LEARNING GUIDE

MIDDLEWARE USE AND OPERATION

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CONTENTS

INTRODUCTION

LEARNING GUIDE

Middleware has played a critical role in helping to support the efficiency of clinical laboratories for several years. When it first emerged, the primary value was in connectivity, simply enabling transmission of orders and results between automated analyzers and the Laboratory Information System. Middleware platforms have since transformed to expand their value and support the needs of the clinical laboratory in response to the evolving healthcare landscape.

Diverse and changing demands, including increasing workload, faster turnaround times for patient results, and regulatory and financial constraints, have created an opportunity for holistic solutions that optimize clinical laboratory operations. For laboratories to adapt and succeed, they need to understand the capabilities of Information Technology and explore the role of Middleware in addressing the many challenges of the modern clinical laboratory.

GETTING THE MOST OUT OF THIS LEARNING GUIDE

This learning guide serves as a primer and provides a basic overview of middleware, its use, capabilities and the benefits of implementing these solutions in the core laboratory, with a focus on applications in Hematology. Multiple stakeholders in the laboratory can draw insights from the guide, including laboratory management, Medical Technologists and Information Technology staff.

Each section provides information on different middleware solutions for laboratory workflow and operations. Middleware platforms vary in their capabilities. The main solutions presented in this learning guide are advanced options.

SECTION 1 introduces middleware, its fit in the hierarchy of different information systems that support the management of patient tests, and outlines its capabilities.

SECTION 2 reviews the laboratory test management process and the associated data managed by middleware. Although test management is discussed in all sections, it's important to look at this topic independently to understand middleware's role in this critical task.

SECTION 3 provides an overview of sample management and some of the main middleware solutions available to help laboratories better navigate sample logistics and workflow.

SECTION 4 details a fundamental solution offered by middleware – expert decision rules. Key concepts are defined, approaches to rules, variables to consider and their impact on laboratory workflow are summarized.

SECTION 5 focuses on the role of middleware in quality management, including quality control and moving average monitoring.

SECTION 6 discusses equipment management solutions for automated analyzers, highlighting Laboratory Automation Management systems and their interactions with middleware.

SECTION 7 summarizes some of the analytics and reporting capabilities that can be provided by middleware to help present and make sense of the data processed by laboratories.

At the end of each section, you will find a short quiz to help reinforce and test your knowledge of the information covered in the section.

SECTION 1

MIDDLEWARE

LEARNING OBJECTIVES

After completing this section, you will be able to:

1. Define middleware in the context of the clinical laboratory
2. Identify and understand some of the main functions of middleware
3. Identify the main information systems available to integrate patient test orders and results
4. Understand the communication stream between middleware, Laboratory Information Systems, and automated analyzers

MIDDLEWARE OVERVIEW

WHAT IS MIDDLEWARE?

In the clinical laboratory environment, **Middleware** is defined as software that sits between automated analyzers and the Laboratory Information System (LIS), enabling transmission and integration of test orders and results between these systems.[1] Middleware was initially developed to manage laboratory connectivity by supporting seamless integration and communication between instruments and the LIS. However, more features were added to middleware, and today, middleware can further enhance the capability of analyzers, as well as optimize the performance of the LIS.[2] Advanced middleware solutions have the potential to significantly improve laboratory operations with multidimensional capabilities. Major middleware functions include automated test order management, automatic results validation and reporting, and quality control management that enable laboratories to more easily comply with local and international regulatory requirements. With these capabilities, middleware has quickly become a central information solution in laboratories, transforming the complex information business of the modern clinical laboratories into a scalable, highly efficient and highly productive operation.[3]

MIDDLEWARE AND INTEROPERABILITY

Laboratories often have automated analyzers from multiple vendors. These analyzers usually have unique communication protocols to allow for the exchange of orders and results, which have historically presented interoperability challenges for laboratories as they struggled to integrate these different analyzers and information management systems.

Interoperability is the ability to share data automatically and seamlessly among devices and information systems.[4] Middleware enables a single point of communication with the laboratory's main information system, the Laboratory Information System, supporting centralized management and monitoring of instruments.

MIDDLEWARE AND THE HIERARCHY OF INFORMATION SYSTEMS

A **Laboratory Information System (LIS)** is a computer-based application that helps to manage several aspects of the clinical laboratory, including entry, processing and storing tests orders and results.[5] The LIS organizes all pre-analytical, analytical and post-analytical data associated with the samples processed by the laboratory.

The LIS integrates with other health care information systems, primarily the Hospital Information System (HIS) and the Electronic Medical Record (EMR) system. The LIS consolidates patient test order information from connected HIS and EMR systems, manages the flow of orders to the middleware, and further directs the flow of results received from the middleware out to the HIS and EMR.

A **Hospital Information System** is a computer-based medical record system that organizes inpatient health care records. It is a central repository for patient information from ancillary systems, including the LIS and pharmacy, within a health system.[6] The HIS manages tasks and activities such as order entry for lab tests and medications, as well as operating room and diagnostic imaging schedules. The HIS stores health care records such as lab results, pre- and post-operative reports, nursing observations and reports, as well as prescriptions.

An **Electronic Medical Record System** is a computer-based patient record system that manages patient health records for a single physician office or a multi-disciplinary outpatient clinic that is affiliated with a larger inpatient health system.[6] The EMR maintains patient demographics, diagnostic information from the LIS and medication history.

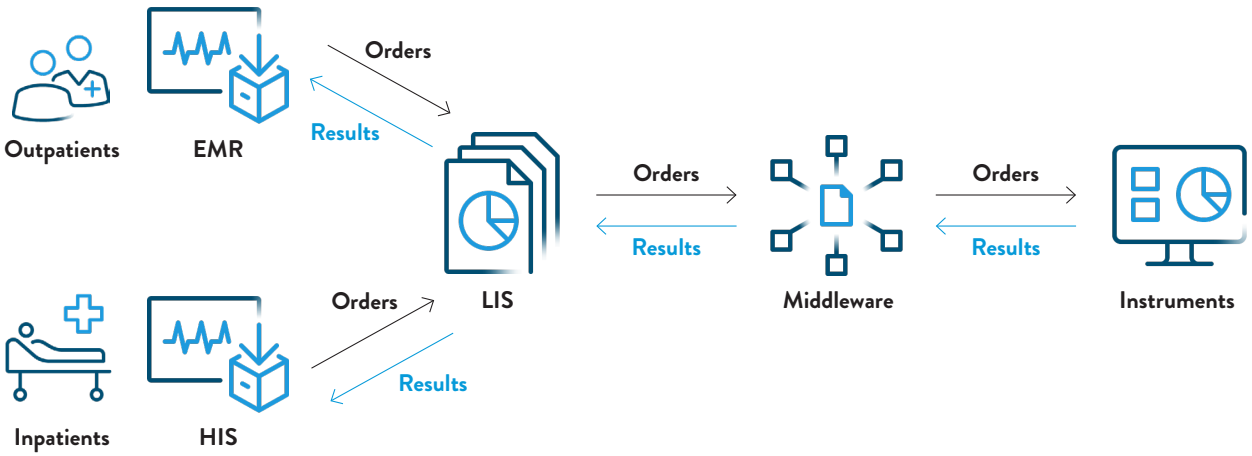

Figure 1.1 Communication diagram showing orders and results flow between middleware, LIS, instruments, EMR and HIS

MIDDLEWARE CAPABILITIES

There are several providers offering a variety of middleware applications; however, they vary in functionality. Some middleware applications offer a wide range of solutions to address the diverse and complex data management and workflow challenges of the core laboratory.[7] Every core laboratory will have different needs and gaps that may be addressed by middleware. There are also instrument vendors that offer middleware solutions. **Abbott's AlinIQ Analyzer Management System (AMS)** offers a middleware solution with open connectivity that enables integration with different analyzers.

Considering the workflow and data management needs of the Hematology laboratory, a middleware solution with a comprehensive set of functionalities, including open connectivity, can help:

- Streamline complex data processing
- Monitor quality control compliance
- Improve staff efficiency with advanced rules set to autovalidate samples
- Autoverification to automate and optimize results release management
- Provide instrument performance analytics
- Improve the management of multi-lab environments

Middleware applications host a variety of capabilities to assist the Hematology laboratory and other disciplines with the management of data, tasks and processes. These capabilities can be categorized into six main groups:

1. **EXPERT DECISION RULES**
   - Automate workflow and data management processes without the need for manual intervention
2. **TEST MANAGEMENT**
   - Automates the analysis of patient test orders and results
3. **SAMPLE MANAGEMENT**
   - Manages sample workflow, logistics and archiving to optimize sample processing
4. **QUALITY MANAGEMENT**
   - Monitors assay and instrument quality performance to help ensure accurate results
5. **ANALYZER AND LABORATORY AUTOMATION SYSTEM MANAGEMENT**
   - Controls the performance of instruments and automation track systems
6. **REPORTS**
   - Track and summarize data from connected analyzers

We will explore these capabilities in the sections to follow.

QUIZ QUESTIONS

1. **Middleware** is defined as software that sits between automated analyzers and the Laboratory Information System, enabling transmission and integration of test orders and results between these systems.

   A. True

   B. False

2. Which of the following health care information system communicates directly with middleware?

   A. Hospital Information System (HIS)

   B. Laboratory Information System (LIS)

   C. Electronic Medical Record (EMR)

3. Match the following:

A. Automates the analysis of patient test orders and results ____	1. Expert Decision Rules
B. Monitors assay and instrument quality performance to help ensure accurate results ____	2. Sample Management
C. Automate workflow and data management processes without the need for manual intervention ____	3. Quality Management
D. Track and summarize data from connected analyzers ____	4. Test Management
E. Controls the performance of instruments and automation track systems ____	5. Reports
F. Manages sample workflow, logistics, and archiving to optimize sample processing ____	6. Analyzer and Automation Management

SECTION 2

TEST MANAGEMENT

LEARNING OBJECTIVES

After completing this section, you will be able to:

1. Describe the basics of test management
2. Recognize major test management middleware capabilities
3. Identify key test management functions essential to Hematology workflow

TEST MANAGEMENT

The primary purpose of the clinical laboratory is to manage the translation of physician test orders into accurate and precise test results. This requires the coordination of staff, automated analyzers, patient specimens, supplies and various procedures needed for the processing of test orders and results.[8] With this coordination comes the generation and exchange of a vast amount of data. Implementation of middleware can help consolidate and manage this data.

Test management is one of the main capabilities of middleware applications. The test management feature coordinates the tasks required to translate test orders to patient results. Extended capabilities include:

- Visual dashboards that display information about patients and specimens
- Test information such as type of test ordered and results
- And lastly, graphs and images relevant to the laboratory

A robust middleware solution can automate pre- and post-analytical manual tasks and processes, which reduces hands-on time with samples, analyzers and software interfaces.[9] Automated test management capabilities for ordering, processing and reviewing patient tests and results include:

- **Order entry and reporting** – enables entry of new patient orders, as a backup to the Laboratory Information System.
- **Test results autoverification** – automates the review and release of test results according to standardized rules.
- **Manual test results review** – provides a centralized workspace for the laboratory staff to review and release patient results.

Advanced test management middleware solutions can provide the laboratory staff with actionable information on patient results. Some benefits include:

- Dynamic worklists with up-to-date information on required activities for pending test orders and results. A **worklist** is a list of open or incomplete orders or results that is pending further action prior to release to the LIS. Worklists can also filter test orders and results by analyzer, test, quality control or by department, such as Hematology, Chemistry, Immunoassay or Serology.
- Alerts to draw attention to data that may impact result quality, such as quality control results.

- Traceability of results using data elements that are not typically captured by the LIS, such as graphs and images; for example, scatterplots and morphology images that are relevant to Hematology.
- Dashboards that provide status monitoring for tests in progress, completed or pending further action.

Middleware can streamline the complexity of Hematology workflow. One of the advanced middleware solutions for the review and release of Hematology results brings all the relevant information to the laboratory staff on one screen, including:

- Specimen and patient information
- Current and previous results allowing comparison between sample runs
- Scatterplot graphs from analyzers
- Cell counter results and manual differential keypad
- Morphology results and comments

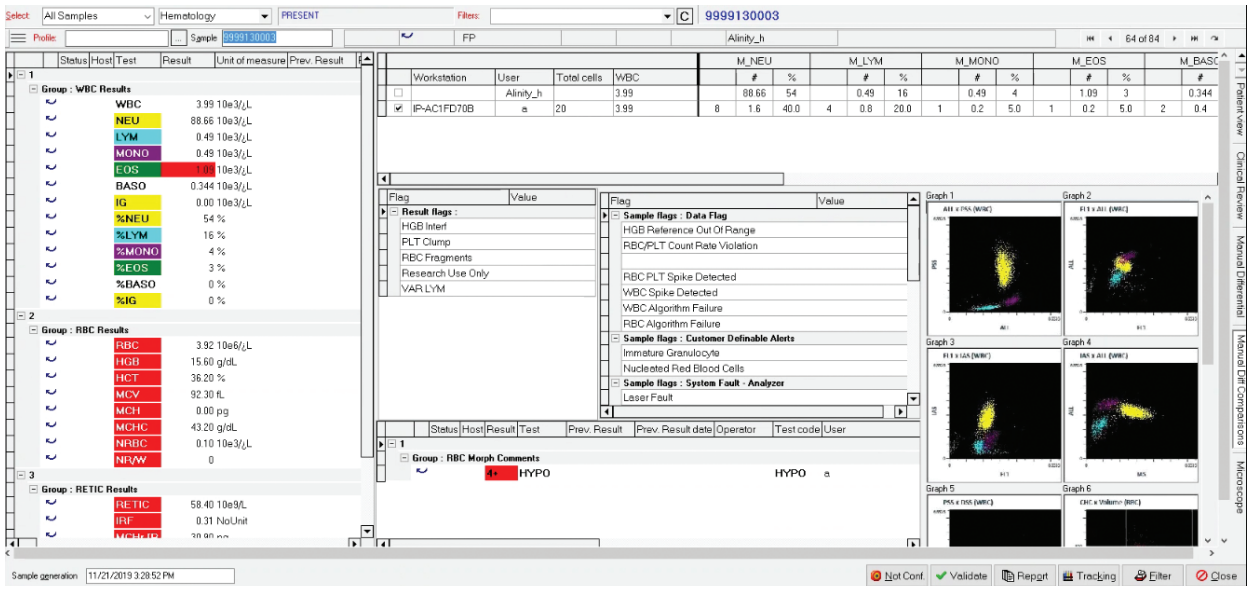

Figure 2.1 Profile View from Abbott's AlinIQ Analyzer Management System (AMS) showing consolidated Hematology results. *For illustrative purposes only.*

While some middleware applications provide a variety of test management options, highly customizable solutions offer flexibility to support the unique needs of the laboratory.[2] A properly utilized middleware solution allows users to customize their own views or workspaces to display relevant information, including specimen and patient information, tests held for manual review or results status for one or multiple analyzers.

QUIZ QUESTIONS

1. The **test management** feature coordinates the tasks required to translate test orders to patient results.

   A. True

   B. False

2. Match the following:

A. Enables entry of new patient orders, as a backup to the Laboratory Information System ____	1.	Autoverification
B. Provides a centralized workspace for the laboratory staff to review and release patient results ____	2.	Order Entry
C. Automates the review and release of test results according to standardized rules ____	3.	Results Review

3. Which of the following information can be included with results for Hematology samples?

   A. Patient demographics

   B. Sample information

   C. Scatterplots from automated Hematology analyzers

   D. Automated differential results

   E. All the above

SECTION 3

SAMPLE MANAGEMENT

LEARNING OBJECTIVES

After completing this section, you will be able to:

1. Define sample management
2. Understand the importance of automated sample management in the clinical laboratory setting
3. Identify the main sample management solutions provided by middleware

SAMPLE MANAGEMENT

Ensuring patient safety through accurate accessioning, coordination and processing of specimens is a priority for clinical laboratories. Laboratory staff operate in a very dynamic and distracting environment. Mistakes can lead to adverse events, such as patient sample mismatch, inaccurate testing and incomplete results. These mistakes can further impact patient care by delaying diagnosis and treatment decisions. Middleware can help reduce the risk of human error by automating the coordination and tracking of patient samples, and improving sample traceability through advanced sample management solutions.

The process of tracking and handling information associated to samples such as patient, specimen and test information, is referred to as **sample management**.[10] Middleware can provide automated and highly customizable end-to-end solutions that allow laboratories to display, track and manage samples or specimens across the health system. A comprehensive sample tracking solution can streamline the entire sample management workflow, including:

1. SAMPLE LOGISTICS

Track samples at a single laboratory location or between sites for health systems that transport samples between sites. Advanced middleware solutions use sensors to monitor sample container temperature during shipment. This can enable laboratories to ensure sample quality and integrity by tracking sample transport times and temperatures between sites.

2. SAMPLE WORKFLOW

Monitors sample movement throughout the entire workflow process and between instruments. This can help the laboratory staff determine where a sample is located and what work remains, which also helps to monitor results turnaround time.

3. SAMPLE STORAGE

Records storage location of samples in refrigerators or cold rooms for future retrieval if needed. Some middleware solutions can provide alerts to the laboratory staff if they are attempting to store a sample that has incomplete tests or additional testing is required.

With advanced middleware solutions, laboratories can streamline the tasks and processes involved in test order and specimen management, reduce the risk of human error and even monitor sample traceability in real time.

QUIZ QUESTIONS

1. **Sample management** is the process of tracking and handling information associated to a sample such as patient, specimen and test information.

   A. True

   B. False

2. What are some of the adverse consequences of mistakes in sample management?

   A. Misidentification of samples

   B. Inaccurate testing

   C. Incomplete testing

   D. Delay in patient treatment

   E. All the above

3. The ability to track the location of a sample is considered a **sample logistics** middleware capability.

   A. True

   B. False

SECTION 4

EXPERT DECISION RULES

LEARNING OBJECTIVES

After completing this section, you will be able to:

1. Define rules
2. Understand the anatomy of rules
3. Understand the main types of rules used in the Hematology laboratory
4. Understand the key benefits of implementing middleware decision rules in the Hematology laboratory

EXPERT DECISION RULES

The Expert Decision Rules function is one of the most popular capabilities and benefits of middleware. They help automate the manual tasks and processes in the laboratory environment, enabling greater efficiency, productivity and error reduction along the testing continuum.

Rules are logic statements that define a set of conditions. These logic statements use **IF, THEN** and **ELSE** to define conditions. Rules take the form: IF some condition is true, THEN perform a certain action, or ELSE perform a different action. The IF, THEN and ELSE statements make up a rule.

- The *IF* portion of the rule defines a condition or series of conditions to determine if the follow up actions (in the THEN or ELSE portion) should be taken.
- The *THEN* portion defines an action or series of actions to be taken if the IF condition(s)is true.
- The *ELSE* portion defines an action or series of actions to be taken if the IF condition(s) is false.

Rules can be applied to different data elements and processes in the sample testing process, such as orders, results, and specimen processing status (e.g., specimen received).

The expert rules found in middleware essentially emulate advice that the Technologist would provide, enabling automation of manual tasks and processes associated with the laboratory workflow. In the Hematology laboratory environment, these processes include managing CBC and differential test results, from reviewing results to determine if they can be released to the LIS or further action is needed, to reviewing results against established laboratory guidelines to determine if it's clinically necessary to perform a slide review or manual differential.

Perhaps the most common uses of rules in middleware is for autoverification and autovalidation. **Autoverification** is the process where test results are automatically reviewed and released to the LIS or held for manual review based on a predetermined set of rules established by the laboratory. Autoverification eliminates the need for human intervention.[11] As results are filed into the middleware from the analyzer, they are automatically reviewed against predefined conditions (rules), and either automatically released to the LIS or held for manual review by the Technologists if there are exceptions.

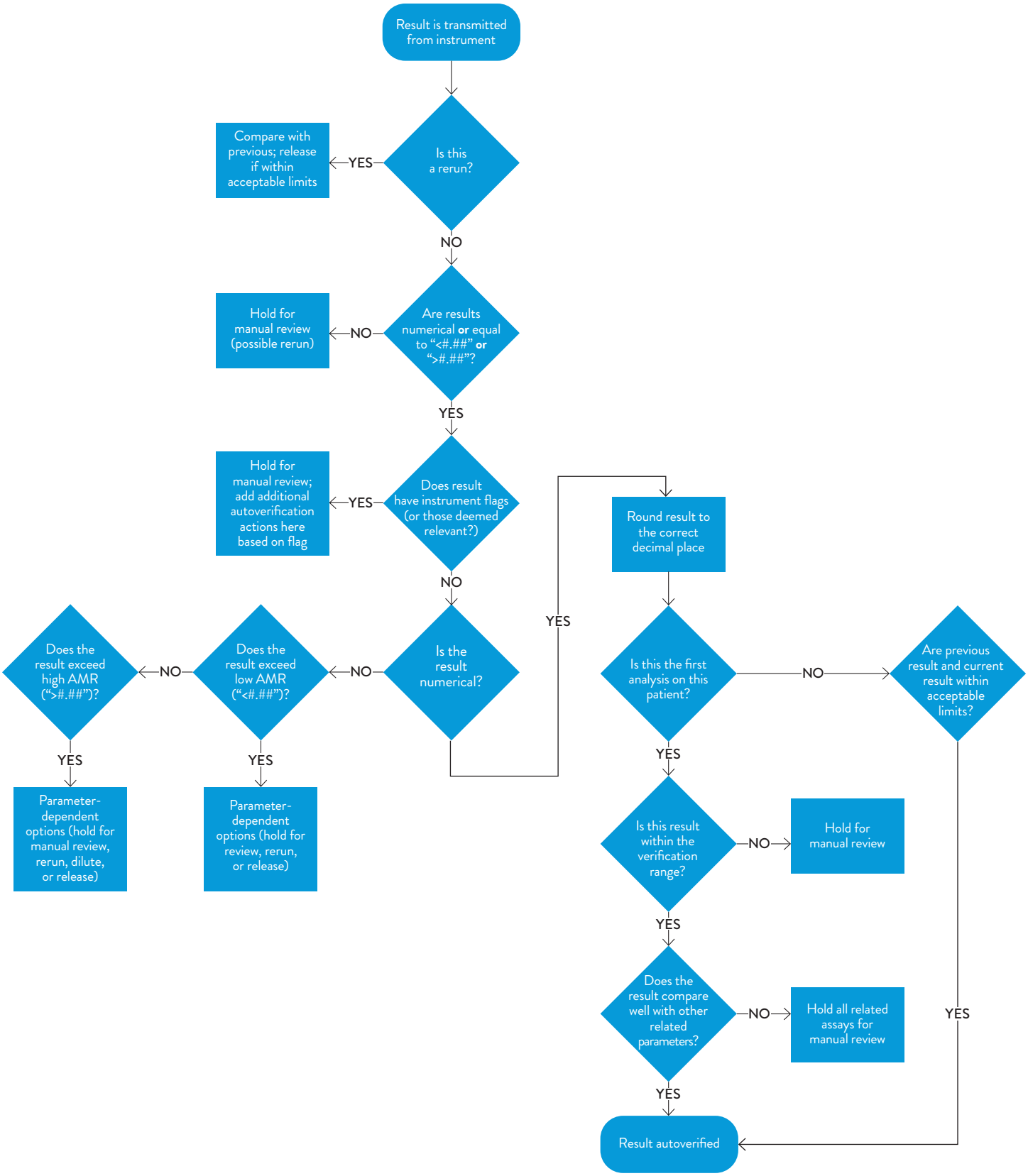

Figure 4.1 An example of a sequential set of autoverification rules for Hematology results release.[11] Although multiple results are transmitted from the instrument as part of the CBC results for each sample, middleware evaluates each result independently as shown here. Advanced middleware decision rules can manage this evaluation and complex combination of steps.

Autoverification of test results in middleware are evaluated against several different parameters.

- **Patient demographic information** – factors in associated patient demographics (e.g., age and gender) when analyzing results to determine whether to auto release results, hold for manual review, rerun or conduct additional testing.
- **Critical values** – ensure test results are not automatically released when clinical validity may be suspect.
- **Delta checks** – compares current results for a given test against previous results that exist for the same patient to determine if, based on established laboratory standards, the difference is acceptable for release to the LIS.
- **Quality control** – blocks the automatic release of results if quality control issues are identified.
- **Instrument flags/exceptions** – prevent the automatic release of results when an associated instrument flag or exception is detected.

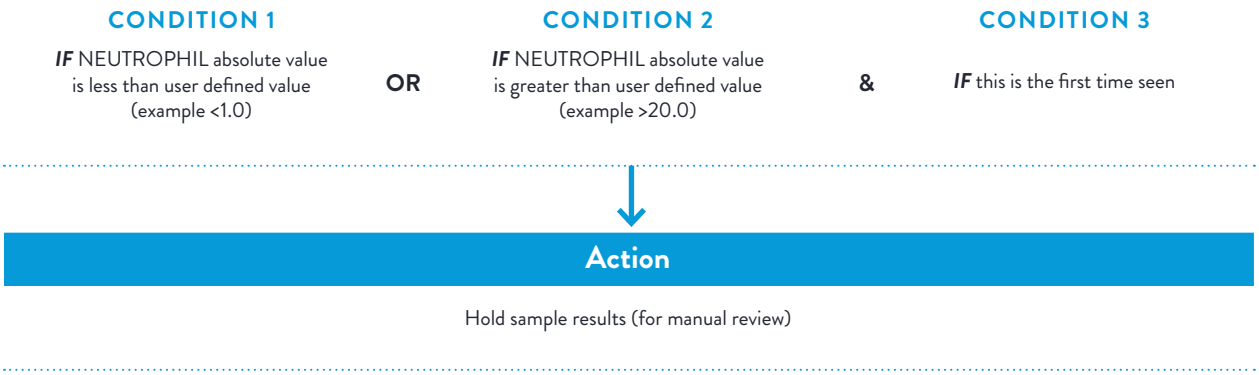

Figure 4.2 Example of an autoverification rule. There are 3 conditions within this rule. Condition 1 and condition 2 are evaluated first; these conditions look at the absolute value for the Neutrophil result and whether the result is less than 1 or greater than 20. If condition 1 or condition 2 is true, then condition 3 is evaluated to determine if this is the first occurrence of the Neutrophil result for the patient. The rule will perform both action (hold sample results) if condition 1 OR condition 2 is TRUE, and condition 3 is TRUE.

Autovalidation is the process whereby sample results are validated automatically based on a predetermined set of conditions. These conditions may be established by a combination of laboratory standard operating procedures, instrument vendor recommendations and/or published guidelines, such as the 41 Consensus Rules developed by the International Society for Laboratory Hematology (ISLH).[12] These rules automatically review and validate CBC and differential results to take actions that might include:

- Ordering a rerun
- Reflexing to a slide review
- Adding comments to notify the laboratory and/or clinical staff

Although middleware platforms offer different criteria that trigger actions to review CBC and differential results from automated Hematology analyzers, one of the most widely used standards is the ISLH Consensus Guidelines. Recognizing that there was little uniformity among laboratories on what prompted the review of CBC and differential results, Dr. Berend Houwen invited 20 Hematology experts to determine criteria and develop rules in 2002. These rules were tested on over 13,000 blood samples in 15 laboratories. Following testing, the data was thoroughly analyzed, leading to further refinement of the rules to a final set of 41 rules.[13] The guidelines include rules for CBC numeric results, differential numerical results and morphological flags. The 41 ISLH Consensus Rules and modified versions are widely used in Hematology laboratories worldwide.

Middleware platforms with sophisticated rules-based solutions, offer the ISLH Consensus Rules as a predefined rules package for Hematology laboratories. This rules package is typically preloaded with the 41 Consensus Rules and are often configurable so that laboratories may customize parameters and values to meet their operating procedures and patient population needs. Some of the criteria evaluated in the rules set include:

- Analytical measurement ranges
- First time events
- Patient age
- Sample age
- Various instrument and morphological flags
- Delta checks

Based on these criteria, the middleware can trigger a variety of actions:

- Slide review
- Rerun
- Hold results for manual review
- Block partial or full results (e.g., block percentage and/or absolute differential results)
- Add comments

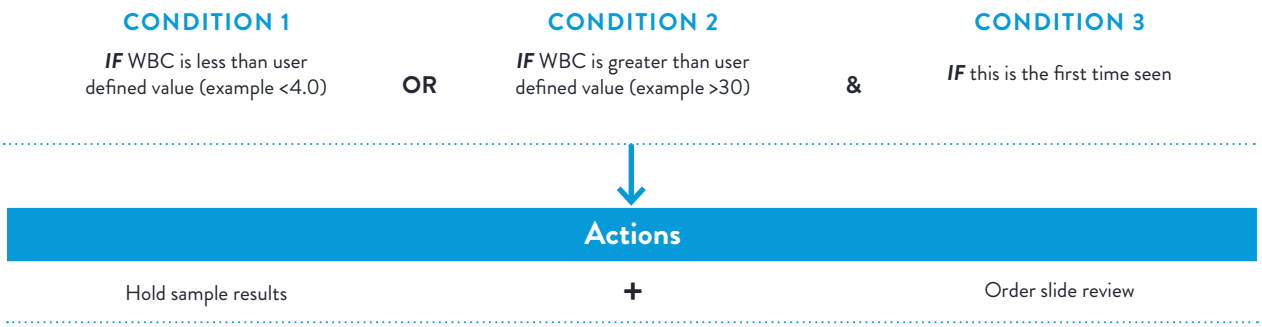

Figure 4.3 Example of an autovalidation rule. There are 3 conditions within this rule. Condition 1 and condition 2 are evaluated first; these conditions look at the value for the WBC result and whether the result is less than 4 or greater than 30. If condition 1 or condition 2 is true, then condition 3 is evaluated to determine if this is the first occurrence of the WBC result for the patient. The rule will perform both actions (hold sample results and order slide review) if condition 1 OR condition 2 is TRUE, and condition 3 is TRUE

KEY BENEFITS OF IMPLEMENTING MIDDLEWARE RULES IN THE HEMATOLOGY LABORATORY

Implementing Expert Decision Rules provided by advanced middleware solutions can automate complex, manual processes and improve the efficiency of Hematology laboratories. Some of the key benefits to the CBC results review process include:

1. Automation of the results review process can significantly improve results turnaround time.
2. Elimination of the review of routine, manual results can improve productivity by allowing the laboratory staff to focus on actual sample exceptions.
3. Minimize tech-to-tech variation during results review through standardization.

Advanced rules solutions are typically customizable and can be adapted and revised as the workflow of the laboratory evolves.

QUIZ QUESTIONS

1. **Rule**s are logic statements that take the form: IF some condition is TRUE, THEN perform a certain ACTION

   A. True

   B. False

2. Match the following:

a. The portion of a rule that defines a condition or series of conditions to determine if the follow up actions (in the THEN or ELSE portion) should be taken ____	1. THEN
b. The portion of a rule that defines an action or series of actions to be taken if the IF condition(s) is true ____	2. IF
c. The portion of a rule that defines an action or series of actions to be taken if the IF condition(s) is false ____	3. ELSE

3. **Autoverification** is the process where test results are automatically released to the LIS or held for manual review, without the need for human intervention, based on a predetermined set of rules established by the laboratory.

   A. True

   B. False

4. **Autovalidation** is the process where sample results are automatically validated based on a predetermined set of conditions. These conditions may be established by a combination of laboratory standard operating procedures, instrument vendor recommendations and/or published guidelines, and direct actions that may include rerunning a sample or reflexing to a slide review.

   A. True

   B. False

5. From the list below, please select some of the key benefits of implementing rules in the Hematology laboratory.

   A. Improves staff productivity

   B. Standardizes results review

   C. Accelerates turnaround time

   D. Enhances workflow flexibility

   E. All the above

SECTION 5

QUALITY MANAGEMENT

LEARNING OBJECTIVES

After completing this section, you will be able to:

1. Define quality control
2. Define moving averages
3. Understand the utilization of automated quality management solutions provided by middleware
4. Recognize some of the benefits of quality management middleware functions

QUALITY MANAGEMENT

International regulatory organizations that govern clinical laboratory accreditation require laboratories to maintain quality management programs.[14] These programs, which ensure that quality and safety standards are upheld, are carefully managed and kept up-to-date to monitor the performance of integrated processes, procedures, test data and automated analyzers in the laboratory. Middleware can help laboratories with their quality management programs through the automation and integration of the following functions:

- Quality Control Results
- Moving Averages
- Integration with Quality Control Software
- Quality Assurance

Quality control (QC) helps ensure that the desired level of integrity, precision and accuracy is achieved in patient test results.[14] Middleware can enable the integration of QC data from connected analyzers, allowing for centralized management. Automated QC solutions provided by middleware are designed to compensate for deficiencies in a laboratory's quality control process and reduce associated risk. For example, they can consolidate monitoring of QC data and automatically change the analytical workflow to prevent the automatic release of results and block new testing, in the event of a QC rule failure.

Some of the QC capabilities provided by middleware include:

- Centralized QC review for all connected instruments
- QC result comparison across different analyzers
- Westgard, RiliBÄK and user-configurable QC rules
- Graphical display of QC results to illustrate precision, accuracy and comparison (e.g. Levey-Jennings and Youdon plots)
- Utilize rules to automatically verify or invalidate test results based on QC results

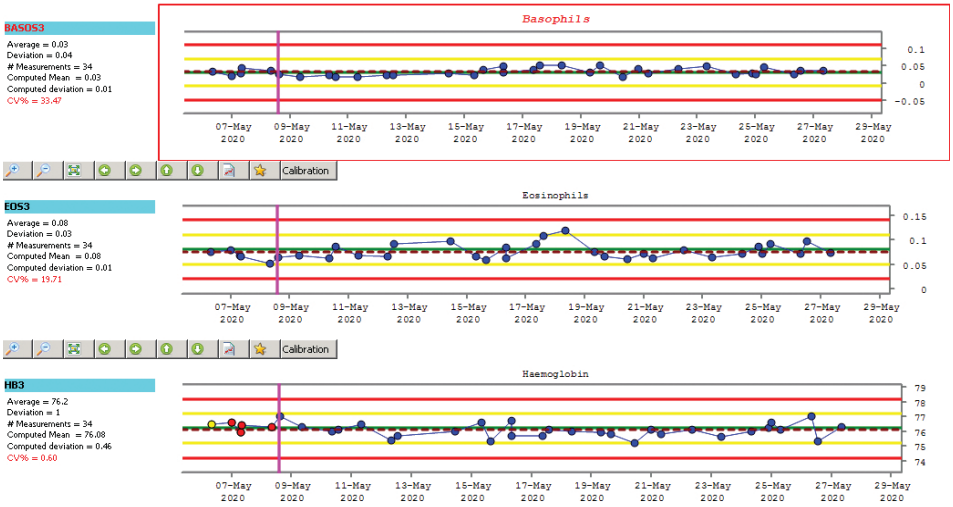

Figure 5.1 Levey Jennings graph from Abbott's AlinIQ Analyzer Management System (AMS). *For illustrative purposes only.*

PATIENT MOVING AVERAGES

An additional layer of QC management that can be assessed and managed by middleware, is the moving average, which is also known as average of normals or running average. **Moving averages** is a statistical concept that uses patient results to monitor a set of data points on a continuous basis. By doing so, unexpected shifts in analyzer or assay performance may be detected.[14] The typical process of assessing moving averages uses a large series of numbers that are divided into overlapping subsets, with each subset containing the same number of data points. These subsets provide the data sets for calculation of the moving average. Middleware utilizes the data received from connected analyzers to monitor performance in real-time with trends presented visually on a graph. Using the graph, laboratories can proactively identify trends and detect changes in analyzer performance.

The moving averages function in some middleware solutions has the potential to offer a robust approach to a laboratory's QC program. In the typical setup of a middleware application, the user establishes different protocols for test runs for a defined analyzer and then configures target means. Target means are used as the baseline to create alerts. The flow of analyzer data into middleware allows for continuous monitoring of moving averages trends and alerts, as well as comparison of CBC results from multiple Hematology analyzers. These capabilities enable real-time monitoring of patient results and support the laboratory with achieving its desired level of sample testing quality.

Middleware solutions designed with moving average capabilities enable the laboratory to more seamlessly assess when the analyzers are performing correctly. The following are some of the benefits of middleware to optimize laboratories' quality management program.

- Provide alerts to operators when unexpected performance shifts occur
- Enable preemptive intervention between periodic QC testing
- Automatically disable an analyzer or assay generating QC errors
- Provide notifications based on predetermined errors and warnings

The QC program in the core laboratory requires a comprehensive management of not just the analytic process of testing materials with a known value. A solid QC program also requires a broader view that encompasses every task associated to testing, from test requisition to the final report.[15] A comprehensive and properly utilized middleware solution can help streamline these complex processes over the entire testing process.

QUIZ QUESTIONS

1. **Middleware** can consolidate monitoring of QC test data from multiple instruments.

   A. True

   B. False

2. Which of the following are benefits of using middleware for **QC management**?

   A. Provide alerts to operators when unexpected performance shifts occur

   B. Enable preemptive intervention between periodic QC testing

   C. Automatically disable an analyzer or assay generating QC errors

   D. Provide notifications based on predetermined error and warnings

   E. All the above

SECTION 6

ANALYZER AND LABORATORY AUTOMATION SYSTEM MANAGEMENT

LEARNING OBJECTIVES

After completing this section, you will be able to:

1. Define and identify the components of a Laboratory Automation System
2. Describe how middleware integrates and communicates with Laboratory Automation Systems
3. Gain an understanding of the capabilities of middleware in managing automated analyzers and Laboratory Automation Systems
4. Recognize the benefits of Laboratory Automation Systems

ANALYZER AND LABORATORY AUTOMATION SYSTEM MANAGEMENT

Automation is a critical part of the Core Laboratory's operations. Given the various operational challenges facing the laboratory, the productivity gains that automation offers through speed and efficiency are in high demand. Holistic middleware applications can help manage analyzers and laboratory automation track systems, automating tasks and processes.[16]

Middleware with robust **analyzer management** capabilities enables the laboratory to manage and monitor performance of analyzer systems from a central location. For example:

- Provides readiness status and lists current work in progress of connected analyzers.
- Provides insights into connected analyzers enabling access to actionable information for real-time management of performance.
- Enables remote access to analyzers to allow for the enabling or disabling of specific analyzers.
- Schedules maintenance tasks for laboratory equipment such as calibration, preventative maintenance or other user-defined events per the laboratory's or equipment manufacturer's standard operating procedures.

In addition to providing a wide range of analyzer management capabilities, some middleware providers offer more comprehensive solutions that can integrate and manage Laboratory Automation Systems (LAS) or automation track systems. A **Laboratory Automation System** is designed to automate pre-analytical and post-analytical processing and sample handling, consolidating multiple analyzers and sample processing equipment into a unified system in the clinical laboratory.[16] LAS offer productivity gains through flexibility and efficiency in sample management that can help laboratories adapt to changing demands in sample throughput.

The implementation of a LAS with a robust middleware solution can help laboratories achieve their operational productivity goals. Considering the total testing process, an efficient automation system offers increased testing capacity, improved turnaround time and reduction in human error.[17]

Integration of a LAS, middleware and automated Hematology analyzers can help the laboratory realize significant cost savings while enabling the staff to focus on the true exceptions and more complex tasks that will ultimately improve the quality of patient care and lead to faster, more actionable results.

Through central equipment management, middleware can help laboratory staff monitor and control operations of their LAS. Some of the automation system monitoring capabilities provided by middleware solutions may include:

- Visual indications to monitor the status of all automation modules, analyzers and assays.
- Proper routing of samples to the correct automation modules and analyzers, and the ability to perform automated reruns, reflex and dilution testing.
- Ability to automatically enable or disable analyzers or assays.
- Provision of detailed information to the operator on sample exceptions and contents of output racks.

In addition to managing the processing of orders and returning results received from the connected instruments through the LIS, the middleware controls the routing of tubes or samples to the various modules of the LAS. The sample routing capability provides instructions to the LAS to determine the path a sample must follow as it travels around the track. The routing of samples on a LAS track is managed by rules defined in the middleware. Typically, a laboratory provides inputs to a middleware Informatics Specialist to define routing rules consistent with the laboratory's needs. The middleware can also handle load balancing to ensure sample processing and testing are managed efficiently at the different modules on the track, including the connected analyzers. A comprehensive LAS may include the following sample processing modules in addition to the connected analytical instruments:

- **Input Output Module** – provides a loading and unloading point for samples using racks
- **Centrifuge Module** – automates centrifugation of samples
- **Decapper Module** – removes tube caps
- **Sealer Module** – seals tubes after analytical processing
- **Storage and Retrieval Module** – stores sample tubes in a temperature-controlled, protected environment
- **Desealer Module** – removes the seal from sample tubes
- **Track Module** – controls the movement of sample tubes in their individual sample carriers; sample carriers transport tubes around the track to the different modules
- **Interface to connected analytical instruments** – provides the path to move the tubes to the analyzer
- **Aliquoter Module** – generates secondary tubes from primary sample tubes

The typical steps in the management of orders and results between the middleware and the Laboratory Automation System include:

1. The LIS sends the order to the middleware.
2. The middleware sends the order to the LAS.
3. The LAS routes the tube to the appropriate analyzer.
4. The analyzer runs the test and sends the test to the middleware.
   Note: If sample requires rerun, dilution or reflex, the middleware processes the appropriate order messages for the analyzer.
5. The middleware sends the results to the LIS.

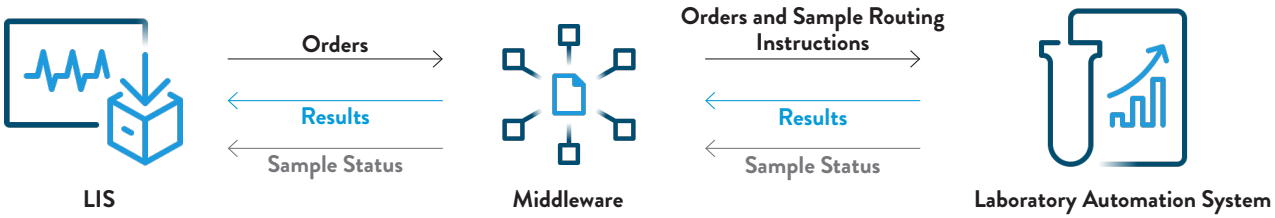

Figure 6.1 Communication diagram showing orders and results flow between middleware and the Laboratory Automation System

QUIZ QUESTIONS

1. Which of the following statements are true? Middleware can:

   A. Monitor the performance of connected analyzers

   B. Schedule maintenance tasks for connected analyzers

   C. Manage orders and results between the LIS and LAS

   D. All the above

2. Where does an analyzer that is connected to a LAS sends test results?

   A. To the LIS

   B. To the middleware

   C. To the EMR

   D. To the HIS

3. **Middleware** provides routing information to the LAS to determine where to send sample tubes on the track.

   A. True

   B. False

SECTION 7

REPORTS AND ANALYTICS

LEARNING OBJECTIVES

After completing this section, you will be able to:

1. Distinguish between different types of middleware reports
2. Understand the value of available management reports
3. Recognize some of the key metrics that laboratories use to track performance

REPORTS AND ANALYTICS

Laboratory managers demand timely metrics to track laboratory performance and quality.[18] A middleware solution addresses this critical need by consolidating test data and providing real-time statistical reports that help laboratories track, understand and manage their performance. Additionally, middleware can present insights regarding the business performance of the laboratory in easy to read and understand reports.

During the processing of one patient sample, hundreds of data points may be generated. This information is used to not only direct patient care decisions, but also to monitor the laboratory's performance against internal and external benchmarks. Hematology laboratories, for example, generate a tremendous volume of test results data from automated analyzers, including CBCs. Unique aspects of Hematology are the CBC scatterplots as well as morphological images from slide review which are linked to each patient sample. There are multiple reporting and analytics functionality that can help the laboratories track and visualize these data.

The different reports and statistics offered by middleware can be extensive. The following is a list of some of the popular management reports provided by middleware.

- **Turnaround time (TAT) analysis** – tracks the time it takes for the lab to process a patient test request from sample receipt in the laboratory to results reported to the clinical staff. The timeliness of laboratories to report final test results is expressed as the turnaround time, and often used as a key effectiveness metric to measure laboratory performance.

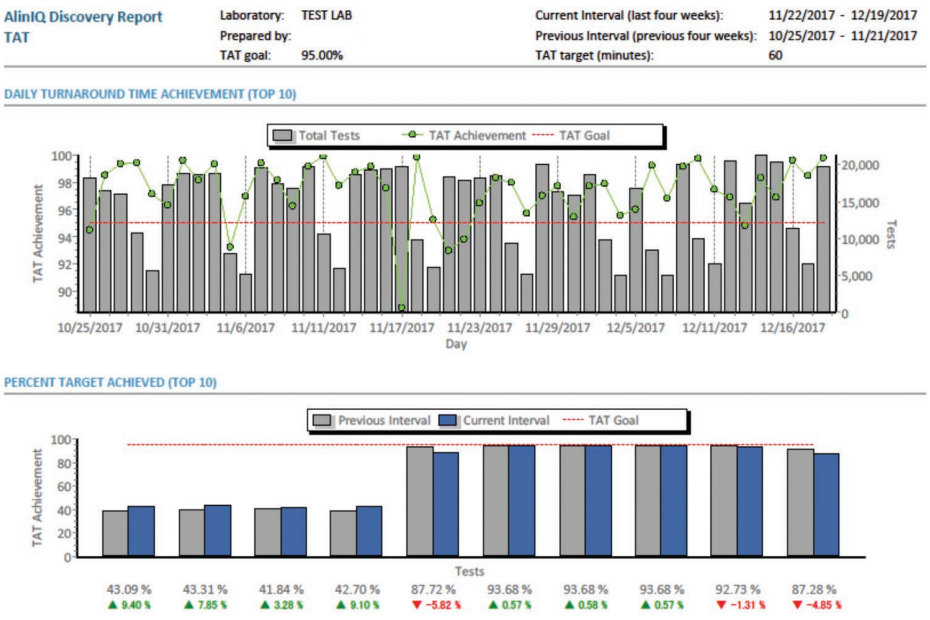

Figure 7.1 Turnaround time (TAT) report from Abbott's AlinIQ Analyzer Management System (AMS). *For illustrative purposes only.*

- **Workload volume** – counts workload trends by patients, samples and tests over a time period (hourly, daily, weekly, monthly).

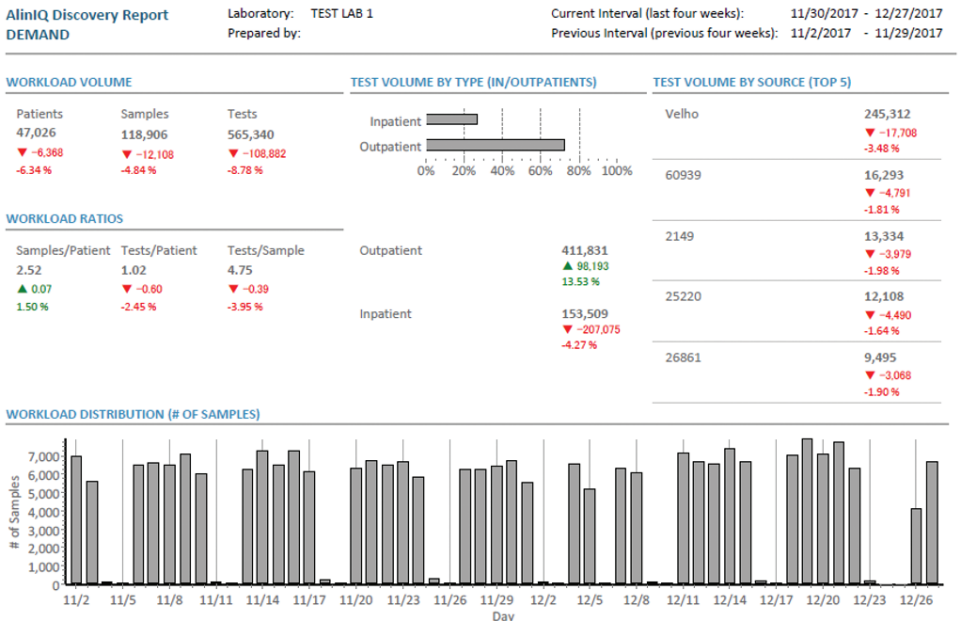

Figure 7.2 Workload report from Abbott's AlinIQ Analyzer Management System (AMS). *For illustrative purposes only.*

- **Analyzer utilization** – tracks volumes, shifts and trends in test runs and analyzer performance.

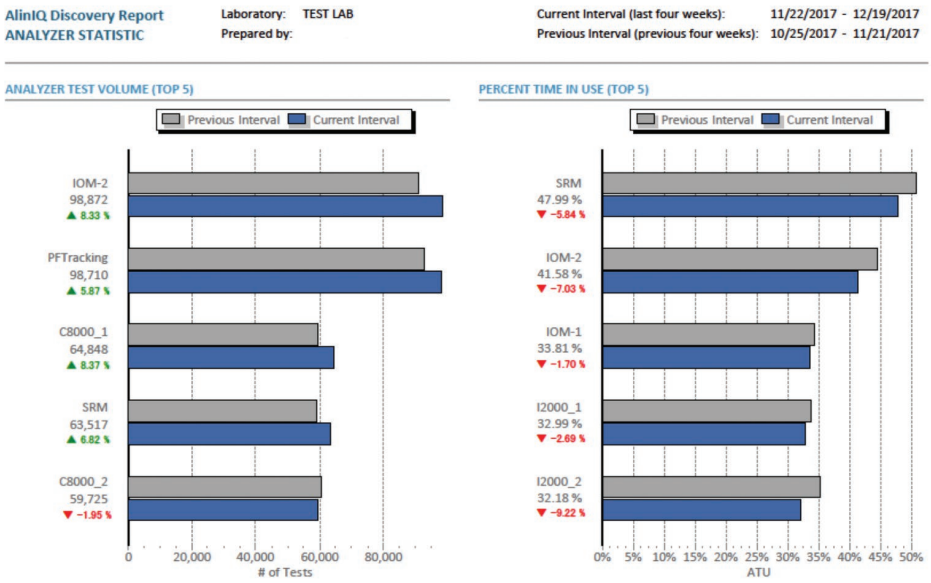

Figure 7.3 Analyzer utilization report from Abbott's AlinIQ Analyzer Management System (AMS). *For illustrative purposes only.*

With these metrics readily available, laboratories can more easily derive actionable insights from their test results and associated activities to achieve their efficiency and performance goals.[18] The automated analytics and reports provided by middleware offer essential tools to monitor and improve quality assurance processes. By tracking, monitoring, verifying and improving the standard of performance of all the different processes in sample testing operations, errors can be reduced, which can invariably lead to improved staff, test and analyzer utilization.

QUIZ QUESTIONS

1. The metrics provided by middleware reports can help laboratories better monitor performance.

   A. True

   B. False

2. Middleware can provide reports on the following:

   A. Test result turnaround time (TAT)

   B. Volume of tests performed on a connected analyzer

   C. Total number of tests performed per patient

   D. Total number of runs for a specific test for the day

   E. All the above

APPENDIX AND REFERENCES

APPENDIX: QUIZ ANSWERS

SECTION 1 MIDDLEWARE

1. A
2. B
3. A -> 4; B -> 3; C -> 1; D -> 5; E -> 6; F -> 2

SECTION 2 TEST MANAGEMENT

1. A
2. A -> 2; B -> 3; C -> 1
3. E

SECTION 3 SAMPLE MANAGEMENT

1. A
2. E
3. A

SECTION 4 EXPERT DECISION RULES

1. A
2. A -> 2; B -> 1; C -> 3
3. A
4. A
5. E

SECTION 5 QUALITY MANAGEMENT

1. A
2. E

SECTION 6 ANALYZER AND LABORATORY AUTOMATION SYSTEM MANAGEMENT

1. D
2. B
3. A

SECTION 7 REPORTS AND ANALYTICS

1. A
2. E

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