National Clozapine Registry

VistA Mental Health Package

Patch YS*5.01*227

Technical Manual



April 2024

Department of Veterans Affairs

Office of Information and Technology

Revision History

NOTE: The revision history cycle begins once changes or enhancements are requested after the document has been baselined.

Table 1 Revision History

Date	Revision	Description	Author
April 2024	1.0	VistA Mental Health package, Patch YS*5.01*227, in support of NCR VistA Wishlist.	Liberty IT Solutions

Artifact Rational

A Technical Manual is a required end-user document for all OIT software releases. The intended audience for the *National Clozapine Registry Technical Manual* is local IT support, management, and development personnel for nationally released software. It provides sufficient technical information about the software for developers and technical personnel to operate and maintain the software with only minimal assistance from Product Support staff.

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1. Introduction

The National Clozapine Registry (NCR) is the Department of Veterans Affairs (VA) enterprise Clozapine patient registry. NCR is sponsored by the Veterans Affairs, National Pharmacy Benefits Management (PBM) organization. The National Clozapine Coordinating Center (NCCC) staff use the NCR to track VA Clozapine patients, their history of Clozapine use in the VA, and related laboratory results. It is the source of data used to prepare reports of VA Clozapine prescriptions and blood test results to the Food and Drug Administration (FDA) Clozapine Risk Evaluation and Mitigation Strategy (REMS) – a legally mandated public health registry. The system contains records of VA Clozapine patients since 1993 including patient demographic information, FDA-required Clozapine identifiers, laboratory results from each time they receive a Clozapine prescription, and any Clozapine pharmacy lock-out overrides that result from VA programmed safety order checks.

This patch modifies VistA to introduce expanded National Clozapine functionality. This update, implemented as patch YS*5.01*227, is also referred to as the VistA Wishlist.

1.1. Purpose

This Technical Manual provides information about the VistA Mental Health package, Patch YS*5.01*227. As further outlined in the patch description document, the purpose of this patch is to implement requested feature enhancements in the VistA Clozapine logic.

The Clozapine order check logic has been updated to use the value of a new field in the Clozapine Parameters file to determine how far back to look for blood test labs when placing Clozapine orders. In addition, lab results entered with only a date in the collection time will no longer be excluded from the search. The nightly process has also been updated to allow 74 days without activity before automatically discontinuing a patient as a Clozapine patient instead of the old period of 28 days for newly-registered patients and 56 days for established patients.

The DCON (discontinue) command in the YSCL MailMan server logic has been modified to toggle the patient's Clozapine status between Active and Discontinued.

The CLOZAPINE PATIENT LIST (#603.01) FILE has been updated to add a new index on the CLOZAPINE REGISTRATION NUMBER (#.01) and CLOZAPINE PATIENT (#1) fields that will trigger when the record is deleted and automatically discontinue that patient as a Clozapine patient in the PHARMACY PATIENT (#55) file.

This document describes how to maintain the components of the NCR as well as how to troubleshoot problems that might occur with this product in production. The intended audience for this document is the Information Technology (IT) teams responsible for hosting and maintaining the system after production release.

1.2. System Overview

The NCR is a web-based Graphical User Interface (GUI) application that contains information on VA Clozapine users and saves data to an Azure Structured Query Language (SQL) database. The NCR application and supporting database are hosted in the VA Enterprise Cloud (VAEC) Microsoft Azure Government (MAG) environment.

The functionality added to VistA as part of YS*5.01*227 is specific to VistA and does not have a dependency on the NCR web application.

1.3. Document Orientation

The audience for this Technical Manual is local IT support (formerly known as IRM), management, and development personnel. It is assumed that the reader has access to VistA.

1.3.1. Disclaimers

1.3.1.1. Software Disclaimer

This software was developed at the Department of Veterans Affairs (VA) by employees of the Federal Government in the course of their official duties. Pursuant to title 17 Section 105 of the United States Code this software is not subject to copyright protection and is in the public domain. VA assumes no responsibility whatsoever for its use by other parties, and makes no guarantees, expressed or implied, about its quality, reliability, or any other characteristic. We would appreciate acknowledgement if the software is used. This software can be redistributed and/or modified freely provided that any derivative works bear some notice that they are derived from it, and any modified versions bear some notice that they have been modified.

1.3.1.2. Documentation Disclaimer

The appearance of external hyperlink references in this manual does not constitute endorsement by the VA of this web site or the information, products, or services contained therein. The VA does not exercise any editorial control over the information you may find at these locations. Such links are provided and are consistent with the stated purpose of the VA.

1.3.2. References

Table 2 lists the manuals related to NCR that are available to view in the VA Software Document Library (VDL) or the NCR GitHub repository.

File Name	Document Name	Location
YS_5.01_227_DIBRG.pdf	National Clozapine Registry Deployment, Installation, Back-out and Rollback Guide (updated for YS*5.01*227)	Located in the VDL
YS_5.01_227 patch description.docx	National Clozapine Registry Patch Description	Located in the NCR GitHub repository

Table 2 NCR Reference Material

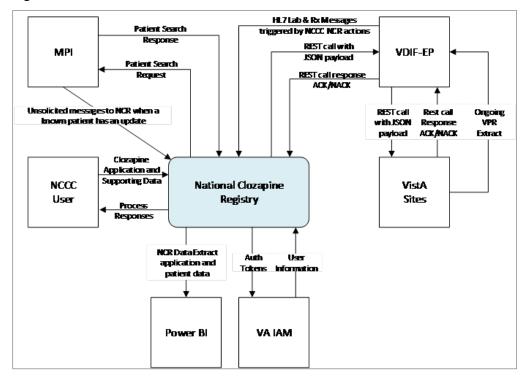
File Name	Document Name	Location
YS_5.01_227_VDD	National Clozapine Registry Version Description Document	Located in the NCR GitHub repository
NCR_UG_ADMIN.pdf	National Clozapine Registry User Guide: Admin (updated for YS*5.01.227)	Located in the VDL
NCR_UG_STAFF.pdf	National Clozapine Registry User Guide: Staff (updated for YS*5.01.227)	Located in the VDL

2. Implementation and Maintenance

Figure 1 provides an overview of the connections and data flows between the NCR web application, VDIF-EP, and VistA sites. The arrows labeled as REST calls and responses with a JSON payload depict the multi-system, end-to-end transactions.

Patch YS*5.01*227 functionality is located within the VistA Sites box.

Figure 1 Overview Flow Chart



2.1. System Requirements

This VistA software is a Kernal Installation and Distribution System (KIDS) software release, distributed as a Packman message via the National Patch Module. It should be installed on an up-to-date VistA system. This software also requires that the local VistA system be accessible to VDIF to receive the data passed from the NCR GUI through the API call added in this release.

2.1.1. Hardware Requirements

The NCR Web App does not employ a physical hardware infrastructure. The infrastructure is composed of logical cloud components hosted in Azure in the VAEC. Each of the Web App environments consists of the following (Figure 2):

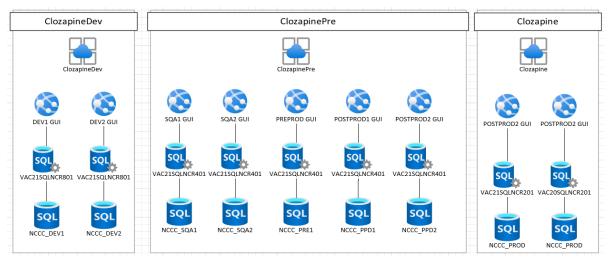


Figure 2 Azure Environment Components

While no change to the existing infrastructure is anticipated, it is expected that the Azure application services will handle the integration between the Clozapine Application process and VA MPI.

This integration's code progression and testing progression will go from VA MPI DEV to VA MPI SQA to SQA UAT then to VA MPI Production. Change control and quality requirements will be met and approved by IDM subject matter experts in each environment before Clozapine Application is allowed to connect to the next environment.

2.1.2. Software Requirements

This product (Patch YS*5.01*227) runs on standard software platforms that are used by each VHA facility. These enhancements are compatible with existing VistA database platforms, compilers, utilities, operating systems, and communication software. The programming language is MUMPS/M/Cache on the Cache Studio developer interface toolset.

The NCR software is not a separate system; it is code contained in the Outpatient Pharmacy, Inpatient Medications, and Mental Health packages located in each VAMCs VistA database. It uses VistA data files as its main database source. The NCR software application has a presentation layer at the top, a service layer in the middle, and a data services layer at the bottom.

As described in more detail earlier, this patch modifies the Clozapine order check logic to use the value of a new field in the Clozapine Parameters file to determine the look-back for blood test labs when placing Clozapine orders. Additionally, lab results entered with only a date in the collection time will not be excluded from the search. The nightly process has been updated to allow 74 days without activity before automatically discontinuing a patient as a Clozapine patient as opposed to the prior 28-day period for newly-registered patients and 56 days for established patients.

The DCON command in the YSCL MailMan server logic now toggles patient Clozapine status between Active and Discontinued.

The CLOZAPINE PATIENT LIST file has a new index on the CLOZAPINE REGISTRATION NUMBER and CLOZAPINE PATIENT fields that triggers when the record is deleted and automatically discontinues the patient as a Clozapine patient in the PHARMACY PATIENT file.

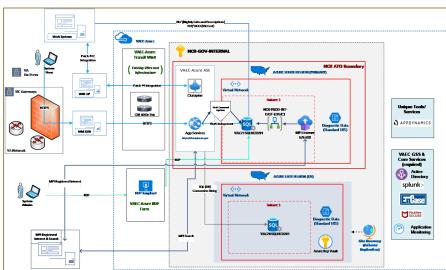
2.1.3. Database Requirements

There are no database requirements in VistA for this patch.

2.2. System Setup and Configuration

To request access to the NCR application, users must complete a new user registration form (details in section 3.1.1 of YS_5.01_227_UG_Admin) or contact the NCCC Administration staff to be added manually to the system (Details in section 4.3.1 of YS_5.01_227_UG_Admin).

Figure 3, below, provides an overview of the NCR application components as deployed within the Microsoft Azure Government environment. This figure also shows the connectivity points with external systems, including VDIF-EP integration introduced with Patch 242.





3. Files

3.1. VistA Mental Health Files

Table 3 provides a listing of the applicable VistA Mental Health package files associated with this patch.

File Number	File Name
601	MH INSTRUMENT
601.2	PSYCH INSTRUMENT PATIENT
601.3	COPYRIGHT HOLDER
601.4	INCOMPLETE PSYCH TEST PATIENT
601.6	MH MULTIPLE SCORING
601.71	MH TESTS AND SURVEYS
601.72	MH QUESTIONS
601.73	MH INTRODUCTIONS
601.74	MH RESPONSE TYPES
601.75	MH CHOICES
601.751	MH CHOICETYPES
601.76	MH INSTRUMENT CONTENT
601.77	MH BATTERIES
601.78	MH BATTERY CONTENTS
601.781	MH BATTERY USERS
601.79	MH SKIPPED QUESTIONS
601.81	MH SECTIONS
601.82	MH RULES
601.83	MH INSTRUMENTRULES
601.84	MH ADMINISTRATIONS
601.85	MH ANSWERS
601.86	MH SCALEGROUPS
601.87	MH SCALES
601.88	MH DISPLAY
601.89	MH CHOICEIDENTIFIERS
601.91	MH SCORING KEYS
601.92	MH RESULTS
601.93	MH REPORT

Table 3 VistA Mental Health Files

File Number	File Name
601.94	MH CR SCRATCH
603.01	CLOZAPINE PATIENT LIST
603.02	CLOZAPINE LAB TEST
603.03	CLOZAPINE PARAMETERS
603.04	CLOZAPINE TESTS
604	ADDICTION SEVERITY INDEX
604.26	ASI PROGRAM TYPE
604.3	ASI LEGAL CODE
604.4	ASI LIVING ARRANGEMENTS
604.45	ASI PATIENT RATING SCALE
604.48	ASI ROUTE OF ADMINISTRATION
604.5	ASI FAMILY HX CODES
604.55	ASI FOLLOW UP
604.66	ASI QUICK FORM
604.68	ASI NARRATIVE
604.77	ASI SUBSTANCE CODE
604.8	ASI PARAMETERS
615.2	SECLUSION/RESTRAINT
615.5	S/R REASONS
615.6	S/R CATEGORY
615.7	S/R RELEASE CRITERIA
615.8	S/R ALTERNATIVES
615.9	S/R OBSERVATION CHECKLIST
627.7	DSM

3.2. VistA File Updates

This patch updates the CLOZAPINE PATIENT LIST (603.01) file. This file is stored in the ^YSCL global.

CLOZAPINE PATIENT LIST (File 603.01)

CLOZAPINE REGISTRATION NUMBER (Field .01)

CLOZAPINE PATIENT (Field 1)

A new index (AD) has been created referencing field .01 and field 1 and triggers when the record is deleted – discontinues the patient as a Clozapine patient in PHARMACY PATIENT (file 55).

CLOZAPINE PARAMETER (File 603.03)

LAB LOOKBACK DEFAULT (Field 12) – New field holding the number of days to pull historical blood test labs when placing Clozapine orders.

DISCONTINUE LOOKBACK (Field 13) – New field holding the number of days of inactivity before the nightly process will discontinue a patient as a Clozapine patient.

The patch will set the two fields on install. Lab Lookback Default is being set to 30 days. Discontinue Lookback is being set to 74 days.

4. Routines

Six routines are being delivered with patch YS*5.01*227:

- Routine Name: YSCLDIS
- Routine Name: YSCLHLAB
- Routine Name: YSCLP227 (New)
- Routine Name: YSCLSRV2
- Routine Name: YSCLTST2
- Routine Name: YSCLTST4

5. Exported Options

No new options are exported in this patch.

6. Mail Groups, Alerts, and Bulletins

VistA MailMan will continue to serve as a communications interface to transmit data between the applications, as well as between NCCC and the facilities. Moving from weekly data Clozapine transmission to "real-time" Clozapine data transmission will increase the number of emails generated on a weekly basis to approximately 1000 to 1500.

7. Public Interfaces

There are no public interfaces for NCR.

7.1. Integration Control Registrations

Table 4 defines the difference between Controlled Subscriptions and Supported References in VistA.

Category	Definition	
Controlled Subscription	Describes attributes/functions that must be controlled in their use. The decision to restrict the Integration Control Registration (ICR) is based on the maturity of the custodian package. Typically, these ICRs are created by the requesting package based on their independent examination of the custodian package's features. For the ICR to be approved the custodian grants permission to other VistA packages to use the attributes/functions of the ICR; permission is granted on a one-by-one basis where each is based on a solicitation by the requesting package. An example is the extension of permission to allow a package (e.g., Spinal Cord Dysfunction) to define and update a component that is supported within the Health Summary package file structures.	
Supported Reference	This applies where any VistA application may use the attributes/functions defined by the ICR (these are also called "Public"). An example is an ICR that describes a standard API such as DIE or VADPT. The package that creates/maintains the Supported Reference must ensure it is recorded as a Supported Reference in the ICR database. There is no need for other VistA packages to request an ICR to use these references; they are open to all by default. NOTE: ICRs categorized as Supported References are listed on the DBA menu on FORUM and are open for use by everyone.	

All the Integration Control Registrations in the patch are supported references, as listed below in Table 5.

Table 5 Integration C	Control Registrations
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Routine	ICR
YSCLDIS	Reference to ^DPT supported by IA #10035
	Reference to ^PS(55 supported by IA #787
	Reference to \$\$SITE^VASITE supported by IA #10112
	Reference to ^DIC supported by DBIA #2051
	Reference to ^DIE supported by DBIA #2053
	Reference to ^DIQ supported by DBIA #2056
	Reference to ^XLFDT supported by DBIA #10103
	Reference to ^XMD supported by DBIA #10070
	Reference to ^%DTC supported by DBIA #10000

Routine	ICR
YSCLHLAB	Reference to ^LAB(60 supported by IA #333
	Reference to ^PS(55 supported by IA #787
	Reference to ^LR7OR1 supported by IA #2503
	Reference to ^DIC supported by DBIA #2051
	Reference to ^DIQ supported by DBIA #2056
	Reference to ^XLFDT supported by DBIA #10103
	Reference to ^%DTC supported by DBIA #10000
	Reference to ^VA(200 supported by DBIA #10060
YSCLP227	None
YSCLSRV2	Reference to ^%ZOSF supported by IA #10096
	Reference to ^DPT supported by IA #10035
	Reference to ^DD("DD" supported by IA #10017
	Reference to ^PS(55 supported by IA #787
	Reference to ^PSDRUG supported by IA #25
	Reference to ^PSRX supported by IA #780
	Reference to ^VA(200 supported by IA #10060
	Reference to \$\$SITE^VASITE supported by IA #10112
	Reference to \$\$FMTE^XLFDT() supported by IA #10103
	Reference to ^PSDRUG supported by IA #221
	Reference to ^LAB(60 supported by IA #333
	Reference to ^%DT supported by DBIA #10003
YSCLTST2	Reference to ^LAB(60 supported by IA #333
	Reference to ^PSDRUG supported by IA #25
	Reference to ^PS(55 supported by IA #787
	Reference to ^XMD supported by IA #10070
	Reference to ^LR7OR1 supported by IA #2503
	Reference to ^DIC supported by DBIA #2051
	Reference to ^DIE supported by DBIA #2053
	Reference to ^DIQ supported by DBIA #2056
	Reference to ^DIR supported by DBIA #10026
	Reference to \$\$SITE^VASITE supported by DBIA #10112
	Reference to ^XLFDT supported by DBIA #10103
	Reference to MIX^DIC1 supported by DBIA #10007
	Reference to ^%ZTLOAD supported by DBIA #10063
	Reference to ^%DTC supported by DBIA #10000
	Reference to ^%DT supported by DBIA #10003
	Reference to PSS^PSS781 supported by DBIA #4480
	Reference to \$\$GETREGYS^PSOCLUTL supported by DBIA #7314

Routine	ICR
YSCLTST4	Reference to ^LAB(60 supported by IA #333
	Reference to ^LR7OR1 supported by IA #2503
	Reference to ^DIC supported by DBIA #2051
	Reference to ^DIQ supported by DBIA #2056
	Reference to ^%DTC supported by DBIA #10000

7.2. Application Programming Interfaces

Table 6 lists the software interfaces for the current patch.

Package	Min. Version Required	Purpose
FileMan	1.0*2	FileMan is VistA's database management system (DBMS)
MailMan	8.0	The VistA MailMan software is designed to allow users, or VistA software applications, to send and receive mail from individuals or groups, electronically, through communication lines, modems, and other networks. Note: Mailman does not support encryption.
Outpatient Pharmacy	7.0	Outpatient Pharmacy provides a method for managing the medications given to Veterans who have visited a clinic or who have received prescriptions upon discharge from the hospital. Outpatient Pharmacy is known as the "Back Door". When orders are processed using the back door, Outpatient
		Pharmacy utilizes the Mental Health software to perform checks to see if the patient is registered and has a Clozapine authorization number.
		Outpatient Pharmacy is used to register patients within the Clozapine program.
		Outpatient Pharmacy uses the Mental Health Clozapine Software to perform safety checks.
		Once an order passes safety checks, the order is dispensed by the Pharmacist. The Clozapine data is transmitted to the national Clozapine database.

Table 6 Software Interfaces

Package	Min. Version Required	Purpose
Inpatient Medications	5.0	The Inpatient Medications package provides a method of management, dispensing, and administration of inpatient drugs within the hospital. When orders are processed using the back door, Inpatient
		Medications utilizes the Mental Health software to perform authorization number.
		Inpatient Medications uses the Mental Health Clozapine Software to perform safety checks and verify changes in the Dose per Day.
		Once an order passes safety checks, the order is activated by the Pharmacist. The Clozapine data is transmitted via MailMan messages to the Hines OI&T VistA RUCL package, and is subsequently downloaded to the National VA Clozapine Registry in Dallas.
Mental Health	5.01	The Mental Health module provides computer support for both clinical and administrative patient care activities associated with mental health care.
		The Mental Health software contains the YSCL server that provides the capability for the NCCC in Dallas to interact (both read and write) with a local VistA system's Clozapine-related files through MailMan messages.
		The Mental Health software also contains Clozapine-related software including the CLAPI and other Clozapine APIs.
		CLAPI is called by CPRS and the Pharmacy applications, when a patient's WBC and ANC lab results must be checked. CLAPI interfaces with the Laboratory system to obtain a patient's WBC and ANC lab results, calculates if Clozapine can safely be dispensed, and returns the results to CPRS, and the Pharmacy applications.
CPRS	Current	CPRS is a VistA computer application. CPRS is the Computerized Patient Record System where authorized providers utilize CPOE Computerized Order Entry.
		CPRS enables doctors and medical professionals to initiate a Clozapine order utilizing the Order or Meds Tab.
		Prior to initiating the order, CPRS utilizes the Mental Health software to perform checks to see if the patient is registered and has a Clozapine authorization number.
		Once an order is initiated, it is sent to a Pharmacy application depending on a patient's status either as an Inpatient Medications or an Outpatient Pharmacy for processing.

Package	Min. Version Required	Purpose
Kernel	8.0	Kernel provides a portability layer between the underlying operating system and the application code. This results in the entire VistA system being portable among different computers, operating systems, and M implementations.

7.3. Remote Procedure Calls

N/A

7.4. HL7 Messaging

N/A

7.5. Web Services

N/A

8. Standards and Conventions Exemptions

N/A

8.1. Internal Relationships

N/A

8.2. Software-Wide Variables

N/A

9. Security

9.1. Security Menus and Options

There are no VistA menus or options required for operation of this patch. Technical staff may be interested in the following related menus listed below:

- CLOZAPINE MULTI TEST LINK
- HLO MAIN MENU
- HL7 MAIN MENU
- PSOL MANAGER
- YSCL HL7 MAIN

9.2. Security Keys and Roles

The following keys are required for operation of this patch.

• YSCL AUTHORIZED

Other associated keys of interest are listed below.

- ORES
- PROVIDER
- PSDRPH
- PSOLOCKCLOZ
- PSORPH

9.3. File Security

N/A

9.4. Electronic Signatures

N/A

9.5. Secure Data Transmission

N/A

10. Archiving

N/A

11. Non-Standard Cross-References

N/A

12. Troubleshooting

Application troubleshooting within the production environment is a collaborative effort that includes Tire 1, Tier 2, and Tier 3 resources. Initial communication of a production defect is reported through the ServiceNow/YourIT ticketing system.

The NCR development and sustainment team does not have access to VA production environments, so involvement of this team entails screen sharing and over-the-shoulder analysis with the help of Tier 1 and/or Tier 2 staff, or production users.

Evaluation of results within VistA can be done by checking the standard VistA/Mumps error trap. This can be done via the Mumps command line or through a VistA menu option.

12.1. Special Instructions for Error Correction

Back-out will be done only with the concurrence and participation of development team and appropriate VA site/region personnel. The decision to back-out or rollback software will be a joint decision between development team, VA site/region personnel and other appropriate VA personnel.

Specific error correction guidance is provided in the NCR DIBRG, which can be found in the VA Software Documentation Library (VDL).

12.2. National Service Desk and Organizational Contacts

The Enterprise Service Desk (ESD) Provides critical IT support to Veterans Affairs. Contact information can be found online at the VA YourIT service portal.

Appendix A: Acronyms and Abbreviations

Table 7 provides the abbreviations and acronyms used throughout the NCR Technical Manual.

Acronym	Description	
ANC	Absolute Neutrophil Count (Lab Test)	
API	Application Programming Interface	
CLAPI	Clozapine Application Programming Interface	
CPOE	Computerized Order Entry	
CPRS	Computerized Patient Record System	
DBA	Database Administrator	
DBMS	Database Management System	
DIBRG	Deployment, Installation, Back-out, and Rollback Guide	
ESD	Enterprise Service Desk	
FDA	Food and Drug Administration	
GUI	Graphical User Interface	
IT	Information Technology	
ICR	Integration Control Registration	
IdM	Identity Management	
IRM	Incident Response Message	
JSON	JavaScript Object Notation	
KIDS	Kernal Installation and Distribution System	
Μ	MUMPS	
MAG	Microsoft Azure Government	
MPI	Master Patient Index	
MUMPS	Massachusetts General Hospital Utility Multi-Programming System	
NCCC	National Clozapine Coordinating Center	
NCR	National Clozapine Registry	
OIT	Office of Information and Technology	
PBM	Pharmacy Benefits Management	
Power Bl	Power Business Intelligence	
REMS	Risk Evaluation and Mitigation Strategy	
REST	Representational State Transfer	
RUCL	Roll-Up Clozaril	
SQA	Software Quality Assurance	
SQL	Structured Query Language	

 Table 7 Acronyms and Abbreviations

Acronym	Description
UAT	User Acceptance Test
VA	Department of Veterans Affairs
VAEC	VA Enterprise Cloud
VDIF	Veterans Data Integration and Federation
VDIF-EP	Veterans Data Integration and Federation Enterprise Platform
VDL	VA Software Documentation Library
VistA	Veterans Health Information Systems and Technology Architecture
WBC	White Blood Count (Lab Test)