



Auto-Validation Don't "Rule" It Out!

Name
Title
Sysmex America, Inc.

Date

Agenda

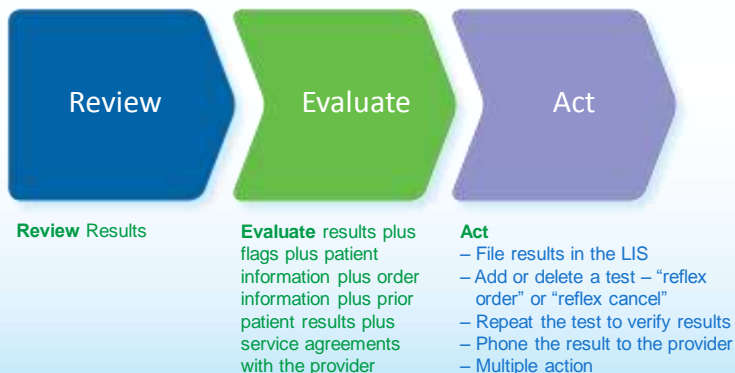


- Barriers to auto-validation
- Rules for success
- Middleware solutions
- Vendor fit
- Success stories

What is Results Validation?



The thought process of techs when they manually validate lab results at the LIS based on SOPs, quality indicators, experience, tribal knowledge.

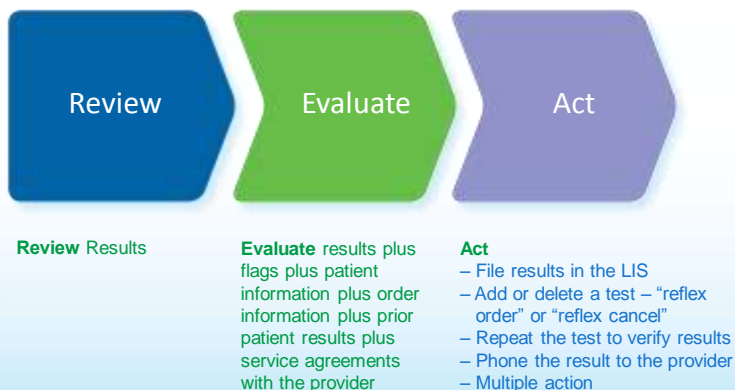


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What is Auto-Validation?



Software that mimics the thought process of techs when they manually verify lab results.



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Barriers

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AACC Auto-validation Survey



- About half of respondents report they are not broadly auto-validating across routine lab sections
- Of those, roughly half selected the response, "Haven't had time to figure it out"



** Leveraging autoverification for greater lab efficiency. Autoverification practices survey (audio conference). AACC, April 22, 2009. Cited in CAP Today, January 2012.*

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Pressures Inside the Lab



Reduce Manual Tasks



How to Focus My Key Staff



Paper Processing



Staff Utilization

QUALITY

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Forces Outside the Lab



Multiple Testing Sites



Test Volume



IT Systems



Physician Preference & Customer Service

QUALITY

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Obstacles



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Rules for Success

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Rule Number One



- Communicate
- Communicate
- Communicate
- Communicate
- Communicate
- Communicate
- Communicate
- Communicate
- Communicate
- Communicate

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Implementing Auto-validation



- Plan
- Identify stakeholders and form team
- Map workflow and plan rules
- Develop validation plan



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Implementing Auto-validation



- Execute test plan and refine rules
- Update SOPs
- Develop go-live checklist
- Train operators
- Go-live



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Hematology Rules

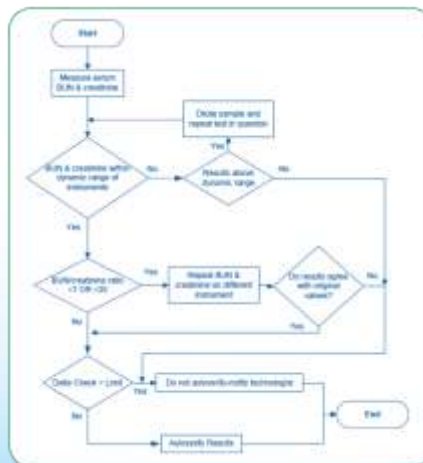


• ISLH Consensus Rules

- www.islh.org

- If Neonate AND First Sample THEN Slide Review

Flowchart Format Example



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We're LIVE! Now What?



Continuous process improvement

- Monitor rules performance
- Change management
 - Rules changes
 - Software updates
 - Training programs
- Vendor support
 - Hotline – 24/7
 - Competent clinical support personnel
 - Remote support
 - Ongoing education resources



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Review the Obstacles



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Overcoming the Obstacles



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Middleware Solutions

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What is Middleware?



Pre-analytical

- Links separate software applications



Analytical

- Used across the healthcare enterprise



Post-analytical

- Applications for all phases of lab

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Lab Middleware for Instruments



Pre-analytical



Analytical



Post-analytical

- Software between the instruments/devices and the LIS
- Typically found in highly automated lab areas
- Some IVD vendors develop and support their own middleware
- Some LIS vendors routinely offload interfacing to middleware vendors

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Why Middleware?



LIS vendors have shifted focus...

- Outreach products/web portal
- EMR
- Other diagnostic testing – e.g. Molecular Diagnostics

...creating gaps in functionality

- Lack of complex rules capability
- Lack of graphical display
- No rules that act upon instrument flags
- Lack of data comparison across instrumentation
- Limited longitudinal patient data correlation



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Why Middleware?



• Benefits

- Optimizes instrument technology
- Supports laboratory quality and operational improvement efforts
- Enhances integration between systems

• Best fits

- Labs with business needs, regardless of size
- Labs automation systems
- Multi-site environments



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Business Drivers for Auto-validation and Middleware



The average age of a Medical Technologist is 50+ years

- Labor shortages
- Laboratory efficiency

Lab TAT and TAT outlier percentage have been shown to impact ED LOS

- Patient safety and quality standards

The average age of the LIS is 15 years

- Laboratory adaptability
- Enhance LIS functionality

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Intelligent Rules Engine



• Characteristics

- Complex combinations
- Variables to create rules
- Rules for sub-sites

• Outcomes

- Higher % of results auto-verify than with LIS alone
- Reduces operator intervention
- Reduces risk for errors
- Improves standardization and control across shifts and labs



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Intelligent Rules Engine



- Rules on the patient level
 - Location, Age, Sex, Diagnosis
- Rules on the order level
 - Physician, Priority
- Rules on the result level
 - Present, outside/inside range, coded comment, flag
 - % or absolute deltas failures
 - Absence/presence of another parameter
- Rule actions
 - Hold for review, perform rerun analysis, create comments, display operator alerts, reflex tests



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Examples of Rules



Test	Rule	Action
RBC	If dimorphic population?	Reflex Smear and Hold ADIF
RBC	If RBC < 3.0 and LOC = PEDs and age < 2 years	Re-run
HGB	If HGB > 16.0 and Requestor = Smith and no previous result	Reflex Smear and HOLD all tests
PLT	If PLT ABN distribution and retic ordered and PLT < 80	Hold CBC and ADIF

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Sysmex WAM Management Reports



- **Count Statistics Report**

Use to measure your auto-validation & manual review rates

- **Turnaround Time Report**

Identifies processing gaps and outliers by % or in minutes

- **Rule Statistics Report**

Determine how many times each rule has triggered

- **Results Statistics Report**

Data mining for management reporting and correlating clinical findings



Over 1,000 reports possible* – No special skills – No IT support required

* Available with WAM v4.1, 4.1.1. and 5.0

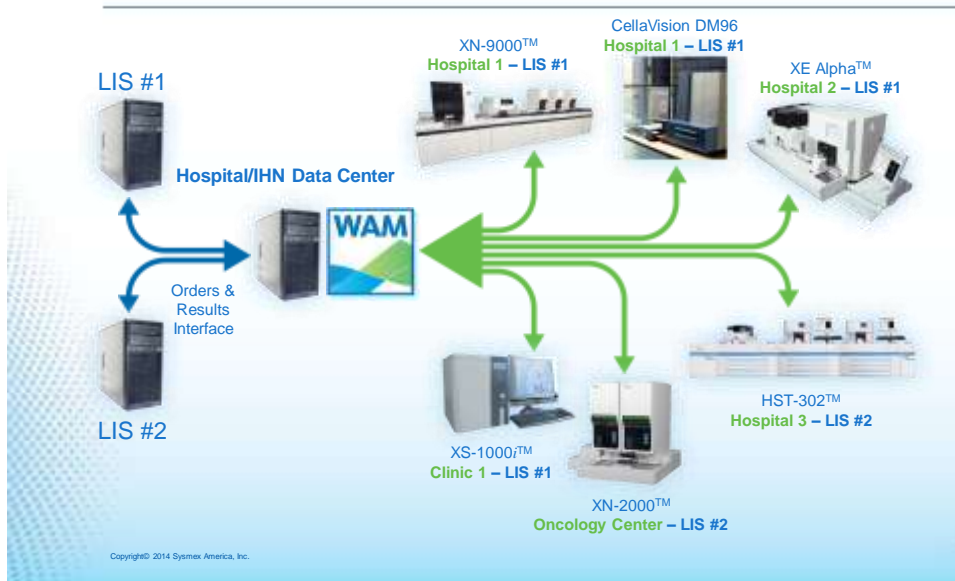
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Total Integrated Solution



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Multi-site and Multi-LIS



Experience Counts



9 of the top 10
America's Best Hospitals* use WAM



*as reported by U.S. News & World Report 2013-2014 Honor Roll

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Vendor Fit



- Product
- People
- Services



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Success Stories

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Real Life Auto-validation Stories

Middleware specific to instruments & department



- Multi-site system, 2,000 beds with large outreach/reference

- Goals

- Eliminate sample handling steps
- Decrease ED TAT
- Add capacity in order to increase outreach business

- Outcomes

- Specialized hematology rules provided by Sysmex WAM reduced slide review rates by 29%
- Reallocated 2.5 FTE while increasing throughput
- Stat CBC orders decreased by 1.3
- “Noise level” decreased – fewer phone calls requesting pending results

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Real Life Auto-validation Stories

Middleware specific to instruments & department



- 4 hospitals with 3 lab testing sites

- Level II trauma center
- ~900 beds, children’s hospital
- 11 outpatient testing sites

- 3 support Oncology
- 4 support an Urgent Care

- Standardized across the system
- One Sysmex WAM database

- Stat CBC TAT: 80% are < 10 min, 96% < 20 min.
- CBC auto-validation rate = 82%

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Would You Auto-validate This?



				Male	Female
WBC	7.55	[10 ³ /uL]		4.8 - 10.5	4.8 - 10.5
RBC	3.13	[10 ⁶ /uL]		4.00 - 5.50	3.70 - 4.90
HGB	10.1	[g/dL]		12.7 - 16.7	11.5 - 14.5
HCT	29.7	[%]		36.0 - 50.0	33.7 - 42.7
MCV	94.9	[fL]		80.0 - 100.0	80.0 - 100.0
MCH	32.3	[pg]		27.0 - 33.0	27.0 - 33.0
MCHC	34.0	[g/dL]		32.0 - 36.0	32.0 - 36.0
PLT	213	[10 ³ /uL]		140 - 440	140 - 440
RDW-SD	71.1	[fL]		39.3 - 49.7	39.3 - 49.7
RDW-CV	20.6	[%]		11.0 - 17.0	11.0 - 17.0
MPV	9.1	[fL]		6.5 - 11.5	6.5 - 11.5
NEUT	3.50	[10 ³ /uL]	46.3 [%]	1.5 - 6.7	[10 ³ /uL]
LYMPH	3.36	[10 ³ /uL]	44.5 [%]	1.0 - 4.0	[10 ³ /uL]
MONO	0.55	[10 ³ /uL]	7.3 [%]	0.2 - 0.9	[10 ³ /uL]
EO	0.10	[10 ³ /uL]	1.3 [%]	0 - 0.5	[10 ³ /uL]
BASO	0.02	[10 ³ /uL]	0.3 [%]	0 - 0.2	[10 ³ /uL]
IG	0.07	[10 ³ /uL]	0.3 [%]	0 - 0.08	[10 ³ /uL]
NRE					

- 88 year old male
- Normal results, no Delta failures

- Rules allowed auto-validation

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Would You Auto-validate This?



				Male	Female
WBC	5.43	[10 ³ /uL]		4.8 - 10.5	4.8 - 10.5
RBC	4.35	[10 ⁶ /uL]		4.00 - 5.50	3.70 - 4.90
HGB	10.6	[g/dL]		12.7 - 16.7	11.5 - 14.5
HCT	33.3	[%]		36.0 - 50.0	33.7 - 42.7
MCV	76.6	[fL]		80.0 - 100.0	80.0 - 100.0
MCH	24.4	[pg]		27.0 - 33.0	27.0 - 33.0
MCHC	31.8	[g/dL]		32.0 - 36.0	32.0 - 36.0
PLT	303	[10 ³ /uL]		140 - 440	140 - 440
RDW-SD	52.9	[fL]		39.3 - 49.7	39.3 - 49.7
RDW-CV	18.8	[%]		11.0 - 17.0	11.0 - 17.0
MPV	10.0	[fL]		6.5 - 11.5	6.5 - 11.5
NEUT	3.47	[10 ³ /uL]	64.0 [%]	1.5 - 6.7	[10 ³ /uL]
LYMPH	1.49	[10 ³ /uL]	27.4 [%]	1.0 - 4.0	[10 ³ /uL]
MONO	0.26	[10 ³ /uL]	4.8 [%]	0.2 - 0.9	[10 ³ /uL]
EO	0.18	[10 ³ /uL]	2.9 [%]	0 - 0.5	[10 ³ /uL]
BASO	0.04	[10 ³ /uL]	0.7 [%]	0 - 0.2	[10 ³ /uL]
IG	0.01	[10 ³ /uL]	0.2 [%]	0 - 0.08	[10 ³ /uL]
NRE					

- 43 year old female
- Low MCV

- If MCV Delta < +/- 5 within 120 days, hold for review
- Recent previous result within 5 so results auto-validated

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Would You Auto-validate This?



				Male	Female
WBC	6.52	$10^3/\mu\text{L}$		4.8 - 10.5	4.8 - 10.5
RBC	4.39	$10^6/\mu\text{L}$		4.00 - 5.50	3.70 - 4.90
HGB	4.1	g/dL		12.7 - 16.7	11.5 - 14.5
HCT	12.5	%		36.0 - 50.0	33.7 - 42.7
MCV	86.9	fL		80.0 - 100.0	80.0 - 100.0
MCH	31.8	pg		27.0 - 33.0	27.0 - 33.0
MCHC	32.8	g/dL		32.0 - 36.0	32.0 - 36.0
PLT	81	$10^3/\mu\text{L}$		140 - 440	140 - 440
RDW-SO	83.1	fL		39.3 - 49.7	38.3 - 49.7
RDW-CV	26.1	%		11.0 - 17.0	11.0 - 17.0
MPV	12.5	fL		6.5 - 11.5	6.5 - 11.5
NEUT	4.09	$10^3/\mu\text{L}$	62.7	1.5 - 6.7	$10^3/\mu\text{L}$
LYMPH	1.49	$10^3/\mu\text{L}$	22.9	1.0 - 4.0	$10^3/\mu\text{L}$
MONO	0.88	$10^3/\mu\text{L}$	13.5	0.2 - 0.9	$10^3/\mu\text{L}$
EO	0.00	$10^3/\mu\text{L}$	0.0	0 - 0.5	$10^3/\mu\text{L}$
BASO	0.04	$10^3/\mu\text{L}$	0.6	0 - 0.2	$10^3/\mu\text{L}$
IG	0.07	$10^3/\mu\text{L}$	0.7	0 - 0.6	$10^3/\mu\text{L}$
NFR			10		

- 78 year old male
- Critical HGB value

- If HGB < 8.0 rerun to confirm
- Rerun confirmed the result, 2nd result auto-validated

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Still Doing Manual Platelets?



- March of 2010: 2,334 Phase Platelet counts
- March of 2013: 3 Phase Platelet counts
 - Decrease of 2,331 Phase Platelet counts
 - Instead reported 1,710 Optical Platelet counts



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Rules Do It Seamlessly



RULE DEFINITION

ORDER LEVEL SELECTION CRITERIA

Rule: PLT DIST
 Priority in the Rule: 8570
 Description: PLT Abn Dist W/ PLT Abn Distribution ABO
 Author: From: 8/22/2014 To: 8/22/2014
 Active: Inactive:

TEST LEVEL SELECTION CRITERIA

Test	Operator	Unit	Value	Comparison	Operator	Unit	Value	Comparison	Operator	Unit	Value	Comparison
PLT			99	>								
RETIC												

ACTIONS OF THE RULE

When: PLT
 Action: Reflex
 Reflex: PLT
 Create Comment: Yes No

HEMATOLOGY WAM

If PLT Abn Dist flag is present AND PLT < 99 AND Retic% is not present, then reflex Optical Platelet

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Summary



- It's not easy to start...
- But the payoff is huge
 - With the right rules in place, auto-validation reduces tech workload and optimizes turn around time
- Successful implementation requires
 - Change management
 - Proper expectations
 - Allocated resources
 - The right tools



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Thank You!