

**VistA Evolution Pathology and  
Laboratory Enhancements-Microbiology  
Requirements Specification Document**



**Department of Veterans Affairs**

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## Revision History

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# 1. Introduction

## 1.1. Purpose

The purpose of the Requirements Specification Document (RSD) is to capture the detailed requirements in support of the Veterans Health Information Systems Technology Architecture (VistA) Evolution (VE) Pathology and Laboratory Enhancements for Microbiology. A decision was made to use the Business Requirements Document (BRD) for New Service Request (NSR) #20131213 for the Microbiology enhancement effort, as it includes very high level requirements pertaining to Microbiology.

The Microbiology enhancements include all of the following:

- Carbapenem Resistant Enterobacteriaceae (CRE) Naming Conventions
- Electronic Interfacing of Automated Identification and Susceptibility Testing Instruments
- Tracking Multi-Drug Resistant Organisms – NSR #20140801

This document will describe the business requirements set forth by the Pathology and Laboratory Medicine Service (PLMS) program office for the enhancements listed above. The intended audience for this document is the Office of Information and Technology (OI&T).

## 1.2. Scope

The scope of this effort includes three primary enhancements covering the standardization of Naming Conventions, Instrument Interfacing, and Tracking Multi-Drug Resistant Organisms. The development and release of these capabilities may be provided incrementally or in their totality. The business owners have indicated that if implemented incrementally, then the first release should include the new standardized naming conventions, second should be the instrument interfaces, and third should be the tracking functionality. These iterations, if sequenced by the development team, are not intended to be synonymous with the OI&T Project Management and Accountability System's (PMAS) increments.

### 1.2.1. Carbapenem Resistant Enterobacteriaceae (CRE) Naming Conventions - NSR #20131213

The scope for this request includes the necessary microbiology enhancements to allow Department of Veterans Affairs (VA) labs the ability to document and utilize standard data in VistA/Computerized Patient Record System (CPRS) for CRE and other Multidrug-Resistant Organisms (MDRO). In addition, it includes the ability to nationally distribute these microbiology enhancements and other MDRO standardized reporting etiologies without requiring each individual lab to update its own local files manually.

At this time, information regarding set up and configuration for CH (CH can refer to many areas or departments in the lab) to subscribed tests for molecular level testing for CRE will not be included in the scope of this project. There is no current molecular level



testing available on the market. In the future, the recommendation would be to follow the Methicillin-Resistant Staphylococcus Aureus (MRSA) directive for test configuration and set up as a template for future testing of CRE and other MDROs as the methodology becomes available.

#### **1.2.2. Electronic Interfacing of Automated Identification and Susceptibility Testing Instruments - NSR #20131213**

The scope for this request includes the ability to electronically transfer organism identification and drug susceptibility testing results (generated by an automated instrument) to VistA. From an information perspective, this contains three separate interactions:

- Informing (upload) the automated identification and susceptibility instrument of patient demographics and specimen orders (VistA-to-Instrument)
- Obtaining (download) results from the automated identification and susceptibility instrument (Instrument –to-VistA)
- Optionally annotating the results (VistA-to-Laboratorian, then Laboratorian-to-VistA)

The primary need is for VistA fields/databases to be built so that middleware can transfer the results from those systems into VistA.

#### **1.2.3. Tracking Multi-Drug Resistant Organisms - NSR #20140801**

The scope of NSR #20140801 (Tracking Drug-Resistant Organisms) includes requests and other enhancements covered by one other NSR (#20140804 Clostridium difficile Program Tools). The scope encompasses the need for the following:

- Timely Identification: Updating the Methicillin-Resistant Staphylococcus aureus Program Tools (MRSA-PT) observation status to align with VHA policy (VHA Directive 1036) and to ensure the timely identification of MDROs (including *C.difficile* and related infections) in VA facilities.
- Automated Data Collection: Improving the MRSA-PT functionality to provide MDRO Prevention Coordinators (MPCs) and Infection Preventionists (IPs) with an automated data extraction program for MDROs (including *C. difficile* and related infections) to eliminate the use of labor hours for manual data collection, and ensure the accuracy of data on healthcare associated infection rates is not compromised by human error.
- Enhanced Reporting: Expanded reporting and report data functionality of the Methicillin-Resistant Staphylococcus aureus Program Tools (MRSA-PT).
  - A system to automatically generate, save and store reports on MDROs including *C. difficile* infections(CDI) and other organisms
  - A system to automatically transfer report data into IPEC, so that the manual entry of data is eliminated, the accuracy of the data is not compromised, and the data is available for national reporting.
  - Capability to add and approve report data before it's transferred to IPEC

- Renaming the current Methicillin-Resistant *Staphylococcus aureus* Program Tools (MRSA-PT) to: Multiple Drug Resistant Organism Program Tools (MDRO-PT) for MDROs including MRSA and *Clostridium difficile* (*C. difficile*).

### 1.3. References

- VE Microbiology Business Requirements Document  
[h](#)REDACTED
- VE Microbiology Requirements Traceability Matrix  
REDACTED
- Tracking Drug Resistant Organisms RTM  
REDACTED
- NSR #20131213 VistA Evolution Pathology and Laboratory Enhancements  
REDACTED
- NSR#20140804 *Clostridium Difficile* Program Tools (include link below)  
[h](#)REDACTED
- VA Handbook 6500 – Information Security Program  
[http://vaww1.va.gov/vapubs/viewPublication.asp?Pub\\_ID=638&FTYPE=2](http://vaww1.va.gov/vapubs/viewPublication.asp?Pub_ID=638&FTYPE=2)

## 2. Overall Description

A driving force behind this effort is the standardized reporting of CRE and other MDROs across the enterprise and help VA facilities identify, monitor, and perform infection prevention and control for Carbapenem Resistant/Carbapenemase-Producing Enterobacteriaceae (CRE/CPE).

Untreatable and hard-to-treat infections from CRE are on the rise among patients in US medical facilities. These bacteria are resistant to all or nearly all the antibiotics available to clinicians today. The mortality from these infections can be as high as 50%. Medical facilities in several states and countries have reduced CRE infection rates by using aggressive prevention and control measures.

Currently, the incidence and prevalence of CRE in Veterans Health Administration (VHA) facilities is unknown. This is a critical time for VHA in which CRE infections can be controlled if addressed in a rapid, coordinated, and consistent effort by doctors, nurses, laboratory staff, medical facility leadership, and health department partners.

The Veterans Health Administration (VHA) Patient Care Services (PCS), Pathology & Laboratory Medicine (P&LMS) National Program Office and the National Infectious Diseases Service (NIDS) support enhancing functionality of the Methicillin-Resistant *Staphylococcus Aureus* (MRSA) Program Tools (MRSA-PT) to be renamed MDRO program tools which will include Clostridium Difficile (*C. difficile*) and other pathogens to be identified.<sup>1</sup> MRSA-PT was developed in 2007 to identify patients who are colonized or infected with MRSA or who have been exposed to MRSA to separate them from the rest of the patient population. VHA policy requires that every patient is screened for MRSA colonization upon being admitted as an inpatient, transferred within a facility, and discharged. For this reason, the MRSA-PT is in need of updates to align with VHA Directive 1036 which requires compliance with Centers for Medicare & Medicaid Services (CMS) standards. VHA Directive 1036 updated the duration of the observation period from 23 hours and 59 minutes to 47 hours and 59 minutes, for patients requiring continued evaluation and treatment but who may not need admission to a VA facility.

Additional enhancements desired for the MRSA-PT include: expanded tracking of multi drug-resistant (MDR), difficult to treat, and clinically significant microorganisms (e.g., *C. difficile*) and an automated data extraction tool to collect information on MDR, difficult to treat, and clinically significant microorganisms (e.g. MDR-MRSA, *C. difficile*). This functionality will also enable expanded capabilities for national reporting of drug-resistant organisms.

Lastly, this work effort includes the development of bi-directional interfacing for microbiology automated instrumentation used in VA laboratory facilities. The current environment for performing microbial organism identification and antibiotic susceptibility testing using automated instruments is not standard across VA's microbiology laboratories. Most sites have no ability to interface with such instruments, requiring manually inputting test information, retrieving printouts, and manually entering results into VistA. Private-sector laboratory information systems (LIS) almost universally provide support for microbiology interfacing; the lack of this capability within VISTA/CPRS endangers VA patients and wastes VA resources.

Some VA microbiology laboratories do have locally-developed (i.e., Class III) interfaces in place, typically through some type of middleware to go between VistA and the instruments. Those interfaces are inefficient in terms of having multiple local resources providing varying degrees of support. They have also proven difficult to implement widely. Locally-developed interfaces can introduce variation in how the test results are captured and annotated in VistA, particularly when interfacing with different instrument/middleware products. Such variation could impede the interoperability of the result information within VA and with health care partners.

Adopting and implementing standard interfacing between automated microbiology instruments and VistA will improve efficiency and enhance patient safety for those laboratories lacking such interfaces today. It will also enhance the process for sites with local interfaces today by lowering total cost of ownership from a nationally-supported

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<sup>1</sup> "Throughout this document, MRSA-PT may be referred to as Multi-Drug Resistant Organisms (MDRO) Program Tools or vice versa.

standard and ensuring results are captured in ways that can support overall interoperability.

The primary need is for VistA fields/databases to be built so that middleware can transfer the results from those systems into VistA.

## **2.1. Accessibility Specifications**

Compliance with 508 guidelines shall be followed

## **2.2. Business Rules Specification**

See the Microbiology Requirements Elaboration document on TSPR

## **2.3. Design Constraints Specification**

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

## **2.4. Disaster Recovery Specification**

This VHA project will inherit the DR procedures of the VA hosting environment supporting the application.

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

## **2.5. Documentation Specifications**

The Microbiology Requirements Specification Document (RSD) shall document functional and non-functional requirements.

The Microbiology System Design Document (SDD) shall document the design constraints related to functional requirements.

The Microbiology Traceability Matrix shall track requirements traceability.

## **2.6. Functional Specifications**

### **2.6.1. Standardized Naming Conventions for laboratory reporting of Carbapenem-Resistant Enterobacteriaceae (CRE) (457870).**

#### **2.6.1.1. 459073 – Business Need**

The system shall provide the ability to identify and report standardized CRE information, enabling the prevention and control of CRE infections within Veterans Health Administration (VHA) medical facilities.

#### **2.6.1.2. 459074 – Business Requirement**

The system shall provide the ability for Microbiology Staff to report organism names with CRE modifying language to alert the clinician that their patient has a Multidrug Resistant Organism (MDRO) and requires contact isolation.

#### 2.6.1.2.1. 487884 - User Story

As a microbiology technologist, I want to view CRE organism names to select from so that I can accurately report the patient's infection from CRE into the Veterans Health Information Systems Technology Architecture (VistA).

#### 2.6.1.2.2. 487491 - Acceptance Criteria

The microbiology technologist can select from the following and see in the Computerized Patient Record System (CPRS) and VistA:

- *Klebsiella pneumoniae*, Carbapenem Resistant (CRE)
- *Klebsiella oxytoca*, Carbapenem Resistant (CRE)
- *Escherichia coli*, Carbapenem Resistant (CRE)
- *Enterobacter cloacae*, Carbapenem Resistant (CRE)
- *Enterobacter* spp, Carbapenem Resistant (CRE)

#### 2.6.1.3. 459075 – Business Requirement

The system will present an organism field for the user to identify and track each occurrence of CREs and other MDROs to ensure better care.

#### 2.6.1.3.1. 487885 - User Story

As a clinician, I need easy access to CRE information so that I can tailor treatment and isolation plans for my patients.

#### 2.6.1.3.2. 487492 - Acceptance Criteria

In cases of CRE, the clinician will see one of the following organism names in the organism field's names:

- *Klebsiella pneumoniae*, Carbapenem Resistant (CRE)
- *Klebsiella oxytoca*, Carbapenem Resistant (CRE)
- *Escherichia coli*, Carbapenem Resistant (CRE)
- *Enterobacter cloacae*, Carbapenem Resistant (CRE)
- *Enterobacter* spp, Carbapenem Resistant (CRE)

#### 2.6.1.4. 460278 – Business Requirement

The system shall provide access for clinicians outside the laboratory (Infection Control staff) to view CRE organism information.

#### 2.6.1.4.1. 487886 - User Story

As an Infection prevention and control specialist or MDRO prevention coordinator, I need to easily view CRE organism information so that I can identify a CRE index case, institute timely isolation, and look for relationships between patients and cross-transmissions that may have occurred in my Department of Veterans Affairs (VA) facility.

#### 2.6.1.4.2. 487493 - Acceptance Criteria

In cases of CRE, the infection prevention and control specialist or MDRO prevention coordinator will see one of the following organism names in both CPRS and VistA:

- *Klebsiella pneumoniae*, Carbapenem Resistant (CRE)
- *Klebsiella oxytoca*, Carbapenem Resistant (CRE)
- *Escherichia coli*, Carbapenem Resistant (CRE)
- *Enterobacter cloacae*, Carbapenem Resistant (CRE)
- *Enterobacter* spp, Carbapenem Resistant (CRE)

#### 2.6.1.5. 460279 – Business Requirement

The system shall provide access for designated users, such as a LIM, to create new organism etiology entries that are repeatable, accurate, and easily implemented so that data entry for the related organisms is standardized and organism names appear consistent in all related reports and extracts.

##### 2.6.1.5.1. 487887 - User Story

As an LIM, I need the new organism entries available in the etiology file for accurate staff documentation in the microbiology report.

#### 2.6.1.5.2. 487494 - Acceptance Criteria

In cases of CRE, the LIM or appropriate Information Technology (IT) staff will be able to add a VistA patch that will add the organism entries, and the lab staff will apply one of the following organism names as applicable in the related microbiology report to both CPRS and VistA:

- *Klebsiella pneumoniae*, Carbapenem Resistant (CRE)
- *Klebsiella oxytoca*, Carbapenem Resistant (CRE)
- *Escherichia coli*, Carbapenem Resistant (CRE)
- *Enterobacter cloacae*, Carbapenem Resistant (CRE)
- *Enterobacter* spp, Carbapenem Resistant (CRE)

#### 2.6.1.6. 460280 – Business Requirement

The system shall allow the ability to aggregate CRE and other MDRO information to provide a national level view to VA Central Office (VACO) leaders of how CRE is affecting the VA.

##### 2.6.1.6.1. 487888 - User Story

As a national level user of lab data, I need a standardized means of CRE and other MDRO organisms' data retrieval from all VA medical centers (or national clinical data repositories) so that these data can be used to inform decision makers who set policy for VA regarding CRE and other MDROs.

#### 2.6.1.6.2. 487495 - Acceptance Criteria

In cases of CRE and other MDROs, the national level data user will be able to query a national level database for standardized reporting for CRE and other MDROs and be able to have a national level view of how CRE and other MRDOs are affecting populations of Veterans served by VA.

In cases of CRE and other MDROs, the national level data user will be able to query a national level database and view results for CREs or MDROs based on the association with patient level data such as:

- Specimen source
- Date of specimen
- Location of patient
- Inpatient/outpatient status.

#### 2.6.1.7. 460282 – Business Need

The system shall provide access for designated users such as the Director of the National Pathology and Laboratory Service Line, the ability to rapidly deploy new entries to the etiology field file, so that new organism names can be updated nationally in a standardized manner.

#### 2.6.1.8. 460283 – Business Requirement

The system shall provide designated users a mechanism to provide approved and standardized organism names so that they can be added to the etiology field file. (This can be similar to the process used for updating the National Drug File.)

##### 2.6.1.8.1. 487890 User Story

As the Director of the National Pathology Service Line, I need the ability to nationally distribute a VistA patch with standardized new organism name updates for the etiology file (61.2).

##### 2.6.1.8.2. 487496 - Acceptance Criteria

The new organism entries are created nationally in the etiology field file in a rapid and standardized manner without disrupting existing entries in the etiology file.

### **2.6.2. Electronic Interfacing of Automated Susceptibility Testing Instruments (487465)**

#### 2.6.2.1. 487466 – Business Need

The system shall provide the ability for organism identification and susceptibility test results to be electronically transmitted to VistA.

#### 2.6.2.2. 487467 – Business Requirement

The system shall provide an electronic interface between automated Microbiology Instrumentation and the VistA Laboratory application.

##### 2.6.2.2.1. 487895 - User Story

As a microbiologist, I need the ability for automated microbiology systems to transfer test results directly to VistA to improve the efficiency of lab operations and to reduce the chance of medical error due to manual result entry.

##### 2.6.2.2.2. 487497 - Acceptance Criteria

VistA will accept identification and susceptibility data from all the major commercial microbiology systems. The main systems in use at VA labs are: Biomerieux VITEK, VITEK2, VITEK-MS, BD-Phoenix, Brucker Biotyper, and Siemens Microscan.

#### 2.6.2.3. 487469 – Business Requirement

The system shall provide an electronic interface to enable the VistA acceptance of Minimum Inhibitory Concentration (MIC) results from automated Microbiology instrumentation.

##### 2.6.2.3.1. 487895 - User Story

As a microbiologist, I need the ability for automated microbiology systems to transfer test results directly to VistA to improve the efficiency of lab operations and to reduce the chance of medical error due to manual result entry.

##### 2.6.2.3.2. 487497 - Acceptance Criteria

VistA will accept identification and susceptibility data from all the major commercial microbiology systems.

#### 2.6.2.4. 487482 – Business Requirement

The system shall provide an electronic interface to enable the VistA acceptance of Susceptible, Intermediate, Resistant, and Susceptible Dose Dependent (S, I, R, & SDD) results from automated Microbiology instrumentation.

##### 2.6.2.4.1. 487895 - User Story

As a microbiologist, I need the ability for automated microbiology systems to transfer test results directly to VistA to improve the efficiency of lab operations and to reduce the chance of medical error due to manual result entry.

##### 2.6.2.4.2. 487497 - Acceptance Criteria

VistA will accept identification and susceptibility data from all the major commercial microbiology systems.

#### 2.6.2.5. 487470 – Business Requirement

The system shall provide electronic interface to enable VistA to accept the NTE HL7 segment from automated Microbiology instrumentation.

##### 2.6.2.5.1. 487898 - User Story

As a microbiologist, I need the ability for automated microbiology systems to transfer notes and comments directly to VistA to improve the efficiency of lab operations and to improve the quality and reliability of interpretive information attached to test results.

##### 2.6.2.5.2. 487501 - Acceptance Criteria

VistA will accept notes and comments tied to results from all the major commercial microbiology systems.



#### 2.6.2.6. 487490 – Business Requirement

The system shall provide the ability to have a bi-directional interface to send and receive the following patient and specimen data to the testing instrument: patient demographics, accession number, collection type/date, specimen type, patient ward/ location and ordering provider so that microbiology data can be used effectively for patient care, epidemiology, infection control, and antibiotic stewardship purposes.

##### 2.6.2.6.1. 487900 - User Story

As a microbiologist, I need VistA to support bi-directional loading of patient and test order data with testing instruments to facilitate reporting of incidence and antibiotic resistance data for patient care, epidemiology, infection control, and antibiotic stewardship programs

##### 2.6.2.6.2. 487502 - Acceptance Criteria

VistA shall support a bi-directional interface to send and receive the following data to the testing instrument: demographics, accession number, collection type/date, specimen type, ordering provider, and patient ward/ location.

### **2.6.3. Tracking Drug-Resistant Organisms (499945)**

#### 2.6.3.1. 466228 – Business Need

The system shall provide designated users access to view information on MDROs, (including *Clostridium difficile* and related infections) collected at VHA facilities so that the user can analyze and track statistics regarding health care associated infections and transmissions.

As a member of the National Multi Drug Resistant Organism (MDRO) Prevention Office, I need to view information on MDROs, (including *Clostridium difficile* and related infections) collected at VHA facilities so that I can analyze and track statistics regarding health care-associated infections (HAIs) and transmissions.

#### 2.6.3.2. 466231 – Business Requirement

The system shall provide designated users the ability to analyze and track data trends (for statistical analysis) regarding health care associated infections and transmissions collected at Veterans Health Administration (VHA) facilities so that the user can improve the quality of patient care outcomes, develop policies, and make recommendations for improvement throughout VHA.

##### 2.6.3.2.1. 466231 – User Story

As a member of the National MDRO Program, I need to analyze and track data trends (for statistical analysis) regarding health care associated infections and transmissions collected at Veterans Health Administration (VHA) facilities so that I can help improve the quality of patient care outcomes, develop policies, and make recommendations and improvement throughout VHA.

##### 2.6.3.2.2. Acceptance Criteria

The system shall accumulate and allow user configurable reporting from all fields for MDRO reporting, across all VA facilities. It shall incorporate role based security already existing in the VistA system, and should automatically generate, save, and store MDRO reports

The system should provide the capability to select, review, save, and print MDRO reports, including:

- Isolation Report Census List and MDRO History
- MRSA Nares Screen Compliance List
- MDRO Inpatient Evaluation Center (IPEC) Admission Report
- MDRO IPEC Admission Summary Report
- MDRO IPEC Discharge/Transmission Report
- All user defined reports
- Electronically upload MDRO report information to the IPEC Data Management System

#### 2.6.3.3. 466232 - Business Need

The system shall provide designated users the ability to generate reports (e.g., on a monthly basis and as needed) on MDROs, difficult to treat, or clinically significant microorganisms documented on site to provide accurate data on health care associated infections and transmissions to VHA leadership.

#### 2.6.3.4. 499949 – Business Requirement

As an MPC or Infection Prevention and Control Professional (IP), I need to review and approve data on MDROs so that it can be made available (e.g. automatically transferred or populated) ) for national reporting (e.g. Inpatient Evaluation Center [IPEC]).

##### 2.6.3.4.1. 499960 – User Story

As an MPC or IP, I need to enter comments when I make corrections or updates to data in the MDRO reports so that I can explain what was changed and why.

##### 2.6.3.4.2. Acceptance Criteria

With appropriate security, fields should be editable but require explanations of why the data was updated. The user performing the update should be automatically recorded by the system.

##### 2.6.3.4.3. 499965 – User Story

As an MPC, I need to enter data (e.g. that a case is clinically confirmed or a healthcare associated infection) into the MDRO report before it's made available for national reporting (e.g. IPEC) so that I can accurately report clinical data.

##### 2.6.3.4.4. Acceptance Criteria

The system should provide an option for the IP to review and approve the MDRO data for release for National Reporting, and results that are left unapproved or with no action should send an alert or message to all authorized MDRO users (at that facility) that outstanding results require attention

#### 2.6.3.5. 466234 – Business Requirement

The system shall provide designated users, the ability to utilize information on MDROs , difficult to treat, or clinically significant microorganisms (e.g., Methicillin-Resistant Staphylococcus Aureus [MRSA], Clostridium Difficile [C. difficile]) on site, to determine proper steps are taken to ensure diseases are not transmitted to others

##### 2.6.3.5.1. User Story

As an MPC, I need to utilize information on MDROs, (e.g., Methicillin-Resistant Staphylococcus Aureus [MRSA], Clostridium difficile [C. difficile]) at my site, so that I can determine proper steps are taken to ensure diseases are not transmitted to others.

##### 2.6.3.5.2. Acceptance Criteria

Reports can be generated that contain information for all patients that have tested positive for MDROs at a given laboratory site.

#### 2.6.3.6. 466236 – Business Requirement

The system shall provide designated users the ability to know when any collected specimen has been released with a positive microorganism result so they can determine next steps for clinical management of a patient.

As an MPC, I need to know when there is a positive microorganism specimen collected so that I can determine next steps for management of a patient.

##### 2.6.3.6.1. 499970 – User Story

As an MPC, I need to know if a positive C. difficile result has been released for any specimen that was collected within a specified timeframe after admission (e.g., greater than 48 hours) so that I can determine if a case is hospital onset.

##### 2.6.3.6.1. Acceptance Criteria

A report can be generated that contains information for all patients that have tested positive for MDROs at a given laboratory site. Information included on this report must include:

- Specimen collection date/time
- Patient admission date/time
- Calculated value for the timeframe from patient admission to specimen collection

##### 2.6.3.6.1. 499985 – User Story

As an MPC or IP, I need to search for data based on patient location or date/time of admission, etc. so that I can look for trends or possible trouble spots.

##### 2.6.3.6.1. Acceptance Criteria

A system option is available that prompts the user for search criteria. These criteria must include:

- Patient location at time of specimen collection
- Patient location at time of search (current location)

- Patient admission date/time

#### 2.6.3.6.2. 499994 – User Story

As an MPC or IP, I need know when patients that have tested positive for C. difficile have also tested positive for NAP1 so that I can track for epidemiological purposes

#### 2.6.3.6.3. Acceptance Criteria

A report can be generated that contains information for all patients that have tested positive for C. difficile and have also tested positive for NAP1

#### 2.6.3.6.4. 470231 – User Story

As an MPC, I need to know the patient identifiers (e.g. name and last four of Social Security Number [SSN]) of a patient who has tested positive for MDROs (including Clostridium difficile and related infections) so that I can place that patient in isolation precautions and see if patient has a healthcare associated infection.

#### Acceptance Criteria

A report can be generated that contains information for all patients that have tested positive for MDROs at a given laboratory site. Information included on this report must include:

- Patient name
- Last four digits of the patient's Social Security Number (SSN)
- Date of Birth

#### 2.6.3.6.5. 470233 – User Story

As an MPC, I need to know the patient's room number (at the time the report is run) who has tested positive for MDROs (including Clostridium difficile and related infections) so that I can place them in isolation precautions and see if they have a healthcare associated infection.

#### 2.6.3.6.1. Acceptance Criteria

A report can be generated that contains information for all patients that have tested positive for MDROs at a given laboratory site. Information included on this report must include:

- Patient's room number at the time of report generation

#### 2.6.3.6.2. 470234 – User Story

As an MPC, I need to know the date and time a specimen was collected (e.g., another positive specimen collected less than or equal to 14 days before this one so that I can evaluate for duplicates) to determine how to classify a specimen.

#### 2.6.3.6.1. Acceptance Criteria

A report can be generated that contains a list of patients that have had two different specimens that have tested positive for MDROs within a specified time frame. (e.g., another positive specimen collected less than or equal to 14 days) This report must contain the date/time of specimen collection.

#### 2.6.3.6.2. 470236 – User Story

As an MPC, I need to know the date and time a specimen was collected (e.g., another positive specimen collected greater than 14 days and less than or equal to 56 days before this one) so that I can evaluate for recurrence of illness.

#### 2.6.3.6.1. Acceptance Criteria

A report can be generated that contains a list of patients that have had two different specimens that have tested positive for MDROs within a specified time frame. (e.g., another positive specimen collected greater than 14 days and less than or equal to 56 days) This report must contain the date/time of specimen collection.

#### 2.6.3.6.2. 500066 – User Story

As an MPC, I need to know the date and time of admission associated with specimen collection so that I can determine whether a positive specimen is healthcare onset or community onset (acquired).

#### 2.6.3.7. Acceptance Criteria

A report can be generated that contains information for patients that have tested positive for MDROs at a given laboratory site. Information included on this report must include:

- Patient admission date and time associated with a given specimen collection

#### 2.6.3.8. 466242 – Business Requirement

The system shall provide designated users the ability to view the patient's location at the time of specimen collection so that the user can determine whether the specimen was collected while inpatient or outpatient to determine the next step of clinical care (isolation precautions).

#### 2.6.3.9. User Story

As an MPC, I need to know the patient's location of specimen collection so that I can determine whether it is collected while inpatient or outpatient to inform on next step of clinical care (isolation precautions).

#### 2.6.3.10. Acceptance Criteria

A report can be generated that contains information for patients that have tested positive for MDROs at a given laboratory site. Information included on this report must include:

- Patient location at time of specimen collection (including patient status of Inpatient or Outpatient)

#### 2.6.3.11. 466247 – Business Requirement

The system shall provide designated users the ability to view the date and time of a patient's most recent discharge from your inpatient facility, (if within 28 days), prior to

the positive specimen collection so that so that the user can determine if the infection or colonization is healthcare associated.

#### 2.6.3.12. User Story

As an MPC, I need to know the date and time of a patient's most recent discharge from your inpatient facility, (if within 28 days), prior to the positive specimen collection so that so that I can determine if the infection or colonization is healthcare associated.

#### 2.6.3.13. Acceptance Criteria

A report can be generated that contains information for patients that have tested positive for MDROs at a given laboratory site. Information included on this report must include the date and time of the patient's most recent discharge from a specified inpatient facility. The report must contain only those patients whose discharge date was within 28 days prior to the collection date of the specimen that tested positive.

#### 2.6.3.14. 469586 – Business Requirement

The system shall provide designated users the ability to notify nursing staff of patients with positive C.difficile tests that have also tested positive for NAP1 so that appropriate isolation procedures for the patient are followed ensuring against the spread of infection.

##### 2.6.3.14.1. User Story

As an MPC, I need to know the date and time of other MDROs, (e.g., MRSA, Carbapenem Resistant Enterobacteriaceae [CRE] tests) so that I can determine if the infection or colonization is healthcare associated.

##### 2.6.3.14.2. Acceptance Criteria

A report can be generated with a listing of patients with positive C. difficile tests that have also tested positive for NAP1. The system should allow the user to specify the parameters for the report (e.g., specimen collection date range, admission date range, etc.)

#### 2.6.3.15. 470229 – Business Requirement

The system shall provide designated users the ability to notify housekeeping staff of patients with positive C. difficile tests that have also tested positive for NAP1 so that appropriate measures can be taken to eliminate C. difficile spores in the environment.

##### 2.6.3.15.1. User Story

As an MPC, I need to know the date and time of other MDROs, (e.g., MRSA, Carbapenem Resistant Enterobacteriaceae [CRE] tests) so that appropriate measures can be taken to eliminate spores in the environment.

##### 2.6.3.15.2. Acceptance Criteria

A report can be generated with a listing of patients with positive C. difficile tests that have also tested positive for NAP1. The system should allow the user to specify the

parameters for the report (e.g., specimen collection date range, admission date range, etc.)

#### 2.6.3.16. 466286 – Business Requirement

The system shall provide designated users the ability to know the date and time of other MDROs, difficult to treat, or clinically significant microorganism specimens collected (e.g., MRSA, Carbapenem Resistant Enterobacteriaceae [CRE] tests) to determine if the infection or colonization is healthcare associated.

##### 2.6.3.16.1. User Story

As an MPC, I need to know the date and time of other MDROs, (e.g., MRSA, Carbapenem Resistant Enterobacteriaceae [CRE] tests) so that I can determine if the infection or colonization is healthcare associated.

##### 2.6.3.16.2. Acceptance Criteria

A report can be generated containing the collection date and time of specimens that have tested positive for MDROs.

#### 2.6.3.17. 466301 – Business Requirement

The system shall provide designated users the ability to view (in a report format) information for inpatients to determine if a patient had clinical symptoms at the time of specimen collection (e.g., diarrhea) to know if the hospital onset case is clinically confirmed.

##### 2.6.3.17.1. User Story

As an MPC, I need to document when a patient has clinical symptoms (e.g. diarrhea) at the time of specimen collection in the national report (e.g. IPEC) or in the report generated by the MDRO Program Tool, so that I can know if the hospital onset case is clinically confirmed.

##### 2.6.3.17.2. Acceptance Criteria

A report can be generated that provides a list of patients who have tested positive for MDROs. The report must contain clinical symptom information for the patients at the time of specimen collection. (e.g., diarrhea)

#### 2.6.3.18. 466305 – Business Need

The system shall provide designated users (assigned at the facility) the ability to configure and modify tools (e.g., MRSA-Program Tools [MRSA-PT]) used for reporting and tracking MDROs, difficult to treat, or clinically significant microorganisms, so the user can ensure data collected is compliant with standard guidelines and necessary updates.

As the Clinical administrator of the Program Tools for MDROs (including Clostridium difficile and related infections) (e.g., MRSA-PT) assigned at the facility, I need the ability

to configure (i.e., make changes to) tools used for reporting and tracking to ensure data collected is compliant with updated standard guidelines.

#### 2.6.3.19. 466343 – Business Requirement

The system shall provide designated users (assigned at the facility) the ability to verify if the program (tools used for reporting MDROs, difficult to treat, or clinically significant microorganisms) set up correctly so that the users can get in the system and use the setup.

##### 2.6.3.19.1. User Story

As the Clinical administrator of the Program Tools for MDROs, assigned at the facility, I need the ability to verify if the program is set up correctly so that the users can get in the system and use the setup.

##### 2.6.3.19.2. Acceptance Criteria

A designated user (by role, e.g., Clinical Administrator of the MDRO-Program Tools) can view the program setup parameters and can tell if users have access to the tool and can perform the setup functions.

#### 2.6.3.20. 466344 – Business Requirement

The system shall provide designated users Tools for MDROs, difficult to treat, or clinically significant microorganism assigned at the facility, the ability to make updates to new or existing locations (facility units) where specimens are collected to ensure accurate data collection or extraction.

##### 2.6.3.20.1. User Story

As the Clinical administrator of the Program Tools for MDROs, assigned at the facility, I need the ability to make updates to new or existing locations (facility units) where specimens are collected so that I can ensure accurate data collection or extraction.

##### 2.6.3.20.2. Acceptance Criteria

A designated user (by role, e.g., Clinical Administrator of the MDRO-Program Tools) can view the existing locations (facility units) from which specimens can be collected, and can make updates to new or existing facility locations.

#### 2.6.3.21. 466345 – Business Requirement

The system shall provide designated users Tools for MDROs, difficult to treat, or clinically significant microorganisms assigned at the facility, the ability to make changes to program tool parameters (e.g., observation status period) to ensure data collection or extraction is compliant with current departmental policies and guidelines.

##### 2.6.3.21.1. 466345 – User Story

As the Clinical administrator of the Program Tools for MDROs, assigned at the facility, I need the ability to make changes to program tool parameters (e.g., observation status period) so that I can ensure data collection or extraction is compliant with current departmental policies and guidelines.



#### 2.6.3.21.2. Acceptance Criteria

A designated user can view and modify the MDRO-Program Tools parameters (e.g., observation status period).

#### 2.6.3.22. 499950 – Business Requirement

As the clinical administrator of the program tools for MDROs, I need the ability to configure reports (e.g. Isolation Report, Nares Screening Compliance List) so that staff can track for potential outbreaks.

##### 2.6.3.22.1. 500036 – User Story

As the clinical administrator of the program tools for MDROs, I need the ability to configure reports (e.g. Isolation Report, Nares Screening Compliance List) to run at set intervals (e.g. every 8 hours) to enable timely results of MDROs, for tracking and tracing potential outbreaks at a facility.

##### 2.6.3.22.2. Acceptance Criteria

A designated user can view and configure the parameters of the MDRO-Program Tools to schedule reports (e.g., Isolation Report, Nares Screening Compliance List) to run at set intervals (e.g., every 8 hours)

## 2.7. Graphical User Interface (GUI) Specifications

The Vista Legacy Lab application and CPRS will be the viewers for these requirements

## 2.8. Multi-divisional Specifications

There are no explicit multi-divisional specifications stated for this project.

## 2.9. Performance Specifications

- There shall be no negative impact on performance or response rates.
- VA user population is estimated to 130,000 plus clinical users.

## 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.

Adhere to an industry recognized User Interface (UI) Best Practices Guideline or Style Guide. Follow the UI guidelines for the defined development platform and if not available, adhere to VA's Best Practices Guidelines/Style Guide.

The MUMPS (M) code developed for this project will be compliant to all VA MUMPS Coding Standards and Conventions.

## 2.11. Reliability Specifications

Maintenance window, including maintenance of externally developed software incorporated into the VistA 4 application(s), will be by mutual agreement between OI&T and the VHA Point of Contact (POC) for the affected facility(ies). VHA will provide POCs for each facility.
VistA application unavailability due to an unplanned outage or planned outages that exceed the defined maintenance window will not exceed 8.76 hours per year and will not exceed 43.8 minutes per month (99.9% availability).
The application shall be available 24 hours a day, seven days a week, with an uptime of 99.9%.
All system updates and scheduled maintenance should occur between the hours of 1800 and 0600 (per local time), when clinical usage would be lightest.
Provide system reliability: <ul style="list-style-type: none"><li>• Threshold = 99.9%</li><li>• Objective = 99.99% system and application</li></ul>
Provide system reliability: <ul style="list-style-type: none"><li>• Level 1 severity =&lt;1 failure per month&gt;</li></ul>

## 2.12. Security Specifications

Any individually identifiable information need to be transmitted/retrieved in a manner that meets all VA Handbook 6500 requirements

## 2.13. System Features

The system features introduced by this project are detailed in Section 1.2.

## 2.14. Usability Specifications

This project shall adhere to 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.

Adhere to an industry recognized User Interface (UI) Best Practices Guideline or Style Guide. Follow the UI guidelines for the defined development platform and if not available, adhere to VA's Best Practices Guidelines/Style Guide.

Where applicable, the following table details Usability/User Interface Requirements:

Identifier	Usability/User Interface Requirements
NONF2661	Left align content in table cells to facilitate quick visual scan.
NONF2662	Left align text for column headers to facilitate visual scan and make columns and content appear more organized.
NONF2663	Use mixed case instead of all caps whenever possible (e.g., dropdown list items, table data, table headers, hyperlinks, tab names). Limit the use of "all caps" throughout the application.
NONF2664	Simplify button labels. Re-label buttons to reflect standard terminology that is common in web interfaces and other applications (e.g., "Cancel"). Emphasize the action being performed in the most succinct way possible. Minimize redundancy in text/terminology that is used to convey the same action.
NONF2665	Left align page/section titles to anchor titles in consistent locations regardless of window sizing.
NONF2666	Labels for fields should be left aligned to facilitate quick visual scan and make forms and field groupings appear more organized.
NONF2667	Avoid using acronyms or abbreviations unless (a) they are widely understood/well known or (b) there is very limited space to display the full meaning. This supports naïve user understanding. If limited space results in using a non-common acronym/abbreviation, ensure it is specified within "Help" and/or as a tooltip.
NONF2668	Use colors such as red and green only for status driven content. Avoid using red for text/content, links, button labels, etc. This will reduce risk for user error, improve link discoverability, and facilitate understanding of differences in navigation/actions/content. It will also help users to isolate important status information (using red, green, etc.) from other less important information when viewing and processing information provided to them on a page.
NONF2669	Provide visual separation between the navigation space and the main content area.
NONF2670	Add field level validation and notification of missing information on the same page without launching a new window or navigating to another page.
NONF2671	Make all text hyperlinks appear consistent in style.
NONF2672	Make drop-down selection box widths appropriate for content and visual appeal.
NONF2673	Use standard and always visible radio buttons for "Yes/No" options instead of requiring the user to click in a drop down box and then click to select the "Yes" or "No" option.
NONF2674	Use standard date and time selection widgets. Where date and time are selected/picked from a standard widget, also provide direct data entry to support keyboard navigation. Enable field level validation immediately upon entry. Include instructional format text within the field entry box.

Identifier	Usability/User Interface Requirements
NONF2675	Provide standard sort behavior and visual indications on columns in all tables.
NONF2676	Define and adhere to a standard model for use and design of controls, buttons, hyperlinks, and navigation elements.
NONF2677	Ensure that text is sized to be readable (for example, by using the 007 Rule to assure text size is readable for users with 20/40 vision. The formula: Text height = .007 * distance between eyes and screen).
NONF2678	Place common navigation elements in consistent locations.
NONF2679	Place critical information “above the fold” (i.e., in the top portion of the screen that is immediately viewable).
NONF2680	Use consistent screen flow models, elements, and terms to support similar workflows.
NONF2681	Use consistently named buttons when actions are the same (e.g., Add vs. Save vs. Submit).
NONF2682	Enable users to print views from where they are in the interface. Avoid requiring the user to “run a report” in order to print something that is viewable on the screen.
NONF2683	Provide field entry tool tips at the field location. Ensure consistency across the application in field labels, formats, location of tooltips, and tool tip text.
NONF2684	Provide visual indication of required fields.
NONF2685	Display field labels in close proximity to entry elements.
NONF2686	Use consistent elements to filter data.
NONF2687	Use consistent elements to sort data.
NONF2688	Use a consistent model for display, layout, and grouping of data entry fields.
NONF2689	Provide alternate row shading in lengthy tables of data, form elements, etc.
NONF2690	Ensure that icons are recognized by users.
NONF2691	Provide some “white space” between status icons in report views, white board views, etc.
NONF2692	Auto-populate default values in entry/selection fields when possible and appropriate.
NONF2693	Visually differentiate status icons from clickable icons, when appropriate.
NONF2694	Define and support the appropriate user tab sequence through fields in forms in order to support keyboard navigation when entering data in forms.
NONF2695	Define and adhere to standard action button placement on screens, forms, etc.
NONF2696	Visually distinguish the primary action button on a page.

Identifier	Usability/User Interface Requirements
NONF2697	Consistently use screen elements, action elements, workflow sequences within/across screens, language, etc.
NONF2698	Provide error messages in user-centric language with specific instructions on the meaning of the error and how to recover from it. Use error messages and method of display consistently across the interface.
NONF2699	Provide context-specific Help.
NONF2700	Do not use the term “sex” or any like abbreviations of that to represent gender.
	<b>System Performance Reporting Requirements</b> (Note: Each system developed by VA Office of Information and Technology (OI&T) must comply with the following mandatory requirements.)
NONF391899	Include instrumentation to measure all performance metrics specified in the Non-Functional Requirements section of the Requirements Traceability Matrix (RTM). At a minimum, systems will have the ability to measure reporting requirements for Responsiveness, Capacity, and Availability as defined in the non-functional requirements section of the RTM.
NONF463749	Make the performance measurements available to the IT Performance Dashboard to enable display of “actual” system metrics to customers and IT staff.
	<b>Operational Environment Requirements</b>
NONF429605	System response times and page load times shall be the same or better than the current VistA system.
NONF429606	Maintenance, including maintenance of externally developed software incorporated into the application(s), shall be scheduled during off peak hours or in conjunction with relevant maintenance schedules. The business owner should provide specific requirements for establishing system maintenance windows when planned service disruptions can occur in support of periodic maintenance.
NONF390684	Information about response time degradation resulting from unscheduled system outages and other events that degrade system functionality and/or performance shall be disseminated to the user community within 30 minutes of the occurrence. The notification shall include the information described in the current Automated Notification Reporting (ANR) template maintained by the VA Service Desk. The specific business impact must be noted in order for OIT to provide accurate data in the service impact notice of the ANR.
NONF390673	Provide a real-time monitoring solution to report agreed/identified critical system performance parameters.



Identifier	Usability/User Interface Requirements
NONF391896	Critical business performance parameters shall be identified e.g., transaction speed, response time for screen display/refresh, data retrieval, etc. in a manner that data capture can occur to support metric reporting and support the OI&T performance dashboard display. If no such performance metrics are required or provided there will be no program specific Service Level Agreements (SLA) created, nor shall there be any active/real time monitoring through OI&T Performance Dashboard to provide the business owners any performance metrics.
NONF390678	Notification of scheduled maintenance periods that require the service to be offline or that may degrade system performance shall be disseminated to the business user community a minimum of 48 hours prior to the scheduled event.
	<b>Documentation Requirements</b>
NONF429609	The training curriculum provided by the applicable Program Office shall state the expected training and task completions time(s) for primary users and secondary users to become proficient at using any IT application or system that is enhanced or created as a result of this New Service Request (NSR).
NONF429610	All training curricula, user manuals, and other training tools, shall be developed and/or updated by the applicable Program Office(s) and delivered to all levels of users prior to release of any IT application or system that is enhanced or created as a result of this NSR. The curricula shall also reflect necessary updates to business processes and procedures that are changed as a result of this NSR.
NONF392051	IT will provide the level of documentation required to support the system and maintain operations and continuity. Documentation shall represent minimal programmatic and lifecycle operations support documentation artifacts as defined by VA standards in ProPath and as required by the VA Enterprise System Engineering Lifecycle and Release Management office for sustained operations, maintenance, and support ( <a href="http://vawww.eie.va.gov/lifecycle/default.aspx">http://vawww.eie.va.gov/lifecycle/default.aspx</a> ) prior to approval by any VA change control board and release into production.
	<b>Implementation Requirements</b>
NONF429612	Technical Help Desk support for the application shall be provided for users to obtain assistance.
NONF390674	The IT solution shall be designed to comply with the applicable approved Enterprise SLA.
NONF429613	The implementation must be completed by timeframes agreed upon by both the Business Owner and OI&T.

Identifier	Usability/User Interface Requirements
	<b>Data Protection/Back-up/Archive Requirements</b>
NONF392156	Based upon the criticality of the system, provide a back-up and data recovery process for when the system is brought off-line for maintenance or technical issues/problems.
NONF429615	Data protection measures, such as back-up intervals and redundancy shall be consistent with systems categorized as routine (30 day restoration).
	<b>Data Quality/Assurance Requirements</b>
NONF391305	A monitoring process shall be provided to ensure that data is accurate and up-to-date and provides accurate alerts for malfunctions while minimizing false alarms.
	<b>User Access/Security Requirements</b>
NONF390698	Ensure the proposed solution meets all Veterans Health Administration (VHA) Security, Privacy, and Identity Management requirements including VA Handbook 6500 (see the Enterprise Requirements section of the RTM).
	<b>Usability/User Interface Requirements</b>
NONF392110	Adhere to good User Interface/User Centered Design (UI/UCD) principles as outlined in the User Interface/User Centered Design Principles Appendix of the BRD.
	<b>VistA Evolution (VE): Conceptual Integrity</b>
NONF392052	Provide standards based messaging and middleware infrastructure needed to support both Legacy Veterans Health Information Systems Technology Architecture (Vista) and future Vista 4 deployments.
	<b>VE: Availability</b>
NONF392024	Maintenance window, including maintenance of externally developed software incorporated into the Vista 4 application(s), will be by mutual agreement between OI&T and the VHA Point of Contact (POC) for the affected facility(ies). VHA will provide POCs for each facility.
NONF392338	Vista application unavailability due to an unplanned outage or planned outages that exceed the defined maintenance window will not exceed 8.76 hours per year and will not exceed 43.8 minutes per month (99.9% availability).
NONF392336	The application shall be available 24 hours a day, seven days a week, with an uptime of 99.9%.

Identifier	Usability/User Interface Requirements
NONF392335	All system updates and scheduled maintenance should occur between the hours of 1800 and 0600 (per local time), when clinical usage would be lightest.
	<b>VE: Interoperability</b>
NONF392343	The system shall support all recognized health system standards i.e., Health Level 7 (HL7), Fast Healthcare Interoperability Resources ( <a href="http://www.hl7.org/implement/standards/fhir/overview.html">http://www.hl7.org/implement/standards/fhir/overview.html</a> ).
NONF487503	Interfaces between VistA and Automated Microbiology Test Instrument Systems must comply with the current VistA HL7 standard (Iteration 2)
NONF392346	Systems must be heterogeneous and agnostic for operating systems and code bases.
NONF392345	Provide the ability to securely transfer large files (of 4-8 gigabyte) from an external source to VA systems.
NONF392350	Provide access to the system over a remote access solution, maintaining normal baseline performance.
NONF	Interfaces between VistA and Automated Microbiology Test Instrument Systems will support the use of a middleware solution.
	<b>VE: Manageability</b>
NONF392352	Provide Service Desk/Incident and Problem Management tracking related to maintenance events of patient care systems with priority over non-patient care systems.
NONF392344	Provide data related to maintenance events, both routine and exceptional, including key metadata: <ul style="list-style-type: none"> <li>• Predicted routine work</li> <li>• Occurrences where maintenance is completed, including restart from down time</li> <li>• Identity of the organization performing maintenance</li> <li>• User performing maintenance (if available)</li> <li>• Identity of the system</li> <li>• Date/time, physical location</li> <li>• Systems impacted</li> <li>• Does it affect patient care</li> <li>• Non-urgent or emergent</li> </ul>
NONF392355	Provide audit capabilities for system access and usage with settings that are configurable to support internal and external audits based on federal and VHA mandates.



Identifier	Usability/User Interface Requirements
NONF392362	The system must comply with VA Directive 6300 Records and Information Management and with VHA Records Control Schedule (RCS) 10-1, in general and specifically with Electronic Final Version of Health Record: Destroy/Delete 75 years after last episode of patient care, or longer (if specified).
	<b>VE: Performance</b>
NONF392347	Provide an Infobutton Query Responder on all platforms with a response time of less than .5 seconds.
NONF392351	The system shall recognize, report, and retransmit data lost, with less than 0-1% chance of incomplete patient records.
NONF392348	Provide patient data (for data within the system) transactions (e.g., capture, search, request for data) within .5 seconds.
NONF392349	Mouse or key-based UI controls, e.g., menus, checkboxes shall provide instantaneous responsiveness (<90ms).
NONF392342	Part-screen refreshes after user action shall complete within a pro-rated interval between 200 ms and 1200 ms times a percentage of the screen area being refreshed. For example, a component 10% of the screen area would refresh in $(1200 - 200) * 0.10 + 200 = 300$ ms.
	<b>VE: Reliability</b>
NONF392353	Provide system reliability: <ul style="list-style-type: none"> <li>• Threshold = 99.9%</li> <li>• Objective = 99.99% system and application</li> </ul>
NONF392354	Provide system reliability: <ul style="list-style-type: none"> <li>• Level 1 severity =&lt;1 failure per month&gt;</li> </ul>
	<b>VE: Security</b>
NONF392360	Provide management of electronic attestation of information including the retention of the signature of attestation (or certificate of authenticity) associated with incoming or outgoing information.
	<b>VE: Supportability</b>
NONF392363	Provide alerts (that extend beyond system messages to external systems like mobile devices) for malfunctions, while preventing false alarms for local, regional, and national evaluations in real time.

Identifier	Usability/User Interface Requirements
NONF436333	Provide national, regional and local reports on performance metrics as specified in the VistA 4 Effectiveness and Value / Benefits Framework ( <a href="http://go.va.gov/6rs9">http://go.va.gov/6rs9</a> ) on a bi-weekly basis.
NONF392356	Provide performance metrics (from request for information to receipt of information on the screen) monitored by the system and system administrators so they know what the user experience is like without users having to call them and tell them the system is running very slow.
NONF392357	Provide the ability for VHA and IT staff to create standard and ad-hoc reports of usage, bandwidth, response time, login time, and other variables with a verification process for measuring the capabilities of the system.
NONF392359	Provide end-user training on how to generate the various system performance reports (e.g., in standard file formats such as Comma Separated Values [CSV], Portable Document Format [PDF], or Excel) depending on the user's needs.
NONF392364	Provide the ability to view system statistics (e.g., information on the specific network environment) and identify areas that are having issues or are beyond capacity, in near-real-time (to be quantified at a later time).
NONF392365	Technical Help Desk support for the application via instant message, on-line, phone, and remote desktop access support, shall be provided for users to obtain assistance 24/7.
NONF392366	The IT solution shall be designed to comply with the applicable approved Enterprise SLAs.
NONF392367	Data protection measures, such as back-up intervals and redundancy shall be consistent with systems categorized as mission critical (1hr restoration, 2hrs backup recovery). Impact of system failure must be monitored on a near real time basis.
NONF392386	Provide the ability to set thresholds and notification type (e.g., email or text alerts) when alerting the user about response time degradation and unscheduled outages.
NONF392388	Disaster Recovery Plans (DRP) and Continuity of Operations Plan (COOP) will be updated and tested semi-annually to address the VistA 4 product (see National Security and Homeland Security Presidential Directive: National Continuity Policy. NSPD-51/HSPD-20, May 9, 2007 <a href="http://www.fas.org/irp/offdocs/nspd/nspd-51.htm">http://www.fas.org/irp/offdocs/nspd/nspd-51.htm</a> )
	<b>VE: Usability</b>
NONF392379	Provide viewability/usability of VistA 4 applications on mobile devices.

Identifier	Usability/User Interface Requirements
NONF392368	User prompts and screen help shall be embedded into the system to guide use of the solution.
	<b>VE: Documentation</b>
NONF392387	The training curriculum shall be provided in two hours or more of training time for primary users and secondary users to become proficient at using the VistA 4 application(s).
NONF392375	All training curricula, user manuals and other training tools shall be developed/updated by the VE Program Office and delivered to all levels of users 4 weeks in advance of the release of the enhancement through mediums that will best support the sharing of information to all affected staff.
NONF392382	Provide follow-up training classes tailored to VHA workflow 4 weeks after the users have begun to use the system.

### 3. Applicable Standards

This project will adhere to the existing Department of Veterans Affairs (VA) legacy development standards and requirements described in the Enterprise Level Requirements maintained by the Veterans Health Administration (VHA) Health Information Technology, Software Engineering and Integration, Enterprise (SEIE) Requirements Management.

Open Source Electronic Health Record Agent (OSEHRA) Gold Disc Certification. VA Enterprise VistA is the standard version adopted by the Department of Veterans Affairs for executable Class 1 code at all 133 VA Medical Center (VAMC) VistA instances. The Enterprise version is known as the "FOIA Release" of VistA.

### 4. Interfaces

The Microbiology enhancements will interface with the following systems:

- Computerized Patient Record System (CPRS)
- VistA Laboratory (Lab) Package Server Software and Fileman
- VistA Order Entry Results and Reporting Package (OE/RR)
- VistA Laboratory Electronic Data Interchange (LEDI)
- Laboratory System Re-Engineering Project (LSRP)

#### 4.1. Communications Interfaces

The interface between VistA and each participating system is established through a persistent or a transient (non-persistent) TCP/IP connection. Two TCP sockets provide bi-directional communications between each participating system. (Reference: LEDI IVHL7 Interface Specification ([http://www.va.gov/vdl/documents/Clinical/Lab-Electr\\_Data\\_Intrchg\\_\(LEDI\)/la\\_52\\_74\\_la\\_52\\_80\\_hl7\\_interface\\_spec.pdf](http://www.va.gov/vdl/documents/Clinical/Lab-Electr_Data_Intrchg_(LEDI)/la_52_74_la_52_80_hl7_interface_spec.pdf) ))

## **4.2. Hardware Interfaces**

The auto instrument interfaces will interface with VistA via HL7. The main automated Microbiology testing instruments in use at VA labs are: Biomeriaux VITEK, VITEK2, VITEK-MS, BD-Phoenix, Brucker Biotyper, and Siemens Microscan.

## **4.3. Software Interfaces**

NA

## **4.4. User Interfaces**

VistA Laboratory Microbiology Application will be the user interface

# **5. Legal, Copyright, and Other Notices**

There are no special legal requirements involved in the use of legacy VistA Laboratory software and Patch LR\*5.2\*425.

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**

No additional purchased components are required to execute the functionality outlined in within the *Requirements Specification Document (RSD)*.

## **6.1. Defect Source (TOP 5)**

N/A

# **7. User Class Characteristics**

LR users will encompass VA healthcare professionals including medical technologists (MT), Laboratory Information Managers (LIM), clinicians, nurses, and clerks.

# **8. Estimation**

N/A

# 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”) Charts here]*

## 9. Approval Signatures

Signed:

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REDACTED

Integrated Project Team (IPT) Chair

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REDACTED

Business Sponsor

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REDACTED

IT Program Manager

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REDACTED

Project Manager

### A. Acronym List and Glossary

OIT Master Glossary:

[http://vaww.oed.wss.va.gov/process/Library/master\\_glossary/masterglossary.htm](http://vaww.oed.wss.va.gov/process/Library/master_glossary/masterglossary.htm)

Term	Definition
AABB	American Association of Blood Banks
AHLTA	Armed Forces Health Longitudinal Technology Application
AIS	Automated Information System
AITC	Austin Information Technology Center
ANSI	American National Standards Institute
AOR	Area of Responsibility

<b>Term</b>	<b>Definition</b>
AP	Anatomic Pathology
ARRA	American Recovery and Reinvestment Act
ASC	Accredited Standards Committee
ASCII	American Standard Code For Information Interchange
BCE	Bar Code Expansion
BHIE	Bidirectional Health Information Exchange
BN	Business Need
BRD	Business Requirements Document
C&A	Certification and Accreditation
CAP	College of American Pathologists
CBT	Computer Based Training
CCHIT	Certification Commission of Health Information Technology
CDC	Center for Disease Control
CH	Chemistry Accessioning
CHCS	Composite Health Care System
CHDR	Central Data Repository/Health Data Repository
CLIA	Clinical Laboratory Improvement Amendments
CLIP	Clinical Laboratory Improvement Program
CLSI	Clinical and Laboratory Standards Institute
CoC	Commission on Cancer
COLA	Commission on Office Laboratory Accreditation
COTS	Commercial-Off-The-Shelf
CPOE	Clinical Provider Order Entry
CPRS	Computerized Patient Record. System
CPT	Current Procedural Terminology
DMDC	Defense Manpower Data Center
DoD	Department of Defense
EHR	Electronic Health Record
ELINCS	EHR Laboratory Interoperability and Connectivity Standards
ESB	Enterprise Service Bus
ESM	Enterprise Systems Management



<b>Term</b>	<b>Definition</b>
FDA	Federal Drug Administration
FHCC	Federal Health Care Center
FIPS	Federal Information Processing Standard
FNA	Fine Needle Aspiration
GIG	Global Information Grid
HI	Health Information
HIPAA	Health Insurance Portability and Accountability Act
HIT	Health Information Technology
HITECH	Health Information Technology for Economic and Clinical Health Act
HL7	Health Level 7
HLA	Human Leukocyte Antigen
ICD-10	International Classification of Diseases, 10th Edition
ICIB	Interagency Clinical Informatics Board
iEHR	integrated Electronic Health Record
IPO	Interagency Program Office
IPv4	Internet Protocol version 4
IPv6	Internet Protocol version 6
IT	Information Technology
LDSI	Laboratory Data sharing Initiative
LEDI	Laboratory Electronic Data Interchange
LIS	Laboratory Information System
LOINC	Logical Observation Identifiers, Names and Codes
LSSC	Laboratory Services Support Center
MDRO	Multi-Drug Resistant Organisms
MHS	Military Health System
MIC	Minimum Inhibitory Concentration
NAACCR	North American Association of Cancer Registries
NAACLS	National Accrediting Agency for Clinical Laboratory Sciences
NCCLS	National Committee for Clinical Laboratory Standards
NIH	National Institutes of Health
NIST	National Institute of Standards and Technology



Term	Definition
NONF	Non-Functional Requirements
NSPD	National Security and Homeland Security Presidential Directive
NwHIN	Nationwide Health Information Network
OB	Obstetrics
OCIS	Office of Cyber and Information Security
OHI	Office of Health Information
OIA	Office of Informatics Analytics
OIFO	Office of Information Field Office
OIG	Office of Inspector General
OIT	Office of Information and Technology
OMB	Office of Management and Budget
ONCHIT	Office of the National Coordinator for Health Information Technology
PCM	Primary Care Manager
PK	Public Key
PKI	Public Key Infrastructure
PPI	Positive Patient Identity
QA	Quality Assurance
RCS	Records Control Schedule
RDM	Requirements Development and Management
ReqPro	RequisitePro
SECDEF	The Secretary of Defense
SECVA	The Secretary of Veteran Affairs
SME	Subject Matter Expert
SNOMED	Systematized Nomenclature of Medicine
SOA	Service Oriented Architecture
TJC	The Joint Commission
VA	Department of Veterans Affairs
VBECS	VistA Blood Establishment Computer Software
VHA	Veterans Health Administration
VistA	Veterans Health Information Systems and Technology Architecture

Term	Definition
VLER	Virtual Life Time Electronic Health Record
VPN	Virtual Private Network