VistA Blood Establishment Computer Software (VBECS) - Erytra Interface Configuration and Setup Guide, Version 3.0

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Introduction

VBECS is a Blood Bank application that facilitates ongoing compliance with Food and Drug Administration (FDA) standards for medical devices and enhances the VA's ability to produce high-quality blood products and services to veterans. The system follows blood bank standards, standards of national accrediting agencies, FDA regulations and VA policies.

VBECS 2.2.0 introduced a new interface for blood bank testing performed by blood bank instrumentation to VBECS. The implementation of the interface and its associated validation are described in this guide.

> *Unauthorized access or misuse of this system and/or its data is a federal crime. Use of all data must be in accordance with VA security and privacy policies.*
>
> *The U.S. FDA classifies this software as a medical device. Unauthorized modifications will render this device an adulterated medical device under Section 501 of the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act. Acquiring and implementing this software through the Freedom of Information Act requires the implementer to assume total responsibility for the software and become a registered manufacturer of a medical device, subject to FDA regulations. Adding to or updating VBECS software without permission is prohibited.*
>
> *Instructions in this Setup Guide must be followed for the interface to deliver information to VBECS. Local validation is required to confirm proper operation before use. Validation and verification is required to ensure connectivity to VBECS.*

This guide is provided to assist you with the multi-faceted required setup of your local blood bank testing instrument(s), Data Innovations Instrument Manager (DI IM) and VBECS to electronically transmit instrument test results to VBECS for use in the transfusion service.

This guide includes download and install of a set of configuration files (.gsb files) as a starting point for your instrument setup. These configuration files are not created and validated by the VBECS team but are shared by other VBECS sites already using this instrument and are made available for installation from the VBECS SharePoint site. As noted above, local validation is required to confirm proper operations with the configurations implemented by your site.

There are specific setup requirements to test and transmit those testing results to VBECS for review using DI IM (Figure 1).

Figure 1: Hardware and Interface Configuration
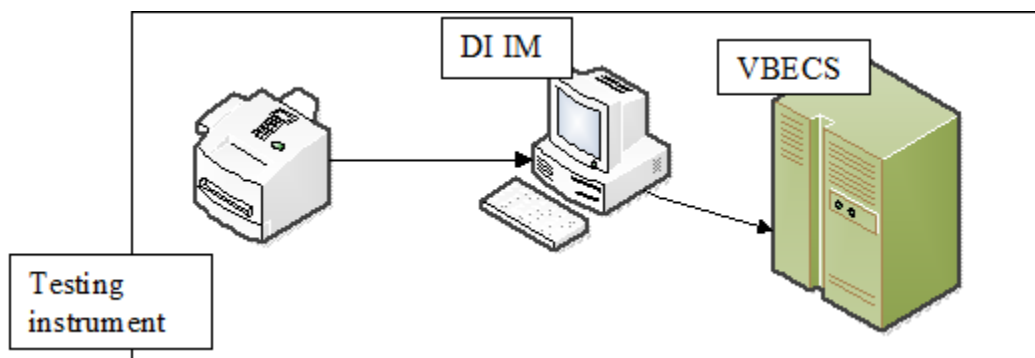
Your local testing instrument(s) communicates with DI IM via an instrument specific driver provided by DI that must be downloaded from DI and installed locally.

DI IM communicates directly with VBECS via a generic HL7 interface driver that must be downloaded from DI and installed, locally. This driver is customized for VBECS by downloading and installing the driver configuration file.

VBECS has an interface that must be configured in VBECS Administrator to receive messages from DI IM (Figure 2).

Figure 2: Setup Path
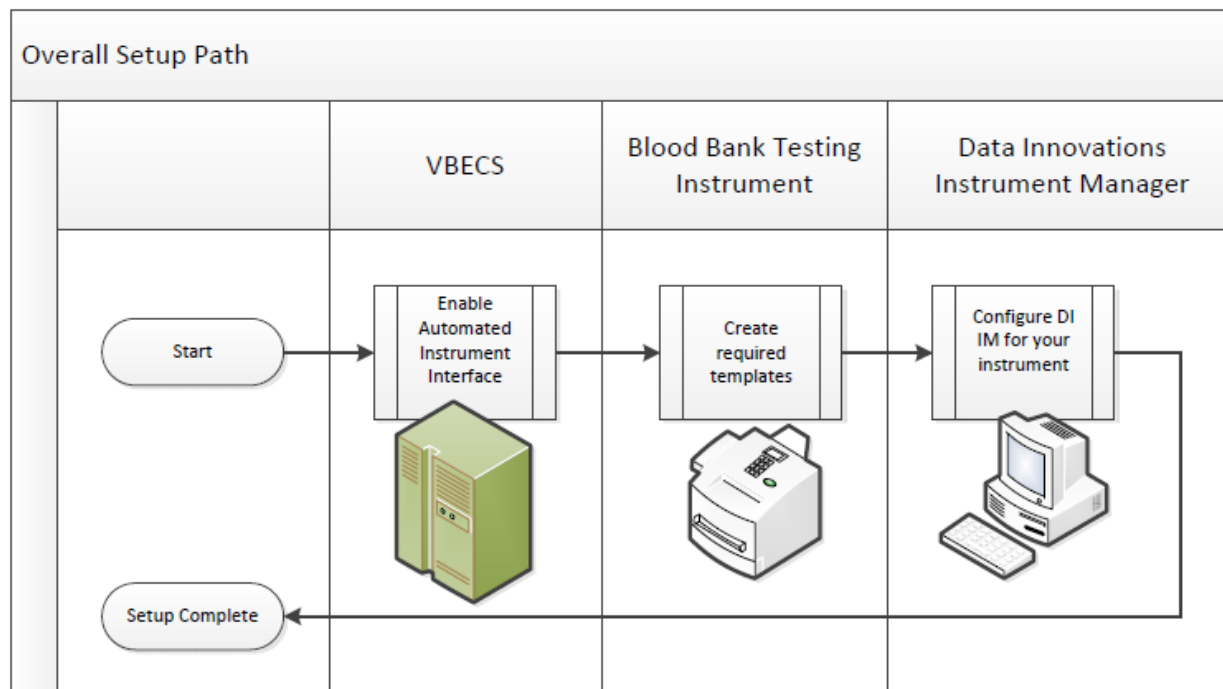
Related *Manuals and Reference Materials*

- *VBECS Technical Manual-Security Guide*
- *Data Innovations Instrument Manager Manual*
- *Blood Bank Analyzer User's Guide (Instrument Manual)*

Set Up Automated Instrument

1   Network Connectivity Setup

In order to ensure proper functioning of an interface between an Automated Instrument and Instrument Manager, the Instrument needs to be connected to the VA network. The static IP Address and Port number has to be assigned to the Instrument (further referred in this document as ***<Instrument IP>*** and ***<Instrument Port>***). Please refer to the Instrument Manual or contact your vendor for the instructions about how to perform this setup. Check with Local IT staff to establish the connection to Instrument Manager.

2   Testing Template Setup

If testing templates are not configured properly it will be impossible for instrument results to be accepted in VBECS.

Please refer to ***Appendix D: Testing Templates*** for the list of instrument templates. These test templates must be set up on your Instrument before any results can be sent to VBECS. Always use them for results that are sent to VBECS. Any results sent that do not follow the above templates will be rejected. Please refer to the Instrument Manual or contact your vendor for the instructions about how to perform template setup.

AABB Standards require a serological XM to detect ABO incompatibility (5.16.1) and a local policy must be in place if the site is not performing an IS AHG as part of their serologic crossmatch test, manual or using an instrument.

3   User ID Setup

Failure to set up proper user IDs on an instrument will prevent instrument results from being accepted in VBECS.

In order for VBECS to properly recognize the person who performed testing on an Instrument, all users accessing the instrument must have their user IDs set up to match their network user IDs (e.g., ==REDACTED==).

Due to the constraints of the Erytra messaging system, only 10 characters of the user name can be transferred with test results to VBECS. To ensure the uniqueness of all user names, please strip the front characters of network user ID to ensure that it is no longer than 10 characters long. For user IDs that are already 10 characters or shorter you can use full user ID in Erytra. For example:

Length of User ID	Example of User ID	Erytra ID
12	VHASFCYOUNGS	SFCYOUNGS
11	VHASFCTRANK	HASFCTRANK
10 or less	VHASFCTSTU	VHASFCTSTU

Please refer to the Instrument Manual or contact your vendor for the instructions about how to perform setup of user IDs.

Set Up Instrument Manager

1   Instrument Manager Version

Please verify that you are using Instrument Manager Version 8.13 or greater (Figure 3). In Instrument Manager navigate to **Help -> About Instrument Manager**.

Figure 3: Instrument Manager Version Screen

> 🛑 *If your version of Instrument Manager is older than 8.13 STOP executing this guide and update the software first.* **Do not proceed until the issue is resolved.**

> *If your Instrument Manager is greater than 8.13 you may proceed. The user must execute the instructions and validate functionality on newer versions. Discrepancies in the instructions must be reported as a service desk ticket.*

> 🛑 *Instrument Manager must have the* **Specimen Management Module** *licensed and activated.* **Do not proceed until this issue is resolved.**

2   Instrument Manager to Automated Instrument Connectivity

Please contact your local network administrative staff and ensure that your local network allows two-way TCP/IP connectivity between **<Instrument Manager IP>** address and **<Instrument IP>** address on **<Instrument Port>**.

3 Installing Instrument Driver

Two drivers are required for the correct operation of the Automated Instrument interface to VBECS (Figure 4).

Figure 4: Required Drivers

Driver	Name	Version	Description
Grifols Erytra	griertri	8.00.0001	Instrument to DI IM driver
Data Innovations LLC, Configurable HL7	diihl7ml	8.00.0049	DI IM to VBECS (HL7) driver

Please refer to the user's manual for Instrument Manager or contact Data Innovations for the instructions on how to install drivers for Instrument Manager.

After successful installation of drivers go to **Report -> Available Drivers** menu option in Instrument Manager and verify that the drivers listed in Figure 4 are present.

4 Set Up Instrument Manager Configuration

Execute instructions in this section for each instrument that will be connecting to VBECS.

Modifying rules or test code mappings as imported using this Instrument Manager configuration Setup Guide may lead to malfunction of the Automated Instrument to VBECS interface.

Prerequisites for the Instrument Manager Configuration files download:

- You must be an administrator on <***Instrument Manager Server***>.
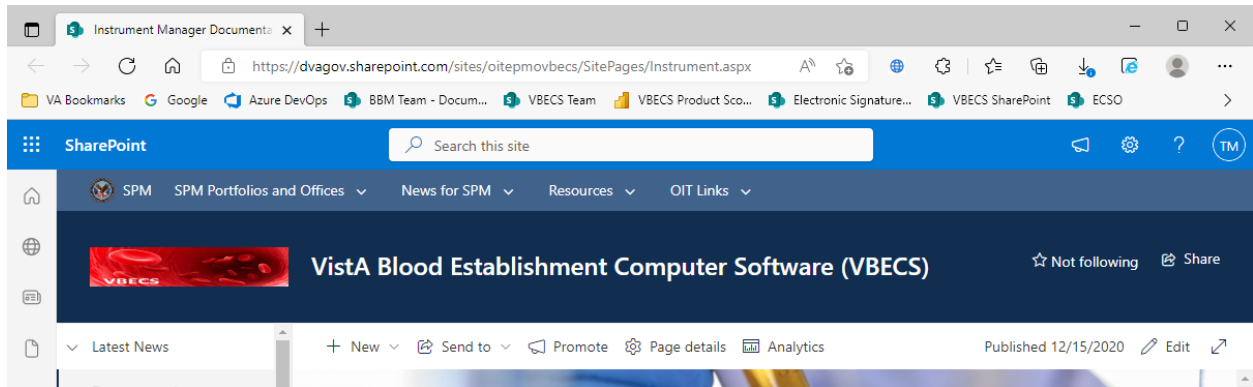- Once the above prerequisite is met you may proceed.

4.1 Download Instrument Configuration Files

ℹ️ **Use local procedures for copying the instrument configuration files to the Instrument Manager server.**
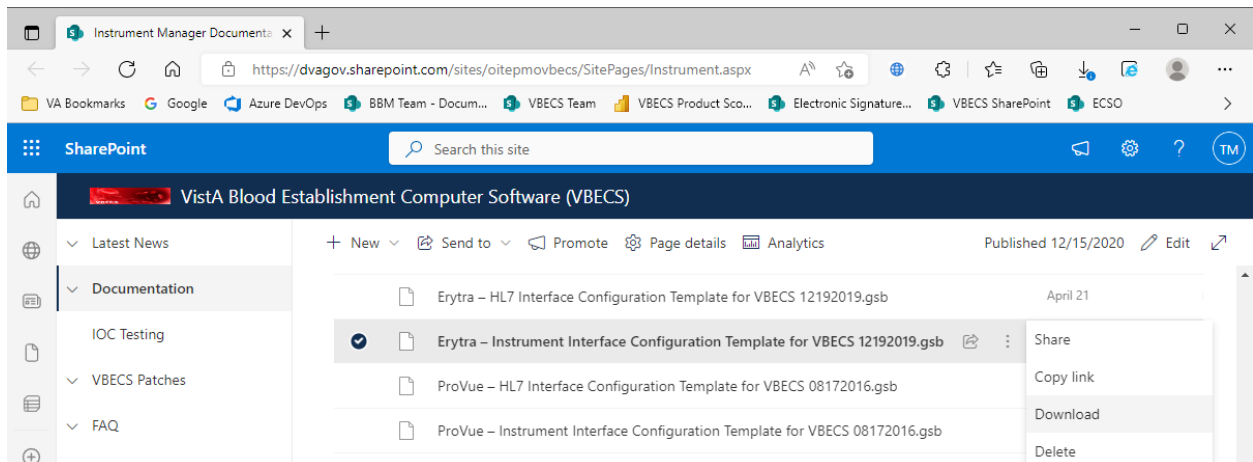
1. Navigate to **REDACTED** (Figure 5).

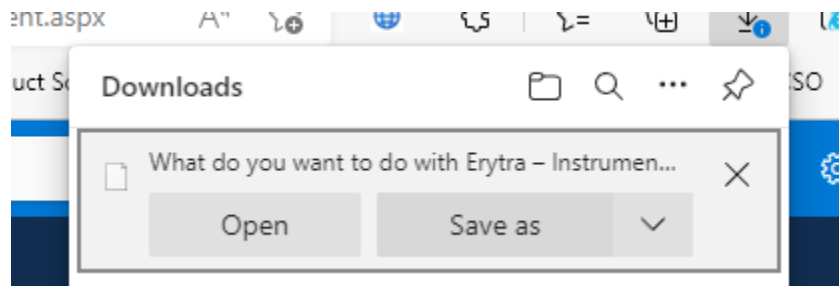**Figure 5: Connecting to the VBECS SharePoint**

2. To download a file from SharePoint, click the ellipses (...) and select **Download** (Figure 6).

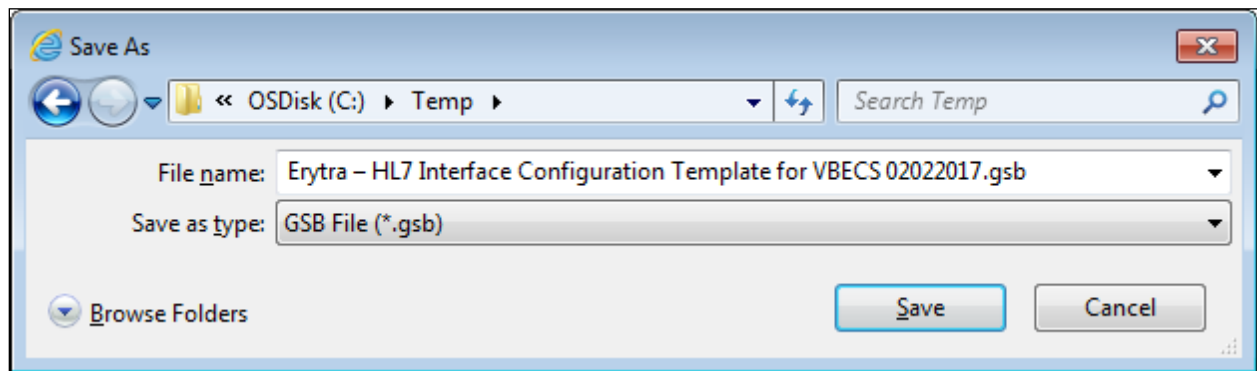**Figure 6: Example of SharePoint Download**

3. In the Downloads screen, select **Save as** (Figure 7).

Figure 7: Example of Downloads

4. In the next screen, specify the directory to save (Figure 8).

Figure 8: Example of Save As

5. Save both the **Erytra - HL7 Interface Configuration Template for VBECS 12192019.gsb** and the **Erytra - Instrument Interface Configuration Template for VBECS 12192019.gsb** files to the **C:\temp** directory.

6. Per local procedures copy both files to C:\temp on the Instrument Manager server

7. On the Instrument Manager server; Click **Start**, and in the "Search programs and files" box type **Run** and hit enter. Type **powershell** and click **OK** to launch PowerShell

8. Copy and paste or type the following commands to generate checksums for configuration files:

certutil -hashfile "C:\Temp\Erytra - HL7 Interface Configuration Template for VBECS 12192019.gsb" MD5 **<press Enter>**

certutil -hashfile "C:\Temp\Erytra - Instrument Interface Configuration Template for VBECS 12192019.gsb" MD5 **<press Enter>**

To copy, highlight the lines in grey and enter CTRL-C.

To insert the copied line into a PowerShell window, right click in the PowerShell window and select "Paste".

9. Verify that checksums for both files match those shown in **Figure 9**.

Figure 9: Instrument Manager Configuration File Checksums

```
PS C:\> certutil -hashfile "C:\temp\Erytra - HL7 Interface Configuration Template for VBECS 12192019.gsb" MD5
MD5 hash of C:\temp\Erytra - HL7 Interface Configuration Template for VBECS 12192019.gsb:
Fad73e90b8e1490072beb463be8e4e68
CertUtil: -hashfile command completed successfully.
PS C:\> certutil -hashfile "C:\temp\Erytra - Instrument Interface Configuration Template for VBECS 12192019.gsb" MD5
MD5 hash of C:\temp\Erytra - Instrument Interface Configuration Template for VBECS 12192019.gsb:
2948d8b38a502aebd195e188d078230d
CertUtil: -hashfile command completed successfully.
```

🛑 *If the checksums do not match, stop and* **<u>file a service desk ticket to coordinate assistance with</u> <u>installation</u>**. ***Do not proceed until the issue is resolved.***

10. Close the **PowerShell** window.

4.2 Import Instrument Side Configuration

1. After downloading and verifying configuration files, open Instrument Manager and navigate to **Configuration -> Configuration Editor**.
2. Click on the **Import** button (Figure 10).

Figure 10: Example of Configuration Editor
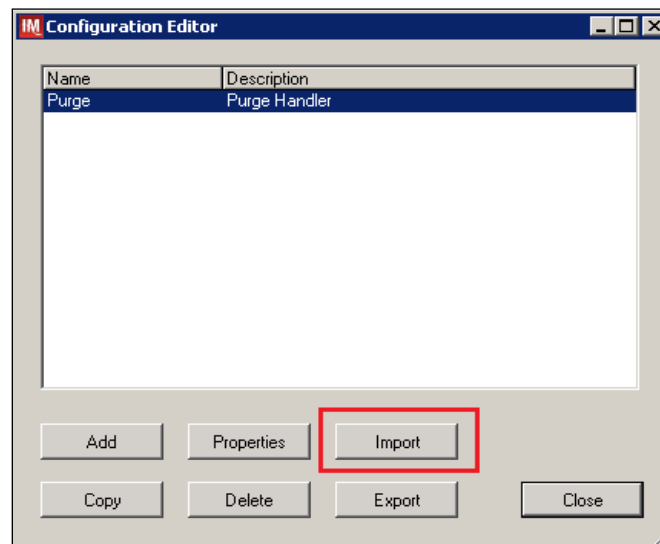
3. Once the import screen opens, click the **Browse** button and select **C:\Temp** folder (Figure 11).

4. Click OK.

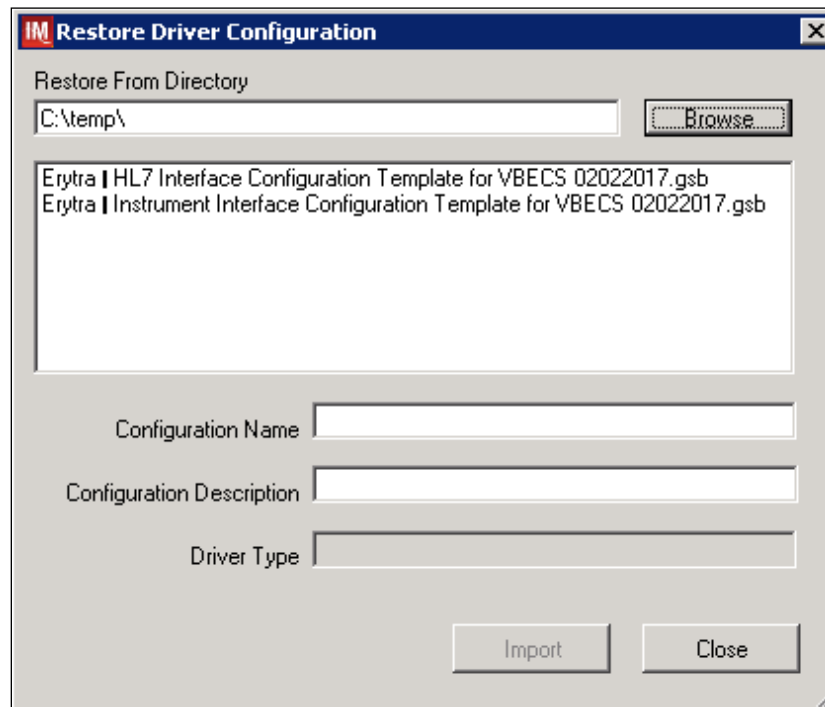**Figure 11: Example of Configuration Import Screen**

5. Select **Erytra - Instrument Interface Configuration Template for VBECS 12192019.gsb** file from the list.

6. Enter **Configuration Name** that contains 3 letter location code of the instrument (e.g., **HIN** for Hines VAMC), word **Erytra** and sequence number (**1** for the first instrument, **2** for the second etc.). Example Configuration Name for instrument configuration located at Hines would be:

> **HIN_Erytra_1**

This configuration name will be further referred in this document as *<Instrument Side Configuration>*.

7. Enter **Configuration Description** and click **Import** button. Verify that the following confirmation window displays (Figure 12).

Figure 12: Example of Successful Configuration Import
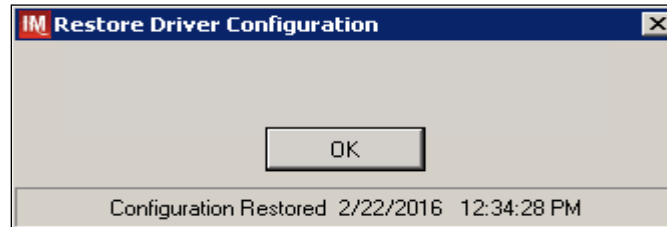
> ℹ️ *If you are using a newer version of the driver than the one mentioned in section 3, the Instrument Manager will warn you about the discrepancy in driver versions. Please acknowledge this warning and continue.*

8. Click **OK** and then close the **Restore Driver Configuration** window.

9. Verify that **Configuration Editor** shows the new configuration on the list (Figure 13).

Figure 13: Example of Configuration Editor Window Showing Newly Imported Configuration
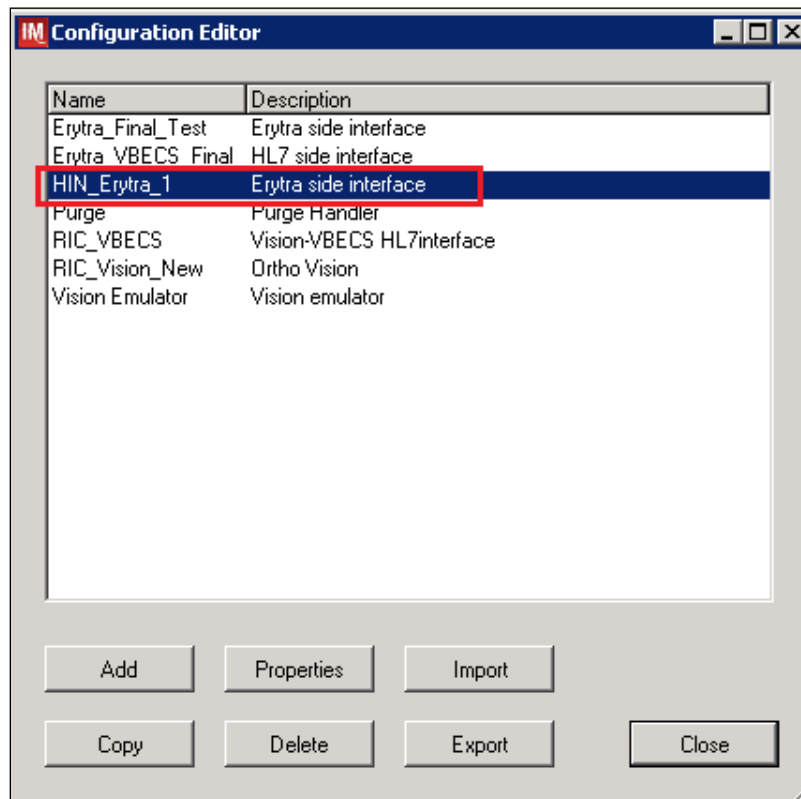
10. **Close** the Configuration Editor Window

4.3 Verify Test Code Mapping for Instrument Side Configuration

1. Navigate to **Reports** -> **Configuration Options and Mappings.**

2. Select the ***<Instrument Side Configuration Name>*** from the pull down menu (Figure 14)

3. Select the **Results Test Code Mapping Tab** (Figure 14).

4. Verify the **Results Test Code Mapping Report Tab** matches the list in ***Appendix A: Instrument Side Mapping.***

Figure 14: Example of Results Test Code Mapping Tab

REDACTED

🛑 *If mismatches in Test Codes names, or missing or extra Test Codes are encountered, **file a service desk ticket to coordinate assistance with installation.** **Do not proceed until the issue is resolved.***

---

5. Close **Configuration Options and Mappings** window.

4.4 Verify Rules

1. Next navigate to **Reports -> Configuration Options and Mappings.**

2. Select the ***<Instrument Side Configuration Name>*** from the drop-down in the upper left corner. (Figure 15).

3. Select the **Rules Tab** (Figure 15).

4. Verify the **Rules Tab** matches all rules listed in ***Appendix C: Rules***.

Figure 15: Example of Rules Tab

REDACTED

5. Close the **Configuration Options and Mappings** window.

🛑 *If mismatches in rules are encountered, **file a service desk ticket to coordinate assistance with installation.** **Do not proceed until the issue is resolved.***

4.5 Configure Rules

In this section your will establish the name of the instrument associated with test results for VBECS reports. *If you are setting up multiple instruments, make sure that each has a unique name.*

1. Navigate to Configuration -> Specimen Management Configuration -> Rules Processing.

2. Select ***<Instrument Side Configuration Name>*** from the pull down menu (Figure 16).

3. Locate rule **SetInstrumentID**.

4. Click on the **Then** line in the rule.

5. Modify the rule by typing **<Instrument Name>** between the quotation marks in the lower box (Figure 16).

Figure 16: Example of Instrument Name Setup
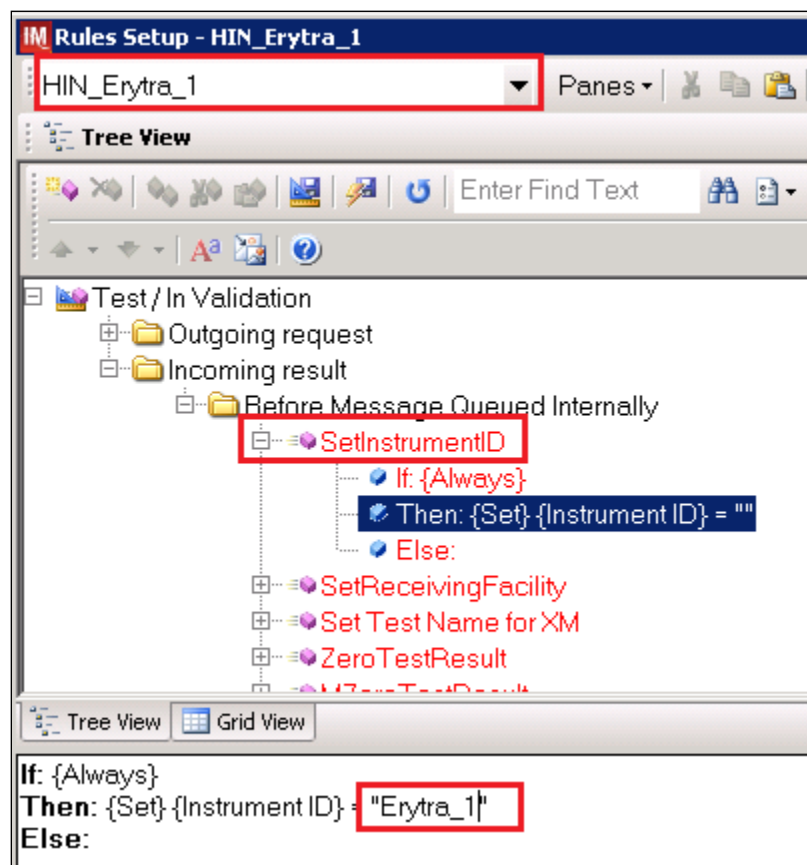
6. Locate rule **SetReceivingFacility**. Click on **Then** line in the rule. Modify the rule by typing the **<Division Code>** between the quotation marks as shown (Figure 17).

> **ⓘ** *<Division Code>* also known as Station Number in VistA is a unique alphanumeric code that is associated with each hospital (e.g. **589** for VA Heartland West VAMC). This code must match the division code configured in **VBECS Administrator** application for a given site.

Figure 17: Example of Division Code Setup
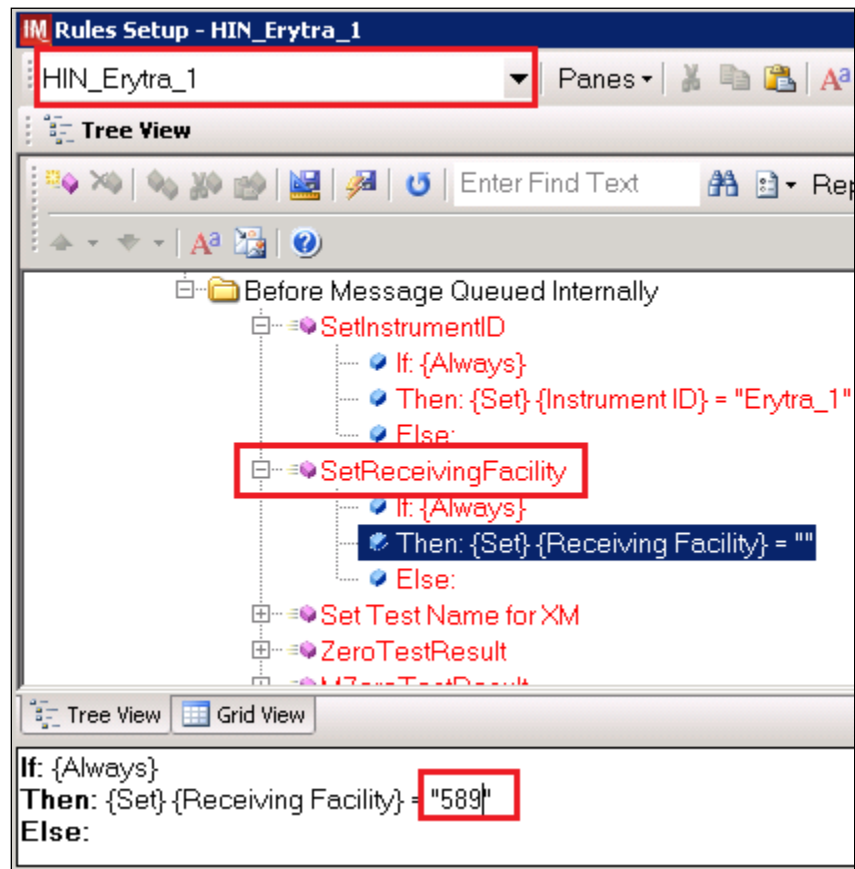
7. After the change was made, both rules' text should be displayed in red color on the screen.

8. Click on **Save Test / In Validation Rule Set** button located in the toolbar above the rules (Figure 18).

Figure 18: Example of Save Rules Button
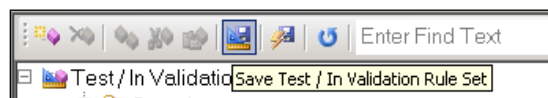
9. Verify that the Test / In Validation Rule Set Saved message is received (Figure 19).

**Figure 19: Example of Successful Rule Save**
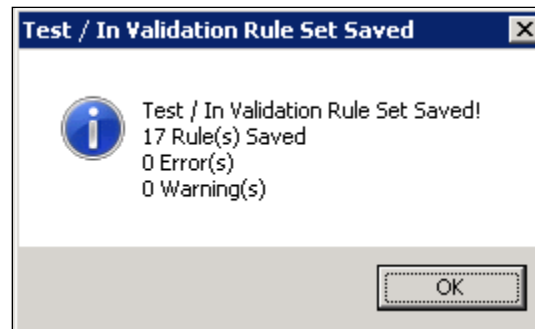
> 🛑 *If errors while saving rules are encountered,* ***file a service desk ticket to coordinate assistance with installation.*** *Do not proceed until the issue is resolved.*

10. Click on the **Save Live Rule Set** button (Figure 20) located in the toolbar and click **Yes** to confirm.

Figure 20: Example of Save Rules in Live Set Button

11. Expand the **Live Rule Set**, and verify that rule text matches *Appendix C: Rules* and includes changes made to **SetInstrumentID** and **SetReceivingFacility** (Figure 21).

Figure 21: Example of Live Rules Set View
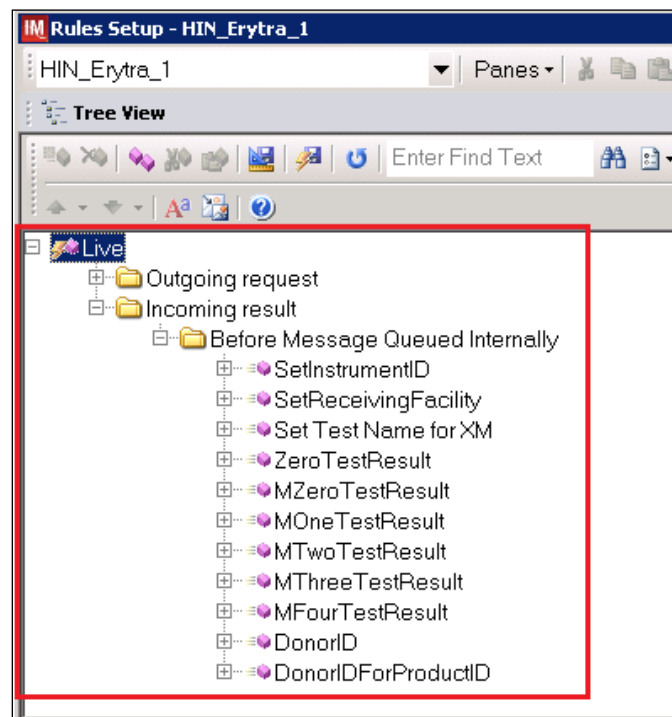
🛑 *If differences in rules are encountered,* **file a service desk ticket to coordinate assistance with installation. Do not proceed until the issue is resolved.**

12. Close the **Rule Setup** window, returning to the main menu.

4.6 Import VBECS (HL7) Side Configuration

ℹ️ **Only one VBECS side configuration is needed even if you use multiple Erytra instruments. All Erytras will share the same configuration.**

🛑 *Modifying rules or test code mappings in the Instrument Manager configuration outside of this Setup Guide is not allowed and may lead to malfunction of the Automated Instrument to VBECS interface.*

1. Navigate to **Configuration -> Configuration Editor** (Figure 22).

2. Click on the **Import** button.

Figure 22: Example of Configuration Editor Window
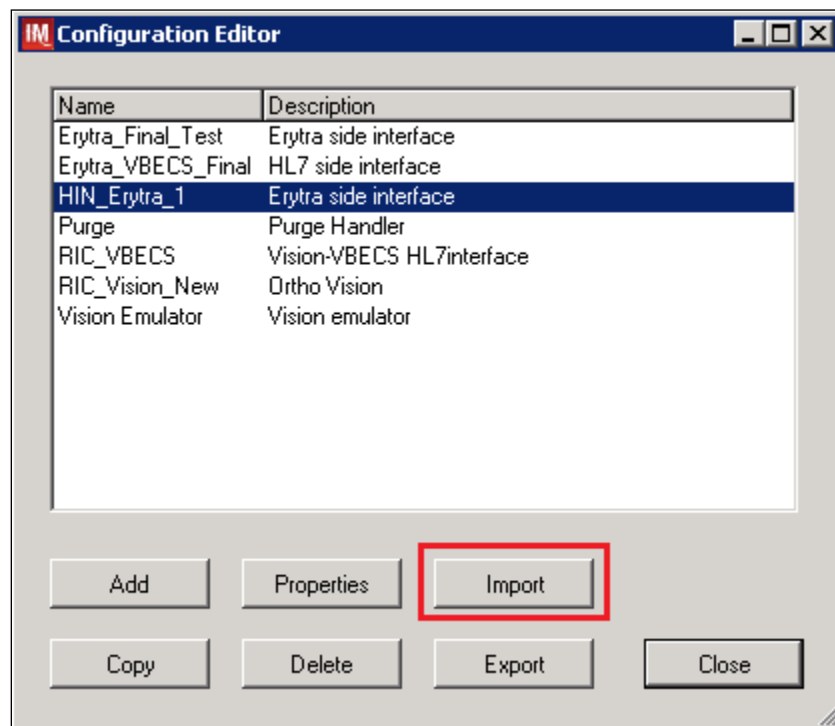
3. Once the **Restore Driver Configuration** window opens, click the **Browse** button and select **C:\Temp** folder (Figure 23).

4. Select **Erytra - HL7 Interface Configuration Template for VBECS 12192019.gsb** file from the list.

5. Enter a **Configuration Name** that contains 3 letter location code of the instrument (e.g. **HIN** for Hines VAMC), word **VBECS** and sequence number (**1** for the first configuration**, 2** for the second etc.). Example Configuration Name for VBECS side configuration located at Hines would be:

HIN_VBECS_1

This configuration name will be further referred in this document as ***<HL7 Side Configuration>***.

Figure 23: Example of Configuration Import Window
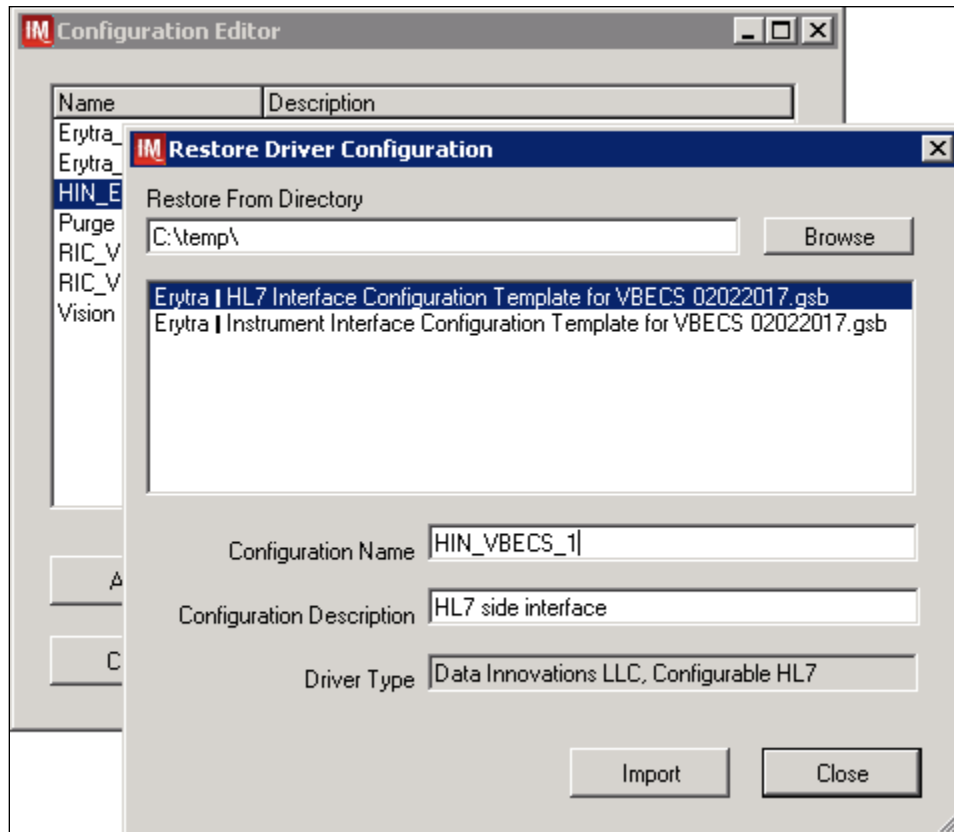
6. Enter **Configuration Description** and click **Import** button. Verify that the following confirmation window (Figure 24) displays.

Figure 24: Example of Successful Configuration Import
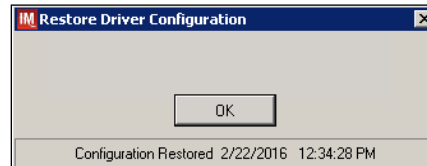
> ℹ️ *If you are using a newer version of the driver than the one mentioned in section 3, the Instrument Manager will warn you about the discrepancy in driver versions. Please acknowledge this warning and continue.*

7. Click **OK** and close the **Restore Driver Configuration** window.
8. Verify that **Configuration Editor** shows the new configuration on the list (Figure 25).

Figure 25: Example of Newly Imported HL7 Configuration
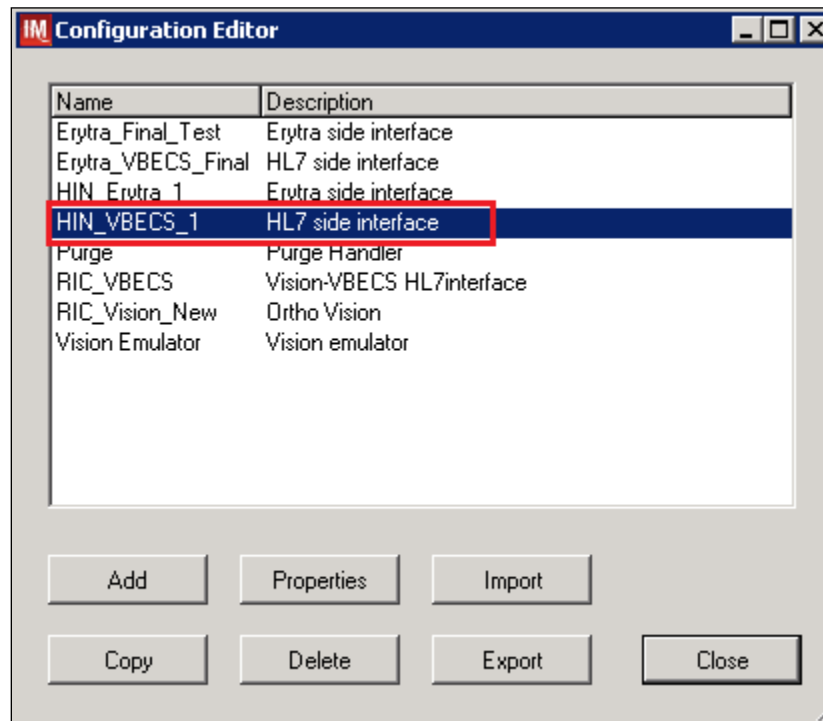
4.7 Verify Test Code Mapping for VBECS Side Configuration

1. Navigate to **Reports ->Configuration Options and Mappings.**
2. Select the ***<HL7 Side Configuration Name>*** from the drop-down in the upper left corner (Figure 26).
3. Select the **Results Test Code Mapping Tab** (Figure 26).
4. Verify that the **Results Test Code Mapping Tab** matches all rules listed in *Appendix B: HL7 (VBECS) Side Mapping.*

Figure 26: Example of HL7 Configuration Report Window

<mark>REDACTED</mark>

5. Close **Configuration Options and Mappings** window.

STOP *If mismatches in Test Codes names, missing or extra Test Codes are encountered, **file a service desk ticket to coordinate assistance with installation. Do not proceed until the issue is resolved.***

---

5 Set Up HL7 Connection to VBECS TEST

> 🛑 *Modifying rules or test code mappings as imported using this Instrument Manager configuration Setup Guide may lead to malfunction of the Automated Instrument to VBECS interface*.

1. Navigate to **Configuration -> Connection Assignment**.

2. On the **Connection Assignment** window click **Add** button.

3. Select **Configuration Name <*HL7 Side Configuration*>** (Figure 27).

4. Enter the **Connection Name** that matches the **<*HL7 Side Configuration*>** and word **Connection**. For example:
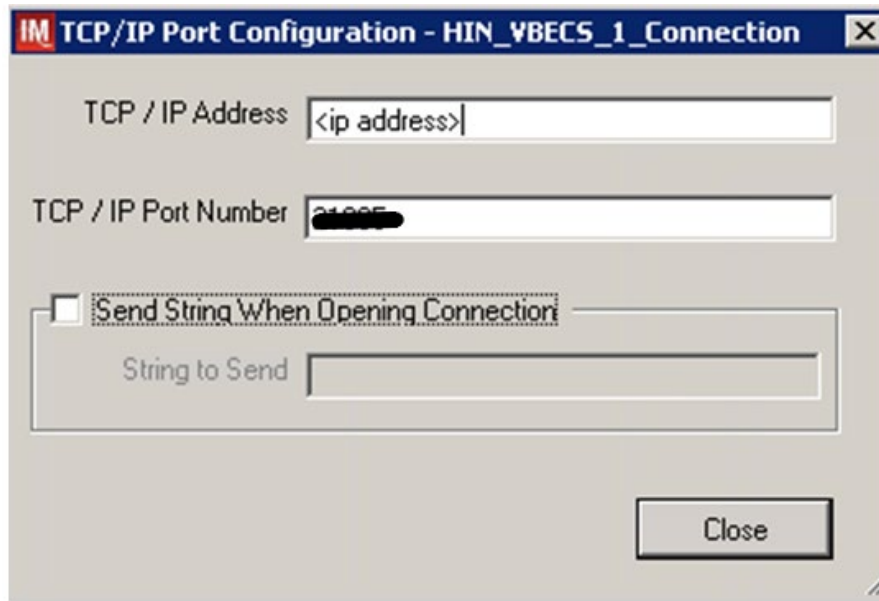
   HIN_VBECS_1_Connection

5. Check **Include in Specimen Management** check box (Figure 27).

6. Select **TCP/IP connection** in Device (Figure 27).

Figure 27: Example of Connection Properties Window

7. Click on **Device Parameters** button.

8. Enter **TCP/IP Address** and **TCP/IP Port Number** that matches **VBECS TEST Application IP Address and IP Port Number** configured in **VBECS TEST Administrator** application for **Auto Instrument Interface** (Figure 28). (Please refer to *VBECS Technical Manual Security Guide* for instruction on how to configure interfaces for VBECS.)
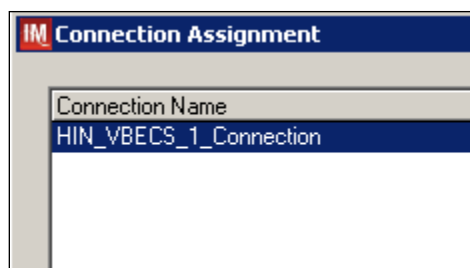
Figure 28: Example of TCP/IP Configuration Window

9. Close the **TCP/IP Port Configuration** window and click **Yes** to save.

10. Close the **Connection Properties** window and click **Yes** to save.

11. Verify that the newly created connection shows on the **Connection Assignment** window (Figure 29).

Figure 29: Example of Newly Created Connection

6   Set Up Instrument Connection

ℹ **Execute instructions in this section for each instrument that will be connecting to VBECS.**

🛑 *Modifying connection settings in the Instrument Manager outside of this Setup Guide is not allowed and may lead to malfunction of the Automated Instrument to VBECS interface.*

1. On the **Connection Assignment** window, click **Add** button.
2. On the **Connection Properties** window, enter the **Connection Name**. Enter a name that contains *<Instrument Side Configuration>* and word **Connection**. For example:

    HIN_Erytra_1_Connection

3. Select *<Instrument Side Configuration>* **as Configuration Name**.
4. Check **Include in Specimen Management** check box.
5. Select **TCP/IP connection**.
6. On the **Destination Lines** list, check the box next to connection configured in previous section (Figure 30).

Figure 30: Example of Connection Properties Window

7. Click on **Device Parameters** button.
8. Enter **TCP/IP Address** and **TCP/IP Port Number** that matches *<Instrument IP>* and *<Instrument Port>* discussed in Section **Network Connectivity Setup**.
9. Uncheck **Send String When Opening Connection** check box (Figure 31).

Figure 31: Example of TCP/IP Configuration Window
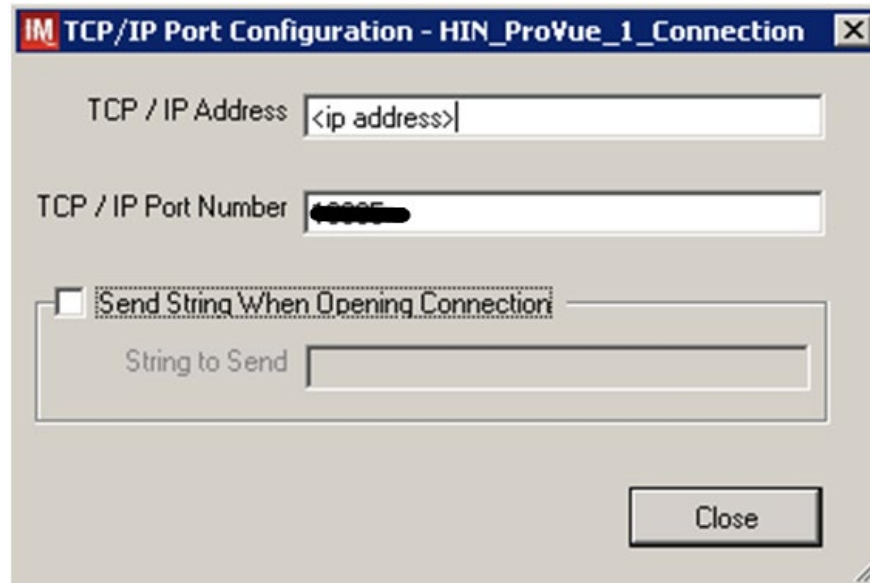
10. Click close on the **TCP/IP Port Configuration** window and click **Yes** to save.
11. Click close on the **Connection Properties** window and click **Yes** to save.
12. Verify the newly created connection shows on **Connection Assignment** window (Figure 32).
13. Close the **Connection Assignment** window.

Figure 32: Example of Newly Created Connection
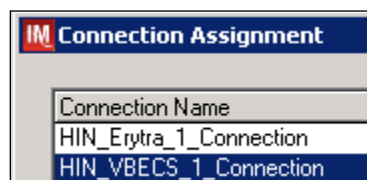
7   Test New Connections

1. Navigate to **System -> Status**.
2. Right-click on each newly created connection and choose option to **Start Selected Connections** (Figure 33).

Figure 33: Example of Connection Status Window
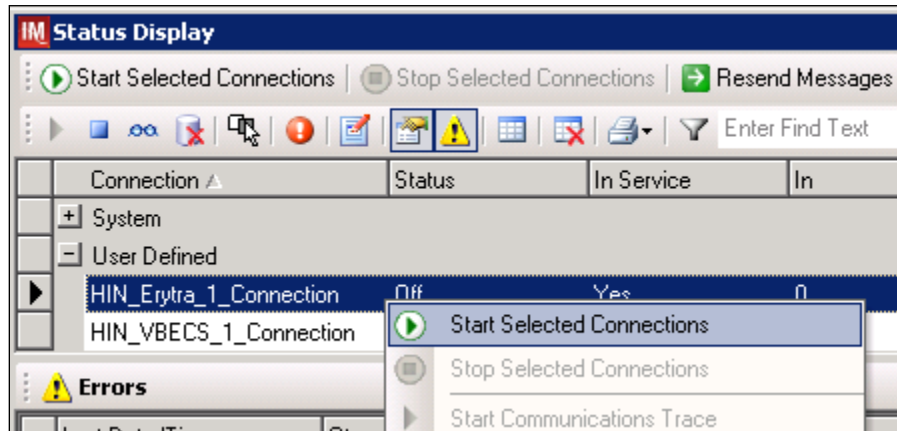
3. Verify that all newly created connections are showing **Status** of **On** after about a minute or so. (Figure 34).

Figure 34: Example of Successful Connection Test
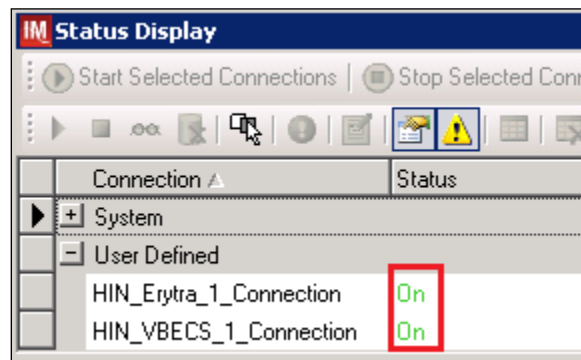
> 🛑   *If one or more connections fail to start, **file a service desk ticket to coordinate assistance with installation. Do not proceed until the issue is resolved.***

4. Close the **Status Display**.

8   Validate Instrument Connectivity to VBECS TEST

Execute validation instructions from *Appendix E: Validation Planning and Example Test Scenarios* to verify that Instrument is properly interfacing with VBECS.

STOP *If one or more validation scenarios fail, **file a service desk ticket to coordinate assistance with installation. Do not proceed until the issue is resolved.***

9   Set up HL7 Connection to VBECS PROD

1. Navigate to **System -> Status**.

2. Right-click **<VBECS_Connection>** and choose option to **Stop Selected Connections** (Figure 35).

Figure 35: Example of Stop Selected Connections
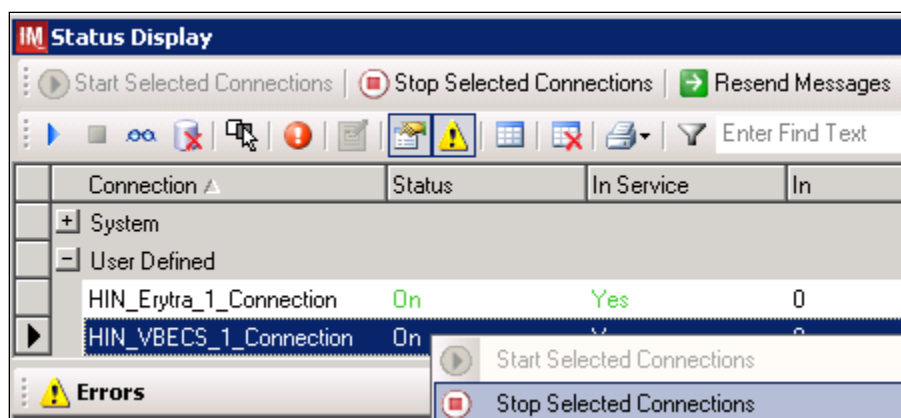
3. Wait until connection status changes to **Off**. Navigate to **Configuration -> Connection Assignment.**

4. Select **<VBECS_Connection>** and click **Properties** (Figure 36).

Figure 36: Example of Connection Assignment
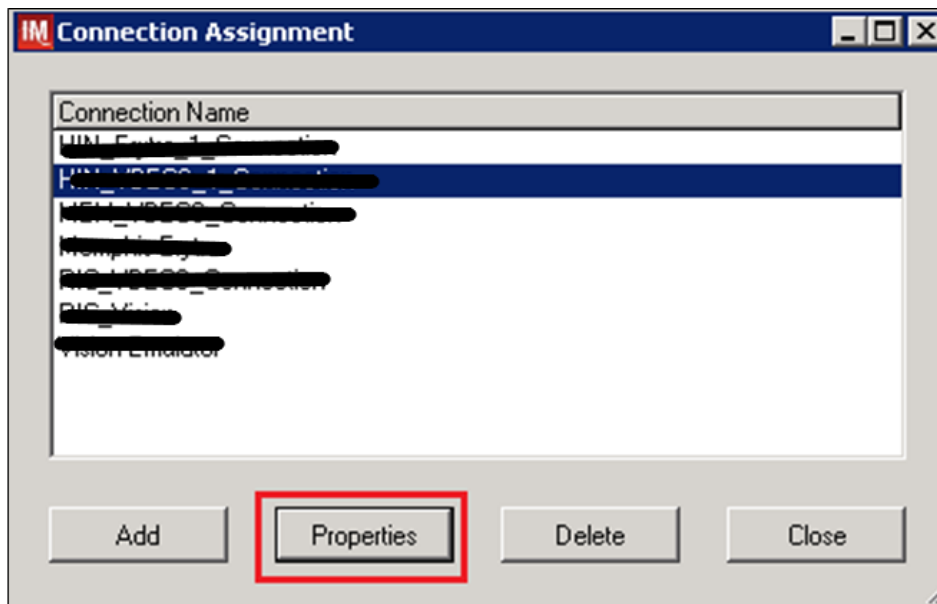
5. On **Connection Properties** window click **Device Parameters** (Figure 37).

Figure 37: Example of Connection Properties

6. Enter **TCP/IP Address** and **TCP/IP Port Number** that matches **VBECS PROD Application IP Address and IP Port Number** configured in **VBECS PROD Administrator** application for **Auto Instrument Interface** (Figure 38). Please refer to *VBECS Technical Manual Security Guide* for instruction on how to configure interfaces for VBECS.

Figure 38: Example of TCP/IP Configuration Window
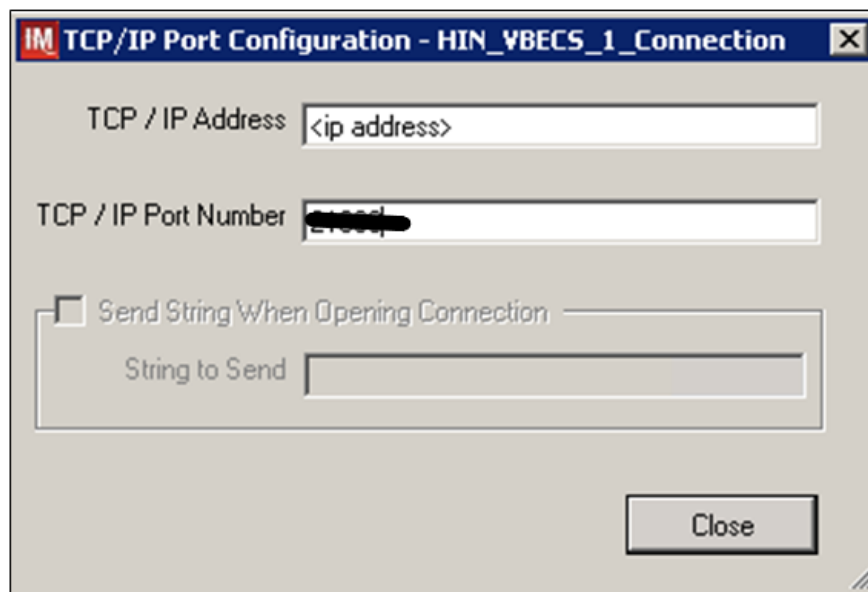
7. Close the **TCP/IP Port Configuration** and click **Yes** to confirm changes.

8. Close the **Connection Properties window** and click **Yes** to confirm changes.

9. Close the **Connection Assignment** window.

10. Navigate to **System -> Status**.

11. Right-click **<VBECS_Connection>** and choose option to **Start Selected Connections** (Figure 39).

Figure 39: Example of Connection Status Window
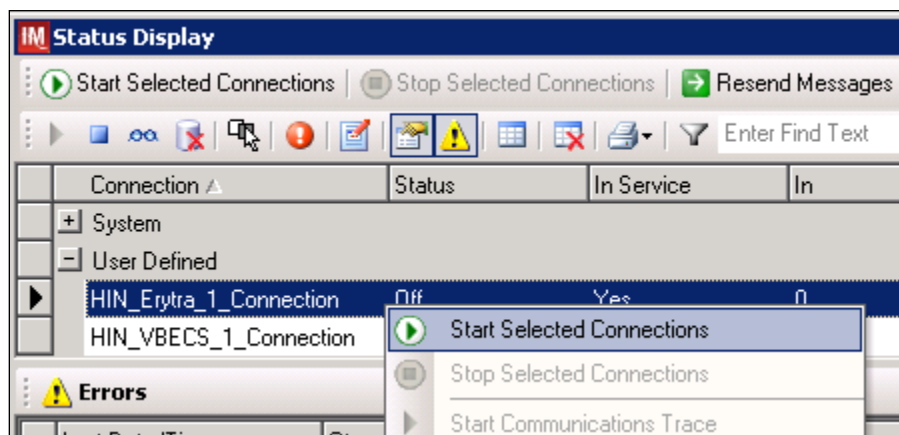
12. Verify that **<VBECS_Connection>** is showing Status of **On** after about a minute or so. (Figure 40).

Figure 40: Example of Successful Connection Test
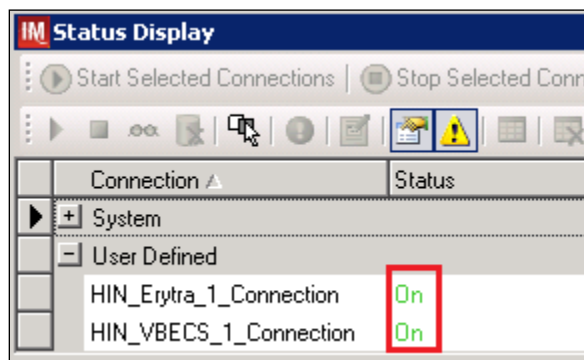
🛑 *If connection fails to start, **file a service desk ticket to coordinate assistance with installation. Do not proceed until the issue is resolved.***

13. Close the **Status Display** and Log Off the system.

Glossary

Acronym, Term	Definition
Automated Instrument	Blood Bank Analyzer that performs blood testing.
Division Code	Also known as Station Number in VistA is the unique alphanumeric code that is associated with each hospital (e.g. 589 for VA Heartland West).
Instrument Manager (IM)	Software created by Data Innovations that serves as a middleware between Automated Instrument and VBECS. It translates messages containing test results sent from an instrument into HL7 messages that are then parsed into VBECS.
VA	Department of Veterans Affairs.
VBECS	VistA Blood Establishment Computer Software.
VistA	Veterans Health Information Systems and Technology Architecture. VistA software, developed by the VA, is used to support clinical and administrative functions at VA Medical Centers nationwide. VistA is composed of packages that undergo a verification process to ensure conformity with name spacing and other VistA standards and conventions.

Appendices

Appendix A: Instrument Side Mapping

Table 1: Instrument Side Mapping

REDACTED

Appendix B: HL7 (VBECS) Side Mapping

Table 2: HL7 (VBECS) Side Mapping

<mark>REDACTED</mark>

Appendix C: Rules

--- Test / In Validation - Incoming result - Before Message Queued Internally ---

Rule # 1
  Desc - SetInstrumentID
  If - {Always}
  Then - {Set} {Instrument ID} = ""

Rule # 2
  Desc - SetReceivingFacility
  If - {Always}
  Then - {Set} {Receiving Facility} = ""

Rule # 3
  Desc - Set Test Name for XM
  If - {Test Code} {On Any Test} {Contains} "Crossmatch"
  Then - {Set} {Test Code Sub ID} {On That Test} = "XM"

Rule # 4
  Desc - Set Test Name for TAS
  Child of Rule # 3 - Else
  If - {Test Code} {On Any Test} {Contains} "TAS"
  Then - {Set} {Test Code Sub ID} {On That Test} = "TAS"

Rule # 5
  Desc - Set Test Name for DAT
  Child of Rule # 4 - Else
  If - {Test Code} {On Any Test} {Contains} "DAT"
  Then - {Set} {Test Code Sub ID} {On That Test} = "DAT"

Rule # 6
  Desc - Set Test Name for Patient ABORh
  Child of Rule # 5 - Else
  If - {Test Code} {On Any Test} {Contains} "ABDRev"
  Then - {Set} {Test Code Sub ID} {On That Test} = "Patient ABORh"

Rule # 7
  Desc - Set Test Name for ABS
  Child of Rule # 6 - Else
  If - {Test Code} {On Any Test} {Contains} "ABS"
  Then - {Set} {Test Code Sub ID} {On That Test} = "ABS"

Rule # 8
  Desc - Set Test Name for Unit ABORh
  Child of Rule # 7 - Else
  If - {Test Code} {On Any Test} {Contains} "Retype"
  Then - {Set} {Test Code Sub ID} {On That Test} = "Unit ABORh"

Rule # 9
  Desc - Set Test Name for Antigen Typing
  Child of Rule # 8 - Else
  If - {Test Code} {On Any Test} {Contains} "Phenotype"
  Then - {Set} {Test Code Sub ID} {On That Test} = "Antigen Typing"

Rule # 10
  Desc - ZeroTestResult
  If - {Result} {On Any Test} = "-"
  Then - {Set} {Result} {On That Test} = "0"

Rule # 11
  Desc - MZeroTestResult
  If - {Result} {On Any Test} = "M-"
  Then - {Set} {Result} {On That Test} = "0"

Rule # 12
  Desc - MOneTestResult
  If - {Result} {On Any Test} = "M1+"
  Then - {Set} {Result} {On That Test} = "1+"

Rule # 13
  Desc - MTwoTestResult
  If - {Result} {On Any Test} = "M2+"
  Then - {Set} {Result} {On That Test} = "2+"

Rule # 14
  Desc - MThreeTestResult
  If - {Result} {On Any Test} = "M3+"
  Then - {Set} {Result} {On That Test} = "3+"

Rule # 15
  Desc - MFourTestResult
  If - {Result} {On Any Test} = "M4+"
  Then - {Set} {Result} {On That Test} = "4+"

Rule # 16
  Desc - DonorID
  If - (({Length of} {Specimen ID} = "16") {AND} ({Specimen ID} {Contains} "="))
  Then - {Set} {Specimen ID} = {Extract Section of} {Specimen ID} {From} "2" {To} "14"

Rule # 17
  Desc - DonorIDForProductID
  If - (({Length of} {Product ID} {On Test} {Value List:crossmatch} = "16") {AND} ({Product ID} {On Test} {Value List:crossmatch} {Contains} "="))
  Then - {Set} {Product ID} {On Test} {Value List:crossmatch} = {Extract Section of} {Product ID} {On Test} {Value List:crossmatch} {From} "2" {To} "14"

Value List
"Row Enabled","crossmatch"
"1","USW14E.gru^VBECS Crossmatch IAT.pln^X"
"1","USW14E.gru^VBECS Crossmatch IAT.pln^Xmatch"
"1","USW14E.gru^VBECS Crossmatch IAT.pln^Remarks"
"1","USW14H.gru^VBECS Crossmatch IS.pln^ISX"
"1","USW14H.gru^VBECS Crossmatch IS.pln^ISXmatch"
"1","USW14H.gru^VBECS Crossmatch IS.pln^Remarks"

Appendix D: Testing Templates

Table 3: Testing Templates

Template Name	Selected Fields	VBECS Test	Test Component
VBECS ABDRev.gru VBECS ABDRev.pln	A B rA1 rB D CTL Group RH Remarks	Patient ABO/Rh	Anti-A Anti-B A1 Cells B Cells Anti-D D Control ABO Interp Rh Interp Comments
VBECS ABS 2 Cell.gru VBECS ABS 2 Cell.pln	I II Scr 2+ Remarks	Antibody Screen (2 Cell)	Screening Cells1 Screening Cells2 ABS Interp Comments
VBECS ABS 3 Cell.gru VBECS ABS 3 Cell.pln	I II III Scr 3 Remarks	Antibody Screen (3 Cell)	Screening Cells1 Screening Cells 2 Screening Cells 3 ABS Interp Comments
VBECS TAS 2 Cell.gru VBECS TAS 2 Cell.pln	A B rA1 rB D CTL Group RH I II Scr 2+ Remarks	Type and Screen (2 Cell Screen)	Anti-A Anti-B A1 Cells B Cells Anti-D D Control ABO Interp Rh Interp Screening Cells1 Screening Cells2 ABS Interp Comments
VBECS TAS 3 Cell.gru VBECS TAS 3 Cell.pln	A B rA1 rB D CTL Group RH I II III Scr 3 Remarks	Type and Screen (3 Cell Screen)	Anti-A Anti-B A1 Cells B Cells Anti-D D Control ABO Interp Rh Interp Screening Cells1 Screening Cells2 Screening Cells 3 ABS Interp Comments
VBECS DAT.gru VBECS DAT.pln	DAT DAT IgG Remarks	DAT	AHG DAT Interp Comment
USW14E.gru VBECS Crossmatch IAT.pln	X Xmatch Remarks	IAT Crossmatch	AHG AHG Interp Comments
USW14H.gru VBECS Crossmatch IS.pln	ISX ISXmatch Remarks	Immediate Spin Crossmatch	IS IS Interp Comments

Template Name	Selected Fields	VBECS Test	Test Component
VBECS POS Retype.gru VBECS POS Retype.pln	A B Fwd Gr Remarks	Unit ABO/Rh Confirmation	Anti-A Anti-B ABO Interp Comments
VBECS NEG Retype.gru VBECS NEG Retype.pln	A B D CTL Fwd Gr Rh Remarks	Unit ABO/Rh Confirmation	Anti-A Anti-B Anti-A,B Anti-D ABO Interp Rh Interp Comments
VBECS Phenotype RH.gru VBECS Phenotype RH.pln	C E sm c sm e Rh Pheno Remarks	Patient and Unit Antigen Typing (RH)	Anti-C Anti-E Anti-c Anti-e N/A Comment
VBECS Phenotype Kell.gru VBECS Phenotype Kell.pln	K K Ag Remarks	Patient and Unit Antigen Typing (K)	Anti-K K Interp Comment

Appendix E: Validation Planning and Example Test Scenarios

The following is a flowchart to help assess any one change and plan accordingly.

Validation Decision Process		
Facility Name	11/5/2013	Evaluator Name

SOFTWARE CHANGE → **Does this change apply to your facility?** → **Does NOT APPLY**

Yes
Evaluate Risks and Need for Validation

Do I have a document change to process? (SOP, Policy, CheatSheet)

Evaluate Training whether Or not documents Changed

Document that no action is required and **why, including risks.**

No SOP, Policy document changes are required

YES

Edit SOP, Policy, Work Around, "Cheat Sheets"

No Training Needed

Training Required?

YES

YES

Document Review and Approve to proceed to testing

- Determine Audience(s)
- Determine Trainer(s)
- Develop Training Plan for various audiences
  - Training Delivery Method
  - Training Materials
  - Competency Assurance Materials

Does the example test scenarios correctly test my Local risks and procedure? —NO→ **CREATE a scenario addressing local risk or process. Perform and review as part of validation.**

YES

Review and Document Staff Readiness

Perform the release note scenario with no changes.

Document Review and Approval to proceed to Training

Document Review and Approval to proceed to Production Install

These are examples of test scenarios. Each site is responsible for evaluating changes for their intended use, assess risk, and for establishing additional validation test scenarios.

All test scenarios have a suggested user role, this may require adjustment to align with the patient or unit data selected to execute the scenario. Process any overrides as well, based on patient or unit selection.

*The Expected Outcome numbering corresponds to the Step number where the change verification appears.

Test Group One: AI interface disabled

Test Objective: Demonstrate that the system will reject test results sent from automated instrument if the Automated Instrument interface is disabled.

Option: VBECS Administrator, Automated Instrument Interface

At least one instrument available in any division and configured for connection with VBECS via Instrument Manager.

Note: This may be executed at only one division if VBECS is used in a multidivisional configuration as the interface is enabled/disabled for all or none.

Data	Before beginning, verify current configuration, activity, and status of the existing interfaces, VistALink, and CPRS in your test account.
	Make sure that the VBECS-OERR HL7 link in VistA is NOT shutdown.
	1. Create RBC and TAS orders in CPRS and accept them in VBECS.
User	VBECS Administrator access is required to configure the AUTOMATED TESTING interface.
	No specific user role is required to process TAS and RBC orders in VBECS.
Steps	1. Log into VBECS Administrator:
	2. Disable the AUTOMATED TESTING interface using Configure Interfaces option.
	3. A message appears (You are about to disable Auto Instrument Interface. It will cause VBECS to stop sending and receiving messages via that interface. Continue?), Click Yes.
	4. Close the window as all fields are disabled.
	5. Perform TAS test on the instrument and send results of testing to VBECS
Expected Outcome	5. Verify that after sending test results from an instrument fails it is possible to complete TAS test using manual testing grids and subsequently issue and transfuse blood unit to a patient.
Reports:	6. Review the Audit Trail report for changes to the interface.

Test Group Two: Verify AI individual test(s)

Test Objective: Demonstrate that the system will allow the selected user role to perform normal workflow activities using your local blood bank testing instrument.

Note: Validate all tests that are performed at your site using an automated instrument.

 Prior to initiating any testing of the automated instrument interface, see the VistA Blood Establishment Computer Software (VBECS) 2.2.0 Technical Manual-Security Guide for instructions for configuring your local instrument and Data Innovations Instrument Manager.

 Configure your Test UID to clearly differentiate from a Production UID during your validation, for example, production is 1234567890, with 123 being your consistent prefix, change 123 or 12 to TS or TST or 999. Please change the Numeric Identifier for the Blood Bank Accession Area in your site Test Account.

Enable Automated Instrument Interface in VBECS Admin if it was disabled while performing testing in Test Group One.

Verify your VBECS processes with the Automated Instrument interface.

Your local test plan will demonstrate that the system will perform normal daily work per your local policies, procedures and local validation plan that may include:

Blood Units: Automated Instrument or via the short cut key

- ABO-Rh confirmation
- Unit Antigen Typing or Repeat

Patients: Automated Instrument or via the short cut key
- Perform a Type and Screen test (ABS and ABS with Auto-control only)
- Perform crossmatch tests: Serologic (*Selected in Blood Units: Select Units before testing.**)
- Patient Tests:
   ABO/Rh or Repeat
   Antibody Screen or Repeat
   Direct Antiglobulin Test or Repeat
   Antigen Typing or Repeat
- Overrides, (ABO/Rh Discrepancy, Crossmatch incompatible: Give with Medical Director Approval)
- Report data from these actions is available for retrieval.
   Testing Worklist Report
   Patient History Report
   Unit History Report
   Exception Report (ABO/Rh Discrepancy, Give with Medical Director Approval)

*Remember to click NO to proceeding to the serologic crossmatch when selecting units for automated instrument testing.

Test Group 2 Scenario 1: Verify AI TAS test

Note: the Type and Screen (TAS) is a combination of two tests and may be saved as individual tests without completing the TAS as a whole.

Data	VBECS: Select a patient. CPRS: Place a Type and Screen (TAS) order for the patient LAB: Accession the order VBECS: Accept the order. (Orders, Accept Orders)
User	No specific user role is required to process TAS order in VBECS.
Steps	1. User checks the Patient testing list to make sure the order is accepted in VBECS and appears on the Pending Task List (PTL). (Patient, Patient Testing, Diagnostic Tests). 2. Close the PTL. 3. Process the specimen on the instrument using the recommended TAS template for that instrument. Complete all work needed to transmit the information to VBECS. 4. Select Patients, Automated Instrument to review TAS results. 5. Select the specimen UID, scanning the UID is preferred. 6. Review TAS test results. 7. Accept only the ABS or ABO/Rh test. Close the window. 8. Open the PTL. 9. Try to select TAS on PTL and complete testing on it manually. 10. Open the Automated instrument window and accept the second part of TAS. 11. Close the automated instrument window. 12. Check Reports
Expected Outcome	5. Verify that the specimen UID is selectable by scanning, entry or patient selection 6. Verify that the correct test results appear on the Automated Instrument review list. 8. Verify that the TAS appears on the PTL with a status of "Instrument Results Pending Review". 9. Verify that system prevents user from completing TAS since they are still pending results from an instrument for it. 12. Verify that the results and comments appear as expected on the reports: • Testing Worklist Report • Patient History Report • Exception Report

	Test Group 2 Scenario 2: Verify AI serologic crossmatch test
Data	VBECS: Select a patient. CPRS: Place a Type and Screen (TAS) order and Red Blood Cell order for the patient LAB: Accession the orders VBECS: Accept the order. (Orders, Accept Orders) Process the TAS to completion. Select a blood unit for a selected patient*: - Previously entered into the division's inventory (Blood Units, Incoming Shipment) - ABO compatible - May be available or selected for another patient (available, selected, crossmatched) status. - May or may not trigger selection overrides *Remember to click NO to proceeding to the serologic crossmatch when selecting units for automated instrument testing.
User	No specific user role is required to process crossmatch test in VBECS.
Steps	1. Process the component unit's specimen on the instrument using the recommended template for that instrument. Complete all work needed to transmit the information to VBECS. 2. Select Patients, Automated Instrument to review crossmatch results. 3. Select the specimen UID, scanning the UID is preferred. 4. Review results, select compatibility and accept crossmatch result. 5. Print or do not print tag as desired. 6. Accept the test and close the automated instrument window. 7. Check Reports.
Expected Outcome	4. Verify that crossmatch results sent from an instrument show correctly on the screen. 7. Verify that the results and comments appear as expected on the reports: - Testing Worklist Report - Patient History Report (interpretations only). - Exception Report

Test Group 2 Scenario 3: Verify AI patient diagnostic tests

(ABO/Rh, Antibody Screen, Direct Antiglobulin Test, Patient Antigen Typing, and the reflex test)

Data	VBECS: Select a patient. CPRS: Place a diagnostic test order for the patient LAB: Accession the order VBECS: Accept the order. (Orders, Accept Orders)
User	No specific user role is required to process diagnostic tests in VBECS.
Steps	1. User checks the Patient testing list to make sure the order is accepted in VBECS and appears on the Pending Task List (PTL). (Patients, Patient Testing, Diagnostic Tests). 2. Close the PTL. 3. Process the specimen on the instrument using the recommended testing template for that instrument. Complete all work needed to transmit the information to VBECS. 4. Select Patients, Automated Instrument to review test results. 5. Select the specimen UID, scanning the UID is preferred. 6. Review and accept test results 7. Close the automated instrument window. 8. Check reports.

Expected Outcome	5. Verify that the specimen UID is selectable by scanning, entry or patient selection.
	6. Verify that patient test results sent from an instrument show correctly on the screen.
	8. Verify that the results and comments appear as expected on the reports:
	    • Testing Worklist Report
	    • Patient History Report
	    • Exception Report

	Test Group 2 Scenario 4: Verify AI blood unit tests
Data	VBECS: Select a blood unit previously entered into the division's inventory (Blood Units, Incoming Shipment). For ABO/Rh Confirmation testing on the instrument, unit should be in a Limited status. For Unit Antigen Typing, the unit may or may not have been confirmed.
User	No specific user role is required to process blood unit tests in VBECS.
Steps	1. Process the component unit's specimen on the instrument using the recommended template for that instrument. Complete all work needed to transmit the information to VBECS. 2. Select Blood Units, Automated Instrument to review test results. 3. Select the blood component unit's Donor Identification Number (DIN), scanning the DIN is preferred. 4. Select the product code (if there are multiple blood units with the same product code) 5. Review the transmitted blood unit test. 6. Accept the test and close the automated instrument window. 7. Check Reports
Expected Outcome	5. Verify that blood unit test results show correctly on the screen. 7. Verify that the results and comments appear as expected on the reports: • Testing Worklist Report • Unit History Report (interpretations only). • Exception Report

Revision History

Date	Revision	Description	Author
02-09-17	1.0	Initial version (Defect 452048).	BBM team
08-03-17	2.0	Added information about requirement for Specimen Management Module being active (Defect 465496)	BBM team
12-29-22	3.0	Header and Footer: Updated. Throughout: Updated references from CA SDM ticket to service desk ticket and removed Appendix E CA SDM Support Ticket Template. Throughout: Updated .gsb file names. Introduction: Added fourth paragraph about configuration files. Related Manuals and Reference Materials: Updated. Section 4.1: Updated Steps 1, 2, 5 and 8, and added Step 3. Updated Figures 5, 6 and 9 and added Figure 7. Appendix A, B and C: Updated crossmatch codes. Appendix D: Updated template names for crossmatch. (Task 61338) All figures: Added alternate text for 508 compliance. (Task 111163)	BBM team

This is the last page of *VBECS - Erytra Interface Configuration and Setup Guide*.