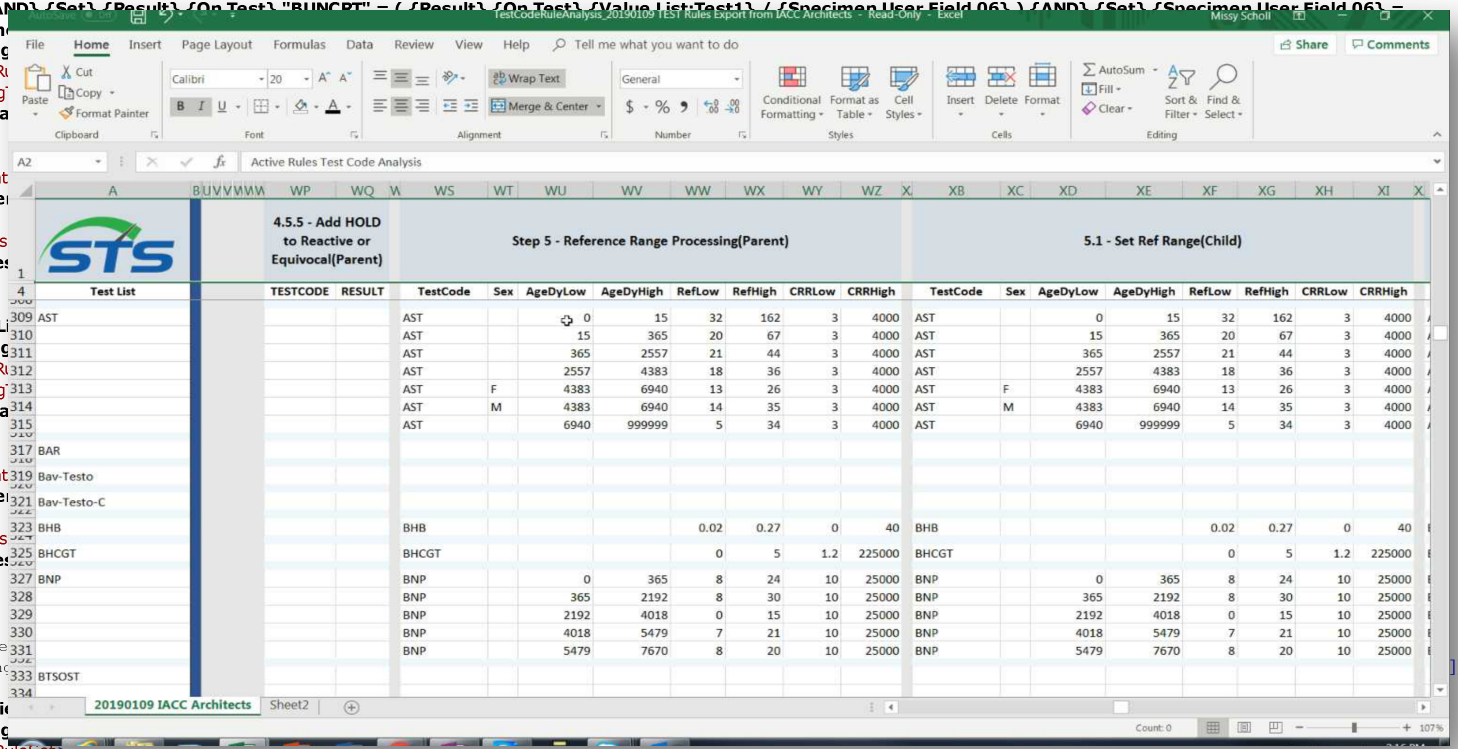


Rules Visibility & Analysis

DI Rules Export: XML to Readable format

```
- <Rule>
    <If>( ( {Specimen User Field 06} {Is Numeric} ) {AND} ( {Test Resulted} {Value List:Test1} ) {AND} ( {Result} {On Test} {Value List:Test1} {Is Numeric} ) {AND} ( {Specimen User Field 04}
      {Contains} {Value List:PaddedTest2} ) )</If>
    <Then>{Add Test} "BUNCRT" {AND} {Set} {Result} {On Test} "BUNCRT" = ( {Result} {On Test} {Value List:Test1} / {Specimen User Field 06} ) {AND} {Set} {Specimen User Field 06} =
      "" {AND} {Set} {Test Instrum
    <Parent>Incoming result-Messag
    <RuleSet>Test / In Validation</Ru
    <MsgType>Incoming result</Msg
    <Desc>Rule IRBM24.2.3 - Calcula
    <RuleNum>133</RuleNum>
    <Active>0</Active>
    <UseParentValueList>1</UseParent
    <Location>Message Queued Inte
    <Position>Before</Position>
    <WarrantsAuditEvent>1</Warrants
    <ParentValueListKey>Incoming res
  </Rule>
- <Rule>
    <If>( ( {Test Resulted} {Value Li
    <Parent>Incoming result-Messag
    <RuleSet>Test / In Validation</Ru
    <MsgType>Incoming result</Msg
    <Desc>Rule IRBM24.2.4 - Calcula
    <RuleNum>134</RuleNum>
    <Active>0</Active>
    <UseParentValueList>1</UseParent
    <Location>Message Queued Inte
    <Position>Before</Position>
    <WarrantsAuditEvent>1</Warrants
    <ParentValueListKey>Incoming res
  </Rule>
- <Rule>
  - <If>
      <![CDATA[ ( ( {Value List:Le
      Field 04} > {Value List:Len
    </If>
    <Then>{Set} {Specimen User Fi
    <Parent>Incoming result-Messag
    <RuleSet>Test / In Validation</RuleSet>
    <MsgType>Incoming result</MsgType>
    <Desc>Rule IRBM24.2.5 - Calculation - BUN:CRT, Get first result</Desc>
    <RuleNum>135</RuleNum>
```

]]>



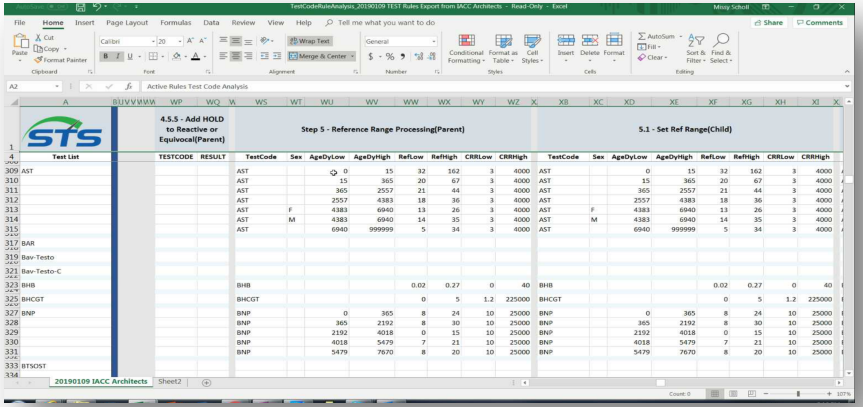
Test List	TESTCODE	RESULT	TestCode	Sex	AgeDyLow	AgeDyHigh	RefLow	RefHigh	CRRLow	CRRHigh	TestCode	Sex	AgeDyLow	AgeDyHigh	RefLow	RefHigh	CRRLow	CRRHigh
AST			AST		0	15	32	162	3	4000	AST		0	15	32	162	3	4000
			AST		15	365	20	67	3	4000	AST		15	365	20	67	3	4000
			AST		365	2557	21	44	3	4000	AST		365	2557	21	44	3	4000
			AST		2557	4383	18	36	3	4000	AST		2557	4383	18	36	3	4000
			AST	F	4383	6940	13	26	3	4000	AST	F	4383	6940	13	26	3	4000
			AST	M	4383	6940	14	35	3	4000	AST	M	4383	6940	14	35	3	4000
			AST		6940	999999	5	34	3	4000	AST		6940	999999	5	34	3	4000
BAR																		
Bav-Testo																		
Bav-Testo-C																		
BHB			BHB				0.02	0.27	0	40	BHB				0.02	0.27	0	40
BHCGT			BHCGT				0	5	1.2	225000	BHCGT				0	5	1.2	225000
BNP			BNP		0	365	8	24	10	25000	BNP		0	365	8	24	10	25000
			BNP		365	2192	8	30	10	25000	BNP		365	2192	8	30	10	25000
			BNP		2192	4018	0	15	10	25000	BNP		2192	4018	0	15	10	25000
			BNP		4018	5479	7	21	10	25000	BNP		4018	5479	7	21	10	25000
			BNP		5479	7670	8	20	10	25000	BNP		5479	7670	8	20	10	25000
BTSOST																		

Every Rule Tells a Story

- Auto-verification rules operate as group of rules
- Rules have dependencies on each other
- Parent-child relationships must be understood
- Rules impact one or more tests

Visualization of your rules story helps you better maintain the integrity of your rule base

Visualize rules across tests



Rules Analysis Tool

- Identifies rule syntax errors
- Locates broken links between parent/child rules
- Identifies reference ranges
- Helps us ask: ‘Do we still need this rule?’

“We have significantly improved our rules alignment between Lab IT and Lab clinical team”

“We now have a platform to engage our medical director in discussions about rules”

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Rules Analysis Tool: A better view

- Our findings with the STS rules analysis tool
  - Rule inconsistencies
  - Rules not firing as we thought
  - Rules canceling each other out
  - Reference ranges not applied as we had expected
- We now understand our rules as a complete ‘rule base’
  - ‘Human-readable rules analysis tool improves understanding by all groups: lab IT, clinical lab team, medical director
  - Helps us verify each rule operation to optimize our rule set
- Moves rule analysis to an intelligent based solution

Automated Rule testing

Process Overview

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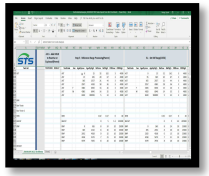

Rule Analysis Tool

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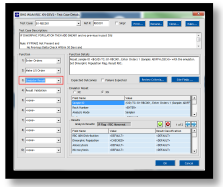

Test Case Creation

04

STS executed the test cases

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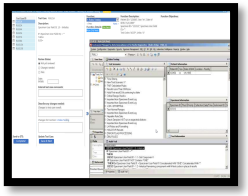
We reviewed & approved rules testing results on-line



06

STS created final report with screen prints

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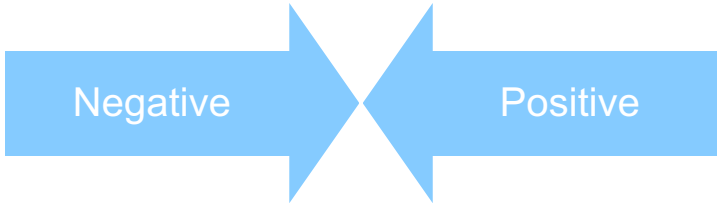
Testing process

- The automation created test cases for each rule & variable(s)
  - Created positive and negative test scenarios
  - Established pass/fail criteria
  - Test cases are re-usable
- Rule types tested
  - All auto-verification criteria
  - Calculations
  - Critical rules
  - Delta checks/previous results
  - Instrument flag & error codes
  - Range Rules
  - Comments



Example:
If positive value is 25.0, then test at: 24.9, 25.0 and 25.01

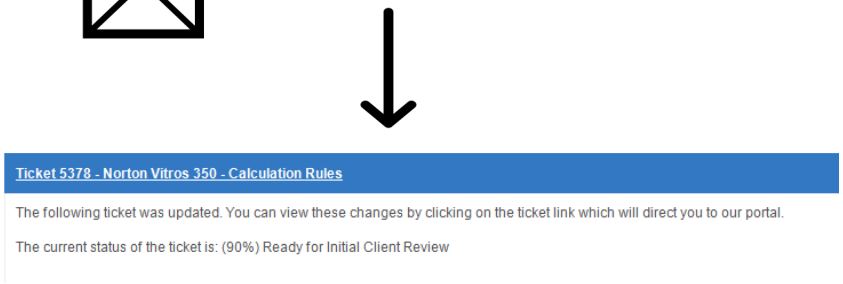
Review and approval

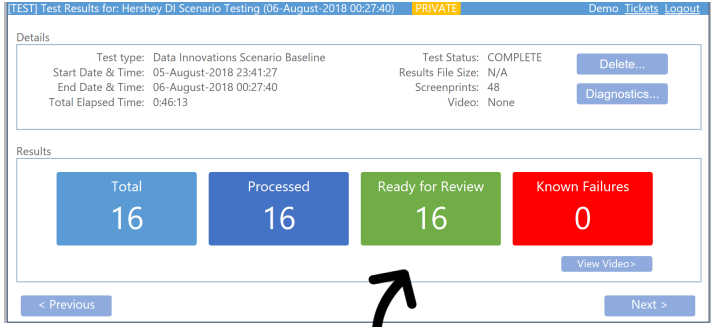
On-line approval of rules testing results

- Web based STS portal was used to approve testing results
- Flexible for us to use from any computer
- Our approvers are set-up ahead of time in the portal by STS
- As sections of testing are completed
  - Our approvers were emailed a link to the portal
  - Completely paperless

Opening a link to the Online Portal

Email is pushed to the Approver with link to Approval Portal





Click on green button takes you to the testing ready for approval

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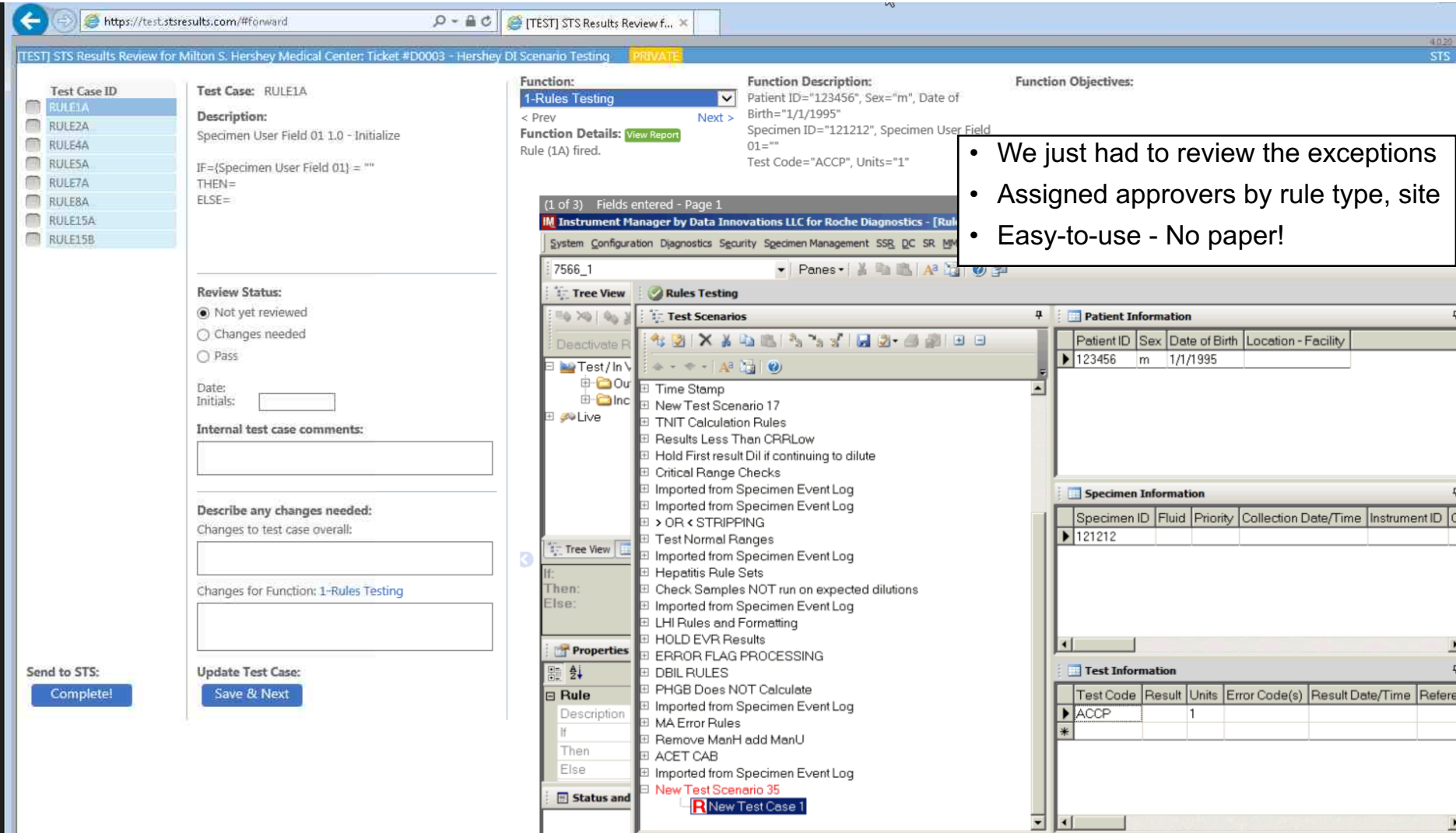
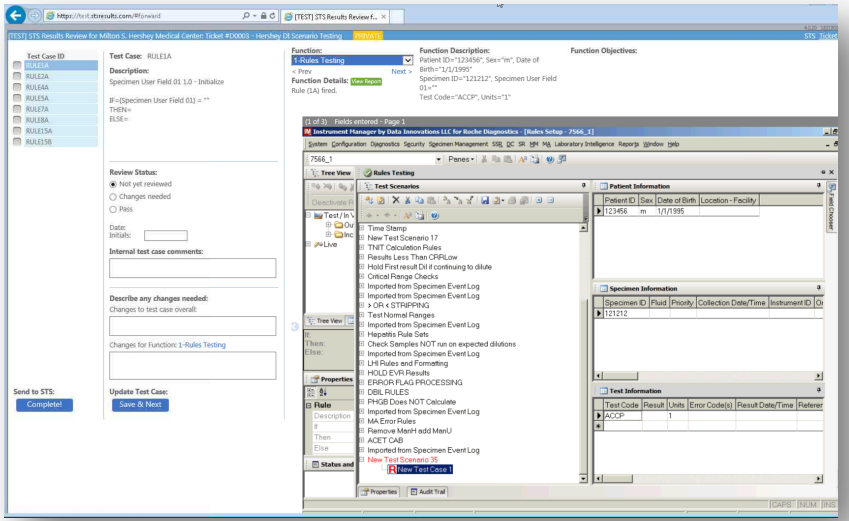

https://test.stsresults.com/#forward
[TEST] STS Results Review f...
[TEST] STS Results Review for Milton S. Hershey Medical Center: Ticket #D0003 - Hershey DI Scenario Testing
PRIVATE
STS
Test Case ID
RULE1A
RULE2A
RULE4A
RULE5A
RULE7A
RULE8A
RULE15A
RULE15B
Test Case: RULE1A
Description:
Specimen User Field 01 1.0 - Initialize
IF={Specimen User Field 01} = ""
THEN=
ELSE=
Review Status:
Not yet reviewed
Changes needed
Pass
Date:
Initials:
Internal test case comments:
Describe any changes needed:
Changes to test case overall:
Changes for Function: 1-Rules Testing
Send to STS:
Complete!
Update Test Case:
Save & Next
Function:
1-Rules Testing
< Prev
Next >
Function Details: View Report
Rule (1A) fired.
Function Description:
Patient ID="123456", Sex="m", Date of Birth="1/1/1995"
Specimen ID="121212", Specimen User Field 01=""
Test Code="ACCP", Units="1"
Function Objectives:
(1 of 3) Fields entered - Page 1
Instrument Manager by Data Innovations LLC for Roche Diagnostics - [Rul
System Configuration Diagnostics Security Specimen Management SSR DC SR
7566_1
Panes
Tree View
Rules Testing
Test Scenarios
Deactivate R
Test / In
Live
Time Stamp
New Test Scenario 17
TNIT Calculation Rules
Results Less Than CRRLow
Hold First result Dil if continuing to dilute
Critical Range Checks
Imported from Specimen Event Log
Imported from Specimen Event Log
> OR < STRIPPING
Test Normal Ranges
Imported from Specimen Event Log
Hepatitis Rule Sets
Check Samples NOT run on expected dilutions
Imported from Specimen Event Log
LHI Rules and Formatting
HOLD EVR Results
ERROR FLAG PROCESSING
DBIL RULES
PHGB Does NOT Calculate
Imported from Specimen Event Log
MA Error Rules
Remove ManH add ManU
ACET CAB
Imported from Specimen Event Log
New Test Scenario 35
New Test Case 1
If:
Then:
Else:
Properties
Rule
Description
If
Then
Else
Status and
Patient Information
Patient ID | Sex | Date of Birth | Location - Facility
123456 | m | 1/1/1995
Specimen Information
Specimen ID | Fluid | Priority | Collection Date/Time | Instrument ID
121212
Test Information
Test Code | Result | Units | Error Code(s) | Result Date/Time
ACCP | | 1
• We just had to review the exceptions
• Assigned approvers by rule type, site
• Easy-to-use - No paper!

Custom views for different approvers

- LIS analyst handled technical review
  - Example: suppress results not needed in the LIS
- Lab technologist completed clinical review
  - Example: calculating the LDL



Rules testing outcomes & documentation

Rule verification testing outcomes

Ortho Vitros 5600

STS tested 74 rules - 7,992 test cases run

34 errors discovered

- Missing age range rules
- Overlapping rule changes results of another test
- Value list conflict with several rules

Top ACL

STS tested 39 rules - 2,148 test cases run

73 errors discovered

- AV fail comment inactivating 37 rules
- Primary rule adjusting 0 value to a < result
  -- 37 rules will not fire

STS provided inspection-ready reports

Data Innovations Scenario Baseline Test: 01/16/19 B06:02:09 (Pass/Expected)
Test Profile: DI Cedars QC.2 Single

Cedars-Sinai Medical Center
8700 Beverly Boulevard
Room 2718
Los Angeles, CA 90048

Test Case	Function	Details
CS-5-QC.2 BioRad QC-1	1-Rules Testing	[SUCCESS] Rule fired - QC.2 BioRad QC Flags Hold Single Test

Function Description:
Date of Birth = @DOB
Patient ID = @PATIENT_ID
Sex = @SEX
Collection Date/Time = @COLLECTION
Specimen ID = @SPECIMEN_ID
Result = @RESULT
Test Code = @TEST_CODE
Units = @UNITS
QC Rule Violated = 1-3S

Function Objectives:
_ {Start Holding That Test with That Instrument ID for Verification} {AND}
_ {Add} {Error Code(s)} QC {On That Test}

Function-Specific Information:
Patient ID: Sex: @SEX Date of Birth: @DOB Location - Facility: <ENTER> Specimen ID: @SPECIMEN_ID
Fluid: <ENTER> Priority: <ENTER> Collection Date/Time: @COLLECTION Instrument ID: <ENTER>
Ordering Physician: <ENTER> Specimen Type: <ENTER> Test Code: @TEST_CODE Result: @RESULT Units: @UNITS
Error Code(s): <ENTER> Result Date/Time: <ENTER> Reference Range: <ENTER> Previous Result: <ENTER>
Previous Result Date/Time: <ENTER> Test Instrument ID: <ENTER>

- Rules described in readable terms
- Defined criteria for rule to fire

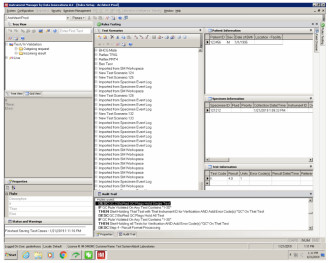
- Screen print of DI audit trail
- Pass indication

Test Profile: DI Cedars QC.2 Single

Cedars-Sinai Medical Center
8700 Beverly Boulevard
Room 2718
Los Angeles, CA 90048

Test Case	Function	Details
CS-5-QC.2 BioRad QC-1	1-Rules Testing	[SUCCESS] Rule fired - QC.2 BioRad QC Flags Hold Single Test

Caption: [SUCCESS] Rule fired - QC.2 BioRad QC Flags Hold Single Test



Testing Performed by Software Testing Solutions, LLC (STS)

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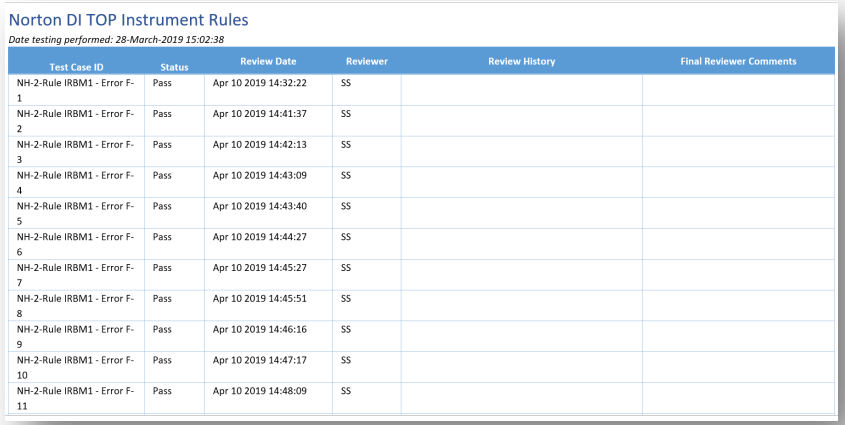
Rule testing summary report

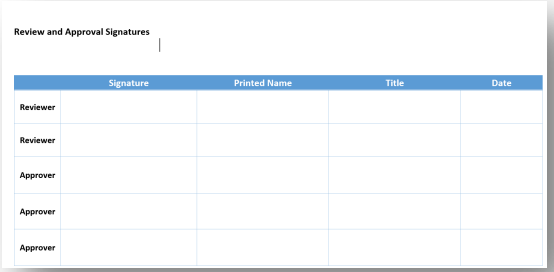
- Audit trail of our approvers
- Revision history by rules
- Summary report and sign off page
- Signature block for senior leadership sign-off



Norton DI TOP Instrument Rules

Date testing performed: 28-March-2019 15:02:38

Test Case ID	Status	Review Date	Reviewer	Review History	Final Reviewer Comments
NH-2-Rule IRBM1 - Error F-1	Pass	Apr 10 2019 14:32:22	SS		
NH-2-Rule IRBM1 - Error F-2	Pass	Apr 10 2019 14:41:37	SS		
NH-2-Rule IRBM1 - Error F-3	Pass	Apr 10 2019 14:42:13	SS		
NH-2-Rule IRBM1 - Error F-4	Pass	Apr 10 2019 14:43:09	SS		
NH-2-Rule IRBM1 - Error F-5	Pass	Apr 10 2019 14:43:40	SS		
NH-2-Rule IRBM1 - Error F-6	Pass	Apr 10 2019 14:44:27	SS		
NH-2-Rule IRBM1 - Error F-7	Pass	Apr 10 2019 14:45:27	SS		
NH-2-Rule IRBM1 - Error F-8	Pass	Apr 10 2019 14:45:51	SS		
NH-2-Rule IRBM1 - Error F-9	Pass	Apr 10 2019 14:46:16	SS		
NH-2-Rule IRBM1 - Error F-10	Pass	Apr 10 2019 14:47:17	SS		
NH-2-Rule IRBM1 - Error F-11	Pass	Apr 10 2019 14:48:09	SS		



Review and Approval Signatures

	Signature	Printed Name	Title	Date
Reviewer				
Reviewer				
Approver				
Approver				
Approver				

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Rules comparison for next testing

Quality program over time

- Testing Events
  - Changes to rules
  - New rules
  - New instrument installations with rules
  - Routine CAP inspection testing

“We needed a way to quickly re-test our rules and easily add rules without ‘going backwards’.”

“We needed a way to continually maintain and keep our rule base clean and well tested”

Next Testing Events

01

Import latest Rule Export (XML)

02

STS executes a Rules Compare

To identify changes in rules & inputs

03

STS runs Rules Analysis Tools

STS creates test cases based on latest inputs

04

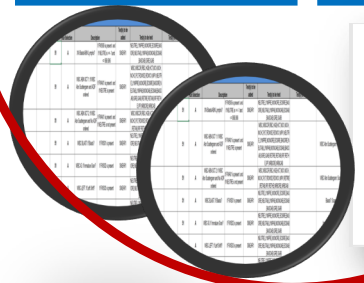
STS executes test cases for us

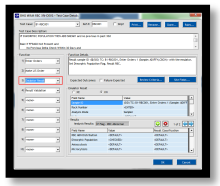
05

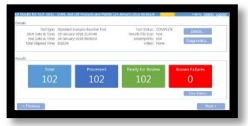
We review and approve rules testing results on-line

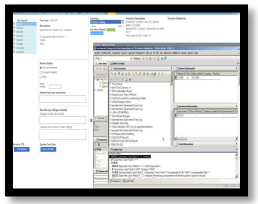
06

STS creates final report with screen shots









Rules comparison and traceability

- Compares two rule exports to identify differences
- Identifies rule column, row and cell differences
- Identifies new or changed test cases required
- Performed prior to each testing event

Rule Differences

Rule	Row	Kaiser NCAL Rules 022717_signoff.xlsx	MWS_WAM_Rules_Export_11_19_2018.xlsx
WBC009	F8|D8	Between Age 14 D and 12 Y only if WBC <= 0.99 Or >= 30.1	Between Age 14 D and 12 Y only if WBC <= 0.9 Or >= 30.1 and ZEXTRA Not Present
WBC009.1	F9|D9	Between Age 12 Y and 199 Y only if WBC <= 0.99 Or >= 999999	Between Age 12 Y and 199 Y only if WBC <= 0.9 Or >= 999999 and ZEXTRA Not Present
WBC009.1S	F10|D10	Between Age 12 Y and 199 Y only if WBC <= 0.99 Or >= 999999	Between Age 12 Y and 199 Y only if WBC <= 0.9 Or >= 999999 and ZEXTRA Not Present
WBC009S	F13|D13	Between Age 14 D and 12 Y only if WBC <= 0.99 Or >= 30.1	Between Age 14 D and 12 Y only if WBC <= 0.99 Or >= 30.1 and ZEXTRA Not Present
WBC018	F18|D18	if FSWBCL Not Present and No Previous Delta Check Within 7 Days and WBC >= 0 and <= 0.99	if FSWBCL Not Present and No Previous Delta Check Within 7 Days and WBC >= 0 and <= 0.9 and ZEXTRA Not Present
WBC019	F19|D19	if WBC <= 1 Or >= 99999.999 and ZEXTRA Not Present	if G6PD Not Present and WBC <= 1 Or >= 99999.999 and ZEXTRA Not Present
WBC019S	F20|D20	if WBC <= 1 Or >= 99999.999 and ZEXTRA Not Present	if G6PD Not Present and WBC <= 1 Or >= 99999.999 and ZEXTRA Not Present
WBC030	E33|C33	NRBC%: If NRBC % > 1	NRBC%: If NRBC % > 0.5
WBC030	F33|D33	if NRBCNE <= -1 Or >= 1.1	if NRBCNE <= -1 Or >= 0.6
CRINWBC009	F38|D38	Between Age 14 D and 12 Y only if WBC <= 0.99 Or >= 30.1	Between Age 14 D and 12 Y only if WBC <= 0.9 Or >= 30.1
CRINWBC009.1	F39|D39	Between Age 12 Y and 199 Y only if WBC <= 0.99 Or >= 999999	Between Age 12 Y and 199 Y only if WBC <= 0.9 Or >= 999999 and ZEXTRA Not Present
RBC009.1	F53|D53	if FRS05 = #Frs05	if FRS05 = #Frs05 and PLT is Present
RBC009.1S	F54|D54	if FRS05 = #Frs05	if FRS05 = #Frs05 and PLT is Present
RBC020	E61|C61	If HGB < 7 and age ≤ 12Y	If HGB < 7 and >20 and age 1mo to 12Y
RBC020	F61|D61	Between Age -1 D and 12 Y only if HGB <= 6.9 Or >= 999999	Between Age 31 D and 12 Y only if HGB <= 6.9 Or >= 20.1
RBC020.3	A66|A66	RBC020.3	RBC020.4
RBC020.3	E66|C66	If HGB >20.0 and Age 30 days to 12Y	If HGB <8.6 and age 0d - 30d
RBC020.3	F66|D66	Between Age 30 D and 12 Y only if HGB <= -1 Or >= 20.1	Between Age 0.0 and 30 D only if HGB <= 8.5 Or >= 99999
RBC020.3S	A67|A67	RBC020.3S	RBC020.4S
RBC020.3S	E67|C67	If HGB >20.0 and Age 30 days to 12Y	If HGB <8.6 and age 0d - 30d
RBC020.3S	F67|D67	Between Age 30 D and 12 Y only if HGB <= -1 Or >= 20.1	Between Age 0.0 and 30 D only if HGB <= 8.5 Or >= 99999
RBC0205	E68|C68	If HGB < 7 and age ≤ 12Y	If HGB < 7 >20.0 and age 1mo to 12Y
RBC0205	F68|D68	Between Age -1 D and 12 Y only if HGB <= 6.9 Or >= 999999	Between Age 31 D and 12 Y only if HGB <= 6.9 Or >= 20.1
RBC024	E71|C71	HCT CRIT 1: If HCT < 21 or > 60 and 30D-12Y	HCT CRIT 1: If HCT < 21.1 or > 59.9 and 31D-12Y
RBC024	F71|D71	Between Age 30 D and 12 Y only if HCT <= 20.9 Or >= 60.1	Between Age 31 D and 12 Y only if HCT <= 21 Or >= 60

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Summary

Results to date

- Advantages
  - Time savings within the Lab and LIS
  - Ability to run all rules in timeframe we normally would only spot check
  - Easy to read and review results of rules testing
  - CAP ready report for pathologist to sign
  - Repeatable process
  - Auto-approve button
- Challenges
  - Slow start up / learning curve for clinical team
- Suggestions
  - Allow time to familiarize clinical team with STS analysis tool and online portal

Next steps

- Phased approach to next STS rules testing
  - Chemistry
  - Coagulation
  - Immunology
  - Microbiology (Molecular)
  - Hematology
- All areas will be completed in 2019
- Repeat testing process annually

Continuous rules quality and reliability

Confidence

Alignment

Reliability

Re-usability