

VistA Laboratory Enhancements (VLE) Project: Autoverification Initiative

VistA Auto Release Capability

Requirements Specification Document



Department of Veterans Affairs

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1. Introduction

The Vista Evolution Laboratory Enhancement of AutoVerification incorporates Decision Support Algorithms or rule sets to automatically review laboratory results and directly post “normal” results to the patient’s chart. Results that are deemed “abnormal” by the rule set will be reviewed by laboratory personnel before being manually released into the patients electronic health record (EHR). AutoVerification will address staffing deficiencies, increase patient safety, decrease manual workload, decrease result turnaround times and reduce costs by automating the result review and charting process.

1.1. Purpose

The purpose of this Requirements Specification Document (RSD) is to convey the analysis and requirements associated to the delivery of enhancements to the Veterans Health Information Systems and Technology Architecture (VistA) Laboratory AutoVerification, VistA Auto Release Capabilities. This is a subset of capabilities of the full Autoverification initiative and focus on the changes needed to VistA Legacy Laboratory System.

Currently, all laboratory test results, both normal and abnormal, are required to be manually reviewed and approved by lab technologists before release. Since the vast majority of lab test results fall in the “normal” range, this translates into a much larger workload for the technologists. By automating verification of normal test results, technologists will have more time to devote to analysis of abnormal test results. The Laboratory AutoVerification process involves automatic review of test results on a lab-established set of boundaries, also referred to throughout this document as rules, rule sets and decision support algorithms. This process will eliminate the need for a qualified technologist to manually approve all “normal” results before they are sent to the patients’ electronic health record (EHR) for clinicians to view.

The intended audience for the RSD includes, but is not limited to, the VistA Lab Working Group members that includes; Project Managers, Analysts, Developers, Testers, Technical writers, and the Business users and consumers of the data.

1.2. Background

Veterans Health Administration (VHA) sponsored an Employee Innovation Challenge in 2013. VA employees were invited to identify the most important challenges that, if solved, would meaningfully increase quality, improve access, increase Veteran satisfaction, and lower costs of meeting the needs of Veterans, their dependents, and caregivers. The Laboratory Auto-Verification presentation was carefully reviewed and chosen due to its compelling potential to improve the accessibility, quality and overall effectiveness of VA as it seeks to deliver the highest quality services to our nation's Veterans.

A pilot solution was developed specifically for the Kansas City Veterans Affairs Medical

Center (KC VAMC). KC VAMC configured the Instrument Manager System to introduce Decision Support Algorithms or rule sets to provide auto-verification within its Clinical Chemistry department. The Instrument Manager System is licensed to VAMC under a separate license agreement. The Pilot included the design and implementation of chemistry rule sets and introduced these rule sets into the production Data Innovations Instrument Manager system currently in use at KC VAMC. Consultation was also acquired for BioRad Unity Real-Time Quality Control (QC) Integration, Moving Averages, eCAP Solutions, and Lab Intelligence Reports Manager software logic for three environments (Production, Shadow and Test).

This model of autoverification uses a middleware system that passes lab results, coming from the lab instruments, through a rule set that determines if the results fall in a “normal” or “abnormal” range. If the lab result passes the rule set, it is given a special character in the Observation Request (OBR) segment that is inserted in an HL7 message and sent directly to the VistA Lab global. If a lab result cannot pass the rule set, it is held in the middleware system for review by a lab technologist. Once the technologist deems the result appropriate for release, it is released from the middleware system and goes to VistA Lab global with the special character in the OBR segment of an HL7 message. The Kansas City Class III MUMPS code recognizes this special character and automatically processes these results out of the global for availability in VistA and the Computerized Patient Record System (CPRS).

Lab instruments can be set up as either available for autoverification or not available for autoverification. Those that are available for autoverification will have the review process done in the middleware. Those instruments not available for autoverification will have the lab results pass from the lab instrument through the lab middleware to the Vista global. The lab technologist must review each lab result using current Vista menus (EA and EM)

1.3. Scope

The scope for this VistA Laboratory Auto Release enhancement includes:

- Receiving an indication of when a test has been successfully autoverified within the middleware (DI)
- Processing test results, with an indicator of successful autoverification, to Auto Release, making results available to appropriate clinicians and providers with privileges to view the results
- Receiving an indication of when a test has been successfully verified by an authorized technologist.
 - This is only for Tests that fail the autoverify rule on DI, and tech with a VistA DUZ/record will manually verify on DI and then the result will include the techs id with the results.
 - Any results performed on a designated Autoverification instrument will be verified by rules set on DI or manually by a lab technician.
 - Delta checks, critical values, instrument flags, specimen specific conditions, etc. functionality currently within VistA will be maintained, even with Autoverified results.

- DI will always have only a subset of result data available
- Reference Ranges will be maintained both in VistA and in the DI middleware
- Processing test results, with an indicator of successful verification by an authorized technologist, to Auto Release, making results available to appropriate clinicians and providers with privileges to view the results
- Sending ordering provider contact information to the instrument middleware for the purpose of making it accessible to authorized technologists who are responsible for verifying test results, contacting caregivers
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1.4. Assumptions

There will be no changes to Corrected Results, handled in VistA lab as per SOP.

1.5. References

- VistA Evolution Program Charter <http://go.va.gov/uq6t>
- VA Handbook 6500 – Information Security Program
http://vaww1.va.gov/vapubs/viewPublication.asp?Pub_ID=638&FType=2
- VLE Laboratory Autoverification Enhancements Requirements Specification Document 2 March 2015
- Vista Evolution Program Plan <http://go.va.gov/wgs5>
- VE Lab AutoVerification Business Requirements Document (BRD) and Requirements Traceability Matrix (RTM):
http://vista.med.va.gov/nsrd/Tab_LinksView.asp?RequestID=20131009
- VistA Laboratory Packages: <http://vista.med.va.gov/>
- CPRS GUI:
[http://www.va.gov/vdl/documents/Clinical/Comp_Patient_Recrd_Sys_\(CPRS\)/cprsguium.pdf](http://www.va.gov/vdl/documents/Clinical/Comp_Patient_Recrd_Sys_(CPRS)/cprsguium.pdf)
- CPRS Technical Manual:
[http://www.va.gov/vdl/documents/Clinical/Comp_Patient_Recrd_Sys_\(CPRS\)/cprsguitm.pdf](http://www.va.gov/vdl/documents/Clinical/Comp_Patient_Recrd_Sys_(CPRS)/cprsguitm.pdf)
- Dawning Instrument Guide: http://www.va.gov/vdl/documents/Clinical/Lab-Universal_Interface/dawning.pdf
- Data Innovations Instrument Guide:
http://www.va.gov/vdl/documents/Clinical/Lab-Universal_Interface/datain.pdf

2. Overall Description

2.1. Accessibility Specifications

The product will comply to 508 specifications.

2.2. Business Rules Specification

The BRD lists all business requirements for this enhancement

2.3. Design Constraints Specification

Design constraints will be documented in the System Design Document (SDD).

2.4. Disaster Recovery Specification

The Laboratory module is part of VistA and will be covered under the current VistA Disaster Recovery Plan.

2.5. Documentation Specifications

- Applicable guides and manuals, required to comply with the VA and Product Development (PD) documentation standards and/or ProPath requirements, will be provided.
- Updates will be made, as necessary, to applicable user manuals and other training tools and will be delivered to all levels of users. If no user documentation exists, it will be produced.
- A Requirements Traceability Matrix (RTM) will track requirements traceability.
- An implementation plan will be developed for the national deployment of LabAutoVerification and one for the VistA Auto Release Capability.
- Training documentation associated with the training curriculum (if deemed necessary) must be developed for Lab AutoVerification. We will update applicable user guides for the VistA Auto Release Capability.
- This Requirements Specification Document (RSD) documents the functional and non-functional requirements.
- The System Design Document (SDD) will document the design constraints related to functional requirements.

2.6. Functional Specifications

Below is a list of functional specifications required to enhance VistA Legacy Laboratory with the capability to Auto Release results that are Autoverified by an external system.

443954 - The system shall automate the verification of normal lab test results to post to the Veterans Health Information Systems Technology Architecture (VistA) Lab and the Computerized Patient Record System (CPRS), providing an efficient quality of service to clinical providers in a timely manner.

- 443954_1 – The VistA Laboratory system shall receive an indicator, with the result from the autoverification system, when a test has been successfully autoverified.

- User Story: As a technologist, I want to know which results in VistA have been verified by the autoverification system, so that I can ensure compliance with all accreditation standards and best practices.
- Acceptance Criteria:
 - Results received from autoverification system contain an indication that the result is 'AutoVerified'.
 - VistA stores the indicator received from the autoverification system with the result.
 - VistA stores the original message transmission for a period of time, as per current VistA capabilities, for troubleshooting purposes.
- 443954_2 – The VistA Laboratory system shall process test results received from the autoverification system, with an indicator of successful autoverified, to Auto Release, making results available to appropriate clinicians and providers with privileges to view the results in both CPRS and VistA Laboratory systems.
 - User Story: As a technologist, I want autoverified results sent to VistA laboratory system to automatically release, so that clinicians treating the patients can have immediate access to the result.
 - Acceptance Criteria:
 - Results received from autoverification system, that are identified as 'AutoVerified' will be automatically released and visible to the clinicians authorized to view the results (as per current VistA/CPRS capabilities) for the patient.
 - Clinicians with appropriate authorization, will immediately be able to view the patients autoverified results via CPRS.
- 443954_3 – The VistA Laboratory system shall receive an indicator and a unique user identifier, with the results from the autoverification system, when a test has been successfully verified by an authorized technologist..
 - User Story: As a technologist, I want to know which results in VistA have been verified by a technologies on the autoverification system, so that I can ensure it is included with the results as well as compliance with all accreditation standards and best practices.
 - Acceptance Criteria:
 - Results received from autoverification system contain unique identification of the technologist who 'Verified' the result.
 - VistA stores the identification of the technologist received from the autoverification system with the result.
 - VistA stores the original message transmission for a period of time, as per current VistA capabilities, for troubleshooting purposes.
- 443954_4 – The VistA Laboratory system shall process test results received from the autoverification system, with an indicator of successful verification by an authorized technologist, to Auto Release, making results available to appropriate clinicians and providers with privileges to view the results in both CPRS and VistA Laboratory systems.
 - User Story: As a technologist, I want verified results sent to VistA laboratory system to automatically release, so that clinicians treating the patients can have immediate access to the result.

- Acceptance Criteria:
 - Results received from autoverification system, that are identified as 'Verified' will be automatically released and visible to the clinicians authorized to view the results (as per current VistA/CPRS capabilities) for the patient.
 - Clinicians with appropriate authorization, will immediately be able to view the patients verified results via CPRS.
 - Ability to identify if the results were verified automatically or verified by lab technician, and will include unique VistA tech identifying code or name
- 443954_5 – The VistA Laboratory system shall send ordering provider contact information (including phone number and/or pager number) to the autoverification system, for the purpose of making it accessible to authorized technologists who are responsible for verifying test results, during the verification process.
 - User Story: As a technologist, I want to be able to look up ordering provider contact information during the verification process, so that I can easily obtain the information while verifying a result and not have to log on to another system.
 - Acceptance Criteria:
 - VistA Laboratory system will include the providers pager and phone number available from New Person File #200, prior to the technologist initiating the results verification process.
 - VistA stores the original message transmission for a period of time, as per current VistA capabilities, for troubleshooting purposes.
- 443954_6 – The VistA Laboratory system shall notify users when there is a failure of the Lab result to post to VistA.
 - User Story: As a Medical Technologists, I want to be notified if a result is received from the Autoverification system by VistA and does not successfully save to the database, so that I can intervene to ensure the results are appropriately and promptly reported to clinicians.
 - Acceptance Criteria:
 - When a result fails to be processed on VistA, the system will log a Lab Universal Interface (UI) error/exception and generate an alert to designated users
 - When a result fails to be processed on VistA, a notification to DI – via an HL7 acknowledgment message with exception/error observed similar to status sent to POC COTS system after processing POC results.

● 443956 - The system shall present to the user, as a laboratory technologist, a view of lab results that have been automatically verified as normal by automation in order to comply with the requirements of accrediting bodies such as the College of American Pathologists (CAP).

- 443956_1 – The VistA Laboratory system shall save and store autoverified results with an indicator, available to the laboratory user, denoting it was autoverified.
 - User Story: As a technologist, I want to be able to look up results on the VistA and CPRS systems and determine whether or not it was autoverified, so that I can be assured the method of results verification and follow up if needed to ensure quality of results produced.
 - Acceptance Criteria:
 - Patient result reports indicate results that are autoverified.

443969 - The system shall enable the management of lab results in a test system environment to ensure comprehensive testing can be done to ensure all configuration functions correctly before it is brought into the production environment.

- 443969_1 – The VistA Laboratory system shall be capable of testing the new Auto Release capabilities in a test system environment, with local autoverification test systems, prior to implementing in a production environment.
 - User Story: As a technologist, I want to be able to test the new autoverification system with my VistA test system, so that I can adequately test the autoverification rules and system processing prior to implementing in a production environment.
 - Acceptance Criteria:
 - VistA Patch successfully installs into VistA Test Systems.
 - VistA Field Test site's Laboratory System can be connected to a local autoverification system prior to production release and used for testing autoverification rules, results posting, and auto release of results to CPRS.

2.7. Graphical User Interface (GUI) Specifications

None

2.8. Multi-divisional Specifications

The VistA Auto Release Capabilities, must be able to work with VistA Laboratory Systems operational in multi-divisional environments.

2.9. Performance Specifications

Performance requirements can be found in the "Performance, Capacity, and Availability Requirements" section in the Business Requirements Document (BRD)

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2.10. Quality Attributes Specification

In accordance with the Office of the National Coordinator for Health Information Technology's Meaningful Use Stage 2 final ruling, employ and industry recognized User Centered Design (UCD) process. The methods for

UCD are well defined in documents and requirements such as ISO 9241-11, ISO 13407, ISO 16982, National Institute of Standards and Technology Interagency Report 7741, ISO/International Electrochemical Commission 62366 and ISO 9241-210. Developers will choose their UCD approach; one or more specific UCD process will not be prescribed.

2.11. Reliability Specifications

Consistent with VistA uptime at 99.9%.

2.12. Scope Integration

Lab AutoVerification module must be interoperable with other software systems including:

VistA Laboratory (Lab)

The VistA Lab service is one of the core VistA Lab packages that processes, stores and transmits Lab Order data and results.

Laboratory System Re-Engineering Project (LSRP)

The LSRP system is a Laboratory Information Management System (LIMS) for the VA Pathology and Laboratory Medicine Service (PLMS). It was developed as a replacement for the current VistA Lab system but was only deployed at one site - the Huntington VAMC. The system uses Cerner Millennium PathNet, a Commercial Off-The-Shelf (COTS) LIMS. The Cerner Millennium PathNet is interfaced with VistA to maintain system integration with the more than 40 applications currently receiving and/or providing information from VistA.

Laboratory Middleware System (Data Innovations)

The Laboratory Middleware system supports the preparation of laboratory data, process and communication between VistA and the instrument for Lab AutoVerification. It also translates laboratory information and results from the instrument and shares it with

.
Most VHA Labs use Instrument Manager as the middleware. It is estimated that only 7 VHA Labs use Dawning middleware. Both Instrument Manager and Dawning are owned by Data Innovations. It is assumed that sites using Dawning will have the option to convert to Instrument Manager as the middleware.

2.13. Security Specifications

VistA Laboratory Enhancements shall comply with all VHA Security, Privacy and Identity Management requirements including VA Handbook 6500.

2.14. Features

ID	FEATURE Name	FEATURE Input	FEATURE Output
F1	Send Laboratory Ordering Provider contact information To be determined if part of scope	Provider Phone Number (New Person File #200; Office Phone Field #.132) Provider Digital Pager Number (New Person File #200; Digital Pager Field #.138) Provider Voice Pager Number (New Person File #200; Voice Pager Field #.137)	Electronic message transmission to Autoverification System with additional information.
F2	Receive Laboratory Result with indication of results Autoverified or verified by a Technologist	Electronic message transmission from Autoverification System with additional information	Patient result viewable in CPRS and VistA Laboratory with
	Develop a master auto release switch		LA7UI AUTO RELEASE MASTER. Its main function would be as a “kill switch”. Namespace would indicate Lab Automated (LA) Universal Interface (UI) Auto Release. This would provide granularity in case in the future auto release is also expanded to include reference lab results (LEDI).

2.15. Usability Specifications

No changes to current VistA Laboratory System or CPRS user interface expected.

3. Applicable Standards

4. Interfaces

Health Level 7 (HL7) version 2.2 messaging currently used in VistA Legacy Laboratory system Universal Interface capability.

4.1. Communications Interfaces

TBD

4.2. Hardware Interfaces

TBD

4.3. Software Interfaces

VistA Laboratory Universal Interface

- HL7 ORM Messages will be modified to include provider contact information, see SDD.
- HL7 ORU Messages will be modified to include indicator of 'Autoverified' results.

4.4. User Interfaces

Existing user interface for VistA Legacy Laboratory Auto Instrument functionality, existing VistA Legacy Laboratory system, and existing CPRS.

5. Legal, Copyright, and Other Notices

The legacy VistA Laboratory software runs within the VistA architecture on the VA's network. The following warning is issued during the log in process:

"This U.S. Government computer system is for official use only. The files on this system include Federal records that contain sensitive information. All activities on this system may be monitored to measure network performance and resource utilization; to detect unauthorized access to or misuse of the system or individual files and utilities on the system, including personal use; and to protect the operational integrity of the system. Further use of this system constitutes your consent to such monitoring. Misuse of or unauthorized access to this system may result in criminal prosecution and disciplinary, adverse, or other appropriate action."

6. Purchased Components

None, for VistA Patch component.

TBD for Autoverification System, which is part of the Data Innovations suite of capabilities.

6.1. Defect Source (TOP 5)

Create a graph to depict the Defect Source (Top 5) by showing the number of defects discovered by component.

7. User Class Characteristics

Laboratory Medical Technologists, Laboratory Information Managers, Information Technology Support Staff, and physicians, nurses, pharmacists, as well as other care givers who use patient results in order to treat and/or care for patients.

8. Estimation

Detail the estimation approach for the project.

If the project chooses to use function point estimation, the Function Point Estimate Workbook must be completed to support the summary information in this section. After the workbook has been completed, the data in the Application Estimate sheets must be entered in this section.

For projects that require development in multiple products, the total estimated function points are calculated as the sum of each product's estimated function points.

Instructions

- 1. Contact The VA Office of Information and Technology (OIT) Product Development (PD) Process, Performance, and Oversight (PPO) Project Estimation Support to request an RSD-based Function Point Estimate*
- 2. Request to have a results summary returned in the format of the following table.*

Project Software Functional Size and Size-Based Effort and Duration Estimate

Application

Item	A	B	C	D	E	Total
Counted Function Points						
Estimated Scope Growth						
Estimated Size at Release						

Size-Based Effort Estimates	Labor Hours	Probability
Low-Effort Estimate -- With indicated probability, project will consume no more than:		
High-Effort Estimate -- With indicated probability, project will consume no more than:		

Size-Based Duration Estimates	Work Days	Probability
Low-Duration Estimate -- With indicated probability, project will consume no more than:		
High-Duration Estimate -- With indicated probability, project will consume no more than:		

Figure 1: Cumulative Probability ("S-curve") Chart

[Insert Cumulative Probability ("S-curve") Chart here]

9. Approval Signatures

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