

Direct Transmission Using Data Innovations Instrument Manager™ User Guide

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1 About Direct Transmission

1.1 What is this service?

The College of American Pathologists (CAP), in conjunction with Data Innovations, LLC (DI), has developed a software connectivity solution to enable the electronic transmission of proficiency testing (PT) data. This service provides laboratories with the ability to electronically transmit quantitative PT results from their automated instruments to the PT result form data entry interface in e-LAB Solutions Suite without user intervention.

1.2 How does it work?

PT results are transmitted through the Data Innovations Instrument Manager[™] middleware using a specifically designed CAP PT driver. This driver translates your laboratory's test codes to the CAP PT codes and then routes the PT results directly to e-LAB Solutions Suite, where it automatically populates the result forms. This process effectively eliminates manual data entry clerical errors, saves laboratories hours of data entry on an annual basis, and meets CLIA and the CAP's Laboratory Accreditation Program checklist requirement to treat PT specimens more like patient specimens.

Submission Mechanism

Automated data submission is triggered by the entry of laboratory orders that comply with a documented convention that "flags" resulting data for submission to the CAP's CLIA-compliant PT service.

PT data is packaged into XML instance documents that comply with a CAP-supplied XML schema.

The XML files are then uploaded to e-LAB Solutions Suite via a secure, SOAP-based web service protocol.

Production Service

PT data will be packaged into XML files and transferred to the CAP via a CAP-supported webservice endpoint.

The Web service will be available on port 443 and 128-bit SSL encryption will be required.

The Web service will be routable at the following addresses:

- Server URL: <u>https://www.cap.org</u>
- Service URL: <u>https://access.cap.org/lab2pt/ResultsUpload</u>
- WSDL URL: <u>https://access.cap.org/lab2pt/ResultsUpload?WSDL</u>

Web protocols are:

- HTTPS (SSL) over TCP/IP
- SOAP-based Web services compliant with WS-Security and WS-Reliability

Scope of the Data to be Submitted Automatically

Automated submission applies only to data that result from laboratory tests of PT specimens delivered to the laboratory by the CAP's PT service.

Automated submission is currently limited to quantitative data (eg, numeric data) that are transferred from an automated instrument to the laboratory's Laboratory Information System (LIS) and/or Health Information System (HIS) via the DI middleware.

Automated submission does not include (by design) any of the following:

- Interpretations (eg, normal/abnormal, present/absent, susceptible/resistant)
- Data entered directly into an LIS user interface
- Textual or encoded data (eg, bacterial species/genus identifications, blood cell identifications)

Privacy and Protection of Patient Information

The CAP/DI systems allow only data identified for PT to be transmitted from the laboratory to the CAP if all recommended procedures are followed. The transmission of this data is accomplished by writing a rule, using the Instrument Manager Rules feature, which will ensure only PT results are collected and sent to the CAP's e-LAB Solutions Suite system. Refer to the section "Instrument Manager Rules" in this user guide for more information about rules.

Customer Service and Support

Service support for direct transmission is available from the CAP and Data Innovations. Support from Data Innovations is covered by the maintenance and support associated with the Instrument Manager connection. The CAP and Data Innovations will work to resolve transmission failures and/or service interruptions as quickly as possible. During such periods, your laboratory can still submit PT data to the CAP's e-LAB Solutions Suite manually.

1.3 Customer Requirements

Use of the direct transmission solution requires the following:

- **Data Innovations Instrument Manager middleware** (version 8.15 or higher with the Specimen Management module)
- CAP Proficiency Testing driver ("CAP PT driver"): The CAP PT driver (capprfcl) contains a user interface to map a laboratory's test descriptions to those recognized by the CAP. The driver must be installed and configured within Instrument Manager to integrate the laboratory's LIS and/or HIS with at least one of its automated instruments. Instructions for obtaining and configuring the CAP driver are provided in the sections, "Obtaining the Data Innovations CAP PT Driver," and, "Configuring the CAP PT Driver and Getting Connected," respectively.
- **Security credentials**: After the CAP PT driver has been licensed, the CAP will provide a user ID and password to a laboratory administrator. These credentials must be added to the configuration data housed within the Data Innovation device's CAP PT driver.
- **Mapped codes**: The laboratory must map the laboratory's test names and/or codes to the CAP codes using the automated functionality within the DI device's CAP PT driver. The mapping process is described in the section, "CAP Code Mapping."
- **Rule installation:** The Rules feature of the Specimen Management module automates the collection of PT results from the instruments. The process for installing rules is described in the section, "Instrument Manager Rules."

- Inbound and outbound firewall access: Use of the direct transmission service requires access to and through any existing laboratory networking firewalls. Specifically, a laboratory's networking firewall must not restrict inbound and outbound connections over SSL (HTTPS over port 443) to access cap.org from the PC or server on which the Data Innovations Instrument Manager software executes.
- Network connection for the CAP PT driver: To connect to the CAP, subscribers will also require an Instrument Manager connection for the CAP PT driver. Instructions for verifying a connection are provided in the section, "Verifying a Network Connection."

1.4 Use Limitations

Personal and Noncommercial Use Limitation

The services provided by CAP/DI software are for your individual laboratory and for noncommercial use only. You may not copy, modify, distribute, transmit, display, perform, reproduce, publish, license, create derivative works from, transfer, or sell any information, software, programs, or services obtained from the service.

1.5 Contact Information

For additional information or help regarding direct transmission, contact the CAP or Data Innovations:

- CAP Customer Contact Center: 800-323-4040 or 847-832-7000 option 1, or contactcenter@cap.org
- Data Innovations: 802-658-2850, or sales@datainnovations.com

1.6 Online Tutorials

Video tutorials are available on cap.org. These tutorials provide step-by-step instructions for configuring and using this service. Note that all of the information in the tutorials is also provided in this user guide.

See: <u>https://www.cap.org/laboratory-improvement/proficiency-testing/direct-transmission-pt-results/how-direct-transmission-using-data-innovations-instrument-manager-works/get-started-with-direct-transmission-using-data-innovations</u>

2 Getting Started

2.1 Verifying a Network Connection

To verify that the service can be reached from the Instrument Manager PC or server, open a web browser such as Internet Explorer or Mozilla Firefox, copy the following URL into the address bar, and press the Enter key:

https://access.cap.org/lab2pt/ConnectToCAP.jsp

If a network connection is possible, then a Web page will display that looks similar to the example below:



If a network connection is not possible, a Web page will display that looks similar to this example:



Note: The CAP PT driver will not work if there is a proxy server in the network path. It is the responsibility of the laboratory to work with their Information Technology department to facilitate access.

2.2 Enrolling/Registering for e-LAB Solutions Suite

Before a laboratory can submit PT results via direct transmission, the laboratory must first enroll/register for e-LAB Solutions Suite by completing the following tasks and steps:

Task 1: Create a CAP web account

1. Go to <u>cap.org</u>.

- 2. Click Login.
- 3. On the Login page, click **Create an Account**.
- 4. In the account creation window, enter your name and credentials, then choose a unique user ID and password. Then, click **Next**.
- 5. Select three security questions and provide answers. This information will only be used to verify your identity if you require assistance logging in at any point in the future.
- 6. Provide either a business or home address to continue.
- 7. Once you have entered at least one address, click **Finish**. You will be notified by email within one business day that your web account has been activated.

Task 2: Request Access to Laboratory Data and Programs

Before you request access, make sure that your laboratory has enrolled/registered. The laboratory director has been assigned as the site administrator. You will also need a Web account to request access (see above).

- 1. Go to cap.org and click **Access e-LAB Solutions Suite**. Log in using the web account user ID and password you created in Task 1.
- 2. Click Request Access From Your Site Admin.
- 3. Enter your organization's seven-digit CAP number, then click **Submit**.
- 4. At the confirmation screen, review the information and click **Submit**.
- 5. Your request will be sent to your laboratory's site administrator to grant or deny access.
- 6. Once you have been granted or denied access, you will receive an email message detailing your access privileges (functions you have been authorized to use by your site administrator).

Task 3 (for Site Administrators only): Enroll/Register Your Laboratory for Online Programs

Only site administrators can opt in their laboratories to e-LAB Solutions Suite. A laboratory only has to enroll/register once to gain access to online programs.

- 1. Go to cap.org, click Access e-LAB Solutions Suite, and log in.
- 2. Click Manage Lab Users Online Permissions.
- 3. Enter the **CAP number** and **PIN** provided on your laboratory's letter, and click **Submit**. If you do not have a PIN available, contact the CAP at 800-323-4040 option 1 for assistance.

Task 4: Enroll in Direct Transmission using Data Innovations Instrument Manager

- 1. Enroll using the form available on cap.org. This form requires both your laboratory's primary seven-digit CAP number and your DI license number, which can be found at the bottom of any Instrument Manager screen or Help > About screen.
- 2. The CAP will email you a user name, password, and user guide to configure the CAP PT driver. Once you have entered these values into the CAP Proficiency Testing Configuration screen, you do not have to re-enter them.

2.3 Registering Data Innovations Instrument Manager

For security purposes, a laboratory must register each DI Instrument Manager license with the CAP. Registration entails the generation of a user name and password by the CAP for each DI Instrument Manager license. The user name and password must be entered into a configuration dialog provided by the CAP PT driver.

To ensure that each license of the DI Instrument Manager software is registered correctly, follow the steps below:

- 1. Start Instrument Manager.
- 2. Open the Help menu and select **About**. The About dialog displays the License number.
- 3. Contact the CAP Customer Contact Center. Read the license number to the Customer Contact Center representative. (Alternatively, you could capture a screen shot and email that screen shot to the Customer Contact Center.)
- 4. Provide the main CAP number of the primary laboratory associated with the DI Instrument Manager license.

Note: A single DI Instrument Manager license may be used for multiple CAP numbers. In this case, one of them needs to be designated as the primary lab number. As desired, the laboratory contact may optionally provide a textual description of the specific DI Instrument Manager license.

- 5. The CAP's Customer Contact Center works with the internal CAP IT staff to generate a user name and password for that specific license of the DI Instrument Manager.
- 6. The CAP representative conveys the user name and password to the laboratory contact, via email. (Later you will enter these values into the User Name and Password fields in the driver properties section of the CAP PT driver.)

2.4 Obtaining the Data Innovations CAP PT Driver

Data Innovations has created a CAP-specific driver that can be loaded into an existing Data Innovations Instrument Manager installation and configured to map laboratory test codes to CAP codes. Once configured, laboratories can transmit their quantitative PT results from the instrument to DI Instrument Manager and subsequently to the CAP.

Follow these steps to download and install the CAP PT driver:

 Download the most current version of the CAP PT driver (capprfcl) from the Data Innovations customer web portal using the CWP user name and password provided by Data Innovations.



- 2. Launch Instrument Manager.
- 3. Load the driver into Instrument Manager.

2.5 Configuring the CAP PT Driver and Getting Connected

Before you can use the CAP PT driver to submit data, you must configure the driver using the credentials provided by the CAP and start a connection with the CAP. To do this, complete the following tasks and steps:

Task 1: Add a configuration

1. Launch Instrument Manager.

2. Open the Configuration menu and select Configuration Editor.





3. In the Configuration Editor screen, click Add.

- 4. In the Add Configuration dialog, type a name for the configuration in the **Configuration Name** field (eg, "CAP PT Driver").
- 5. Type a description for the configuration in the **Configuration Description** field (eg, "CAP PT Result Uploader").
- 6. Select the CAP PT Driver from the **Driver Type** drop-down menu.
- 7. Click Close.



8. In the confirmation dialog, click **Yes** to save your changes.

Task 2: Configure the CAP PT driver properties

- 1. Select the CAP PT driver in the list of drivers.
- 2. Click **Properties**.

2 ⁷ Instrument Manager by Data Innovations, LLC	
System Configuration Diagnostics Security Specimen Management SSR DC SR MM MA Reports Window Help	
Add Properties Import Click Properties	IS
Logged On User: IM_ADMIN Locale: Default License #: IM-100001 Customer Name: Data Innovations; LLC 4/24/20)13 1:11 PM

Instrument Manager by Data Innovations, LLC	
stem Configuration Diagnostics Security Specimen Management SSR DC SR MM MA Reports Window Help	
Configuration Properties - CAP PT Driver	
Configuration Name CAP PT Driver (Configuration Description CAP PT Result Uploader Driver Type CAP Pt Result Uploader	
Driver Properties Error Code Map Instrument ID Map Code Map Code Map Test Load Eactors Close	
Click Driver Properties	ER™
Copy Delete Export Close DATA I	INNOVATIONS e Ideas, Better Solutions

3. The Configuration Properties window opens. Click **Driver Properties**.

4. The CAP Proficiency Testing Configuration window opens. Enter the Username and Password provided by the CAP.

Tip: It is a best practice to copy and paste these items from your email rather than typing them manually.

- 5. Enter the contact information for the person in your laboratory who will be responsible for managing this solution for direct transmission of PT results. This includes name, email address, and telephone number.
- 6. (Optional) The **Transmission Errors** preference defaults to resending messages three times every ten seconds. You may change this to a different setting if you prefer.
- 7. **Kit # Contents** and **Specimen # Contents** menus will have a default value of "none" when you first set up the program. The CAP recommends using "Patient First Name" and "Patient Last Name" respectively.
- 8. Enter the **Default CAP Number**. This is your laboratory's primary seven-digit CAP number.
- 9. Click the **Test Connection** button to test the connection with the CAP.

Webservice Information Kit # Contents HTTP(S) Address Inttps://access.cap.org/lab2pt 5 Speciment Email ismith@yourlab.org 7 Username test Password Password Password Test Service TestConn 6 Default CAP Number 1234567 Upload Service ResultsU freed 6 Delay Between Retries 10 Seconds Instrument Definition Patient First Name Instrument Definition Patient Kit # Contents Connection Name Instrument Code CAP Number Instrument Definition Contact Name Instrument Contact Email Test Submission CAP Mapping	CAP Proficiency Testing Configuration	
Instrument Definition Connection Name Instrument ID Instrument Code CAP Number Contact Name Contact Email Test Submission CAP Mapping Edit *	Webservice Information HTTP(S) Address Inttps://access.cap.org/lab2pt 5 Username test Password Fest Test Service TestConn Upload Service ResultsU load 6 9 Test Connection	Contact Information Kit # Contents Name Jane Smith Email jsmith@yourlab.org Phone 123-555-6789 Transmission Errors Default CAP Number Attempt to Resend Message 3 ÷ Time Delay Between Retries 10 ÷ Seconds
Connection Name Instrument ID Instrument Code CAP Number Contact Name Contact Email Test Submission CAP Mapping * Edit		Instrument Definition
	Connection Name Instrument ID Instrument Code	CAP Number Contact Name Contact Email Test Submission CAP Mapping A
		Edit
Close		▼ Close

10. If the connection has been established you will see an "OK" message indicating that the Instrument Manager has been successfully configured to communicate to the CAP.



Note: If the connection fails, a pop-up similar to the one shown below appears.

Test Connection

Response From WebService: ERROR #6248: SOAP response is a SOAP fault: faultcode=ns1:FailedAuthentication
faultstring=The security token could not be authenticated or authorized
faultactor=
detail=

If this occurs, verify that Port 443 has been opened in your firewall and that the user name, password and
CAP number have been correctly entered. If this information has been correctly entered, then you should

CAP number have been correctly entered. If this information has been correctly entered, then you should also verify that basic network connectivity exists as described in the section "Verifying a Network Connection." If basic connectivity does not work, then troubleshoot to isolate the problem. If you continue to have problems establishing a connection, call the CAP at 800-323-4040 or 847-832-7000, option 1 for assistance.

- 11. Assuming the connection is established, click **OK**.
- 12. Click **Close** to close the Configuration window.
- 13. Click Yes to save your changes.
- 14. Click **Close** to close the Configuration Properties window.
- 15. Click **Close** to close the Configuration Editor window.

Tip: If you need help using Instrument Manager, you can access the Instrument Manager Help file by pressing the **F1** key on your keyboard. The Help file provides instructions for:

- Accessing the e-LAB Solutions Suite interface
- Testing your connection to the e-LAB Solutions Suite interface
- · Configuring how information is submitted to the CAP
- Mapping local test codes to the CAP codes

Task 3: Add a Connection Assignment for the configuration you just created

1. Open the Configuration menu and select Connection Assignment.



stem con	figuration	Diagnostics	Security	Specimen Management	SSR D	DC SR	MM	MA Rep	orts Windo	w Help		
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2. In the Connection Assignment window, click Add.

- 3. In the Connection Properties window, enter a name for the connection in the **Connection Name** field (eg," CAP Connection").
- 4. Open the **Configuration Name** menu and select the configuration you created using the Configuration Editor ("CAP PT Driver").

Note: Because the driver is an outbound unidirectional driver it doesn't ever send data to other connections so you don't have to change the destination line settings.

Leave the default setting for the **Number of Days to Keep** set to three days. This controls the number days before data is purged.

Leave the **Device** set to "NULL."

- 5. Check the checkbox for Include in Specimen Management under Advanced Options.
- 6. (Optional) Check the checkbox(es) for **Update Specimen Management in Status Messages** and/or **Overwrite Patient Data**
- 7. Click Close.

Connection Name	CAP Connection	Number of Days to Keep	
Configuration Name	CAP PT Driver	Incoming Messages	3
Site		Outgoing Messages	3
Location		Communications Trace	3
	Start on System Start	Error Messages	3
Destination Line(s)	ABL8351 ABL8352 ABL90-1	Driver Data	3
	ABL90-2 ADVANTUS ATLAS AUW LIS AUWI PRO LIS AUWI PRO ORDERS AUWI PRO ORDERS CA1500 CA560 CAP- Lab Solution CEPHEID GENEXPERT DADEXLCL DADEXLCL DADEXLCL DADEXLCLM	Advanced Options Advanced Options Explode Coded Entries for Include in Specimen Mana Default userid Update Specimen Man Messages Overwrite Patient Data Shared Orders DB Connection	this Connection gement agement on Status ge and Retrieval
Integrated QC		Device © NULL С СОМ С ТСР/ЛР Character Encoding	None · 💌

- 8. Click **Yes** to save your changes.
- 9. Click **Close** to close the Connection Assignment window.

Task 4: Start the connection

1. Open the System menu and select Status.



- 2. The Status Display window opens. In the list of connections, the status of the CAP Connection is "Off." Select the **CAP Connection**.
- 3. Click Start Selected Connections.



- 4. The status changes from "Off" to "On." Once the connection status is listed as "On," Instrument Manager will be ready to route all PT tests to the CAP PT driver (after you set up Instrument Manager rules, described later in this user guide).
- 5. Click **Close** to close the Status Display window.

3 CAP Code Mapping

3.1 About CAP Code Mapping

The CAP maintains a list of codes to map your test codes to enable standardization of language. These codes provide a consistent means by which analytes can be identified across various systems. CAP Codes will be used to identify the PT results from your instruments transmitted to e-LAB Solutions Suite.

3.2 Why use CAP Code Mapping?

Each laboratory has its own "local" code originating from instrumentation or the LIS. For example, when testing for glucose, one laboratory system might issue results for "glu," another for "test 29," and another for "glucose, serum." The CAP system has its own naming convention to identify data from customers from all the proficiency testing programs.

CAP code mapping <u>enables recognition of each laboratory's local code and matches it to the</u> <u>correct CAP test code. The CAP PT driver provides the mechanism to link your local code to the</u> CAP code that has been established as the "one to use" for a certain analyte and unit of measure. In this way, your PT data are filed directly into e-LAB Solutions Suite for your verification of accuracy without any manual intervention.

The CAP Code Database

The CAP code database is a universal master file of standard test names and codes that will cover most of the entries in the files of operational laboratory systems. This database allows the terms in the operational laboratory system files to be mapped directly to universal master codes and names. The names created correspond most closely to the "long test descriptions" seen in test master files. The CAP code names are fully specified names, meaning all the information needed to map a local test name to one of the fully specified names is present in the CAP code name.

CAP code mapping aims to achieve a level of detail in the definition of a test that will map oneto-one to the separately reported observations on a clinical laboratory report. If a test has its own column on a clinical report, a reference range that is significantly different from other tests, or a different clinical meaning than other related tests, it will usually be assigned a separate code and name. CAP code mapping delivers these fully specified names, their codes, and their related names as a database in which each line corresponds to a unique test measurement.

Each record corresponds to a single result. The record includes fields for specifying:

- **Component (analyte)**—eg, potassium, hemoglobin, hepatitis C antigen
- **Property measured** (units of measure)—eg, a mass concentration or enzyme activity (catalytic rate)
- **Timing** (whether the measurement is an observation at a moment of time or an observation integrated over an extended duration of time)—eg, 24-hour urine
- **Type of specimen**—eg, urine or blood

- **Type of scale**—eg, whether the measurement is quantitative (a true measurement), ordinal (a ranked set of options), nominal (such as *Escherichia coli* or *Staphylococcus aureus*), or narrative (such as dictation results from x-rays)
- Method used, where relevant—to produce the result or other observation

There can be multiple CAP codes for the same type of Survey if there are different analytes and/or units of measure for that Survey. Here are examples:

Survey	Analyte	Unit of Measure	CAP Code*
B-type Natriuretic Peptides	B-type Natriuretic Peptide	pg/mL (ng/L)	CAP123
B-type Natriuretic Peptides	NT-proBNP	pg/mL (ng/L)	CAP456
Basic Hematology	Hematocrit	%	CAP789
Basic Hematology	Hemoglobin	g/L	CAP1011
Basic Hematology	Hemoglobin	g/dL	CAP1213
Basic Hematology	MCV	fL	CAP1415
Basic Hematology	Platelet count	x 10E9/L	CAP1617
Basic Hematology	RBC count	x 10E12/L	CAP1819
Basic Hematology	WBC count	x 10E9/L	CAP2021
Chemistry	ALT (SGPT)	U/L	CAP2223
Chemistry	AST (SGOT)	U/L	CAP2425
Chemistry	Albumin	g/L	CAP2627
Chemistry	Albumin	g/dL	CAP2829
Chemistry	Alkaline phosphatase	Ū/L	CAP2425
*Data is for illustrative purposes only.			

Note: The CAP will provide the CAP code mapping to be used for result reporting. Laboratories are responsible for setting up their local test codes to map to the corresponding CAP codes through the CAP/DI driver interface.

3.3 Test Code and Fluid Code Mapping

The CAP PT driver provides a configuration screen to map test codes to the associated CAP codes. A situation may occur whereby it is required to map a single test code to multiple CAP codes based upon the fluid type. When this is required, the test code and fluid code mapping functionality within the CAP PT driver must be utilized.

Within the Instrument Manager architecture, the CAP PT driver is considered an LIS interface. Refer to the Instrument Manager Getting Started Setup Guide Chapter A-6 for a complete description of mapping.

Note: Fluid code mapping is now configured with your test code mapping. This section will only be utilized if you are manually entering fluid type. Refer to the "Mapping Your Codes to the CAP Codes" tutorial for additional information.

Example:

- 1. An instrument has the ability to process GLU on two different fluids but reports the test as GLU in both cases with an identifier of Serum or Urine for the fluid type.
- 2. Test code and fluid code mapping must be configured for the CAP PT driver to map these to two separate LIS/Host test codes.
- 3. The CAP Code Mapping Configuration screen is then used to map the LIS/Host test codes.

3.4 Mapping Your Proficiency Testing Menu to the CAP Codes

Follow these instructions to map your laboratory's codes to the CAP codes.

Task 1: Turn off the CAP PT driver

- 1. Launch Instrument Manager.
- 2. Open the **System** menu and select **Status**.



- 3. The Status Display window opens. In the list of connections, the status of the CAP Connection is "On." Select the **CAP Connection**.
- 4. Click Stop Selected Connections.

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Status Display								x
Start Selected Conn	sctions (Stop Se	Acted Connections	A isages	× Clear SendQ	Mark Out-of-Sen	vice 💘 Log Minimal SEL Ev	ents 🛠 Utility 🔔	
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Connection	Status /	In I	nQ Se	ndQ	ient	Errors		
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User Defined								
CAP Connection	0n 3					0		
Inbound Messages	On	. () 0	(0		
Logged On User: IM_ADMIN	Locale: Default	License #: IM-100001	Customer Name: Data	a Innovations, LLC			5/31/2013	3:34 PM

5. The status changes from "On" to "Off."

Note: While the CAP PT driver must be offline during this mapping, the individual instrument does not have to be offline.

Task 2: Map the codes

- 1. Open the Configuration menu and select Configuration Editor. / Instrument Manager by Data Innovations, LLC _ **D** X System Configuration Diagnostics Security Specimen Management SSR DC SR MM MA Reports Window Help Configuration Editor Stat -Connection Assignm St. nd Messages | 🗙 Clear SendQ | 🕋 Mark: Out-of-Service | 🍕 Log Minimal SEL Events | 🛠 Utility 🍦 Specimen Managem ¥ 1 🖻 • | 🚰 🚍 🖓 🖓 🖕 Quality C Select Configuration Editor Sent Errors C Moving - 5 Specimen Storage and Retrieval Configuration 5 0 F Data Collection Setup 0 C 0 0 Specimen Routing Setup -11 Maintenance Manager Configuration • ¢ Dictionary Editor 0 0 0 Report Designer Language Locale Setup Notifier Setup Backup Setup Hot Backup Setup Save Configuration to File Restore Configuration from File Backup/Restore Load Driver(s) Logged On User: IM_ADMIN Locale: Default License #: IM-100001 Customer Name: Data Innovations, LLC 5/31/2013 3:34 PM

2. Select the CAP PT driver in the list of drivers.

3. Click **Properties**.

Instrument Manager b System Configuration	Data Innovations, L Diagnostics Securi	LC	
🖋 Status Display	ctions) Stop Selec	Configuration Editor	×
Connection	Status / I On On (2/2) Off O On O	n Name Description CAP PT Driver CAP PT Result Uploader DI LLC Adv Conf Purge Purge Handler	
		Add Properties Import Copy Delete Export Close Click Properties	
ogged On User: IM_ADMIN	Locale: Default	icense #: IM-100001 Customer Name: Data Innovations, LLC 5/31/2013	3:34 PM

stem Configuration Diagnostics Security Specimen Management SSR DC SR MM MA Reports Window Help
ystem Configuration Diagnostics Security Specimen Management SSR DC SR MM MA Reports Window Help Status Display Status Elected Connections Configuration Properties - CAP PT Driver Configuration Name CAP PT Driver Con

4. The Configuration Properties window opens. Click Driver Properties.

- 5. The CAP Proficiency Testing Configuration window opens showing the contact information you entered earlier when configuring the driver. Open the **Connection Name** menu.
- 6. Select a connection name for the instrument you will be mapping to.

CAP Proficiency Tes	sting Co	nfiguration	patientines (C	and the second						X	
-Webservice Informa	tion —			Contact Infor	rmation		Kit # Contents				
HTTP(S) Address	https://	'access.cap.org/la	b2pt	Name	Jane Smith			Patient First Name	•		
Username	test			Email	jsmith@yourlab.org		Specimen # Contents Patient Last Name				
Password	skokokokokoko	٠		Phone	123-555-6789						
Test Service	TestCo	onn		Transmission Errors				Default CAP Number			
Upload Service	Upload Service ResultsUpload Test Connection			Attempt	to Resend Message 3	Times					
			Connection	Del	lay Between Retries 10	÷ Seconds	Patient Middle Name				
					Instrument Definition						
Connection N	ame	Instrument ID	Instrument Code	CAP Number Contact Name Contact Email			Test Submission CAP Mapping			-	
	•								Edit		
* MRE1										_	
MRE2 MRE3 MRE4 MRE5 MRE6 MRE6											
									Close		

7. Enter a different CAP Number, Contact Name, and/or Contact Email.

Note: If you leave the **CAP Number**, **Contact Name**, and **Contact Email** fields empty, the system will send alerts to the default person or group named in the Contact Information section. Such alerts include error messages that can be useful for troubleshooting.

If you want these alerts to be sent to another contact in addition to the default contact, you should enter that person's or group's contact information here. If this person is affiliated with the same laboratory as the default contact, there's no need to enter a CAP number. If the person is affiliated with another CAP number, that number should be entered in the **CAP Number** column.

8. Verify that the **Test Submission** checkbox is checked.

Note: Checking the **Test Submission** checkbox lets you test your mapping later, before you go live. This process is explained in the section "

Testing Submission Configurations." Remember to uncheck the **Test Submission** box once you are ready to submit actual proficiency testing data to the CAP.

9. Click the **Edit...** button in the CAP Mapping column.

CAP Proficiency Tes	sting Configuration	Apartment (and PT Second					×		
Webservice Informa	tion		Contact Info	rmation		_−Kit # C	Kit # Contents			
HTTP(S) Address	https://access.cap.org/	lab2pt	Name Jane Smith Email jsmith@yourlab.org							
Username	test		Phone	123-555-6789		Patient Last Name				
Password	TestConn		Transmission Errors Attempt to Resend Message 3 ↔ Times Delay Between Retries 10 ↔ Seconds				IIt CAP Number			
Upload Service	ResultsUpload						I234567			
	Te	st Connection								
				Instrument Definition						
Connection No	ame Instrument ID	Instrument Code	CAP Number	Contact Name	Contact Email		Test Submission	CAP Mapping 🔺		
/ MRE1				Henry Jones	hjones@yourlab	.org		Edit		
*		-								
								Close		

- 10. If a pop-up dialog asks you if you want to save your changes, click **OK**.
- 11. The CAP Test Code Mapping screen opens. Verify that the **Suppress** checkbox is unchecked. Leaving the box unchecked ensures that all your direct transmission-eligible tests will be transmitted.
- 12. (Optional) Click the **Import** button to import a previously-exported mapped codes file if appropriate.

Tip: The Import/Export feature is useful if you have multiple identical instruments that perform the same testing. See the section "Exporting and Importing Mapping Codes" for more information.

In this example we're mapping codes for the first time, so there is no file to import.

- 13. Verify that the **My Lab Only** checkbox is checked. This tells the system to display a list of direct transmission-eligible Surveys to which your laboratory currently subscribes.
- 14. Click Get CAP Codes.

			CAP 1	Test Code Mappin)		
	IM Test Code	Test Description	IM Fluid Code	CAP Code	CAP Description	Instrument Type	Suppress
¥.	-						
				N			-
	12 (optional)			6			
	12 (optional)	14	13	6			
	12 (optional)	14	13	Ş			
	12 (optional)	14	13	Ş		1	

- 15. The Get CAP Codes screen appears, displaying only the direct transmission-eligible Surveys that your laboratory has ordered. Verify that the checkbox for **Query for Selected Surveys Only** is checked.
- 16. Select all the Surveys for which you want to map codes for this instrument from the Available Surveys list. We recommend you map just one Survey at a time. (In this example, we have selected **Cardiac Markers**.)
- 17. Click the **Select >>>** button to move the survey(s) to the Selected Surveys list.

Available Surveys			Coloriad Surveys	
Activated Clotting Time, CT Activated Clotting Time, CT2 Activated Clotting Time, CT3 Alcohol/Ethylene Glycol/Volatiles B-type Natriuretic Peptides Blood Dximetry Body Fluid Chemistry Body Fluid Chemistry 2 Cardisc M, Kers Cerebrospikg Fluid Chemistry Chemistry Clinical Microscopy Coagulation, Limited Crit Care/Aqueous Blood Gas Diagnostic Immunology Erythrocyte Sedimentation Rate Hematology Auto Differentials, FH6 Hemocytometer Fluid Count	17 16	Select >>>		
promotive and the second			1	

18. Click Update.

Available Surveys			Selected Surveys	
Activated Clotting Time, CT2	â		Evalation and Kets	
Activated Clotting Time, CT3 Alcohol/Ethylene Glycol/Volatiles		Select >>>		
B-type Natriuretic Peptides Blood Oximetry				
Body Fluid Chemistry Body Fluid Chemistry 2	=	KKK Remove		
Cerebrospinal Fluid Chemistry				
Chemistry Clinical Microscopy				
Coagulation, Limited Crit Care/Aqueous Blood Gas				
Diagnostic Immunology				
Hematology Auto Differentials, FH6				
Hemocytometer Fluid Count Ketones	-			

19. The CAP Code Mapping screen is updated with the CAP codes for your selected Surveys. Review the list of codes.

Note: There might be a single assay with different units of measure. The CAP does not convert units of measure so be sure to choose the appropriate IM test code that corresponds to the CAP Code with the unit of measure used by your laboratory.

		CA	AP Test Code Ma	pping		
IM Test Code	Test Description	IM Fluid Code	CAP Code*	CAP Description	Instrument Type	Suppres
			CAP123	CK-MB Activity (U/L)		
			CAP456	CK-MB, mant (ng/mL)		
			CAP789	Myoglab ot		
			CAP1011	Troponi		m
			CAPIUII	Tiopora		
Rows hig	ghlighted in ye	llow		In this example, t	here are two c	codes f
Rows hig indicate p have not	ghlighted in ye possible codes yet been map	llow that ped.		In this example, t assay CK-MB t different u	here are two c because each init of measure	odes uses a

*Data is for illustrative purposes only.

20. For each analyte that you want to map, open the drop-down menu under the IM Test Code column and select the appropriate instrument test code.

		CA	P Test Code Ma	poing		
IM Test Cod	le Test Description	IM Fluid Code	CAP Code*	CAP Description	Instrument Type	Suppress
	It.		CAP123	CK-MB Activity (U/L)		
1	131		CAP456	CK-MB, guant (ng/mL)		
GLU	GLU		CAP789	Myoglobin, guant		
Number of Ce	Its C Number of Cells Counted		CAP1011	Troponin I, Qnt		
TC1	TC1					
1010	1010					
TC1	TC11					
TC	00					
lect the	annronriate tes	t code (e	$\sigma TC1$			
lect the	appropriate tes	t code (e	g, TC1)			
lect the	appropriate tes	t code (e	g, TC1)			
lect the	appropriate tes	t code (e	g, TC1)			
lect the	appropriate tes	t code (e	g, TC1)			
TC7 TC8 TC9	appropriate tes	t code (e 	g, TC1)		1	

			C/	AP Test Code Ma	pping		
IM Test	Code Test	Description	IM Fluid Code	CAP Code*	CAP Description	Instrument Type	Suppress
TC1	TC1			CAP123	CK-MB Activity (U/L)		
				CAP456	CK-MB, quant (ng/mL)		
TC2	TC2			CAP789	Myoglobin, quant		
TC3	- TC3			CAP1011	Troponin I, Qnt		
	The Tes	st Descrip	otion, as	it is			_
G	The Tes defined in t driver, po	et Descrip he individ pulates a	otion, as dual instr automatic	it is ument cally.			

*Data is for illustrative purposes only.

21. In the IM Fluid Code column, select the appropriate matrix if necessary.

Note: If you report on only a single fluid type, then you do not have to define a fluid code. If you report on more than one fluid type, you have to define all appropriate fluid types for that analyte.

In our example, serum is the only fluid type used for a Cardiac Markers program. So while we could select Serum "S" for all the analytes, it is not necessary so we won't enter any fluid codes.

22. To save your mapped codes, click Close.

Tip: You could add more Surveys by clicking the **Get CAP Codes** button, but we recommend that you map one Survey at a time and save your mapped codes after that Survey's mapping is complete.

_			CAF	P Test Code Mappir	0		
	IM Test Code	Test Description	IM Fluid Code	CAP Code *	CAP Description	Instrument Type	Suppress
,	TC1	TC1		CAP123 CK	MB Activity (U/L)		
*	1C2 TC3	TC2 TC3	0 S U	21 inst	(If necessary). In rument uses fluid	this example, t code "O" for c	he ther,
			2	3	tor serurii, anu C	b lor unne.	
		1	1				

*Data is for illustrative purposes only.

- 23. A pop-up dialog asks you if you want to save your changes. Click Yes.
- 24. If you have not selected a test code associated with this Survey, a dialog reminds you that one or more test codes are null. If you want to go back to select more test codes, click **No**. If you want to continue, click **Yes**.



- 25. Repeat step 14–24 until you have mapped all the surveys for the instrument.
- 26. Close the Configuration Properties window.
- 27. Close the Configuration Editor window.

Task 3: Turn on the CAP PT driver

1. In the Status Display screen (which should still be open), click **Start Selected Connections** to turn the CAP PT driver connection back on.

3.5 Exporting and Importing Mapping Codes

If you have multiple identical instruments that perform the same testing, you can save mapping time by using the "Export" and "Import" tools in Instrument Manager.

The Export tool lets you save the entire mapping chart for an instrument that has already been mapped. The chart is saved as a single file on your computer that you can later import into another instrument that uses the same testing configuration.

Exporting a Mapping Code File

To export a mapping code file, follow the steps below.

- 1. If you haven't yet done so, map all the codes for an instrument in Instrument Manager that you wish to use as the "template" for other instruments. To map codes, follow the steps in the section "Mapping Your Proficiency Testing Menu to the CAP Codes" up through Task 2, step 25.
- 2. In the driver configuration window, click the **Edit...** button for the Connection Name that contains the instrument whose mapping codes you wish to export.

Webservice Informa	tion		Contact Info	mation		Kit # Contents		
HTTP(S) Address	https://access.cap.org	/lab2pt	Name	Jane Smith		Patient Fi	rst Name	<u>•</u>
			Email	jsmith@yourlab.org		- Specimen # Co	ntents	
Username	Itest		Phone	123-555-6789		Patient L	ast Name	-
Password	Amatatatata					1		
	TestConn		Transmissio	on Errors		Default CAP Nu	mber	
Test Service	Treatedini		Attempt	to Resend Message 3	- Times	1234567		
Upload Service	ResultsUpload		caternipe	ino rico sono message [-	· · · · · · · · · · · · · · · · ·	_ Instrument Turns	Definition	
	Te	est Connection	De	elay Between Retries 10	Seconds	Determine	Dennidon	
			3 - 13			Fallent M	iddie Name	<u> </u>
				Instrument Definition				
Connection N	ame Instrument ID	Instrument Code	CAP Number	Contact Name	Contact Email	Test Su		CAP Mapping
Connection 14				Henry Jones	hjones@yourlab.	org	2	Edit
/ MRE1								
MRE1								
MRE1	L							
∬ MRE1 *								
MRE1								
MRE1								

- 3. Confirm that the CAP Test Code Mapping chart is complete and correct. Make any changes if necessary.
- 4. Click **Export**.

_			U	aP Test Lode Ma	pping			-
_	IM Test Code	Test Description	IM Fluid Code	CAP Code*	CAP Description	Instrument Type	Suppress	_
•	-			CAP123	hsCRP (mg/L)			
_	AFP	AFP		CAP456				_
	BNP	BNP		CAP789	BNP			
	BR	BR		CAP1011				
	CA125	CA125		CAP1213				
	CA153	CA153		CAP1415				
	CA199	CA199		CAP1617				
	CEA	CEA		CAP1819				
	CORT	CORT		CAP2021				
	CpS	C-peptide		CAP2223				1
	DHEAS	DHEAS		CAP2425				-
	FT3	FT3		CAP2627				
	FT4	FT4		CAP2829				
1	4	Export Get CAP C	odes 🔽	My Lab Only		Cancel	Close	

*Data is for illustrative purposes only.

- 5. A Save As dialog box will appear. Use the dialog to choose the folder where you wish to save the export file.
- 6. Enter a file name for the export file.
- 7. Make sure the "Save as type" option is set to **Tab Delimited Files (*.txt)**.
- 8. Click Save.
- 9. Turn the CAP PT driver back on following the steps described in "Mapping Your Proficiency Testing Menu to the CAP Codes," Task 3: Turn on the CAP PT driver."

Importing a Mapping Code File

To import a mapping code file to an unmapped instrument, follow the steps below.

- 1. If you had turned on the CAP PT driver, be sure to turn it off before importing.
- 2. Decide which unmapped instrument you want to map using the export file you created earlier. With that instrument in mind, follow all the steps in the section "Mapping Your Proficiency Testing Menu to the CAP Codes" up to Task 2, step 12.
- 3. In the CAP Test Code Mapping window, click Import.

			CAF	P Test Code Mappin	g		
	IM Test Code	Test Description	IM Fluid Code	CAP Code	CAP Description	Instrument Type	Suppress
F	-						
				2			
						0.1	
1 not	port 2	t Get LAP	Lodes 🔽 M	ly Lab Only		Lancel	Llose

- 4. An Open dialog box appears. Browse to and select, or enter, the code file you wish to import.
- 5. Click Open.
- 6. The CAP Test Code Mapping chart will be completed.
- 7. Save the mapping by following the steps in "Mapping Your Proficiency Testing Menu to the CAP Codes" Task 2, step 22–26.
- 8. Turn the CAP PT driver back on following the steps described in "Mapping Your Proficiency Testing Menu to the CAP Codes," Task 3: Turn on the CAP PT driver."

4 Instrument Manager Rules

4.1 About Instrument Manager Rules

To meet requirements, you must create a rule in Instrument Manager that distinguishes PT samples from patient samples. This rule allows IM to route the PT samples correctly to the CAP PT driver. Each instrument must have this rule defined in Instrument Manager.

Recall that when you configured the CAP PT driver, you specified which fields would contain the values for the Kit # Contents and Specimen # Contents. The CAP recommends using the "Patient First Name" and "Patient Last Name" fields respectively. This means that the Kit # contents (the eight-digit kit number) will be found in the Patient First Name field and the Specimen # contents (specimen ID) will be found in the Patient Last Name field.



4.2 Rule Syntax

Rules contain at least two logical statements: If and Then. The "If" statement is a condition. If the condition is met, then the software performs the "Then" statement. If the condition is not true, then the software does nothing (unless you specify a third, "Else" statement).

In general, a simple two-statement in the instrument drivers will follow this format:

```
IF ({Specimen # data element} {Matches Pattern of} "1.5E1""-
""2.3E" ) {AND} ({Kit # data element} {Matches Pattern of} "8N" )
Then: {Set Destination Connection} e-LAB Solutions Connect
Connection
```

This rule will look for Kit # contents and Specimen # in these data elements. If this information is found in the results coming from the instrument, the rule then sets the destination connection to the CAP PT driver.

4.3 The "CAP PT Specimen Identification" Rule

When you create the rule, we recommend you call it the "CAP PT Specimen Identification" rule. To create the "CAP PT Specimen Identification" rule, copy the appropriate code below into Instrument Manager. Make sure you copy the code for your version of your Instrument Manager application. If you are using Instrument Manager version 8.7 to 8.11:

For this rule statement	Copy this code:
lf:	If: (({Extract Component of} {Patient Name} {Using} {Component Delimiter} {From} "1" {To} "1" {Matches Pattern of} "1.5E1""-""2.3E"){AND}({Extract Component of} {Patient Name} {Using} {Component Delimiter} {From} "2" {To} "2" {Matches Pattern of} "8N"))
Then:	{Set Destination Connection} "CAP"

If you are using Instrument Manager version 8.12 or higher:

For this rule statement	Copy this code:
lf:	If: (({Extract Component of} {Patient Name} {Using} {Component Delimiter} {From} "1" {To} "1" {Matches Pattern of} "1.5E1""-""2.3E"){AND}({Extract Component of} {Patient Name} {Using} {Component Delimiter} {From} "2" {To} "2" {Matches Pattern of} "8N"))
Then:	{Add Destination Connection(s)} "CAP"
Else:	Not applicable (no code needed)

Note: It is the laboratory's responsibility to test the rule it uses to ensure that no patient samples will transmit to the CAP.

Note: Depending on the version of Instrument Manager installed, not all data elements may be available for use within the rules engine. Please refer to your Instrument Manager Rules Manual for details on how to write rules and which data elements will be available.

4.4 Creating Instrument Manager Rules

Before you create the "CAP PT Specimen Identification" rule, make sure you have a copy of this user guide available and open on the computer you're using to run Instrument Manager. Use a flash drive if necessary. Follow the instructions below to create the rule.

Task 1: Create the Rule

- 1. Launch Instrument Manager.
- 2. Open the **Configuration** menu.
- 3. Select Specimen Management Configuration.

4. Select Rules Processing.



- 5. The Rules Setup screen appears. Open the **Select Configuration** drop-down menu.
- 6. Select the instrument configuration for which you want to create the rule.

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P		부 × 고 Value List Items	4 ×
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- 7. In the Tree View section, click the plus sign next to the **Test/In Validation** folder if it isn't already expanded.
- 8. Click the plus sign next to the **Incoming Result** folder.
- 9. Select the Before Message Queued Internally folder.
- 10. Click **New Rule** in the toolbar.

of Instrument Manager by Data Innovations, LLC - [Rules Setup - MRE]		
System Configuration Diagnostics Security Specimen Management SSR DC SR MM MA Reports Window	Help	- 6 ×
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🔍 🔨 10 📓 🖉 😈 Enter Find Text 🛛 🗛 🗈 - Replace 🍡 💞 🖉 Protect Rule	IN STATE	Rule
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Then:		
se.	1	
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Rule A		
Description		
Then		
Else		
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11. An item called New Rule appears with If, Then and Else sub-items. In the box below the Tree view, copy and paste the appropriate rule code from this user guide to create the If statement for this rule.

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MRE 🔻 Panes 🔹 🕌 隆 🗛 🛅 🥘 🚰			
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		* * Aa 🔄 🜒	
• Then:			
e Else:	-	*	
1 see Live	*		
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Properties and Then statements here. Status and Warnings	₽ ×		ф х

Tip: You can type the rule manually, but to avoid errors we *strongly* recommend that you copy and paste the rule from the user guide.

- a. Switch over to the user guide (which should be open on your computer) and locate the "CAP PT Specimen Identification" in the guide.
- b. Highlight the code for the If statement and copy it to the clipboard.

Note: There is more than one version of the code. Make sure you copy the code for your version of your Instrument Manager application.

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	If you are usin	g Instrument Manager version 8.12 or higher:
E #Live	For this rule statement	Copy this code:
I: Grid Vie If: Then: Else: If: Image: Properties Image: Properties Image: Properties Image: Properties	lf:	<pre>(({Extract Component of} {Patient Name} {Using} {Component Delimiter} {From} "1" {To} "1" {Matches Pattern of} "1.4A1""2N") {OR} ({Extract Component of} {Patient Name} {Using} {Component Delimiter} {From} "1" {To} "1" {Matches Pattern of} "1.3A1N1"-""2N")) {AND} (({Extract Component of} {Patient Name} {Using} {Component Delimiter} {From} "2" {To} "2" {Matches Pattern of} "8N")]</pre>
Description	Then:	{Add Destination Connection(s)} "CAP"
lf Then	Else:	Not applicable (no code needed)
Else	3.50 x 11.00 in ≺	· · · · · · · · · · · · · · · · · · ·
Logged On User: IM_ADMIN Locale: Defa	ult License #: IM-8	CAPS NUM INS 00008 Customer Name: Data Innovations, LLC 10/7/2013 4:28 PM

- c. Switch back to Instrument Manager.
- d. Click next to the "If" heading in the section below the tree and paste the code.

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Tree View Grid View .4A1"=""2N") {OB} { {Extract Compon Atache Pattern 0} "1.3A1N1""=""2N") elimiter } {From} "2" {To} "2" {Matches box Properties 2 Pule Description	ent of}-{Patient Name} {Using} {Component Delimiter} {From} "1) (AND) (({Extract Component of} {Patient Name} {Using} {Com Pattern of} "8N")) New Rule	*{To}*1" ponent # ×	11d	
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12. Repeat step 11 for the "Then" statement code. The "If" and "Then" codes automatically populate their respective parts of the New Rule in the Tree View above.

Note: Ensure that the destination connection name that appears in quotes in the Then statement matches the name of your CAP connection exactly. In this example, the connection name is "CAP"; however, your name may be different.



13. Name the rule. In the Properties section click into the Description field, highlight the default description ("New Rule") and replace it by typing "**CAP PT Specimen Identification**" into the field.

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Task 2: Save the Rule Set

1. Click Save Test/In Validation Rule Set.

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2. Click Yes.

3. A dialog displays the results of the save process, including errors, if any. Click **OK**.

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Tip: If an error in the rule is detected, the error will be highlighted in yellow in the Tree View. If there were an error, you would have to go back and fix it before continuing to the next Task.

Task 3: Save the Rule Set to the Live Environment

1. Click Save Live Rule Set.

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2. Click Yes.

Note: Clicking **Yes** will replace *all* live rules for this configuration with the rules from the **Test/In Validation Rule Set**.

Task 4: Copy the Rule Set to another instrument configuration

- 1. Open the **Live** folder
- 2. Open the **Incoming Result** folder.
- 3. Open the Before Message Queued Internally folder.
- 4. Select the rule.
- 5. Click the **Copy Rule(s)** button in the toolbar.

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- 6. A window opens showing a list of available instrument configurations. Check the configuration to which you want to copy the rule.
- 7. Click Copy Rules.
- 8. Click Close.

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9. Repeat steps 1-7 for all other instrument configurations.

Note: You must save this rule within each instrument's connection for the rule to apply for that instrument.

Tip: If you have any issues setting up this rule or other rules, please contact your Data Innovations Support Representative.

5 Testing Submission Configurations

5.1 About the Test Submission Service

The test submission service allows laboratory personnel to test their CAP PT driver configurations without actually submitting live PT results to e-LAB Solutions Suite. These configurations include new instrument updates, CAP code mapping, and instrument rules.

Tip: The phrase "Test Submission Service" refers to a service that *tests* the submission process. It does not refer to a service that submits tests.

Recall that when you mapped your laboratory's PT codes to the CAP codes in Instrument Manager, you left the check box for **Test Submission** checked on the CAP Proficiency Testing Configuration screen. This check box enables the test submission service and prevents submissions from going live until you uncheck it.

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5.2 Using the Test Submission Service

To use the test submission service to test a submission, follow the steps below.

- 1. Verify that you have selected the **Test Submission** check box for each Instrument for which you would like to validate your PT driver configurations.
- 2. Select a valid kit and specimen number from a prior PT activity that is past the due date.

Note: The kit number and specimen ID must be from the year in which you are testing the submission.

Note: If you were to run this specimen without having checked the Test Submission box, you will receive a "too late" error message as the PT due date has passed.

3. Log the PT specimen into your LIS using the Kit and Specimen ID numbers in the first and last name demographic fields of your LIS.

Tip: The CAP recommends using first and last names as a best practice; if necessary, your laboratory may use another configuration.

4. Accession the specimen and run the sample for the analytes you want to test on the instrument.

Tip: Any random patient or QC sample that contains the appropriate analyte(s) may be used to perform the testing.

5. You will receive an email that includes the challenge details and success or failure status for each challenge in the submission. (This process is similar to sending the data through the direct transmission process and viewing the results via e-LAB Solutions Suite.)

In this example email, the overall status indicates that errors were detected:

Subject: To: From:	Direct LabMa norepl	Transmissior nager@labs y@cap.org	n Test Subm .com	hission Error:	CAP #:1234567, Kit #:98765432
Overall Sta Submission Specimen: CAP #:1234	tus: Error n Date: 2019- CHM-01 4567 Kit #: 98	12-28T11:19: 8765432 M a	:14-06:00 hiling: C-A 2	019	
Challenge	CAP Code*	Response Value	Unit of Measure	<u>Analyte</u>	Status
1	CAP123	144	U/L	Amylase	Successful
2	CAP456	13	mg/ <u>dL</u>	Urea Nitrogen	Warning (Invalid kit / CAP code / specimen combination (response))
3	CAP 789	22	mg/l	Calcium	Error (Invalid kit / specimen combination)

*Data is for illustrative purposes only.

Details about any errors or warnings are provided in the Status column for that challenge. You can address these errors before submitting the PT data to the live server. In this example, all the challenges were successful, so no action is required:

Subject: To: From:	Direct LabMa noreph	Transmissio nager@acm y@cap.org	n Test Subi nelabs.com	mission: CAP #:	1234567, Kit #:98765432
Overall Sta Submissior Specimen: CAP #:1234	tus: Successf 1 Date: 2019- CHM-01 1567 Kit #: 98	ful 12-28T11:19 8765432 M	9:14-06:00 ailing: C-A	2019	
Challenge	CAP Code*	Response Value	Unit of Measure	<u>Analyte</u>	Result
1	CAP123	144	U/L	Amylase	Successful
2	CAP456	13	mg/dL	Urea Nitrogen	Successful
3	CAP789	22	mg/l	Calcium	Successful

*Data is for illustrative purposes only.

6. When you are ready to transmit your PT data to the live e-LAB Solutions Suite environment, uncheck the **Test Submission** check box in Instrument Manager for the relevant instruments.

ebservice Information TTP(S) Address [https://access.cap.org/lab2;	Contact Information Name Jane Smith Email Ismith@yourlab.org	KR	# Contents Patient First Name	T
Password Sussesses	Remember to un	check the Tes	t Submission	1 check box
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6 Proficiency Test Data Submission, Review, and Approval

6.1 Entering and Submitting PT Data

Your laboratory should follow its normal processes for logging in and testing PT specimens. Ensure that the kit number (preprinted on the result) and the specimen ID (exactly as it appears on the individual specimen) are placed into the positions as defined in the CAP PT driver configuration. This information must accompany the results as they are sent from the instrument to ensure that the specimens are identified to DI Instrument Manager as PT specimens and for the e-LAB Solutions Suite server to be able to file the result into the PT form. Once the data have been received and saved, the result form can be viewed in e-LAB Solutions Suite.

6.2 Reviewing and Approving Results in e-LAB Solutions Suite

On-time reporting of PT results remains the responsibility of the laboratory. Implementation of the technology still requires that laboratories ensure that they test, enter, submit, and approve result data prior to the due date on the result form.

Note: The result forms indicate the due date in which results *must* be received. Any data received *by any means* (fax, online entry, or direct transmission) after midnight (CST) of the date indicated will not be evaluated, resulting in a failure for all analytes included in the specific Survey event. Cut-off dates are mandated by the Centers for Medicare and Medicaid Services (CMS) for all approved PT providers.

Remember to review and approve your results by the due date!

To review and approve PT results in e-LAB Solutions Suite, follow the steps below.

Note: Wait at least 30 minutes until after the last PT sample was processed by the instrumentation for that specific PT kit; otherwise your data might not be available.

1. After logging on to cap.org, click View, enter, or submit PT Results.

View, enter, or submit PT Results	-
Claim CME/CE credit for faxed AP results	4
Access the Cancer Protocols	÷
Search our Learning courses	÷
Renew your membership or join the CAP	÷
Access your Competency Assessment Program	

2. To view all the PT kits and results you have transmitted through direct transmission, click **Result Form Data Entry** using either the link on the page or the link in the Access e-LAB Solutions Suite menu.

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Result Form Data Entry	Laboratory Data Main (Link no longer in use. Click on the above.)	Itenance Organization Profile link	Launch Dashboard

3. The Result Form Data Entry page appears. If you are authorized to access only one laboratory in e-LAB Solutions Suite, that laboratory's information appears by default. If you are authorized to access multiple laboratories, click **Lab Selector** to select the appropriate laboratory before continuing.

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	Click here for fi Applied Filters: Applied Filters: Applied Filters:	ilter option(s) to	modify the list of kits d I in last 250 days, All	isplayed or	search for o	other kits.			
	Denotes that kit is due been received.	within 10 days and resu	Its have not Denc	tes that kit is due received.	within 5 days and	i results have not	* Date: mm/dd/yyyy	10 Records Per Page	
	Due Date 🔺 🔻	Ship Date 🔺 🔻	Mailing 🔺 🔻	Kit # 📥 🔻	Seq ▲▼	Status 🔺 🔻	CAP # ▲ ▼	Owned by	
	05/08/2019	10/01/2018	C-C 2018	31611931	1	Pending Approval	4197601-01		
	11/13/2018	10/22/2018	AQ-C 2018	12345678	1	Received	4197601-01		
	11/20/2018	10/29/2018	SO-C 2018	87654321	1	Not Received	4197601-01		

The page shows all PT kits due within 60 days. The list includes the associated mailing number, kit number, sequence number, status, and CAP number. Here are the possible kit statuses and their meanings:

Status	Meaning
Not Received	The CAP has not received any PT result data for that kit.
Pending Approval	The kit data have been saved and are ready for review and approval.
Received	You have successfully reviewed and approved that kit.

4. To review and approve all the pages within a kit whose status is pending approval, click the **row**.

been received.		been been	received.			mm/dd/yyyy	10 Necolda Fel Fage
Due Date 🔺 🔻	Ship Date 🔺 🔻	Mailing 🔺 🔻	Kit # 🔺 🔻	Seq ▲▼	Status 🔺 🔻	CAP # 🔺 🔻	Owned by
05/08/2019	10/01/2018	C-C 2018	31611931	1	Pending Approval	4197601-01	
11/13/2018	10/22/2018	AQ-C 2018	12345678	1	Received	4197601-01	
O 11/20/2018	10/29/2018	SO-C 2018	87654321	1	Not Received	4197601-01	

For each result form page, you'll see its status, date received, and method of receipt (either fax or online).

5. Click the Approve and Submit to CAP to review and approve all available pages.

	Step 1: E	nter/Edit/View result	s				College Chicago	Of American Pathologists IL 60625
1	Page	Status	Date Received		Via	Data	OTHER	ACTIONS
	1	Pending Approval	11/15/18 11:14 AM	/1	Online	View/Edit		f you wanted to review
	2	Pending Approval	11/15/18 11:14 AM	1	Online	View/Edit	0	nly a specific page, you
	3	Pending Approval	11/15/18 11:14 AM	A	Online	View/Edit	C	ould click the View/Edit
	4	Pending Approval	11/15/18 11:14 AN	1	Online	View/Edit		link for that nade
	5	Pending Approval	11/15/18 11:14 AM	4	Online	View/Edit		
						₩4 1 2 3 4 📦	4	
	Step 2: R	eview and submit re	sults					

Tip: When one or more pages in a kit are in a "Pending Approval" status, the **Approve and Submit to CAP** button is activated. You would click that button to review all pages. If you wanted to review only a specific page, you could click the **View/Edit** link for that page instead.

Remember: Page data submitted within the last 30 minutes might not be available. If you try to view this page too soon, a message will remind you that if the links are disabled you'll have to check back after a certain time. This prevents anyone at the customer's laboratory from altering the result form while the electronic data is being processed.

Once sufficient time has passed, click **Refresh** to update the list and verify that transmission is complete. The link appears in an onscreen message:

Are the links to your result forms data disabled?

We are now processing the electronic submissions recently sent by your lab. Please check your kit transaction history and/or check back after July 10, 2019 5:31:03 PM (CDT). If the links are still disabled, please Refresh this page to check again.

- 6. A window with all of the pages for which you transmitted data is generated. Review your result form and verify that the data is presented exactly as you wish it to be evaluated. Make sure that:
 - Quantitative results were transmitted correctly in the appropriate response boxes/fields.
 - All required fields are populated, for example method, instrument, or reagent codes.
- 7. If you need to make edits, (a) enter the changes directly into the form and (b) click **Save**.
- 8. When you're done reviewing or editing the current page, use the arrows or drop-down menu at the top of the window to review the other pages.
- 9. After you have reviewed the last page in the kit, and are satisfied that the data is complete, the kit is ready for approval. To approve the kit, click **Approve & Submit to CAP**.







Note: As with any other form of data submission, the customer can alter data on a result form *prior* to the cut-off date for that Survey. Notify the CAP if you are unable to make edits before the cut-off date.

Remember: To approve a kit, you must review and approve **all pages in the kit** for the data to be evaluated. Data on result forms not approved by the customer **cannot be evaluated**.

10. If the Approval is successful, the Result Form Detail page status column will display "Received."

Due Date 🔺 🔻	Ship Date 🔺 🔻	Mailing	▲▼ Kit # ▲▼	Seq ▲▼	Status	▲▼	CAP # ▲ ▼	Owned by
05/08/2019	10/01/2018	C-C 2018	31611931	1	Received		4197601-01	
Step 1: Er	nter/Edit/View res	Date Rec	eived	Via	Ki	ts th	College (of American Pathologists L 60625 ccessfully approved are
1	Received	11/15/18 2	:54 PM	Online	1		given "R	eceived" status.
2	Received	11/15/18 2	:54 PM	Online	View/E	dit		ansaction history
3	Received	11/15/18 2	:54 PM	Online	View/E	dit	View kit in Contact I	Is instructions
				0.00000000000000			Somaci	10
4	Received	11/15/18 2	:54 PM	Online	View/E	dit		

Caution: It is important that a laboratory have policies and procedures cautioning/admonishing employees from accessing patient or proficiency reports under other CLIA certificates than the one by which they are employed. Failure to adhere to such prescribed policies and procedures could result in federal sanctions.

6.3 Tracking Proficiency Testing Results in e-LAB Solutions Suite

The e-LAB Solutions Suite interface provides an audit trail for results submitted via direct transmission. Currently, if you access result entry information for your laboratory, a display will list PT kits in process.

Note: If the due date for any of the kits on your list is within five days, the kit will be tagged with a red alert (!) and your site administrator will receive an email alerting him/her to the fact that results are due within five days.

The audit trail for PT results submitted via direct transmission will be similar to the audit trail generated if you submit your data online or via fax.

You or another e-LAB Solutions Suite user can track your laboratory's PT kit review history at any time by following the steps below.

- 1. Go to cap.org and click View, enter, or submit PT Results.
- 2. Log in.
- 3. Navigate to the **Result Form Data Entry** page.
- 4. Click the row for the kit you wish to track.
- 5. The Result Form Details page shows basic information about whether and when a kit's pages were received. To see all of the transactions related to each page in the kit, click **View Kit Transaction History**.

Due Date 🔺 🛪	Ship Date 🔺 🔻	Mailing 🔺 🔻	Kit # ▲ ▼	Seq ▲▼	Status 🔺 🔻	CAP # ▲ ▼	Owned by
05/08/2019	10/01/2018	C-C 2018	31611931	1	Received	4197601-01	
Step 1: E	nter/Edit/View res	ults			1	College (Chicago, I OTHER /	Df American Pathologists L 60625 ACTIONS
Page	Status	Date Receive	d	Via	Data	Print a bla	ank result form
1	Received	11/15/18 2:54 P	м	Online	View/Edit		terre and data
2	Received	11/15/18 2:54 P	M	Online	Vie 5	<u>View kit t</u>	ransaction history
3	Received	11/15/18 2:54 P	M	Online	View/Edit	Contact I	le le
4	Received	11/15/18 2:54 P	M	Online	View/Edit	Sonact	
5	Received	11/15/18 2:54 P	M	Online	View/Edit		

6. The Kit Transaction History window shows an audit trail for each page in a kit, including each action taken on that page, the date and time of the action, and the ID of the user who performed the action.

Ki	t/Customer Kit Details: Ins	#: 3161193 titution Na	1, CAP #: ame : Colle	4197601, S ege Of Am	Survey : C-C 2018, erican Pathologists	
Page	Action	Date/Ti	me	User		
)	Kit Unlocked	11/15/18	11:44 AM	LAB2PT		~
)	Kit Locked	11/15/18	11:14 AM	LAB2PT		
)	P ved Online	11/15/18	11:14 AM	DTLIS		
The was the	window will show v s locked and unlock a 30 minute waiting	vhen a kit ked after period.	1:57 AM 1:38 AM	DTLIS DTLIS	The ID "LAB2PT" ide as a direct transn Instrument M	ntifies this action nission using lanager.
1	Approved	11/15/18	2:54 PM	smith		
1	Saved Data	11/15/18	11:14 AM	DTLIS		
1	Saved Data	11/14/18	11:58 AM	DTLIS		
1	Saved Data	11/13/18	3:57 PM	smith		~

6.4 Instrument and Method Verification and Maintenance

The CAP will continue to maintain each laboratory's instrument and method codes within the CAP computer system.

Note: Customers must verify that the codes that have been retained by the CAP are still accurate. If a code changes, it is **the responsibility of the laboratory** to make the changes on the appropriate result form prior to approving and submitting data.

6.5 Quality Cross Check Result Reporting

To report Quality Cross Check results using direct transmission, your laboratory will need to identify the primary (first) and secondary (second) instruments performing this testing in Instrument Manager. Third instrument results cannot be directly transmitted to the CAP at this time. You can only enter results for a third instrument online via e-LAB Solutions Suite. To identify primary and secondary instruments, follow the steps below.

1. In Instrument Manager open the System menu and select Status.



- 2. In the Status Display screen, select the CAP PT driver connection.
- 3. Click **Utility**.

I on Minimal SEL Eve		Selected Connections	Hesend Mes
			Y Enter Find T
Connection /	Status	In Service	In
_ System			
Purge	On		
Qmgr	On		
Quality Control	On		
Specimen Routing	Off		
- User Defined			
Analyzer	Off	Yes	0
CAP Proficiency Tes	ting On	2 Yes	0
Analyzer CAP Proficiency Tes	ting On	2 Yes	0

- 4. The CAP Instrument Configuration window opens. Locate the connection name that you want to designate as the primary instrument. Open the **Instrument Type** drop-down menu for that connection name.
- 5. Select **Primary** from the menu.
- 6. Locate the connection name that you want to designate as the secondary instrument. Open the **Instrument Type** drop-down menu for that connection name.
- 7. Select **Secondary** from the menu.
- 8. Click Close.



9. Click **OK** to confirm that you want to save your changes.

Note: You do not have to stop the driver to access/change the primary or secondary instrument designations. You may change the designations as many times as you want.

Another way to report primary and secondary instruments is to use the data stream from the LIS. To do this, pick a field that identifies the type, then use **the Instrument Type Definition** drop-down menu in the CAP Proficiency Testing Configuration window to select the data element you want to use. You would then have to include the value in the downloaded message.

	00 11101110						=	ut bleme -	-
HTTP(S)	Address	https://a	ps://access.cap.org/lab2pt		You	can use the I I	nstrument Type	e streame	-
U Pi	Usemame Usemame Password		Definition field to select the data element you want to use to report primary or secondary instruments.				tents st Name		
Test	t Service	TestCor	nn					hber	
			Te	est Connection	De	lay Between Retries 10	Seconds	Patient Middle Name.	•
10					loven i	Instrument Definition	le sure se	T	
Lon	nection No	me In	strument ID	Instrument Code	CAP Number	Contact Name	Contact Email	Lest Submission	CAP Mapping
ABI	2				0123430			2	Edit
Svs	mex A	-		West	0123456				Edit
Sys	mex B	_		East	7654321	Al Ernate	Alen.T.Eemate@generic.	c 🗹	Edit
Sys.	mex WAM	2		1141.03	10.051000000	19992302000	and the second sec	ĺ. ₹	Edit
Sys	mex WAM	In	ist A					2	Edit.
Sys	imex WAM	In	ist B		-				Edit

A third method for reporting primary and secondary instruments is to designate the instrument type during CAP mapping.

			CA	P Test Code Ma	pping		
	IM Test Code	Test Description	IM Fluid Code	CAP Code*	CAP Description	Instrument Type	Suppress
	В	В		CAP123	Bilirubin (mg/dL)	Primary	
	Ca(7.4)	Ca(7.4)		CAP456	Calcium (mg/dL)	Primary	
- 9	K+	K+		CAP789	Potassium (mmol/L)	Secondary	
Ø	Na+	Na+		CAP1011	Sodium (mmol/L)		
	cCI-(U)	cCI-(U)		CAP1213	Chloride (mmol/L)		2
				Instr	rument Type drop-	down menu.	
							`

*Data is for illustrative purposes only.

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