SYSMEX WAM Tidbits

Sysmex WAM™ Support of Regulatory Compliance for WAM v4.1/v4.1.1 and v5.x

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1 Overview

All Laboratories must meet certain standards of operation to be certified to perform testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) which is under the auspice of CMS (Medicare). Laboratories must register and meet standards of quality for accuracy, reliability and timeliness of test results regardless of where the test was performed. The College of American Pathologists (CAP) performs accreditation of laboratories under deemed authority by CMS Medicare. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) operates accreditation programs for hospitals. A majority of state governments have come to recognize Joint Commission accreditation as a condition of licensure and the receipt of Medicaid reimbursement. All laboratories within these hospitals must also meet JCAHO requirements for accreditation.

The Centers for Medicare and Medicaid Services (CMS) has granted the CAP Laboratory Accreditation Program deeming authority. It is also recognized by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), and can be used to meet many state certification requirements.

All laboratories therefore must meet standard requirements for operation set forth by CAP inspection checklists. These checklist items include standards for which the laboratory must prove compliance. *Software such as Sysmex WAM provides tools by which the laboratory can meet these requirements.* This document describes how Sysmex WAM can help the laboratory meet these CAP standards and requirements.

(*) Laboratory Inspection Organizations:

- CAP – College of American Pathologist – www.CAP.org
- CAP Checklists:
  - COMO (Common)04212016
  - GEN (General) 04212016
  - HEM (Hematology) 0421016
- JCAHO – Joint Commission on Accreditation of Healthcare Organizations - www.jointcommission.org
- CLIA – Clinical Laboratory Improvement Amendments - www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance

This document provides an overview section of each applicable CAP requirement that Sysmex can assist the laboratory using the Sysmex WAM application. The Common, General and Hematology checklists are provided by requirement with an overview and detailed section.

1.1 Disclaimers

SYSMEX PROVIDING THIS INFORMATION DOES NOT MEAN THAT SYSMEX IS RESPONSIBLE FOR PROVIDING DOCUMENTATION FOR CUSTOMER REGULATORY INSPECTIONS. THE CUSTOMER MUST CREATE POLICIES AND PROCEDURES TO SUPPORT ANY INSPECTION REQUIREMENTS. THE CUSTOMER ASSUMES ALL RISK AND RESPONSIBILITY FOR ITS USE OF THE SYSMEX SOFTWARE. CUSTOMER SHALL USE SUCH SOFTWARE ONLY IN ACCORDANCE WITH INSTRUCTIONS CONTAINED IN SYSMEX WAM USER AND OTHER PUBLISHED MATERIALS AND LABELING, WHICH MAY BE AMENDED FROM TIME TO TIME.

2 Laboratory General CAP Checklist: CAP Requirement Matrix

The following is an overview of the CAP requirements in summary view.

Reference document: Laboratory General Checklist: 2016 CAP Documents - 08.17.2016

2.1 General Matrix Overview

Table 1: General Laboratory Checklist

Category/Item #	Title	WAM Support of Compliance
GEN.41096	Report Elements	• Reporting elements to the LIS • Sample ID Report
GEN.41300	Report Retention and Retrieval	• On-line availability of all results, flags, rules triggered and graphic images from Sysmex instrumentation for 2 years
GEN.41304	Patient Data Accessibility	• Required login and password • Expiration of password • Cannot re-use password
GEN.41306	Analyst Tracking	• User ID for manual intervention in WAM and to the LIS • System ID for auto-validated results in WAM and to the LIS

Category/Item #	Title	WAM Support of Compliance
GEN.41307	Report Errors	• Ability to modify results in WAM • Modification event in audit trail with previous and new result values in time sequence • V5 – modified result highlighted in lavender color • V5 – lavender indicator in demographic area to identify modified results

Category/Item #	Title	WAM Support of Compliance
GEN.41310	**Revised Report**	• Ability to modify results in WAM • Modification event in audit trail with previous and new result values in time sequence • V5 – modified result highlighted in lavender color
GEN.41312	**Multiple Revisions**	• Ability to modify results in WAM • Modification event in audit trail with previous and new result values in time sequence • V5 – modified result highlighted in lavender color
GEN.41345	**Turnaround Time**	WAM provides a TAT Management Statistic Report time report by test and/or profile to use to monitor laboratory TAT results.
GEN.41312	**LIS Testing**	• WAM provides an initial LIS test plan to validate the WAM to LIS order and result transmissions for system validation at WAM implementation. Sysmex provides all documentation to the customer for regulatory purposes. • WAM provides a customer test plans for any WAM software update for system validation and for documentation of testing activities.
GEN.43150	**Access Patient Data**	Sysmex WAM provides the following security features to support the user access to WAM with the v5.x version: • Roles based access by functionality and site • Re-use of password restrictions • Password expiration and change management features • Audit trail & report of successful/unsuccessful logins
GEN.43200	**Computer Access Codes**	Sysmex WAM provides the following security features to support the user access to WAM with the v5.x version: Previous versions of WAM provided compliance to 1 and 5. 1. Roles based access by functionality and site 2. Password complexity 3. Re-use of password restrictions 4. Password expiration and change management features 5. Audit trail and report of success and unsuccessful login

Category/Item #	Title	WAM Support of Compliance
GEN.43262	Unauthorized Software Installation	Sysmex provides the following notifications for any software updates for Sysmex WAM: • Product Notices • Customer Test Plans • The customer can ascertain their software level and last installation date from the following WAM screen: • Help About
GEN.43325	Public Network Security	Sysmex provides a secure connection line into Sysmex WAM via SNCS via port 443. **Document Name**: Sysmex® Health Information Security and SNCS™ Installation Instructions: 1101-TS Rev.2.
GEN.43450	Calculated Patient Data Verification	• Sysmex provides the following methods to verify calculations are working as expected: • Manual verification in the test area • Identification of Sample IDs with calculated results via the Management Report module using the Detail Statistics report
GEN.43750	Specimen Quality Comment	• Sysmex WAM provides the ability for the following methods to capture the specimen quality comment: • Specimen quality comment received into WAM from the LIS to be displayed in the Result Validation screen • Manual entry of the specimen comment in WAM Result Validation screen in the LIS, Internal or test level comment fields
GEN.43800	Data Input ID	• Sysmex WAM provides the following event tracking by sample ID by user and/or WAM auto-validation activities: • Order audit trail • Test level audit trail
GEN.43825	Result Verification	Sysmex WAM provides a Result Validation screen with all consolidated information on the screen for result review. The user must manually approve the results before they are transmitted to the LIS.
GEN.43837	Down Time Result Reporting	Refer to the Sysmex WAM downtime procedure.

Category Item #	Title	WAM Support of Compliance
GEN.43875	Autoverification Validation	Sysmex offers the following options: 1) Implementation – automated rule testing using the STS testing tool. 2) Post Implementation: o Manual testing using the Emulator (dry testing) and instrumentation (wet testing) o For WAM v5.x Rule Tester via the Rules sub menu o Purchase Automated rule testing program from STS
GEN.43878	Autoverification QC Samples	Sysmex offers the following options: • **Auto-validation Control feature** to turn off all rules for all workplaces (instruments) or one or more workplaces by site and by test or profile in the event the laboratory determines that all sample IDs must be reviewed before release.
GEN.43881	Autoverification Results	Sysmex WAM provides the following rule capability to meet this requirement: • High/Low Range rules with defined limits <x and or >x) with operator alerts to identify any abnormal and/or absurd result. • Critical rules with defined limits = <x and or >x) with operator alerts and color-coding (Red=critical high and Blue=critical low) to notify the user immediately of the criticality of the test result. • Delta Rules with absolute or percentage change with the last validated result – with operator alerts and color-coding (Delta = green) to notify the user immediately of a delta check failure.
GEN.43887	Autoverification Audit Trail	Sysmex WAM provides a comprehensive audit trail by Sample ID for all test and result transactions including interface tracking to/from the LIS. The audit trail in the computer system identifies all test results that were auto-validated and date/time of autoverification.

Category/Item #	Title	WAM Support of Compliance
GEN.43890	Autoverification Delta Checks	Sysmex WAM provides the following rule capability to meet this requirement: • Delta Rules with absolute or percentage change with the last validated result – with operator alerts • +/- delta values in either direction • Color-coding (Delta = green) to notify the user immediately of a delta check failure. • V4 – Delta values based on validated values only • V5 – Delta values based on validated and 'un-validated results.' • Delta values based on date/date range
GEN.43893	Autoverification Suspension	Sysmex WAM v4.x and 5.x provides Auto-validation functionality to meet this requirement via the Auto-validation Control feature. • Ability to manually suspend autoverification *on demand* by instrument group, instrument ID and/or test via the Auto-validation Control menu. All rules by test will be suspended and the users will be required to manually validate Sample ID results from the point of suspension. • Complete documentation of use of the Auto-validation Control feature by requiring a coded comment to document the suspension of the rules and re-enabling of the rules • Display of the auto-validation control history with search, sort and print capability
GEN.43900	Archived Test Result	WAM provides 2 years of on-line storage
GEN.43920	Multiple Analyzer ID	Sysmex WAM tracks the analyzer ID and stores this data in the audit trail for 2 years
GEN.43946	Data Preservation/ Destruction Event	Sysmex WAM provides the following control features: • Backup and restore from the customer's network • Optional switch server:
GEN.46000	Reference Ranges/Unit Transmission	• Sysmex WAM DOES not support reference ranges within the application. • Sysmex WAM does configure the test result units to match Sysmex supported analyzers and devices and transmits the result in the correct unit format to the LIS.

Category/Item #	Title	WAM Support of Compliance
GEN.48500	Interface Result Integrity	• **LIS Test Plans** – provided by Sysmex to validate the interface integrity with the full loop of testing • **Dry/Wet Test Plans** – provided by Sysmex to validate the rules and result transmission from WAM to the LIS
GEN.48750	LIS Interface Shutdown/Recovery	Sysmex provides a downtime document in the event that the LIS goes down so that Sample ID orders and results can still process if the LIS is not operational.

Table 2: Common Cap Checklist

: Common Checklist: 2016 CAP Documents - 08.17.2016

Category/Item #	Title	WAM Support of Compliance
COM.29950	Reference Intervals	• Sysmex WAM DOES not support reference ranges within the application. • Sysmex WAM does configure the test result units to match Sysmex supported analyzers and devices and transmits the result in the correct unit format to the LIS.
COM.30000	Critical Result Notification	• Sysmex WAM provides an optional critical result documentation feature. • The Critical Call Documentation screen displays the call information when you validate the sample ID results with critical results on the Result Validation screen. • Critical Documentation screen records the call back date/time, who called and a read-back indicator. • All relevant fields are recorded and transmitted to the LIS for display on the patient report. .
COM.30100	Critical Result Read-back	The Critical Documentation procedure provides a mandatory read-back indicator that the technologist must indicate by checking a box that the read-back has been completed.

Table 3: Hematology CAP Checklist

Hematology Checklist: 2016 CAP Documents - 08.17.2016

Category/Item #	Title	WAM Support of Compliance
HEM.23050	Reference Intervals	• Sysmex WAM DOES <u>not</u> support reference ranges within the application. • Sysmex WAM does configure the test result units to match Sysmex supported analyzers and devices and transmits the result in the correct unit format to the LIS.
HEM.3010	Detection/Correction Procedure - WBC	• **X-Series analyzers:** Sysmex WAM will provide a correction calculation to correct the WBC counts for the presence of nucleated red cells or megakaryocytes. Sysmex will provide a standard calculation as a rule for the correction calculation. • **XN-Series analyzers:** The Sysmex XN-Series analyzers provide a direct measurement of the nucleated red cells or megakaryocytes and therefore there is no need for a correction calculation***. Sysmex WAM is <u>not</u> designed and or configured with a correction calculation for XN-Series analyzers***
HEM.30150	Spurious Results	• Rules based on Flags – • Rules based on result or instrument errors – • High/Low Range rules with defined limits <x and or >x • Critical rules with defined limits = <x and or >x) • Delta Rules with absolute or percentage change with the last validated result
HEM.30200	Red Cell Indices	Sysmex WAM provides best practice standard rules for MCV that aid in the identification of random errors to identify random errors, instrument results or spurious results
HEM.30250	Reportable Ranges	Sysmex WAM provides the capability for the customer to select standard rules for high or low values appropriate for the analyte for Sysmex WAM. **<u>However, WAM does not support configuration of reportable reference ranges in WAM and/or to the LIS.</u>**

Category/Item #	Title	WAM Support of Compliance
HEM.30300 Platelet Abnormalities	Platelet Abnormalities	Sysmex provides standard rules to identify spurious platelet results that display in the Result Validation screen with an operator alert and instructions to the user for the appropriate handling procedures. Listed below are examples of our rule standard set.
HEM.30400	Platelet Count Verification	Sysmex provides standard rules to identify platelet results that display in the Result Validation screen with an operator alert and instructions to the user for the appropriate handling procedures. Listed below are examples of our rule standard set.
HEM.34200	WBC Differential Verification	Sysmex provides standard rules to identify WBC differential results that display in the Result Validation screen with an operator alert and instructions to the user for the appropriate handling procedures. Listed below are examples of our rule standard set.
HEM.34500	Morphology Assessment-PLT/RBC	Sysmex provides standard rules to identify morphology results that display in the Result Validation screen with an operator alert and instructions to the user for the appropriate handling procedures. Listed below are examples of our rule standard set
HEM.34600	Criteria for Blood Film Review	Sysmex provides standard rules to criteria for blood film reviews that display in the Result Validation screen with an operator alert and instructions to the user for the appropriate handling procedures. Listed below are examples of our rule standard set
HEM.35150	Spurious Results-Retics	Sysmex provides standard rules to criteria for spurious retic results that display in the Result Validation screen with an operator alert and instructions to the user for the appropriate handling procedures. Listed below are examples of our rule standard set
HEM.35471	Cell Clumps/Debris – Automated	Sysmex provides standard rules to criteria for cell clumps and debris results that display in the Result Validation screen with an operator alert and instructions to the user for the appropriate handling procedures. Listed below are examples of our rule standard set
HEM.35585 Slide Review – Body Fluids	Slide Review – Body Fluids	Sysmex WAM provides the ability define a PATH review test in WAM with the intent of either reflexing a PATH test to the LIS or providing the ability of the laboratory to record path results from the Pathology staff.

Category/Item #	Title	WAM Support of Compliance
HEM.35604 Microscopic Result Comparison – Body Fluids	Microscopic Result Comparison – Body Fluids	Sysmex WAM provides the ability to perform a fluid manual differential in the application. The laboratory can define rules that can alert the user when a specific cell type or pattern is identified. The laboratory can notify medical personnel via the optional use of the Critical Alert module.

3 Laboratory General CAP Checklist - Detail

3.1 GEN.41096 Reporting of Results

Requirement:

The paper or electronic report includes the following elements.
1. Name and address of testing laboratory (see note below)
2. Patient name and identification number, or unique patient identifier
3. Name of physician of record, or legally authorized person ordering test, as Appropriate
4. Date of specimen collection, and if appropriate, time of collection
5. Date of release of report (if not on the report, this information should be readily accessible)
6. Time of release of report, if applicable (if not on the report, this information should be readily accessible)
7. Specimen source, when applicable
8. Test result(s) (and units of measurement, when applicable)

NOTE: All of the above data elements, as applicable, must be available in the laboratory information system or in paper records, and must be in the report that is available/sent to the clinician, whether electronic or paper, including electronic reports in systems interfaced to the laboratory information system directly or through middleware or an interface engine. (For electronic reports, data elements need not all be present on one screen, but must be readily available.) The paper or electronic report must include the name and address of referral laboratories where patient testing was performed. For laboratories subject to US regulations, a “referral laboratory” includes outside referral laboratories as well as any affiliated or special function laboratory that is separately accredited and has a different CLIA registration number than the referring laboratory. For electronic reports, the name and address of referral laboratories need not all be present on the same screen(s) as the results but must be available to the clinician in the information system. Under some circumstances it may be appropriate to distribute lists or tables of reference intervals to all users and sites where reports are received. This system is usually fraught with difficulties, but if in place and rigidly controlled, it is acceptable.
Patient reports must state the name of the physician (or other legally authorized person) ordering the test(s) or a physician of record. In those institutions where there are multiple ordering physicians and/or frequent changing of attending physicians, the ordering physician should be easily identifiable through a computer audit trail or other records of the test order.
Referral laboratories accredited by the CAP must provide a copy of the results to the referring laboratory (Exceptions to this requirement may be made under special circumstances or for special categories of testing, such as drugs of abuse or employee drug testing. The laboratory

director may make these exceptions.). Results may be reported to the ordering physician of record (or other legally authorized person) by either the referral laboratory or the referring laboratory.

WAM Support of Laboratory Regulatory Compliance

1) WAM Reporting of Results to the LIS

Sysmex WAM provides data elements that are included in the final LIS patient report that includes:

- Numerical results from the instrument
- Calculated results – e.g. manual absolute calculations
- Test and/or order level comments
- Critical call comments

Sysmex provided 'Dry/Wet Test Plans' – defined methodology to be used with the Sysmex WAM XE or XN-Series Emulator to validate results that are transmitted from Sysmex WAM to the LIS. It is the customer's responsibility to appropriately validate and document that the results/date from Sysmex WAM is appropriately and accurately displayed on the patient report as received from WAM. This can be done using the emulator and/or wet testing.

2) Sample ID Report

Sysmex WAM provides a Sample ID report that includes the following information:

The paper or electronic report includes the following elements:

- Name and address of testing laboratory **and/or sub-site**
- Patient name and identification number, or unique patient identifier
- Name of physician of record, or legally authorized person ordering test, as appropriate
- Date and time of specimen collection when appropriate
- Date of release of report (it not on the report, this information should be accessible) –
    - Name and date of printed report from WAM
- Time of release of report, if applicable (if not on the report, this information must be readily accessible.
    - Name and date of printed report from WAM
- Specimen source, when applicable
    - Name of discipline – Hematology or Chemistry for HBA1C
- Test result(s) (and units of measurement when applicable)
- Reference intervals as applicable
    - Not applicable. WAM does not provide reference ranges
- Condition of specimen that any limit adequacy of testing
- Comments on test or order level

3.2 GEN.41300 Report Retention and Retrieval

Requirement:

Copies or files of reports are legible and retained by the laboratory in a manner that permits prompt retrieval of the information.

NOTE: The length of time that reported data are retained in the laboratory may vary; however, the reported results must be retained for that period encompassing a high frequency of requests for the data. In all circumstances, a hospital laboratory must have access to the patient's chart where the information is permanently retained.

WAM Support of Laboratory Regulatory Compliance

Sysmex WAM provides on-line data availability for all patient data, audit trails and Sysmex instrument graphical data. Sysmex WAM patient data is available online for a maximum of 730 days (2 years). Automated patient data deletion will occur on a rolling basis after the 730th day.

3.3 GEN.41304 Data Accessibility

Requirement:

There is a written policy to ensure that patient data are accessible in a timely manner only to those individuals who are authorized to retrieve test results.

NOTE: Only those healthcare personnel authorized to review a patient's test results should have access to those results. Laboratories subject to US regulations must provide final test results to the patient or the patient's personal representative upon request. For completed tests, these results must generally be provided no later than 30 days after such a request.
Under the HIPAA Privacy Rule, only the patient or a personal representative, defined as an individual who has authority under applicable law to make health care decisions for the patient, can be given access to a patient's personal health data. Laboratories must take reasonable steps to verify the identity of the patient and the authority of a personal representative to have access to an individual's protected health information. The Rule also allows for the release of test reports to authorized persons responsible for using the test reports and to the laboratory that initially requested the test, if applicable.

WAM Support of Laboratory Regulatory Compliance

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Sysmex WAM supports the laboratory protocols by providing roles based security access for patient result viewing and resulting in the applications as a standard feature of the software.

3.4 GEN. 41306 Analyst Tracking ID

Requirement

There is a system whereby the identity of the analyst performing or completing the test and the date of the test can always be established.

NOTE: If results are released using autoverification, the system must be capable of identifying those test results that have been autoverified. In addition, the laboratory should be able to identify the technologist responsible for the instrument producing the result, such as through daily bench assignment charts, instrument set-up logs, or electronic audit trail.

WAM Support of Laboratory Regulatory Compliance

Sysmex WAM supports the laboratory protocols by tracking each user action (Entry of results, entry of comments, add/remove tests, cancellations, validation actions) via the Order and Test audit trail with the login ID of the user. In addition, the User ID is transmitted to the LIS with each result.

3.5 GEN.41307 Report Errors

Requirement

When errors are detected in patient test reports, the laboratory promptly notifies responsible clinical personnel or referring laboratory as applicable and issues a corrected report.

NOTE: Notification should include the department of health or other legal entity as required by local regulations

Evidence of Compliance:

- ✓ Records of report error notification and corrected report

WAM Support of Laboratory Regulatory Compliance

Sysmex WAM provides the ability for modify results if there is an error or issue detected after user validation and result acceptance. All modified results are identified in the sample ID audit trail by user and date/time. The Sysmex WAM v5.x application provides a 'lavender' color coding identifier for all modified results in the Result Validation, Manual Differential and Morphology screens.

3.6 GEN.41310 Corrected Report

Requirement:

All corrected reports of previously reported, incorrect patient results are identified as corrected, and both the corrected and original data are clearly identified as such.

NOTE: 1. As clinical decisions or actions may have been based on the previous report, it is important to replicate previous information (test results, interpretations, reference intervals) for comparison with the corrected information. The previous information and the corrected information must be identified as such, and the original data must be present in the corrected report (for paper reports), or linked electronically or logically to the corrected information (in

electronic reports).2. This requirement applies to electronic reports in the laboratory information system and to the data systems interfaced to the laboratory information system either directly or through middleware or an interface engine (but not to systems that are further downstream in the interface chain).3. Displays in an electronic medical record (EMR) downstream from the laboratory should include the original report as well as the corrected report. The report elements listed in GEN.41096 should be included in the EMR.4. The correction should add explanatory language if an explanation would be helpful to the user. For example, a comment about transport or sample storage conditions uncovered post-analysis can help frame an original, invalid result.
5. For changes to anatomic pathology and cytopathology reports, refer to ANP.12185 and CYP.06475.

WAM Support of Laboratory Regulatory Compliance:

Sysmex WAM provides the ability for modify results if there is an error or issue detected after user validation and result acceptance. All modified results are identified in the sample ID audit trail by user and date/time. The Sysmex WAM v5.x application provides a 'lavender' color coding identifier for all modified results in the Result Validation, Manual Differential and Morphology screens.

3.7 GEN.41312 Multiple Corrections

Requirement:
When there are multiple sequential corrections of a single test result, all corrections are referenced in sequential order on subsequent reports.

NOTE: When there are multiple sequential corrections of a previously reported result, it is considered inappropriate to note only the last correction made, as the clinician may have made a clinical decision based upon erroneous data rather than the "true" result. All corrections should Be referenced in the patient report.

WAM Support of Laboratory Regulatory Compliance:

The Sysmex WAM test level audit trail provides all corrected events by test for each Sample ID in sequential time order for easy identification.

3.8 GEN.41345 Turnaround Time

Requirements:

The laboratory has defined turnaround times (*i.e*. the interval between specimen receipt by laboratory personnel and results reporting) for each of its tests, and it has a policy for notifying the requester when testing is delayed.

NOTE: This does NOT imply that all instances of delayed reporting for all tests must lead to formal notification of clinical personnel. Rather, clinicians and laboratory must have a jointly agreed upon policy for when such notification is important for patient care.

Evidence of Compliance:

✓ Written policy defining test reporting turnaround time and process for communication of delays in turnaround time

WAM Support of Laboratory Regulatory Compliance:

Sysmex WAM can support the laboratory tracking of CBC, Smear, Manual diff and single hematology test turnaround time via the Management Report module which includes a Turnaround Statistic Report. This report can be used on demand to determine TAT by workstation, site, location and/or user.

3.9 GEN. 43022 LIS Testing

Requirement:

There are records that programs are adequately tested for proper functioning when first installed and after any modifications, and that the laboratory director or designee has approved the use of all new programs and modifications.

NOTE: Computer programs must be checked for proper performance when first installed and after any changes or modifications. Any changes or modifications to the system must be recorded, and the laboratory director or designee must approve all changes, additions and deletions in programs, the test library, and major computer functions before they are released. Records must be retained for at least two years beyond the service life of the system

WAM Support of Laboratory Regulatory Compliance:

Sysmex WAM provides standard test plans to ensure the software features, functions, programs and or configuration changes are thoroughly tested by the customer.

- **Sysmex provided 'Dry/West Test Plans'** - detailed test plans are provided for the initial installation of the Sysmex WAM system. The customer tests and provided documentation of all testing prior to go live. Sysmex reviews the test documentation prior to go live to ensure the proper testing has been conducted. These test plans can be used for additional customer testing after the initial go live.

- **Sysmex provided Test Plans** – Sysmex provides detailed test plans for all defect notices and/or system changes distributed to all customers.

- **Acceptance of Software** – The customer is required to sign acceptance documents upon final system validation and any subsequent defect or changes to the software.

3.10 GEN.43033 Custom LIS

Requirement:

Customized software, and modifications to that software, is appropriately documented and records allow for tracking to identify persons that have added or modified that software.

NOTE: The purpose of the computer program, the way it functions, and its interaction with other programs must be clearly stated. The level of detail should be adequate to support troubleshooting, system modifications, or additional programming.

WAM Support of Laboratory Regulatory Compliance:

Sysmex WAM provides standard test plans to ensure the software features, functions, programs and or configuration changes are thoroughly tested by the customer. These test plans can be used for 'custom LIS's with approved adaptation by QA/RA and the testing teams to meet the operational requirements of the LIS.

- **Sysmex provided 'Dry/West Test Plans'** - detailed test plans are provided for the initial installation of the Sysmex WAM system. The customer tests and provided documentation of all testing prior to go live. Sysmex reviews the test documentation prior to go live to ensure the proper testing has been conducted. These test plans can be used for additional customer testing after the initial go live.

- **Sysmex provided Test Plans** – Sysmex provides detailed test plans for all defect notices and/or system changes distributed to all customers.

- **Acceptance of Software** – The customer is required to sign acceptance documents upon final system validation and any subsequent defect or changes to the software.

3.11 GEN. 43200 Computer Access Codes

Requirement:

Computer access codes (security codes, user codes) are in place to confine individuals' access to those functions they are authorized to use, and the security of access codes is maintained (e.g. inactivated when employees leave, not posted on terminals).

NOTE: The laboratory should establish security (user) codes to permit only specifically authorized individuals to access patient data or alter programs. A system that allows different levels of user access to the system based on the user's authorization is desirable and usually provides effective security. Examples of best practices include: periodic alteration of passwords by users; minimum character length for passwords; password complexity requirements (e.g. a combination of alphanumeric characters); recording of failed log-on attempts with user lock-out after a defined number of unsuccessful log-on attempts.

WAM Support of Laboratory Regulatory Compliance:

Sysmex WAM supports the laboratory protocols by providing roles based security access for patient result viewing and resulting in the WAM applications as a standard feature of the software. The Sysmex WAM site Administrative manager can define and/or inactivate users as necessary.

Sysmex WAM provides the ability for the site to determine upon set up the password complexity level (password length, use of alpha numeric and symbols in the password) and re-use of the password requirements. In addition, there is a system parameter for lockout of the user after an 'x' number of unsuccessful attempts.

Sysmex WAM also provides a User Access report to retrieve on demand for activity of log in, log off and unsuccessful attempts at accessing the WAM application.

3.12 GEN.43262 Unauthorized Software Installation

Requirement:

There are written policies and procedures that govern installation of software on any computer used by the laboratory.

NOTE: Laboratory computers often serve multiple functions. Many of these computers are connected in a network. The security of the system should be sufficient to prevent the casual user from installing software. Such unauthorized installation may cause instability of the operating system or introduce other unwanted consequences. Many operating systems allow procedures to restrict certain users from installing software.

WAM Support of Laboratory Regulatory Compliance:

Sysmex WAM is the only authorized entity to install Sysmex WAM software directly onto the WAM server. The customer is notified via Product Notices the software available to be installed by Sysmex. The site is contacted by Sysmex to schedule the installation of the software. All software is tested by the customer in the TEST environment prior to moving the software to the PRODUCTION environment using Sysmex approved test plans.

3.13 GEN.43225 Public Network Security

Requirement:

The facility uses a public network, such as the Internet as a data exchange medium, there are network security measures in place to ensure confidentiality of patient data.

NOTE: Information sent over a public domain such as the Internet or stored in "the cloud," is considered in the public domain. Thus it is potentially accessible to all parties on that network. Systems must be in place to protect network traffic, such as "fire walls" and data encryption schemes.

Evidence of Compliance:

- ✓ Written policy defining mechanism for data protection

WAM Support of Laboratory Regulatory Compliance:

Sysmex Network Communications System™[1] (SNCS) is used to provide remote monitoring and support over an SSL/TLS encrypted connection. SNCS tools and services include: proactive analyzer support, remote calibration verification, reagent inventory management*, error monitoring, and analyzer maintenance. The software also allows for user initiated, password protected remote support sessions.

Communication is initiated by the SNCS agent that resides on the Sysmex analyzer Information Processing Unit (IPU) computer. Bi-directional communication will be required for full SNCS functionality between the Sysmex analyzers and the SNCS servers. A more detailed listing for middleware and analyzers follows.

Per CAP and CLIA requirements, the customer is responsible for the physical security of the laboratory and, by extension, Sysmex equipment in the lab. Access to Sysmex software and equipment should be granted by the lab (or its designee) only to those individuals with an immediate business need within the lab. This includes removing access for those individuals who no longer require access.

Sysmex WAM will comply with the site's requirements for accessing their network to install, monitor and support the Sysmex WAM server and the client supplied workstations.

WAM Reference Document:

- Sysmex WAM v4.1/v4.1.1 Client Workstation Installation Guide - MKT-70-1180 Rev2
- Sysmex WAM v5.0 Client Workstation Installation Guide – 1038-MKT Rev 3
- Sysmex WAM v5.0.2 Client Workstation Installation Guide – 1209-MKT
- Sysmex® Health Information Security and SNCS™ Installation Instructions - 1101-TS Rev.2.

3.14 GEN.43450 Calculated Patient Data Verification

Requirement:

Calculated values reported with patient results are reviewed every two years or when a system change is made that may affect the calculations.

NOTE: This checklist requirement applies only to calculations based on formulas modifiable by the user. .Errors can be inadvertently introduced into established computer programs. Calculations involving reportable patient results must be rechecked to ensure accuracy and records retained. This requirement applies to laboratory information systems, middleware, and analyzers. More frequent checks may be required for certain specific calculations, as delineated elsewhere in the checklists (e.g. INR).

[1] Not available in Canada

WAM Support of Laboratory Regulatory Compliance:

The Sysmex WAM calculations are not modifiable by the user and/or the customer after verification during the implementation period and system sign off. Only approved Sysmex implementation and/or support personnel can modify calculations. However, if there is a change in the calculation on Sysmex WAM, the customer is responsible for testing the calculation in the test area from Sysmex WAM to the LIS patient generated report to ensure that the data inputs and output are correct. .The customer is responsible for maintaining the records of testing and verification on the patient report.

The following calculations are standard with Sysmex WAM:

- Calculation of the manual differential absolute counts
- Calculation of the citrated platelet count adjustment
- Calculation of ANC and ALC
- WBC correction calculation based on a NRBC manual differential count of >0
- WBC correction calculation based on the NRBCAB > 0 for XS and XT instruments ONLY
- Rounding of results generated from the manual differential

Annual Testing:
The customer is responsible for verifying that the WAM calculations are working as expected. The X/XN-Series emulator can be utilized to create results with an LIS order in the test area to verify the calculations are working as expected. An alternative method is to identify Sample IDs via the Sysmex WAM Management Result Statistic Report that meet the search criterial. These Sample IDs can be printed and/or exported to verify that the calculations are performing as expected within the customer's production system.

3.15 GEN.43750 Specimen Quality Comment

Requirement:

The system provides for comments on specimen quality that might compromise the accuracy of analytic results (*e.g.* hemolyzed, lipemic).

Evidence of Compliance:
✓ Patient reports

WAM Support of Laboratory Regulatory Compliance:

Sysmex WAM provides the ability for the following methods to capture the specimen quality comment:

- Specimen quality comment received into WAM from the LIS to be displayed in the Result Validation screen

- Manual entry of the specimen comment in WAM Result Validation screen in the LIS, Internal or test level comment fields

3.15 GEN.43800 Data Input ID

Requirement:

There is an adequate system to identify all individuals who have entered and/or modified patient data or control files.

NOTE: When individual tests from a single test order (e.g. multiple tests with same accession number) are performed by separate individuals and the test result is entered into the LIS, the system must provide an audit trail to record each person involved. For example, a single accession number having orders for electrolytes and a lipid panel may have testing done by two or more individuals. The laboratory should be able to identify the responsible personnel who performed each test and posted the data. This includes sequential corrections made to a single test result. If autoverification is used, then the audit trail should reflect that the result was verified automatically at a given time. With point-of-care testing, if the individual performing the test is different than the individual entering test data into the LIS, both should be uniquely identified by the system and retrievableby audit trail.

WAM Support of Laboratory Regulatory Compliance:

Sysmex WAM provides the following audit trails and tools to meet this requirement for all Sample IDs managed on the application.

- **Order and Test Audit Trail** – Access the Audit trail for Order and Test in the Result Validation screen or Query Order screen. The user can view the events associated with the specific Sample ID. The summary will indicate the user and/or WAM that was associated with each result entry for the following:
    - Initial result integration by instrumentation
    - If auto-validated by WAM
    - If user approved and/or modified results
    - Addition of comments and/or critical result comments
    - If user modifies a result

- **Order Audit Trail** – The Result interface to the LIS will indicate the user and/or WAM that validated the result.
    - User ID that manually validated the result
    - WAM designation to denote that the results were auto-validated
    - Instrument ID

3.16 GEN.43825 Result Verification

Requirement:

Manual and automated result entries are verified before final acceptance and reporting by the computer.

NOTE: Data entered into the computer system either manually or by automated methods must be reviewed by an authorized individual who verifies the accuracy of the input data before final acceptance and reporting by the computer. An example of best practices for this step is

checking the result against the reportable range and critical results for the test. Depending on the local environment, this may or may not require a second person. Verification procedures must generate an audit trail. This checklist requirement does not apply to autoverification procedures (see below).

WAM Support of Laboratory Regulatory Compliance:

Sysmex WAM provides a Result Validation screen to review all sample IDs with results that require a technologist review. A tech is required to review all sample ID results with one or more rules that have been executed and for all manually entered results.

The default operation is that all results received from the analyzer which do not trigger a rule are auto-validated and considered approved and are automatically sent to the LIS. All sample ID results received from the analyzer that have triggered one or more rules are available for review and approval in the **Result Validation** screen

The Result Validation screen provides three options for result review and result acceptance:

- Validate All Results
- Validate CBC Results (only) – this option holds the ADIFF for further evaluation
- Validate Selection – selection of one or more tests to review and approve

3.17 GEN. 43875 Auto-verification Validation

Requirement:

There is documentation that the autoverification process was validated initially, and is tested at least annually and whenever there is a change to the system that could affect the autoverification logic.

NOTE: The range of results for which autoverification is acceptable must be defined for all patient tests subject to autoverification.Validation of autoverification must include a process to confirm that the autoverification algorithm decision rules are functioning properly, including the use of previously assayed specimens with results that challenge the algorithm. Examples of specimens that may be needed to validate the autoverification algorithm decision rules may include specimens with analyte concentrations within the normal reference limit, above or below the reference limits, above or below the analytic measurement range, and in the critical range. Specimens with known interferences and specimens that require calculations should also be used, when applicable.
When changes are made that might affect the autoverification decision algorithm, validation appropriate to the scope and nature of the change must be performed.

Evidence of Compliance:

✓ Records of autoverification validation studies, including laboratory director approval **AND**

✓ Records of ongoing retesting of the autoverification process at least annually and at changes to the system.

WAM Support of Laboratory Regulatory Compliance:

Sysmex WAM provides the following:

- Each system setting and/or rule modification (addition or editing) should be tested with a specimen that reflects the order characteristics and outcome of the rule with the Sysmex instrumentation for final testing.

- Sysmex provides 'Dry/Wet Test Plans' – defined methodology to be used with the Sysmex to validate *initial rules and any subsequent change to rules. It is the customer's responsibility to use appropriate documents/tools for all subsequent rule changes after goes live to verify the rules work as they expect in their specific environment.*

- The customer must determine the extent of annual rule testing that may include testing each rule on an annual basis using the Sysmex instrumentation and X/XN-series emulator.

Annual Rule Testing:

The customer is responsible for verifying that the WAM rules are working as expected. The X/XN-Series emulator can be utilized to create results with an LIS order in the test area to verify each auto-validation rule. The customer is also responsible for retaining the data verifying that the WAM rules are working as expected for two years beyond the life of the system.

NOTE: *When there is no expiration date, records shall be retained indefinitely*

An alternative method is to identify Sample IDs via the Sysmex WAM Management Result Statistic Report and/or Rules Statistic report to identify rules that have triggered in the production system. These Sample IDs can be printed and/or exported to verify that the rules are performing as expected within the customer's production system. The customer is also responsible for retaining the data verifying that the WAM rules are working as expected for two years beyond the life of the system.

NOTE: *When there is no expiration date, records shall be retained indefinitely*

Note: Contact STS (Software Testing Solutions) at http://www.sts-healthcare.com/ for information on a Sysmex WAM-STS solution designed to deliver automated testing software for annual WAM rule validation. This software package must be purchased directly from STS.

3.18 GEN.43878 Auto-Verification QC Samples

Requirement:

For all test results subject to autoverification, the laboratory ensures that applicable quality control samples have been run within an appropriate time period, with acceptable results.

NOTE: This requirement may be met by, 1) the computer system automatically checking quality control status prior to autoverification, or, 2) manually disabling autoverification after any unacceptable QC result, or when QC has not been run within the required time interval.

Evidence of Compliance:

✓ Procedure defining the QC process **AND**
✓ QC data to show that QC was performed at defined intervals

WAM Support of Laboratory Regulatory Compliance:

Sysmex WAM does not offer a QC module for WAM v5.x series. However the following functionality can be provided if the QC is transmitted via WAM to the LIS via the Result interface.

- **Review at the Instrument and Sysmex Insight Software**: Check QC for any rules that have triggered and follow the laboratory QC policy for follow up and verification
- **Review on the LIS**: Check QC on the LIS for any rules that have triggered and follow the laboratory QC policy for follow up and verification
- **Auto-validation Control:** If the WAM rules need to be disabled based on the laboratory's determination that all patient samples need to be held up for review, the Key Operator and/or WAM administrator can disable all WAM rules via the Auto-validation Control feature on WAM until the QC has been verified to function as expected and WAM rules can be turned back on.

3.19 GEN.43881 Auto-Verification Results

Requirement:

Results are compared with an appropriate range of acceptable values and flags or warnings reviewed prior to autoverification.

NOTE: Appropriate comparisons include checking patient results against absurd and critical results requiring manual intervention (repeat testing, dilution, telephone notification of results, etc.). The mere presence of a flag may not disqualify a result from autoverification, but any flag that is not specifically recognized by the autoverification program must cause the flagged result to be held for manual review.

Evidence of Compliance:

✓ Records of system rules including comparison of patient results against absurd and critical values

WAM Support of Laboratory Regulatory Compliance:

Sysmex WAM provides the following rule capability to meet this requirement:

- *High/Low Range rules with defined limits* <x and or >x) with operator alerts to identify any abnormal and/or absurd result.
- *Critical rules with defined limits* = <x and or >x) with operator alerts and color coding (Red=critical high and Blue=critical low) to notify the user immediately of the criticality of the test result.

- *Delta Rules with absolute or percentage change with the last validated result* – with operator alerts and color coding (Delta = green) to notify the user immediately of a delta check failure.

3.20 GEN. 43887 Autoverification of Audit Trail

Requirement:

The audit trail in the computer system identifies all test results that were autoverified, and the date/time of autoverification.

WAM Support of Laboratory Regulatory Compliance:

Sysmex WAM provides the following for audit trail support:

- Result audit trail that identifies user ID for manual validation
- Result audit trail that identifies autoverification actions with a code of WAM
- Result interface that transmits user ID (manual validation) or WAM (autoverification) code on a test level

3.21 GEN.43890 Autoverification Delta Checks

Requirement:

The autoverification process includes all delta checks that the laboratory performs prior to manual release of test results.

NOTE: This requirement does not require delta-checking for all autoverified results, but the laboratory's delta-checking procedures should be the same for manually released and autoverified test results.

Evidence of Compliance:
✓ Records of system rules including the use of delta checks when appropriate

WAM Support of Laboratory Regulatory Compliance:

Sysmex WAM provides the following rule capability to meet this requirement:

- *Delta Rules with absolute or percentage change with the last validated result* – with operator alerts and color coding (Delta = green) to notify the user immediately of a delta check failure.
- +/- delta values in either direction
- Color coding (Delta = green) to notify the user immediately of a delta check failure.
- V4 – Delta values based on validated values only
- V5 – Delta values based on validated and 'un-validated results.'
- Delta values based on date/date range

3.22 GEN.43893 Autoverification Suspension

Requirement:

The laboratory has a procedure for rapid suspension of autoverification.

NOTE: Laboratory personnel should be able to suspend autoverification in the event of a problem with a test method, analytic instrument or the autoverification program.

WAM Support of Laboratory Regulatory Compliance:

Sysmex WAM v4.x and 5.x provides Auto-validation functionality to meet this requirement via the Auto-validation Control feature.

- Ability to manually suspend autoverification *on demand* by instrument group, instrument ID and/or test via the Auto-validation Control menu. All rules by test will be suspended and the users will be required to manually validate Sample ID results from the point of suspension.
- Complete documentation of use of the Auto-validation Control feature by requiring a coded comment to document the suspension of the rules and re-enabling of the rules
- Display of the auto-validation control history with search, sort and print capability.

3.23 GEN.43900 Archived Test Result

Requirement:

A complete copy of archived patient test results can be retrieved, including original reference ranges and interpretive comments, including any flags or footnotes that were present in the original report, and the date of the original report.

NOTE: Stored patient result data and archival information must be easily and readily retrievable within a time frame consistent with patient care needs.

WAM Support of Laboratory Regulatory Compliance:

WAM provides on-line data availability of all Sample ID data for 730 days (2 years).

WAM provides support for GEN.43900 by providing network back up to the network for data retrieval and disaster recovery and send results to the LIS for permanent documentation to include patient results with Instrument and user ID and any comments attached to the test results or on an order level.

It is the responsibility of the LIS to provide complete patient reporting with reference ranges and report comments.

Sysmex WAM **does not provide** the following features for archived test information:

- Archiving capability.
- Patient reporting with reference ranges, flags or footnotes

- Transmission of the graphical ranges to the LIS
- Transmission of flags or rules triggered to the LIS

3.24 GEN.43920 Multiple Analyzer ID

Requirement:
When multiple identical analyzers are used, they are uniquely identified such that a test result may be appropriately traced back to the instrument performing the test.

NOTE: Best practice is to store these data in the LIS.

WAM Support of Laboratory Regulatory Compliance:

Sysmex WAM provides the following support for identification of multiple instruments:

- Assignment of a unique ID to each instrument
- Display of the instrument ID on the result validation screen for each test result by run
- Transmission of the instrument ID to the LIS by test result

3.25 GEN.43946 Data Preservation/Destruction Event

Requirement:

There are written procedures for the preservation of data and equipment in case of an unexpected destructive event (e.g. fire, flood), software failure and/or hardware failure, and these procedures allow for the timely restoration of service, including data integrity check.

NOTE: Procedures must 1) be adequate to address scheduled and unscheduled interruptions of power or function; 2) be tested periodically for effectiveness; and 3) include systems to backup programs and data.

These procedures can include, but are not limited to, 1) steps to limit the extent of the destructive event, 2) periodic backing up and storing of information, 3) off-site storage of backup data, and 4) restoring information from backed up media. The procedures should specifically address the recoverability of patient information. Changes to hardware and software commonly require review and reevaluation of these written procedures. These procedures must specifically address the physical environment and equipment and are often addressed by the organization's disaster plan.

WAM Support of Laboratory Regulatory Compliance:

Optional Switch Server:

Sysmex WAM provides an optional switch server to meet this requirement. The purpose of the Switch Server is to transfer WAM services from one system to another system in a planned or unplanned downtime event. In the case of a down time event of the WAM server due to software or hardware malfunction, all services will be transferred to the switch server without the need for backup tapes or images.

Sysmex WAM performs daily backups:

- **Sysmex Daily System Backup: Sysmex Daily System Backup:** The Sysmex WAM server is configured to perform a daily disk-to-disk backup automatically on a scheduled basis. This daily backup consists of database, application software, rules and settings and is copied to a client provided destination.

- **The WAM Server will send an email up to three (3) email addresses** for Sysmex-Scheduled WAM Server Disk-to-Disk backups that have completed successfully. Effectiveness of Customer-Scheduled Network Daily Backup will not be noted or tracked by the WAM Server. If the backup does not complete as expected, an alert will display on the Sysmex WAM Alert bar.

3.26 GEN.46000 Reference Range/Unit Transmission

Requirement:

As applicable, reference ranges and units of measure for every test are transmitted with the patient result across the interface.

NOTE: The reference range, including units of measure, may be specific for a given patient result and should be attached to that result such that it will be displayed along with the patient result.

WAM Support of Laboratory Regulatory Compliance:

Sysmex WAM does not configure reference ranges in the application. It is the responsibility of the LIS to apply the appropriate reference ranges when the result is received from WAM to the LIS.

Sysmex WAM however configures the test results with the appropriate units of measure to match the Sysmex supported analyzers and devices both in the interfaces, WAM application and results transmitted to the LIS.

3.27 GEN.48500 Interface Result Integrity

Requirement:

There is a procedure to verify that patient results are accurately transmitted from the point of data entry (interfaced instruments and manual input) to patient reports (whether paper or electronic).

NOTE: Verification must be performed prior to implementation of an interface (i.e. pre go-live), and every 2 years thereafter. This includes evaluation of data transmitted from the LIS to other computer systems and their output devices. Reference ranges and comments, as well as actual patient results and report formats, must be evaluated.
Verification of accurate data transmission from the LIS to other systems must be performed by reviewing data in the first downstream (or interfaced) system in which the ordering clinician/client (e.g. referring laboratory) may be expected to routinely access patient data. This requirement can be met by printing screen shots or by other methods that record that a verification procedure has

been performed. If the LIS has separate interfaces to multiple receiving systems in which patient data can be accessed by clinicians, then reports from each receiving system must be validated. However, where multiple sites use the same recipient system (e.g. the same installed instance of an electronic medical record system), validation need only occur for the interface (i.e. at one of the sites) and not for each individual site that is served by that single installed system.
At implementation of a new interface, or change to an existing interface, validation of at least 2 examples of reports from each of the following disciplines, where applicable, satisfies the intent of this checklist requirement. Subsequently, at least 2 examples of reports from at least 4 of these disciplines should be validated every 2 years. Not all of these report types will be applicable to every laboratory:

1. *Surgical pathology reports*
2. *Cytopathology reports (preferably gynecologic and non-gynecologic)*
3. *Clinical laboratory textual reports (e.g. molecular, protein electrophoresis, coagulation panel interpretation)*
4. *Quantitative results (e.g. chemistry, hematology, or coagulation)*
5. *Qualitative or categorical results (e.g. serology)*
6. *Microbiology reports (e.g. culture and antimicrobial sensitivity)*
7. *Blood bank reports (e.g. type and screen)*

Interface validation should include examples of individual results, test packages or batteries, abnormal flags, and results with comments/footnotes. Initial interface validation should include verification that corrected results for clinical laboratory and anatomic pathology results are handled accurately in the receiving system.

Evidence of Compliance:
✓ Records of verification

WAM Support of Laboratory Regulatory Compliance:

Sysmex employs a comprehensive testing program for all new installations of Sysmex WAM to verify the result integrity of result transmission from the Sysmex supported analyzers and devices to the WAM application and subsequent transmission to the LIS.

- **LIS Testing** – defined methodology used by Sysmex to test the full loop of testing from the order from the LIS to Sysmex WAM and then results back from the analyzers and devices to WAM for rule execution. The full loop is testing from WAM back to the LIS to ensure that the test results are traceable and accurate through the multiple systems. The customer participates in this testing and is provided full documentation with signatures from both parties that they have reviewed the interface testing and agree with the results.

- **Sysmex provides 'Dry/Wet Test Plans'** – defined methodology to be used with the Sysmex to validate initial rules and any subsequent change to rules on Sysmex WAM. The customer participates in this testing and is provided full documentation with signatures from both parties that they have reviewed the dry and wet testing and agree with the results.

- It is the customer's responsibility to use appropriate documents/tools for all subsequent rule changes after goes live to verify the rules work as they expect in their specific environment

3.28 GEN. 48750 LIS Interfaces Shutdown/Recovery

Requirement:

There are procedures for changes in laboratory functions necessary during partial or complete shutdown and recovery of systems that interface with the laboratory information system.

NOTE: These procedures must ensure integrity of patient test data. Procedures must include verifying recovery of interfaced systems, and replacement or updating of data files, as necessary

WAM Support of Laboratory Regulatory Compliance:

Sysmex WAM provides a downtime procedures in the event that the LIS is not operational. The following documents provide guidance on the procedures to employee in the following situations:

- LIS not operational (down), WAM is operational (up)
- LIS down, WAM up, Orders in WAM
- LIS up, WAM down
- LIS up, WAM up, XN-9000 CT-90 down

Refer to the following documentation that can be accessed on the CRC:

- **Compact Automaton:** Sysmex WAM v5.0 Compact Automation Downtime Guide – 1060-MKT

- **XN-9000 Systems:** Sysmex WAM v5.0 XN-9000 Comm Downtime Guide – 1059-MKT

WAM Reference Information:

- LIS-WAM XN v4.1_v4.1.1 Communications Downtime for XN Compact Automation – 1022-MKT
- WAM v4.1_v4.1.1 XN-9000 Comm Downtime- 1031-MKT
- LIS-WAM XN v5.0 Communications Downtime for XN Compact Automation (XN-3000) – 1060-MKT
- WAM v5.0 XN-9000 Communications Downtime for XN scalable Automation – 1069-MKT

4 Common CAP Checklist - Detail

4.1 COM.29950 Reference Intervals

Requirement:

All patient/client results are reported with reference (normal) intervals or interpretations as appropriate.

NOTE: The laboratory must report reference intervals or interpretations with patient/client results, where such exist. This is important to allow proper interpretation of patient/client data. Age and/ or sex-specific reference intervals or interpretive ranges must be reported with patient test results, as applicable. In addition, the use of high and low flags (generally available with a computerized laboratory information system) is recommended. It is not necessary to include reference intervals when test results are reported as part of a treatment protocol that includes clinical actions, which are based on the test result. Under some circumstances it may be appropriate to distribute lists or tables of reference intervals to all users and sites where reports are received. This system is usually fraught with difficulties ,but if in place and rigidly controlled, it is acceptable.

WAM Support of Laboratory Regulatory Compliance:

Sysmex WAM does not configure reference ranges in the application. It is the responsibility of the LIS to apply the appropriate reference ranges when the result is received from WAM to the LIS.

Sysmex WAM however configures the test results with the appropriate units of measure to match the Sysmex supported analyzers and devices both in the interfaces, WAM application and results transmitted to the LIS.

4.2 COM.3000 Critical Result Notification

Requirement:

The laboratory has written procedures for immediate notification of a physician (or other clinical personnel responsible for the patient's care) when results of designated tests exceed established "critical" values that are important for prompt patient management decisions. Records of notification are maintained.

NOTE: Alert or critical results are those results that may require rapid clinical attention to avert significant patient morbidity or mortality. Each laboratory may define the critical values and critical results that pertain to its patient population. The laboratory may establish different critical results for specific patient subpopulations (for example, dialysis clinic patients). Critical results should be defined by the laboratory director, in consultation with the clinicians served. For changes to anatomic pathology and cytopathology reports, refer to ANP.12175 and CYP.06450 instead. Allowing clinicians to "opt out" of receiving critical results is strongly discouraged. Records must be maintained showing prompt notification of the appropriate clinical individual after obtaining results in the critical range. These records must include: date, time, responsible laboratory individual, person notified (the person's first name alone is not adequate documentation), and test results. Any problem encountered in accomplishing this task should be investigated to prevent recurrence.

Referral laboratories may report critical results directly to clinical personnel, or to the referring laboratory. The referral laboratory should have a written agreement with the referring laboratory that indicates to whom the referral laboratory reports critical results.
In the point-of-care setting, the identity of the testing individual and person notified need not be recorded when the individual performing the test is the same person who treats the patient. In this circumstance, however, there must be a record of the critical result, date, and time in the test report or elsewhere in the medical record.

WAM Support of Laboratory Regulatory Compliance:

Sysmex WAM provides the following support for critical result notification:

- Entry of free text or coded comments on a test level to indicate who was called, date & time
- Optional use of the Critical Call feature in Sysmex WAM
    - All critical results immediately after validation are required to be documented via the Documentation Edit screen
    - The Documentation Edit screen records the user ID, date/time of the call, read back status (Yes or No) and the ability to add a coded comment
    - WAM will transmit the critical call information to the LIS based on the test level

4.3 COM.30100 Critical Result Read-Back

Requirement:

When critical results are communicated by phone, “read-back” of the results is requested and recorded.

NOTE: Transmission of critical results by electronic means (FAX or computer) is acceptable. If critical results are transmitted electronically, the laboratory must confirm receipt of the result by the intended recipient (e.g. by a phone call); however, no read-back is necessary.

Evidence of Compliance:

✓ Records of critical result notification, including read-back as necessary

WAM Support of Laboratory Regulatory Compliance:

Sysmex WAM provides the following support for critical result notification:

- Entry of free text or coded comments on a test level to indicate who was called, date & time
- Optional use of the Critical Call feature in Sysmex WAM
    - All critical results immediately after validation are required to be documented via the Documentation Edit screen

- The Documentation Edit screen records the user ID, date/time of the call, **read back** status (Yes or No) and the ability to add a coded comment

- WAM will transmit the critical call information to the LIS based on the test level **including the read-back indicator**

5 Hematology CAP Checklist – Detail

5.1 HEM.23050 Reference Intervals

Requirements:

Patient results are reported with accompanying reference intervals (ranges) or interpretive ranges.

NOTE: The results of commercial quality control plasmas that may be used in coagulation assays are internal data for quality assurance purposes, and must NOT be externally reported; if reported with patient results, they may be confused as normal values.
For WBC differential counts, the CAP recommends that laboratories report absolute cell counts, along with their corresponding reference intervals. The CAP discourages the reporting of percent cell counts only on WBC differentials. If percent cell counts are reported, the reporting of results with reference intervals is not required as there are no well-established reference intervals and individual values regarded as normal, high or low may be discordant with the corresponding absolute values, leading to misinterpretation of CBC data. At the discretion of the laboratory director, laboratories reporting percent cell counts may provide laboratory established reference intervals. Under some circumstances it may be appropriate to distribute lists or tables of reference intervals to all users and sites where reports are received. This system is usually fraught with difficulties, but if in place and rigidly controlled, it is acceptable

WAM Support of Laboratory Regulatory Compliance:
Sysmex WAM does not configure reference ranges in the application. It is the responsibility of the LIS to apply the appropriate reference ranges when the result is transmitted from WAM to the LIS.

Sysmex WAM however configures the test results with the appropriate units of measure to match the Sysmex supported analyzers and devices both in the interfaces, WAM application and results transmitted to the LIS.

5.2 HEM.30100 Detection/Correction Procedure - WBC

Requirements:

There is a written procedure available and in use for detecting and correcting automated WBC counts for the presence of nucleated red cells or megakaryocytes.

NOTE: The effect of nucleated erythrocytes and blood megakaryocytes on the apparent WBC count varies with the system used for analysis. Each laboratory should evaluate its system(s) and develop appropriate detection and correction procedures. This is important to prevent reporting a falsely high WBC concentration. With some automated CBC instruments, nucleated erythrocytes or megakaryocytes may present themselves histographically or cytographically, and this can

serve as an indicator for careful stained blood film inspection. The laboratory must establish if its particular instrument(s) includes some or all nucleated non-leukocytes in its apparent WBC "count".

Evidence of Compliance:
✓ Records showing actions taken to verify CBC concentration prior to reporting

WAM Support of Laboratory Regulatory Compliance:

Sysmex WAM provides the following features:

1. **X-Series analyzers:** Sysmex WAM will provide a correction calculation to correct the WBC counts for the presence of nucleated red cells or megakaryocytes. Sysmex will provide a standard calculation as a rule for the correction calculation.

2. **XN-Series analyzers**: The Sysmex XN-Series analyzers provide a direct measurement of the nucleated red cells or megakaryocytes and therefore there is no need for a correction calculation. Sysmex WAM is not configured with a calculation for these types of analyzers.

5.3 HEM.30150 Spurious Results

Requirements:

A written procedure is in use to detect other spurious CBC instrument results that may be clinically significant (*e.g.* pseudomacrocytosis from rouleaux or agglutinates; pseudoleukocytosis with erroneous hemoglobin, falsely low erythrocyte count and hematocrit; hyperlipemias).

NOTE: Analytic sources of error with automated instruments depend on the type of instrument and reagents used by the laboratory. Common potential errors for the hemogram (without platelets) include pseudomacrocytosis (due to microclots, cold agglutinins, rouleaux, or osmotic matrix effects), pseudoleukocytosis (due to platelet agglutination, giant platelets, unlysed erythrocytes, nucleated erythrocytes, megakaryocytes, red cell inclusions, cryoproteins,circulating mucin), erroneous hemoglobin and indices (due to lipemia or leukocytosis), falsely low red cell concentration and hematocrit (due to in vitro hemolysis or extreme microcytosis), and falsely depressed results for all parameters (due to clots).

Evidence of Compliance:
✓ Record of action taken when spurious CBC instrument results are detected

WAM Support of Laboratory Regulatory Compliance:

Sysmex WAM provides rules that support the detection of spurious results

- *Rules based on Flags* –provides a rule for all instrument flags generated by the X-Series instrumentation.
    - *Rules based on result or instrument errors – rules support any instrument/result error generated by the X-Series instrumentation.*

- *High/Low Range rules with defined limits* <x and or >x) with operator alerts to identify any abnormal and/or absurd result.

- *Critical rules with defined limits* = <x and or >x) with operator alerts and color coding (Red=critical high and Blue=critical low) to notify the user immediately of the criticality of the test result.

- *Delta Rules with absolute or percentage change with the last validated result* – with operator alerts and color coding (Delta = green) to notify the user immediately of a delta check failure.

5.4 HEM.30200 Red Cell Indicies

Requirements:

Red cell indices (MCV, MCH, MCHC) are monitored routinely to detect random errors.

NOTE: Patient sample red cell indices (Wintrobe indices or MCV, MCH, MCHC) should be monitored routinely to detect random errors, instrument malfunction, or spurious results. If semiautomated methods are used, indices should be calculated. On many automated instruments, the MCHC is the most useful parameter to ensure accuracy of the red cell parameters in individual patient samples. Since MCHC varies over a narrow range, an abnormal MCHC will often flag potentially spurious red cell parameters. Truly elevated MCHCs may be seen with spherocytosis, while decreased MCHCs can accompany a low MCV in severe iron deficiency anemia. If such RBC abnormalities are not present on the blood film, one or more of the measured RBC parameters is likely erroneous. Incorrect data may be due to instrument malfunction or to problems with the blood sample itself. Some examples include: spuriously elevated MCVs and MCHCs with cold agglutinins, falsely elevated MCHCs with lipemia and plasma paraproteins, spuriously low MCHCs with leukocytosis and osmotic effects such as hyperglycemia altering MCV. MCV and MCH are fairly constant for each patient, and monitoring these indices in a delta check error detection program may provide rapid patient-based detection of instrument malfunction or specimen misidentification.

Evidence of Compliance:

✓ Written procedure defining the criteria used to monitor the red cell indices to detect random errors **AND**

✓ Record of action taken when RBC indices are in question, including the reporting of results

WAM Support of Laboratory Regulatory Compliance:

Sysmex WAM provides best practice standard rules for MCV that aid in the identification of random errors to identify random errors, instrument results or spurious results. The rules are displayed in the Result Validation screen with an operator alert and instructions to the user for the appropriate handling procedures. Here are examples of rules that standardize result review.

Rule #	Instr. Flag	Rule	Action	Operator Alert
RBC004	High MCHC	MCHC>37 (Default)	Hold CBC, ADIFF	Turbidity/HGB Interference: Spin HCT, follow protocol.
RBC0027	Hypochromia	Hypochromia flag (MCHC set on XE) <30.0	Reflex SMEAR Rerun all tests	MCHC Low: Perform slide review. Check for sample contamination
RBC028	MCV high	If MCV **> 105**	Reflex SMEAR Rerun all tests	MCV High: Scan for macrocytic changes, follow protocol
RBC029	MCV low	If MCV **<75**	Reflex Opt PLT and Smear Rerun all tests	MCV Low: Scan slide, follow protocol

5.5 HEM.30250 Reportable Ranges

Requirements:

Upper and lower limits of all reportable parameters on the CBC instrument are defined, and results that fall outside these limits are reported properly

NOTE: The laboratory must initially establish or verify the reportable range for each parameter of its automated or semi-automated CBC instrument. In particular, the laboratory must have data on its instrument's accuracy with thrombocytopenic and leukopenic samples. Platelet concentrations below the established lower limits must be reanalyzed by another method (e.g. manual hemocytometry, or semiquantitative blood film estimates, or fluorescence flow cytometry using specific platelet monoclonal antibodies). Particle (WBC, RBC, PLT) concentrations above the established upper limits must, as clinically needed, be reanalyzed by doing the minimum dilution necessary to bring the counts into the instrument's analytic range. When clinically appropriate, apparent analyte concentrations that are lower or higher than the reportable range may be reported as "less than" the lower limit or "greater than" the higher limit.

WAM Support of Laboratory Regulatory Compliance

Sysmex WAM provides the capability for the customer to select standard rules for high or low values appropriate for the analyte for Sysmex WAM. **However, WAM does not support configuration of reportable reference ranges in WAM and/or transmission to the LIS.**

5.6 HEM.30300 Platelet Abormalities

Requirements:

There is an adequate system (such as microscopic correlation with the blood film) to prevent reporting of spurious thrombocytopenia when platelet clumps, giant platelets, or platelet satellitism are present.

NOTE: When platelet satellitosis (satellitism), significant numbers of giant platelets and/or platelet clumps are suspected/detected by cyto/histographic abnormalities or instrument rejection of a platelet result, the platelet concentration must be independently verified. Correlation with a well-prepared blood film must be made. If platelets are clumped after collection in an EDTAanticoagulated tube that was well-mixed at the time of collection, this may represent in vitro EDTA-induced changes; platelets should be quantified from blood collected directly into a counting diluent, or by use of a different anticoagulant (e.g. liquid sodium citrate with subsequent adjustment for dilution) or by estimation from a non-anticoagulated blood film.

WAM Support of Laboratory Regulatory Compliance:

Sysmex provides standard rules to identify spurious platelet results that display in the Result Validation screen with an operator alert and instructions to the user for the appropriate handling procedures. Listed below are examples of our rule standard set.

Rule #	Instr. Flag	Rule	Action	Operator Alert
PLT001.1	FPS01	PLT CLUMP	Reflex SMEAR HOLD WBC,PLT ,ADIFF	PLT Clumps? Scan for abnormal morph, WBC and PLT estimate if necessary
PLT003	FPSO2	PLT CLMP	Reflex SMEAR HOLD CBC,ADIFF IPF	If PLT Clump(s): Clot check, scan for abnormal morph, PLT and WBC EST if required
PLT005	PLT005	Thrombocytopenia	Reflex Opt PLT Rerun PLT	Thrombocytopenia. Follow SOP.

5.7 HEM.30400 Platelet Count Verification

Requirements

If significant numbers of microcytic erythrocytes and/or small cell fragments are detected/ suspected, the platelet count is determined or verified using an alternate method.

NOTE: When a significant number of interfering particles are identified at the upper or lower PLT counting threshold (by inspection of the PLT histogram or instrument flag), the PLT concentration must be determined or verified by an alternate method. Such methods could include alternate instrumentation, hemocytometry, or blood film estimate, depending upon the PLT concentration

and the degree of clinical accuracy required.

Evidence of Compliance:

✓ Written procedure defining the criteria for detection of microcytic RBC and cell fragments that interfere with platelet counts **AND**

✓ Records showing action taken to verify platelet concentration prior to reporting

WAM Support of Laboratory Regulatory Compliance:

Sysmex provides a standard rule to identify lyse resistant RBCs that may affect the WBC concentration.

Sysmex provides a standard rule to identify RBC fragments. This rule will display in the Result Validation screen with an operator alert and instructions to the user for the appropriate handling procedures.

Rule #	Instr. Flag	Rule	Action	Operator Alert
RBC009	FRS05	If Fragments?	Reflex SMEAR And OPLT, Hold CB	Fragments?: Scan for abnormal RBC morphology, PLT est if required
RBC029	NA	MCV Low If MCV **<75**	Reflex Opt PLT Smear HOLD ALL Rerun PLT	MCV Low: Perform slide review, follow SOP

5.8 HEM.34200 WBC Differential Verification

Requirements

The laboratory establishes criteria for checking and reviewing leukocyte differential counter data, histograms, and/or blood films for clinically important results flagged by the automated differential counter.

NOTE: Clinically important results include pathologic quantities of normal cell types and abnormal cells. Flagging mechanisms include those within the particular instrument, inspection of histographic/cytographic displays, laboratory criteria based on local experience, and awareness of published evaluations.

Evidence of Compliance:

✓ Written procedure defining criteria for review and evaluation of automated differential results prior to reporting **AND**

✓ Records of verification of flagged values

WAM Support of Laboratory Regulatory Compliance:

Sysmex WAM provides the capability for the customer to select standard flag rules that represent the technology of the Sysmex X-Series and XN-Series analyzers. Sysmex provides a standard set of rules to choose rules that reflect the laboratory operations.

The current Sysmex WAM standard Rules document includes all the instrument flags with associated rules that represent the best practices of use of Sysmex instrumentation

WAM Reference Documents:

- Sysmex WAM Customer Standard Rules 1046-MKT, Rev 04

5.9 HEM.34500 Morphology Assessment –PLT/RBC

Requirements

The laboratory staff fully assesses, and accurately reports, RBC and PLT morphology as part of a manual WBC differential and/or blood film review.

NOTE: The laboratory must have a system to ensure that technical personnel have fully assessed all morphologic findings in each patient film. Each laboratory director should, in consultation with the medical staff, determine which morphologic findings are reportable. For example, minor degrees of anisocytosis and poikilocytosis without specific types of RBC abnormalities may be considered within the normal spectrum and not reportable to the chart. For RBC abnormalities that are reported, the laboratory must define a qualitative or semiquantitative grading system. When defined abnormalities (e.g. spherocytes, target cells, fragments, etc.) are present, non-specific listings of "anisocytosis" and/or "poikilocytosis" may not provide additional clinically useful information.

Evidence of Compliance:
✓ Written procedure defining the criteria for microscopic assessment of RBC and platelet morphology
✓ Patient reports that show assessment and reporting of RBC and PLT morphology

WAM Support of Laboratory Regulatory Compliance:

Sysmex WAM provides a standard list of RBC and PLT morphology as selections in the Sysmex WAM standard rules document. The laboratory can set the standard of reporting using a selection of RBC and PLT morphology that displays on the Morphology screen. The laboratory can select the standard result responses available to all users and thereby driving standardization on the selection and use of the morphology test codes specific to their laboratory operations.

WAM Reference Documents:

- Sysmex WAM Customer Standard Rules 1046-MKT, Rev 04

5.10 HEM.34600 Criteria for Blood Film Review

Requirements

There are written criteria with specified findings for blood films that are reviewed by the pathologist, supervisor or other technologist qualified in hematomorphology, and there is evidence of such review.

WAM Support of Laboratory Regulatory Compliance:

Sysmex WAM has the capability of providing rules that trigger a PATH review test that can be handled in the following manner:

- Reflex a PATH review test based on specific rules and/or morphology findings
- The reflex PATH test can be resulted by either one of the following methods:
  - Reflex PATH test transmitted to the LIS for the Pathologist to enter results in the LIS

OR

  - Reflex PATH test can be resulted in Sysmex WAM with standard coded comments and/or free text

The following are examples of rules that can manage the PATH testing within and/or with the LIS.

Rule #	Instr. Flag	Rule	Action	Operator Alert
WBC011	NA	WBC Path Review If WBC <2.0 OR > 3.0 AND ____ (specify)	Reflex PATH Hold ALL	Path review ordered. Provide slide and paperwork to pathologist.
RBC012	NA	RBC Path Review If RBC < ___ OR > ___	Reflex PATH	Path review ordered. Provide slide and paperwork to pathologist
RBC023	NA	HGB Path Review If HGB 7 -20	Reflex PATH	Path review ordered. Provide slide and paperwork to pathologist
RBC030	NA	MCV Path Review If MCV < ___ OR >__	Reflex PATH	Path review ordered. Provide slide and paperwork to pathologist
PLT007	NA	PLT Path Review If PLT <_____ OR >_____	Reflex PATH	Path review ordered. Provide slide and paperwork to pathologist

WAM Reference Documents:

- Sysmex WAM Customer Standard Rules 1046-MKT, Rev 04

5.11 HEM.35150 Spurious Results-Retics

Requirements

There are written criteria for identifying samples that may give spurious reticulocyte results by the automated method.

NOTE: Since all DNA- and RNA-containing cells will stain with DNA-RNA fluorescent dyes, a procedure must be in place to identify when the instrument cannot discriminate such stained particles from true reticulocytes. Potential interferences include Howell-Jolly bodies, nucleated erythrocytes, Heinz bodies, basophilic stippling of red cells, macrothrombocytes, megakaryocyte fragments, platelet clumps, and malaria or other intracellular organisms. Erythrocyte agglutination also may give spuriously high results, as may very high leukocytosis or thrombocytosis. Interfering particles may vary, depending on instrumentation, dye, and reaction conditions. Based upon initial evaluation of the instrument by the laboratory, criteria must be developed to detect samples with potentially erroneous results. This may be accomplished through flagging algorithms incorporated in the instrument and by examination of a blood film from every sample to ensure absence of relevant interferences.

Evidence of Compliance:
✓ Records showing actions taken to verify reticulocyte count prior to reporting

WAM Support of Laboratory Regulatory Compliance:

Sysmex provides standard rules that provide the ability to identify spurious Reticulocyte results from the Sysmex X and XN-Series instrumentation. The following rules will display in the Result Validation screen with an operator alert and instructions to the user for the appropriate handling procedures.

Rule #	Instr. Flag	Rule	Action	Operator Alert
RBC014	FRA10	Reticulocytosis If RETIC # >_____ AND No previous results	Reflex SMEAR RET%, RET#, IRF, RETHE	Retic Critical: Follow SOP
RBC015	FRA09	Ret Abn Scat and if RETIRE is present	Reflex SMEAR RET%, RET#, IRF, RETHE	Ret Abn Scat: Dilute 1:5 with CELLPACK® (XE) and run in manual mode or dilute w/DCL(XN),rerun,calc w/dilution factor.

WAM Reference Documents:

- Sysmex WAM Customer Standard Rules 1046-MKT, Rev 04

5.12 HEM.35471 Cell Clumps/Debris – Automated Counts - Body Fluids

Requirements

The laboratory has a procedure to detect clumps of cells or debris that may give spurious cell counts**.**

NOTE: The procedure should include performing macroscopic assessment of body fluid samples processed on cell counting instruments. Instrument generated flags and findings on microscopic examination that suggest the presence of debris are important observations and may require the performance of a wet mount. Marked clumping or clots precludes reporting an automated count. The laboratory report should note the limited accuracy of cell counts in these situations, and include a description of the specimen problem.

WAM Support of Laboratory Regulatory Compliance:

Sysmex provides standard body fluid rules for applicable flags and linearity results from the Sysmex X and XN-Series instrumentation. The following rules will display in the Result Validation screen with an operator alert and instructions to the user for the appropriate handling procedures.

Rule #	Instr. Flag	Rule	Action	Operator Alert
BFLD01	FWA01	If WBCBF Abn Scattergram	Reflex SMEAR Hold WBCBF	WBCBF Abnormal scattergram: Perform alternate method, add Fluid MDIFF
BFLD02	n/a	WBCBF Linearity	Hold BFP	WBCBF Linearity: Dilute 1:5 with CELLPACK and rerun
BFLD02.1	n/a	XN WBCBF Linearity	Hold BFP	WBCBF Linearity: dilute, rerun as BF,calc x dilution factor
BFLD03	n/a	RBCBF Linearity	Hold BFP	RBCBF Linearity: Dilute 1:5 with CELLPACK and rerun
BFLD03,1	n/a	XN RBCBF Linearity	Hold BFP	RBCBF Linearity: Dilute,rerun as BF,calc x dilution factor
BFLD04	n/a	WBCBF Linearity	Hold BFP	WBCBF Linearity: Perform slide review or cytospin
BFLD05	n/a	RBCBF Linearity	Hold BFP	RBCBF Linearity: Perform slide review or cytospin

WAM Reference Documents:

- Sysmex WAM Customer Standard Rules 1046-MKT, Rev 04

5.13 HEM.35585 Slide Review – Body Fluids

Requirements

Slides with suspected malignant cells are reviewed by a pathologist or other qualified physician before results reporting.

Evidence of Compliance:
✓ Written policy defining criteria for slide review by pathologist/physician **AND**
✓ Records of slide review

WAM Support of Laboratory Regulatory Compliance:

Sysmex WAM provides the ability define a PATH review test in WAM with the intent of either reflexing a PATH test to the LIS or providing the ability of the laboratory to record path results from the Pathology Staff. The following options are available:

Option 1:

- Reflex PATH in the WAM rule and consider it similar to morphology that any level tech results with a standard coded entry.
- PATH test code setup in WAM is for it to be seen, resulted and validated for any tech.
- PATH needs to be setup in the same report group as the Morphology test codes for this option. Once the test code is in the LIS, the LIS can setup a calculation rule to order the LIS Path Review test. The Pathologist enters the text in the LIS.
- This should be independent of the LIS.

Option 2:

- PATH to be used to enter pathology information directly in WAM by pathologist or senior tech.
- Option 2A - Site does not want any MDIFF/MORPH results to go out until PATH is resulted.
    - No issues with REFLEX or NON-Reflex LIS.
    - PATH would need to be put in same report group as MDIFF/MORPH.
- Option 2B - Site wants automated parameters and MDIFF/MORPH results to go out PRIOR to PATH being resulted.
    - Non-Reflexing LIS should not be an issue provided multiple transactions can go out.
    - Sunquest – this is not a Sunquest approved workflow due to piggyback.
    - Reflexing LIS
- Right now all parameters need to be resulted for the REFLEX response to be created.

- Workaround to still make this work
- Create a code (similar to PATH) that is reflexed. ADPTH.
- ADPTH is auto-resulted via Profile setup. ADPTH is used to generate the PR REFLEX.
- LIS responds back with PATH. PATH is in own report group.
- Allows for senior tech/path to enter results in PATH. Can validate PATH and results go out. No additional tests can be added from the ACTION box.

5.14 HEM.35604 Microscopic Result Comparison – Body Fluids

Requirements

If a body fluid specimen has a microscopic examination in more than one area of the laboratory, there is a mechanism to compare the data and interpretations from these different areas when a diagnosis of malignancy is suspected.

Evidence of Compliance:
✓ Written procedure for comparing microscopic results performed in multiple laboratory sections when malignancy is suspected **AND**
✓ Records of comparison

WAM Support of Laboratory Regulatory Compliance:

Sysmex WAM provides the ability to perform a fluid manual differential in the application. The laboratory can define rules that can alert the user when a specific cell type or pattern is identified. The laboratory can notify medical personnel via the optional use of the Critical Alert module.

WAM Reference Documents:

- Sysmex WAM Customer Standard Rules 1046-MKT, Rev 04