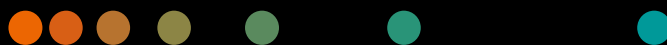


Sysmex® CS-2500 System

Operator

Training Workbook



Siemens Healthineers

Sysmex CS-2500 System

Operator

Training Workbook



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Table of Contents

1:	Welcome
2:	System Overview
3:	Daily Setup
4:	Loading Reagents
5:	Sample Processing
6:	Result Information
7:	Day 2 Morning Review
8:	Calibration
9:	Quality Control
10:	Day 3 Morning Review
11:	Analysis Result Errors
12:	Maintenance and Troubleshooting
13:	Sample Integrity Check

1 Welcome

Welcome to Training

Siemens Healthineers Training would like to welcome you to basic training on the Sysmex CS-2500 System.

This course is designed to teach you the skills needed to operate and maintain the Sysmex CS-2500 System. Our staff welcomes the opportunity to present this training program to you.

Training Material

This training workbook includes an agenda, learning goals, and practical exercises.

Course Objectives

Upon completion of this class, you will be able to:

- Identify major hardware components.
- Perform the steps to start up the system.
- Navigate the main software screens.
- Locate the Error Help screen.
- Discuss preparation of reagents and QC.
- Perform Daily Maintenance.
- List the steps to create a login to the system.
- List the steps to create a user defined maintenance task.
- Describe the on-board stability for reagents.
- Demonstrate loading reagents on the system.
- Describe how to use the C rack and SLD mini cup.
- Identify Reagent screen messages.
- Identify main areas of Reagent screen.
- Perform QC processing.
- Perform sample processing.
- Discuss ordering in micro mode and longer measurement time.
- Identify key areas of the Joblist screen.
- Locate Result information on the Joblist.
- Identify key areas of a normal reaction curve.
- Perform a calibration.
- Identify information on Package Inserts and Application sheets.
- Identify QC that is out of range.
- List steps to process D-Dimer QC.
- Identify corrective actions for Analysis result errors.
- Perform Weekly, Monthly, As needed Maintenance.
- List the steps to replace the Halogen lamp.
- Perform a data backup of the system.

Agenda

Day 1

- System Overview
- Daily Setup
- Loading Reagents
- Sample Processing

Day 2

- Day 2 Morning Review
- Result Information
- Calibration
- Quality Control

Day 3

- Day 3 Morning Review
- Troubleshooting Abnormal Results
- Maintenance & Troubleshooting

Sysmex CS-2500 System Operator Training

Course Validation Checklist

The participant places a checkmark beside the competency when it is completed. When all competencies are checked, the instructor and participant sign and date below as record of completion.

Topics	Competencies	Completed
System Overview	Identify major hardware components.	
	Perform the steps to start up the system.	
	Navigate the main software screens.	
	Locate the Error Help screen.	
Daily Setup	Perform Daily Maintenance.	
	List the steps to create a login to the system.	
Load Reagents	Describe on-board stability for reagents.	
	Identify Reagent screen Messages.	
	Demonstrate loading reagents on the system.	
	Identify main areas of Reagent screen.	
Quality Control	Describe how to use the C rack and SLD mini cup for QC.	
	List steps to activate Auto QC.	
	Identify key areas of the QC chart screen.	
	Identify QC points that are out of range.	
	Perform the steps to process D-Dimer QC.	
Sample Processing	Perform QC processing.	
	Identify key areas of the Joblist screen.	
	Perform sample processing.	
	Discuss ordering in micro mode and longer measurement time.	
	Process samples using manual order entry.	

Topics	Competencies	Completed
Result Information	Locate Result Information on the Joblist.	
	Identify information on a printout.	
	Identify key areas of a Normal Coagulation Reaction curve.	
Calibration	Identify information on the application sheet and package insert.	
	Demonstrate entering reagent information into Reagent Lot Master.	
	Perform a calibration.	
	Perform calibration validation.	
	Locate ISI and normal values for the PT reagent.	
Analysis Result Errors	Identify difference between the status of Review and Error.	
	Distinguish between normal and abnormal results on the Joblist.	
	Locate information on the Browser screen and the Reaction Curve screen.	
	Identify Corrective actions for Analysis Result Errors in Quick Reference Guide.	

Topics	Competencies	Completed
Maintenance and Troubleshooting	Identify weekly maintenance tasks.	
	Identify monthly maintenance tasks.	
	Identify As needed maintenance tasks.	
	List the steps to replace the Halogen Lamp.	
	Perform a backup of database.	

Instructor: _____

Student: _____

Date: _____

What was most helpful to you during this program?

How can we improve this program to make it more meaningful to you?

Training Center Safety Information

In this classroom, you will use materials and/or specimens that are potentially hazardous. To that end, we at Siemens Healthineers have requirements for using personal protective equipment that we strongly urge you to follow.

- Eating, drinking, storing foods, applying cosmetics, or handling contact lenses is not permitted.
- Laboratory coats are required at all times.
- Gloves and safety glasses are required when:
 - Handling calibrator and control materials, test specimens which originate from human blood and urine, or waste material produced by the instrument.
 - When performing any activity at the instrument while the instrument is in operation.
- When gloves are removed, they must be placed in the biohazard container provided. Hands should be washed after gloves are removed.
- After using any sharps, these items must be placed in the sharps disposal container provided.
- Gloves and safety glasses are not required in the lecture area.
- Hands should be washed before exiting the classroom.

2 System Overview

System Overview

Resources

- *Sysmex CS-2500 System Quick Reference Guide*

Objectives

Upon completion of this exercise, you will be able to perform the following tasks:

- Identify system hardware components.
- Perform the steps to start up the system.
- Navigate the main software screens.
- Locate the Error Help screen.

System Overview

Identify System Hardware Components

Using the Sysmex CS-2500 Quick Reference Guide, locate the following components and label accordingly.

- Light Shield Lid
- Sample Probe-cap piercer
- Cuvette Hopper
- Reagent Table
- Dispensing table
- Reagent section lid
- Alarm indicator light
- Mechanical stop
- Start button
- STAT/ buffer table
- Sampler
- Cuvette Trash box
- Condensation Tray (No. 48)
- Monitor touch screen
- 2d barcode reader
- Computer (IPU)
- Pneumatic Unit
- Halogen Lamp
- Trap Chamber, 2 adjustment knobs
- Power switch
- Fuse box and power cord
- Air Filter, left side (No. 16)
- 3 Air Filters, back of instrument (No. 513 and No. 514)
- UPS

1. Remove the Reagent Table Covers. Take out the reagent racks.
How many reagents does it hold?
Place racks back inside Reagent Table. Replace and lock covers.

2. Locate the Stat/Buffer Table.
This area is used to store buffer, diluents.

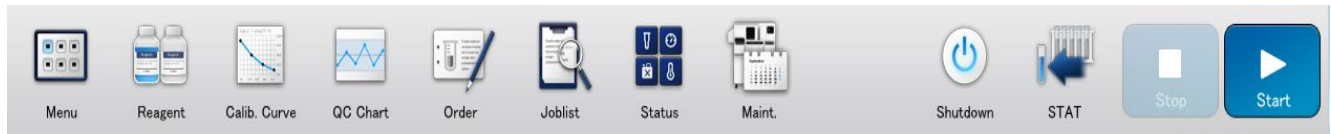
Perform the Steps to Start Up the System

1. Press Power button on IPU computer.
2. Computer starts up.
3. Press enter on keyboard to select User. (CS User)
4. Enter User password. _____
5. Instrument software starts up.
6. Select logon icon, enter password. _____
7. Press analyzer power switch on.

Please return to your seat.

Navigating Toolbar Shortcut Buttons

Answer the following questions using the *Sysmex CS-2500 Quick Reference Guide* and by navigating the toolbar of the CS 2500 System.

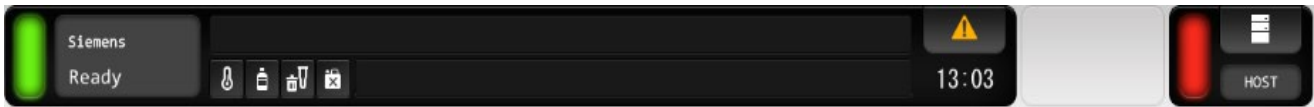


1. How many hours has the **CA Clean I** been onboard? What is the volume?
2. Which toolbar icon displays the ISI/Normal for PT, displays calibration curves?
3. Which toolbar icon displays Levey-Jennings charts?
4. In **Order** Screen, what operation button is used to manually ID a sample?
5. Locate the last sample run on the **Joblist**. What date was it run?
6. In **Status**, what is the temperature of the Reagent Table? Are the cuvettes adequate for the morning run? What color is the indicator symbol for cuvettes?
7. When was Daily Maintenance last performed?
8. When was the last time the lamp was replaced and calibrated?
9. In the **Operators log**, find the last User to perform maintenance.
10. Find the **Error Help** button. What was the last error on your instrument?

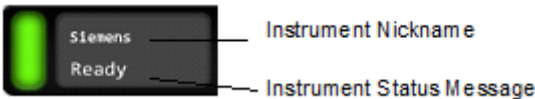
Please return to your seat.

Resource Material

Status Bar



Status of Main Unit



Error Help Button



Color	Status
White	All errors have been corrected.
Yellow	Errors require corrective action.

Indicators

Temperature



Color	Status
Light Gray	All temperatures are in normal range.
Red	Some temperatures are outside normal range.
Gray	The main unit is not connected.

Reagent



Color	Status
Light Gray	There is a sufficient amount of reagent.
Yellow	Reagent is low.
Red	• A reagent has run out • A detergent has run out
Gray	Remaining volume of reagent is unknown or the Main Unit is not connected.

Cuvette

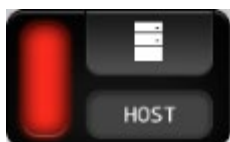


Color	Status
Light Gray	The remaining number of cuvettes and the capacity of the cuvette trash box are sufficient.
Yellow	The remaining number of cuvettes and the capacity of the cuvette trash box are low.
Red	• Set cuvettes • There is no capacity in the cuvette trash box • Cuvettes are accumulated in the cuvette disposal section
Gray	The main unit is not connected.

Rinse Water



Color	Status
Light Gray	There is a sufficient amount of rinse water.
Yellow	Rinse water is used up.
Red	There is no rinse water.
Gray	The main unit is not connected.

Status of Host computer

Color	Status
Green	Connecting
Red	A communication error occurred.
(Space)	The setting on the instrument indicates that the host computer will not be used.

3 Daily Setup

Daily Setup

Resources

- *Sysmex CS-2500 System Quick Reference Guide*

Objectives

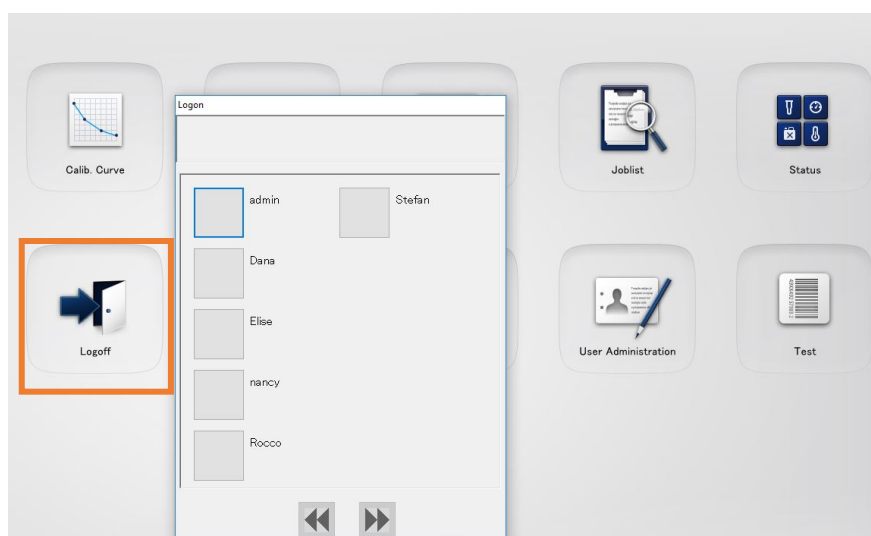
Upon completion of this exercise, you will be able to perform the following tasks:

- Perform Daily Maintenance.
- List steps to create a login to the system.

Daily Setup

Create a login to the system

1. Select **Menu** from the toolbar.
2. Select **User Administration**.
3. Select **Add**.
4. Enter a **Logon**. (your name)
5. Select **Change Password**.
 - a. New Password – Enter Password
 - b. New Password (Confirmation) – Re-enter Password
 - c. Select **OK**.
6. Enter a **Username**. (your name)
7. User Right – Use down arrow to select **Laboratory Supervisor**.
8. Select **Save**.
9. Press **OK**.
10. Select **Menu** from the toolbar.
11. Select **Logoff**.
12. Select the **Icon** Username you created.
13. Enter password.
14. Select **OK**.



Create a customized logon with User right “Lab Technician”

1. A Laboratory Supervisor level can assign a user right's level: Laboratory Supervisor, Lab Technician, or Night-Shift Operator.
2. Create a **Lab Technician** user with restricted system function permissions.
 - a. Select **User Administration**.
 - b. Select **Add**.
 - c. Login name: Tech
 - d. Select **Change Password**.
 - e. Enter New password and confirmation (example: 123)
 - f. Username: Tech
 - g. Select User right: **Lab Technician**
 - h. Select/deselect permissions from the list.
 - i. Press **Save**, press **OK**.

ID	Logon Name	User Name	Exp. Date	User Right	Comment
1	admin	administrator	2007/12/31	Laboratory Supervisor	
2	Dena		2007/12/31	Laboratory Supervisor	
3	Elise	Elise	2007/12/31	Laboratory Supervisor	
4	nancy		2007/12/31	Lab Technician	
5	Rocco		2007/12/31	Laboratory Supervisor	
6	Stefan		2007/12/31	Laboratory Supervisor	

Logon Name:

User Name:

Exp. Date:

User Right:

Comment:

Permissions:

- ☒ Reagent replacement / addition
- ☒ Operation for Quality Control
- ☒ Operation for Calibration Results
- ☒ Operation for Analysis Results
- ☒ Validate analysis results
- ☒ Maintenance
- ☐ Setting
- ☐ Assay Group Settings

Calendar: December 2007

Buttons: Up, Down, Add, Delete, Save, Close

Perform Daily Maintenance

Refer to **Sysmex CS-2500 Quick Reference Guide** to perform Daily Maintenance tasks.

1. Perform Daily Maintenance. Document tasks using **Manual Maintenance** key.
2. Go to **Operation Log** to view list of maintenance tasks with the name of the tech that performed it. Initials can be added as a comment. Use the pencil icon.

The screenshot displays the 'Daily Maintenance' screen. At the top, there are navigation buttons: '<<', '<', 'This Month', '>', '>>', and a date field showing '2021/06'. Below this is a table for daily tasks. The tasks listed are: Rinse Probe, Discard used cuvettes, Dispose of waste, Check and discard trap chamber fluid, and Shutdown. Each task has a row of 31 circles representing the days of the month. The 'Manual Maintenance' button is highlighted with an orange box on the right side of the screen. Below the daily tasks, there are sections for 'Weekly' and 'Monthly' tasks, and a 'Check Maintenance' dialog box is open, showing a list of items and their status (checked or not).

Daily Maintenance	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Rinse Probe	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	
Discard used cuvettes	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	
Dispose of waste	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	
Check and discard trap chamber fluid	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	
Shutdown	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	

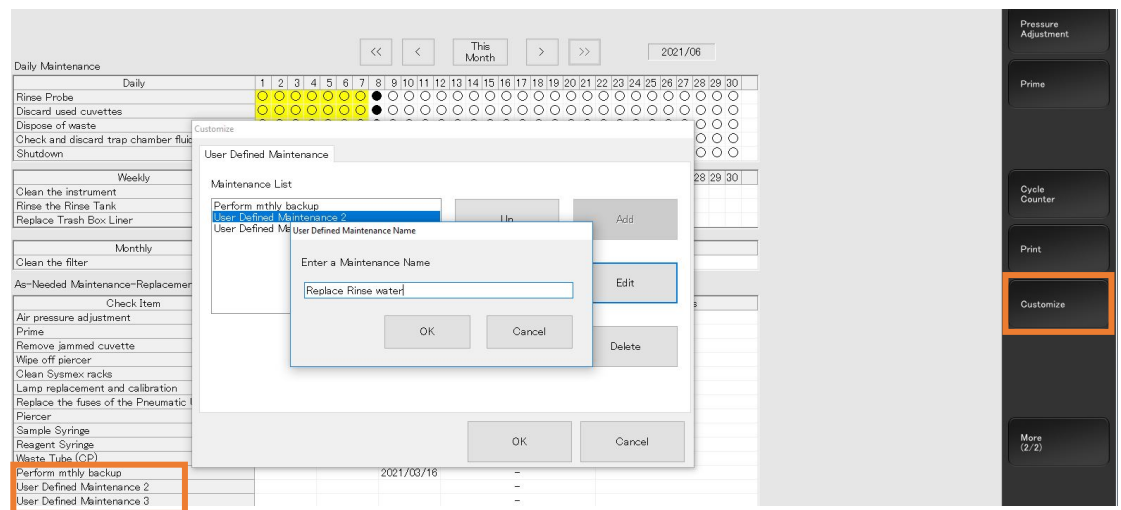
Maintenance history/schedule is saved for 1 year.

1. Navigate to the previous month maintenance log using the arrows.
2. Print maintenance screen monthly if a paper copy is required for record keeping.

This screenshot shows the same 'Daily Maintenance' screen as the previous one, but with the navigation buttons at the top highlighted by an orange box. The buttons are: '<<', '<', 'This Month', '>', '>>', and a date field showing '2021/06'.

Create a User Defined Maintenance Task

1. Use the following steps to create a User Defined Maintenance task to replace rinse water.
 - a. Select **More** on Operation Panel.
 - b. Select **Customize**.
 - c. Select **User Defined Maintenance 1**.
 - d. Select **Edit**.
 - e. Name your User Defined Maintenance task. (example: Replace Rinse Water)
 - f. Select **OK**, select **OK**.



2. Document completion of the new User defined task under **Manual Maintenance**.

How is it indicated on the screen?

4 Loading Reagents

Loading Reagents

Resources

- *Sysmex CS-2500 System Quick Reference Guide*
- *Sysmex CS-2500 Application Sheets*

Objectives

Upon completion of this exercise, you will be able to perform the following tasks:

- Discuss preparation of reagents and QC.
- Demonstrate loading reagents on the system.
- Describe how to use the C-rack and SLD mini cup.
- Identify main areas of the Reagent screen.
- Identify Reagent screen messages.

Loading Reagents

Prepare QC and Reagent

1. Use the **Sysmex CS Systems Routine Reagent Preparation guide**, prepare reagents and Quality Control for PT and aPTT tests.

Siemens Healthineers Job Aid

Sysmex® CS Systems Routine Reagent Preparation Guide



PT/INR Dade® Innovin® Reagents

Reagent	Prep	Placement	On-Board Stability (10°C)	Refrigerated Stability (2-8°C)
Dade® Innovin	Reconstitute with volume of de-ionized water specified on bottle, swirl to mix, allow to clear	Reagent Table	72 hours	10 days
Dade® Ci-Trol® 1	Reconstitute with 1 mL de-ionized water, let stand for 15 mins, swirl to mix	Reagent Table (SLD mini Cup, C rack)	24 hours	16 hours
Dade® Ci-Trol® 3	Reconstitute with 1 mL de-ionized water, let stand for 15 mins, swirl to mix	Reagent Table (SLD mini Cup, C rack)	24 hours	16 hours

2. View Sysmex CS-2500 Application sheets for **PT INR with Dade Innovin** and **APTT with Dade Actin FSL Reagent**. Locate on-board stability for reagents and Quality Control materials.

CS-2500
Reference GuidePT INR / Dade® Innovin® (V. 05)
Page 1 of 4

Application Sheet

PT INR /

Dade® Innovin®

For additional information, limitations and interferences please refer to the Instructions for Use of the analyzer and check current Instructions for Use for reagents, controls and calibrators and tables of assigned/analytical values.

The parameters defined in this application sheet have been developed by Siemens Healthcare Diagnostics to provide optimal product performance with the assay and instrument combination. Any modification to these parameters may affect performance of this and other assays in use on your system and the resulting assay values. It is the responsibility of the user to validate any modifications and their impact on all assay results. Results of this test should always be interpreted in conjunction with the patient's medical history, clinical presentation and other findings.

The application sheet lists all combinations of controls and calibrators for use with the reagent and instrument system; other combinations are not validated or supported by Siemens.

Version	05
Release Date	2019-05
Software Version	≥ 01-68
USA only	

Materials Required

Product	Order No.	Order No.	Order No.	Order No.	Name in Test Pro-
• Component(s)	Package Size 1	Package Size 2	Package Size 3	Package Size 4	tocol
Dade® Innovin®	[REF] B4212-51	[REF] B4212-101			
	10 x → 10 mL	12 x → 20 mL			PT Inn
Ci-Trol [CONTROL 1]	[REF] B4244-10				
	20 x → 1 mL				Citrol 1
Ci-Trol [CONTROL 2]	[REF] B4244-20				
	20 x → 1 mL				Citrol 2
Ci-Trol [CONTROL 3]	[REF] B4244-30				
	20 x → 1 mL				Citrol 3
[CONTROL IN]	[REF] ORKE45				

Reagent table racks and adaptors



A-rack



D-rack



C-rack

Stat-buffer table adaptors



The adaptors pictured above are for GW15, GW5, and 4ml cup in the Stat-buffer table.

Load Reagents and QC

Use the *Sysmex CS-2500 System Quick Reference Guide*

Loading Reagents Tab> Reagent Table Loading

1. Add reagents to the system.

Use the *Sysmex CS-2500 System Quick Reference Guide*

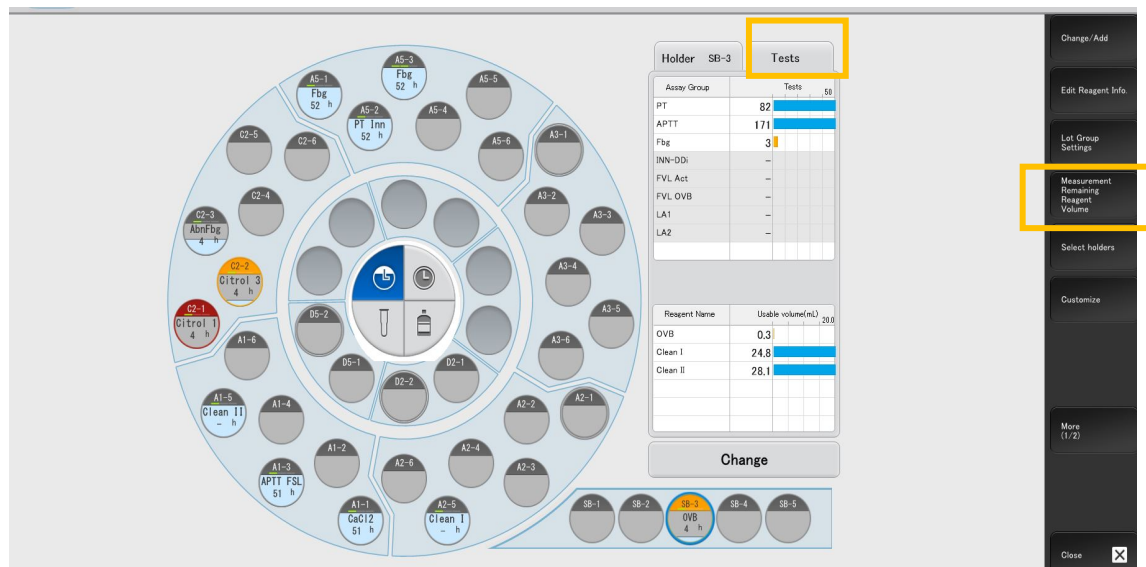
Loading Reagents Tab> Loading QC or Calibrator

2. Pour/pipette QC material into a SLD mini cup and place in the QC vial. Place QC vials in C rack and place onboard the system.
3. **Scenario:** Before the morning run, you want to know how many tests can be run from your new PT Innovin reagent vial.

Perform a level sense of your reagent volumes by selecting the **Measurement Remaining Reagent Volume** button from the Operation Panel.

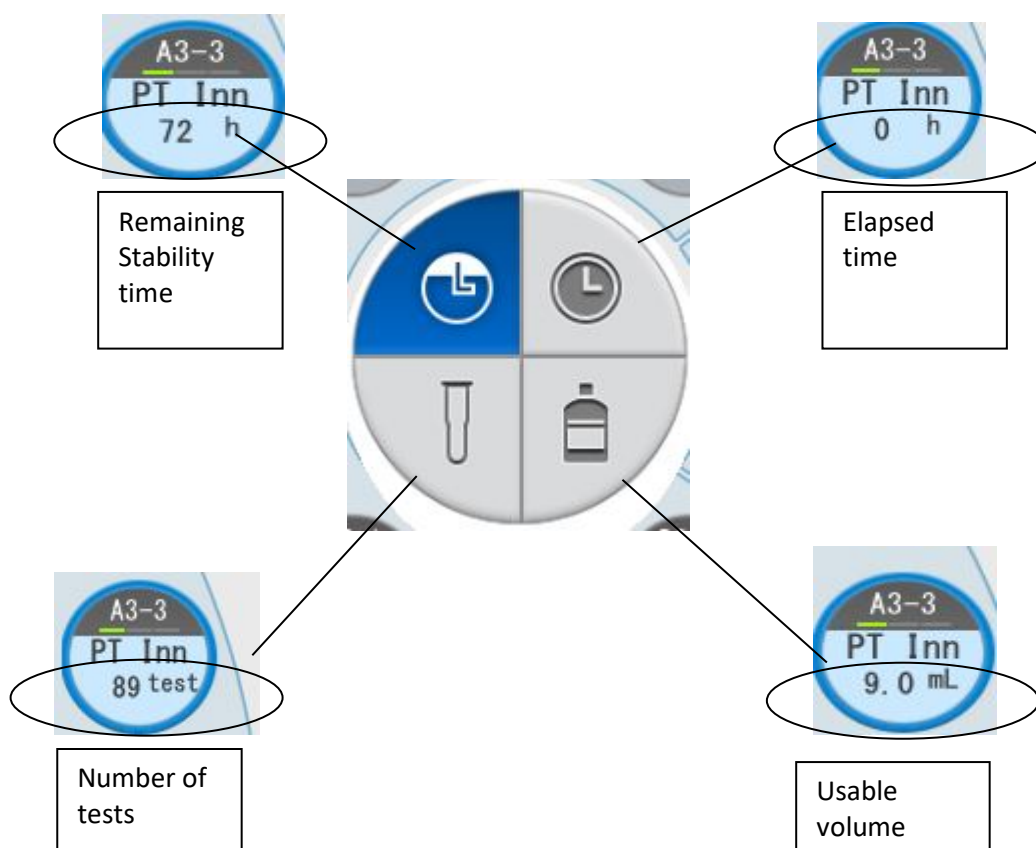
Select **Ok**.

How many tests are available? Press **Tests** tab to view number of tests.



Identify Main Areas of the Reagent Screen

1. Navigate to the **Reagent** Screen.
2. Highlight **PT Inn** reagent. Press each section of the center switch button to see how reagent information changes

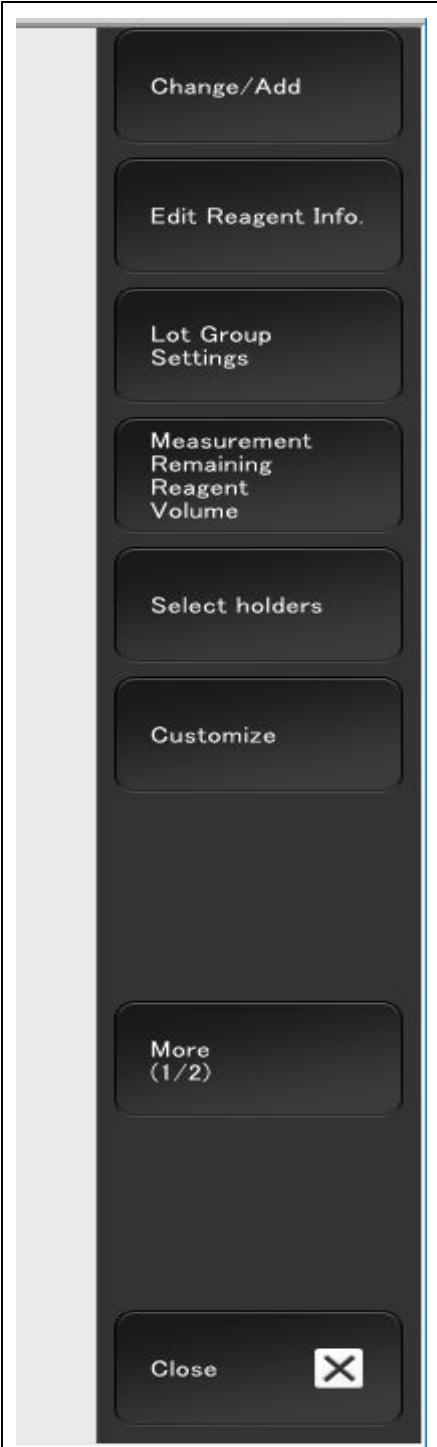


Use the center switch buttons on your instrument to answer the following questions.

1. What is the **Remaining stability time** for the PT and PTT reagents?
2. How many tests can be performed with the PT reagent?
3. What does the **Elapsed time** indicate?

Reagent Operation Panel

1. Press each operation key to display the screen.
2. Press **Print** to print a list of on-board reagents and QC.

	Allows user to select a specific rack for removal. The rack moves to the replacement position under the reagent cover for removal.
	Used for editing or manually entering the information on the reagent set on the reagent table. Reagent lot must be listed in Reagent Lot Master.
	Displays a checkmark that allows a specific lot number to be used for the assay. This checkmark is enabled through calibration validation.
	Performs a volume check on reagents. This enables the usable volume and number of tests to be displayed.
	Collectively selects multiple reagent holders that have conditions such as barcode read error, no reagent volume, reagent not registered in Reagent lot master.
	Customizes the buffers and detergents displayed on the Tests tab.
	Press More to view the Print key. Press Print to print the reagent information list.
	Press Close, to close the screen.

Identify Reagent Messages

Use the *Sysmex CS-2500 System Quick Reference Guide*

Loading Reagents Tab > Reagent Table features, and Reagent Messages to answer the following scenarios.

1. The barcode was not read on the reagent vial, what symbol is displayed?
2. The reagent was loaded to the Stat-buffer table and it should be on the Reagent table, what symbol is displayed?
3. The tech put on a new lot (unknown lot) of reagent; what symbol is displayed?
4. The reagent stability time has expired, what symbol is displayed?
5. The reagent lot has reached its expiration date, what symbol is displayed?
6. A new lot of D-Dimer was loaded and needs calibration, what symbol is displayed.

The diagram illustrates the reagent carousel layout and the associated data tables. The carousel is divided into sections for different reagents, each with a specific lot and stability time. The central area contains icons for a test tube and a reagent bottle. The right side of the image shows two data tables: 'Holder A3-3' and 'Tests'.

Holder A3-3

Assay Group	Tests	50
PT	89	
APTT	169	
Fbg	-	
INN-DDi	0	
FVL Act	-	
FVL OVB	-	
LA1	-	
LA2	-	

Reagent Name Usable volume(mL) 20.0

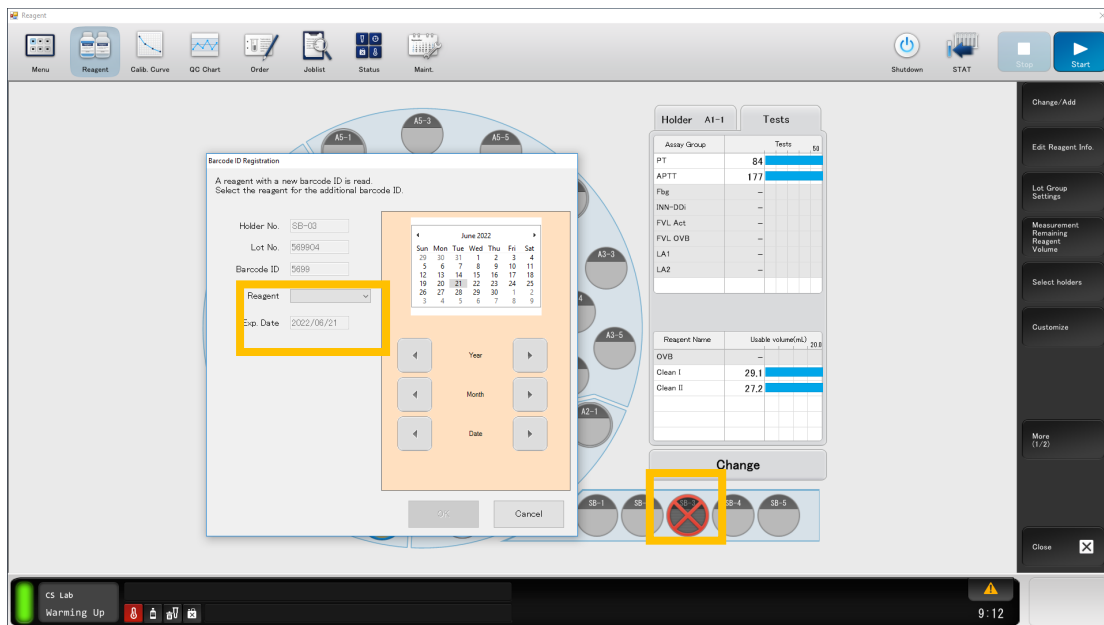
OVB	-	
Clean I	17.5	
Clean II	25.9	

Change

The carousel also displays various reagent messages and symbols, including a question mark, a crossed-out symbol, and a 'CAL' (calibration) symbol.

Load a reagent that has a new Barcode ID

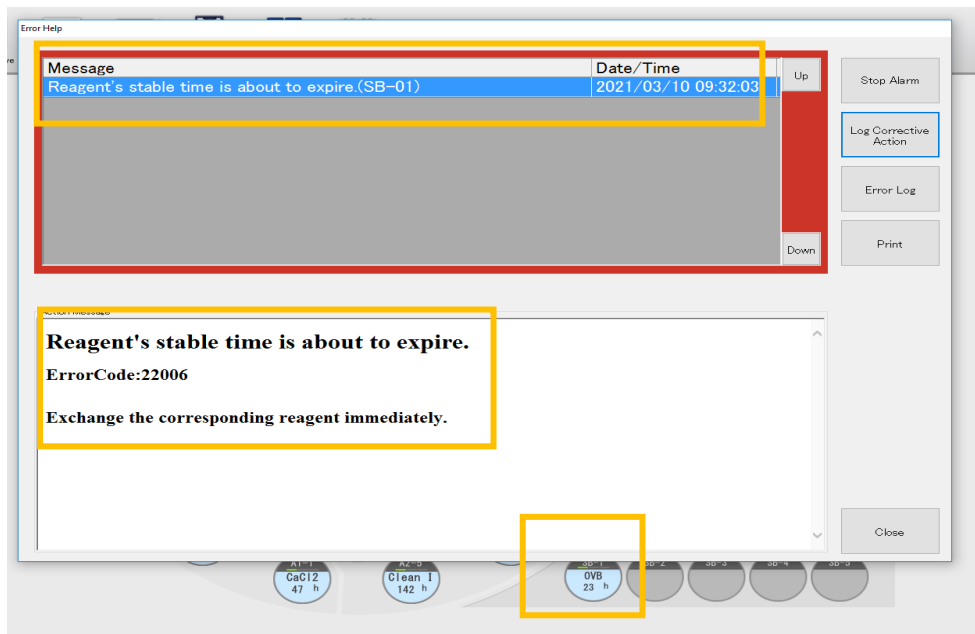
If a reagent with a new barcode ID (first 4 digits of lot number) is loaded, a screen appears after the barcode is read. The reagent position is marked with a red X. To fix, the operator selects the reagent name from a drop down and enters the correct expiration date using the calendar. This new information is saved in the Reagent Lot Master. The red X disappears and the reagent is correctly identified.



Reagent on-board stability warning message

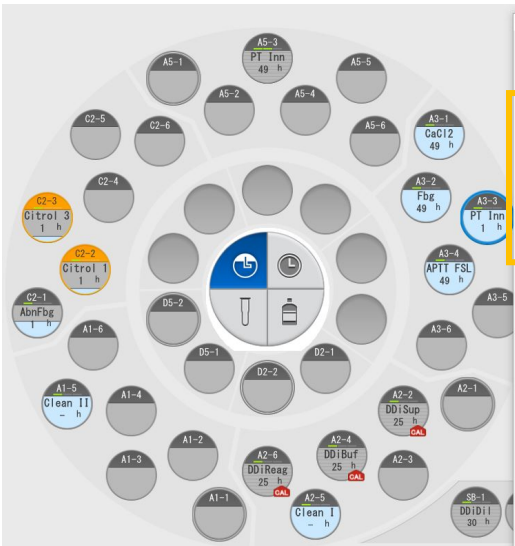
There will be an alarm message when reagents/QC are close to expiration. This alarm can occur up to 30-60 minutes before expiration.

The warning is set up in System Setting>Instrument setting>Timer



Reagent volume will be short alarm message

An alarm message will occur when a reagent/QC volume is low. The position turns orange when the volume is low.



The Reagent screen displays a circular layout of reagent positions. Positions A3-3, C2-2, and C2-3 are highlighted in orange, indicating low volume. The error message window shows the following details:

Message	Date/Time
Reagent's stable time is about to expire.(A3-03)	2021/03/1
Reagent volume will be short(Citrol 3)	2021/03/1
Reagent volume will be short(Citrol 1)	2021/03/1

Action Message

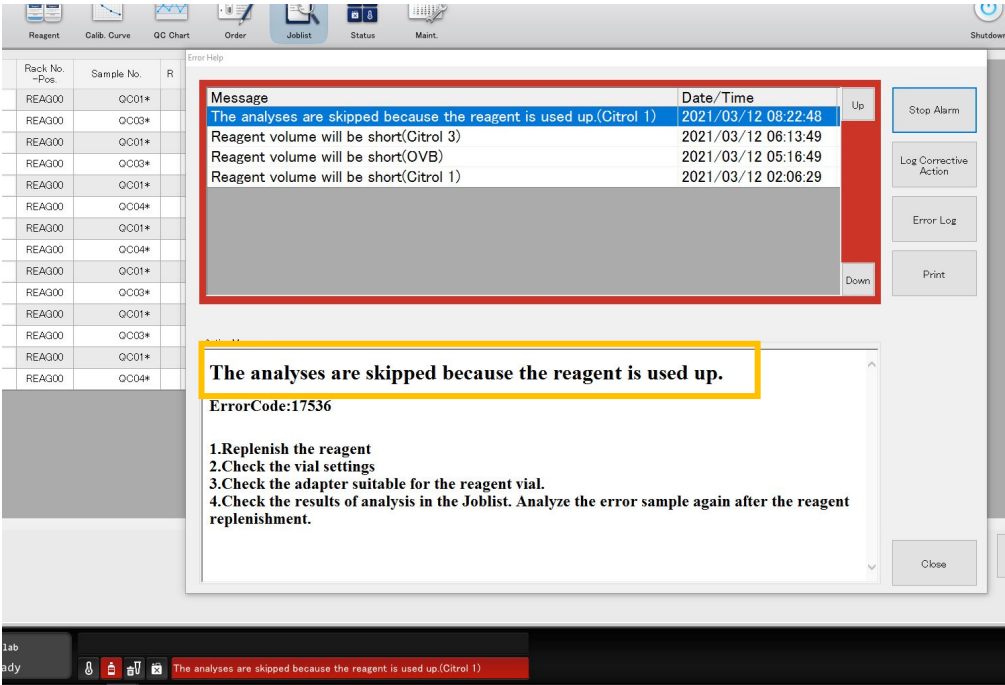
Reagent's stable time is about to expire.

ErrorCode:22006

Exchange the corresponding reagent immediately.

Reagent is used up alarm message

After pressing **Start**, an alarm message will occur when a reagent or QC is used up. The reagent position on the Reagent screen turns red to indicate it has no more usable volume.



The Reagent screen displays a circular layout of reagent positions. Positions A2-2, A2-3, and A2-4 are highlighted in red, indicating they are used up. The error message window shows the following details:

Message	Date/Time
The analyses are skipped because the reagent is used up.(Citrol 1)	2021/03/12 08:22:48
Reagent volume will be short(Citrol 3)	2021/03/12 06:13:49
Reagent volume will be short(OVB)	2021/03/12 05:16:49
Reagent volume will be short(Citrol 1)	2021/03/12 02:06:29

The analyses are skipped because the reagent is used up.

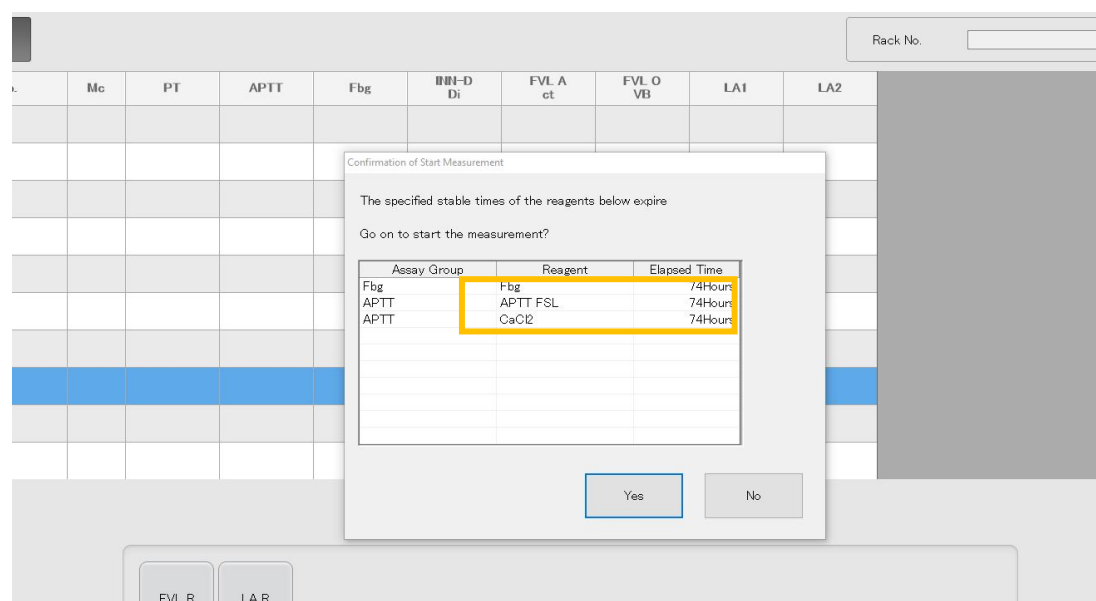
ErrorCode:17536

- 1.Replenish the reagent
- 2.Check the vial settings
- 3.Check the adapter suitable for the reagent vial.
- 4.Check the results of analysis in the Joblist. Analyze the error sample again after the reagent replenishment.

Reagent stability time is expired alarm message

After pressing **Start**, a message will appear if reagents/QC stability time has expired.

Select **No**, to prevent testing from starting. Select **Yes** to start processing.



5 Sample Processing

Sample Processing

Resources

- *Sysmex CS-2500 System Quick Reference Guide*

Objectives

Upon completion of this exercise, you will be able to perform the following tasks:

- Perform QC processing.
- Perform Sample processing.
- Identify key areas of the Joblist.

Sample Processing

Process Quality Control from the Reagent Table

Use the *Sysmex CS-2500 System Quick Reference Guide*

Quality Control Tab> Processing from the Reagent Table-QC Files

Perform the following tasks:

1. Order QC01 (Ci-Trol 1) for PT and PTT.
2. Order QC03 (Ci-Trol 3) for PT and PTT.
3. Can SLD mini cups be used on A or D reagent racks?

Locate QC results on the Joblist

Document your quality control results on the chart below. Find these points in QC Chart.

Control/Test	Result
Ci-Trol 1 / PT	
Ci-Trol 1 / APTT	
Ci-Trol 3 / PT	
Ci-Trol 3 / APTT	

Sample Processing

Process Samples in Normal Mode

Use the Sysmex *CS-2500 System Quick Reference Guide*

Sample Processing Tab

1. Process samples.
Find the “End Time” for the sample. View progress of samples on the **Joblist** until first results are displayed.
2. Select **Display condition** operation key and change to “Today”.

Use the Sysmex *CS-2500 System Quick Reference Guide*.

Joblist Information Tab> Joblist Information Symbols

3. What do the following Analysis progress symbols indicate?

Joblist Symbol	What does the symbol indicate about the sample?
✓	
⊙	
⊙	
⊙	

Key areas of the Joblist screen

1. The Joblist holds up to 10,000 results.

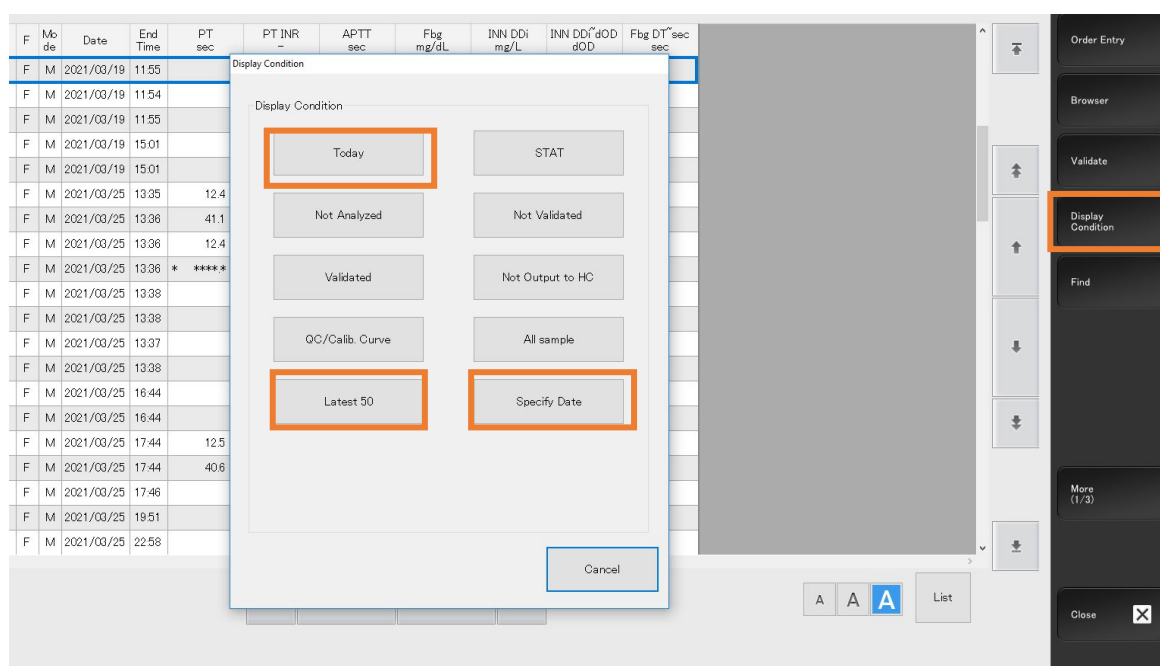
The **Display Condition** operation key is used to filter the results.

Latest 50- displays the last 50 samples processed.

Today- displays results from the current day.

Specify Date- displays the Joblist results from a specific date.

All sample- displays all samples, up to 10,000.



2. The **List** key displays sample results in vertical form.
3. The **"A"** keys change the font.

APTT sec	Fbg mg/dL	INN DD ⁱ mg/L	INN DD ⁱ dOD ⁱ dOD	Fbg DT ^{sec} sec	Assay Group (Dil. Ratio)	Value
59.6	*	209			PT (1/1)	12.4
		113			APTT (1/1)	29.6
		229			Fbg (1/1)	141
		114				
29.6	141					
54.6						
28.9						
55.0						
	132					
	70					
	139					
	75					
55.0						
	79					
	71					

Navigation buttons: Left, Right, Double Right, Font A, Font A (bold), Font A (italic), List

4. **Multiple Result flags can be displayed with results on the Joblist screen.**

	REAG00	QC01*	V	F	M	2021/03/17	08:43				258		
	REAG00	QC04*	V	F	M	2021/03/17	08:43				119		
Review	REAG00	QC01*	V	F	M	2021/03/17	09:13	*	10.9		27.3	258	
	000016-01	SHP	V	F	N	2021/03/17	09:49		11.4	1.09	27.0		
Review	000021-01	datafi x2	V		N	2021/03/17	10:39	*	****	*	106.4	< 50 *	
Review	000021-01	datafi x2	R	V		N	2021/03/17	10:39	*	****	*	106.6	< 50
Review	000021-01	datafi x2	V	F	N	2021/03/17	10:39	*	****	*	106.6	< 50	

The Low-reliability flag (*), and dilution analysis flag (d) will be displayed at the same time as report limit flags (<,>).

For a complete list of **Result flags**, use the *Sysmex CS-2500 System Quick Reference Guide*.

Joblist Information Tab> Joblist Information: Symbols

6 Result Information

Result Information

Resources

- *Sysmex CS-2500 System Quick Reference Guide*

Objectives

Upon completion of this exercise, you will be able to perform the following tasks:

- Locate Result Information on the Joblist.
- Identify key areas of a normal coagulation reaction curve.

Locate Result Information

Use your *Sysmex CS-2500 System Quick Reference Guide* Joblist Information Tab: **Browser and Reaction Curve** to answer the following questions:

1. Highlight a sample on the Joblist.
2. Navigate to the **Browser** screen.
 - a. Navigate to the **Reaction Curve** screen.
 - b. Select tabs: **Evaluation info, Evaluation Data**
 - c. Find the following information in the **Measurement Info** tab.

Reagent Lot
Elapsed Time
Hem/Lip detection level
Vol detection level
QC Performed Date

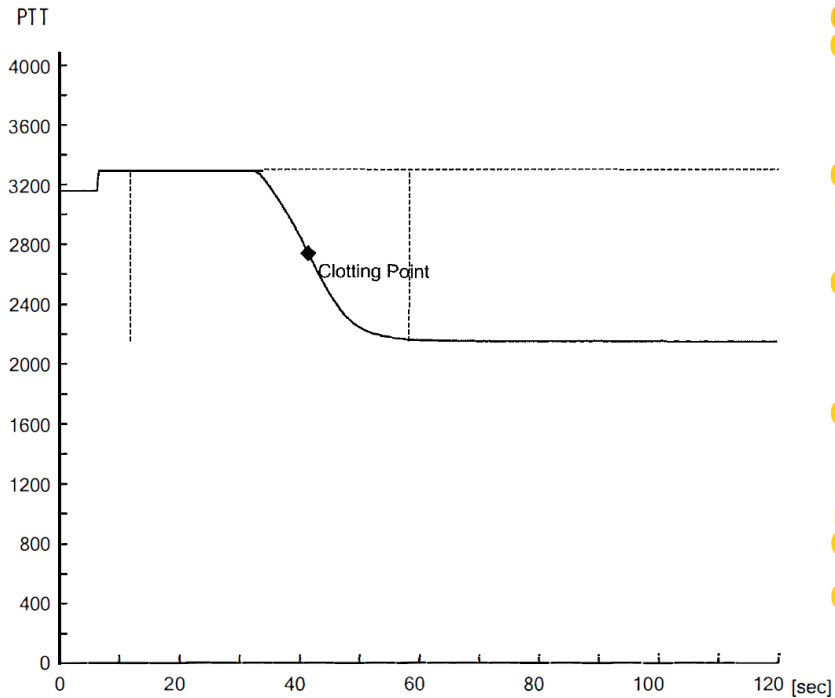
3. Print the Reaction Curve screen of a PT and PTT result.

CS Lab

Elise : Elise

***** Graph Detail Print *****

Sample No: 100123 B Seq: F
Rack Tube Pos: 000002-01 **Re-analysis flag:**
Status: Validate: Performed
S. Code: Validated on : 10/02/2019 09:32:50
Analysis Mode: Normal Cp Validated by : SYSTEM
Patient Name:
Sample Comment:
Sample Info.: **Meas. Date:** 10/02/2019 09:25:24



Result
PTT 41.5 sec

Evaluation Info.
 bH_point_time 12.0
 bH 3303
 End_point_time 58.4
dH 1141
 Coag. % 50
 dOD 0.1841

Measurement Info.
 Temperature 37.0
 Channel No. 5
 Management ID 3250
 Dilution 1 / 1
Reagent Lot APTT FSL 556962
 CaCl2 563846
Elapsed Time APTT FSL 47
 CaCl2 48

Detail

Hem Detection Level 0
 Ict Detection Level
 Lip Detection Level 0
 Vol Detection Level 56.2
 Calibration Curve ID

QC Performed Date 10/02/2019
 09:22:43

Evaluation Data

1%	32.4	21%	37.0	41%	40.2
2%	32.9	22%	37.3	42%	40.4
3%	33.3	23%	37.4	43%	40.5
4%	33.6	24%	37.6	44%	40.7
5%	33.9	25%	37.8	45%	40.8
6%	34.2	26%	37.9	46%	41.0
7%	34.4	27%	38.1	47%	41.1
8%	34.6	28%	38.2	48%	41.2
9%	34.7	29%	38.4	49%	41.4
10%	35.0	30%	38.6	→ 50%	41.5
11%	35.1	31%	38.7	51%	41.6
12%	35.3	32%	38.9	52%	41.8
13%	35.6	33%	39.0	53%	41.9
14%	35.8	34%	39.2	54%	42.1
15%	35.9	35%	39.3	55%	42.2
16%	36.2	36%	39.5	56%	42.4
17%	36.3	37%	39.7	57%	42.5
18%	36.5	38%	39.9	58%	42.7
19%	36.7	39%	39.9	59%	42.8
20%	36.8	40%	40.1	60%	42.9

Reagent	Table Temp.	10.1	
61%	43.0	81%	46.5
62%	43.2	82%	46.7
63%	43.3	83%	47.0
64%	43.6	84%	47.2
65%	43.7	85%	47.4
66%	43.9	86%	47.7
67%	44.0	87%	47.9
68%	44.1	88%	48.2
69%	44.3	89%	48.6
70%	44.4	90%	48.9
71%	44.7	91%	49.3
72%	44.8	92%	49.6
73%	45.0	93%	50.1
74%	45.2	94%	50.6
75%	45.3	95%	51.0
76%	45.5	96%	51.8
77%	45.7	97%	52.7
78%	45.9	98%	53.8
79%	46.1	99%	55.6
80%	46.3	100%	58.5

11334/01-18 build40

1/1

10/04/2019 10:13

Result Information

Describe the Multi-Wavelength Detection System

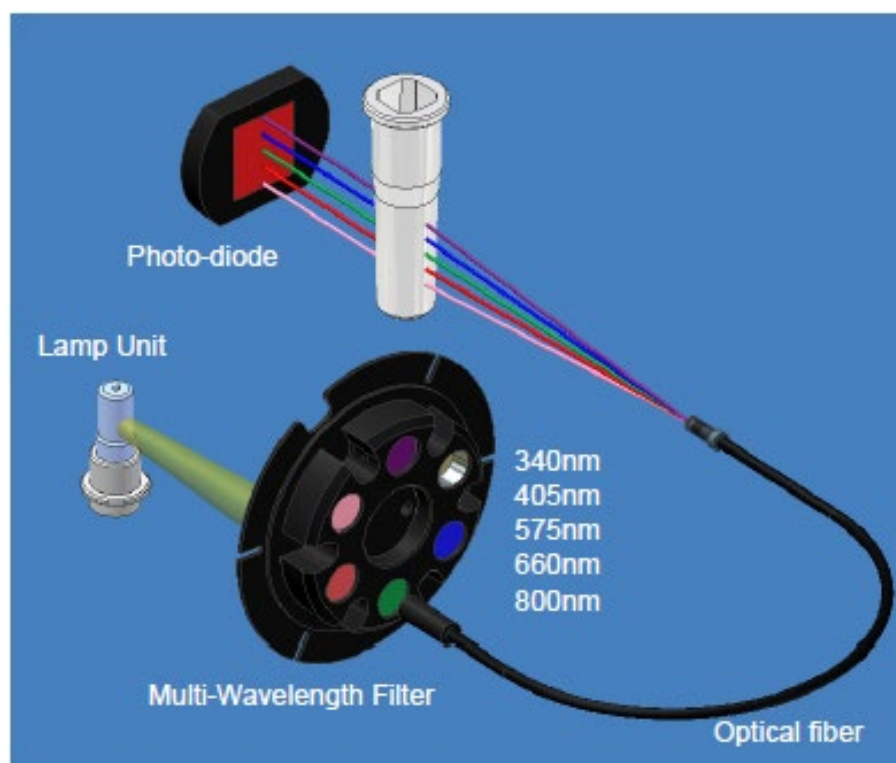
The light source on the Sysmex CS-2500 System provides simultaneous multi-wavelength scanning of reactions at 340, 405, 575, 660, and 800nm.

For clotting assays, multiple wavelengths can be evaluated by each detector well. A sample is evaluated by a primary wavelength and a secondary wavelength at the same time.

If the result from the primary wavelength has analysis errors, the result from another wavelength may be displayed on the Joblist.

The function of using the result of a sub-wavelength is called a **Wavelength Switch**. This function makes it possible to obtain a result on the first run thereby minimizing repeats.

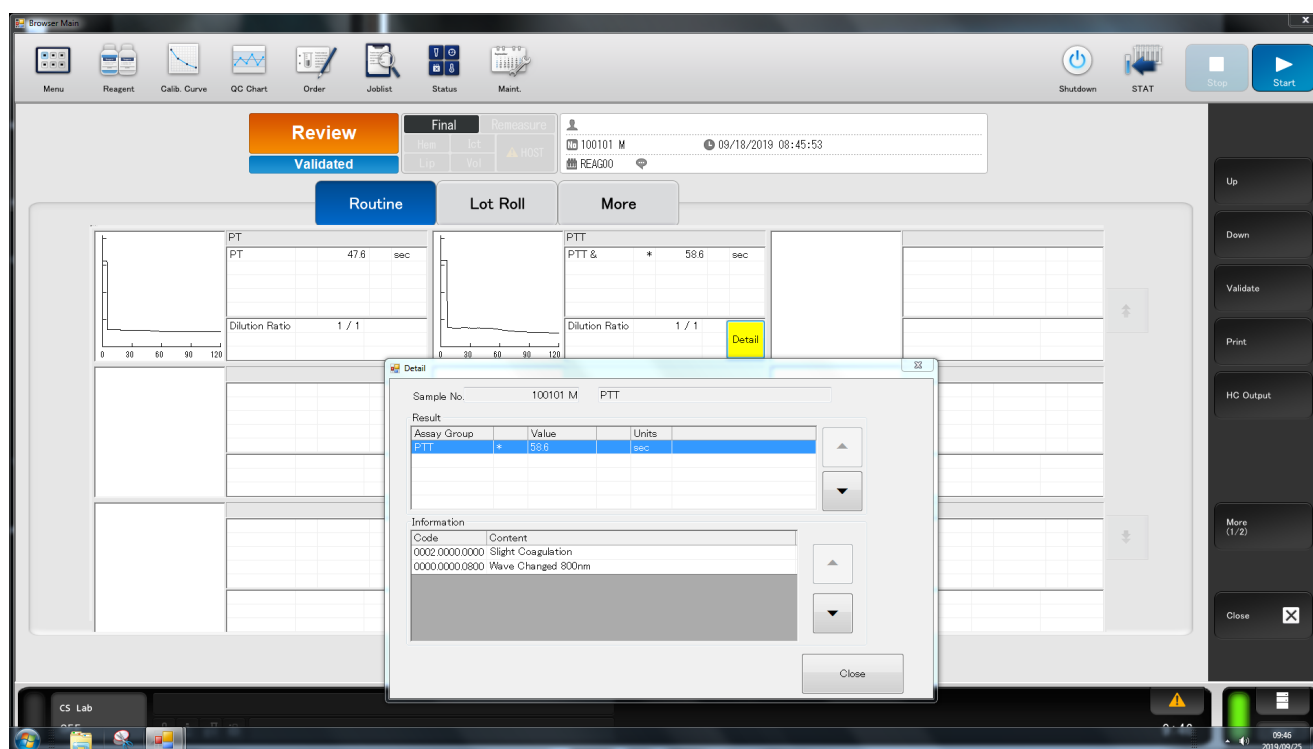
List of Wavelengths used on the CS-2500



Wavelength Switch

Error Code	Benefit of Wavelength Switch
No Coagulation Slight Coagulation	A sample with a weak clot @ 660 nm may demonstrate a stronger clot (higher dH) @ 800 nm and therefore be reportable with the first analysis.
Turbidity Level Over	Optically challenged samples tend to exhibit interference @660 nm; this interference is typically minimized @ 800 nm.
Trans Light High	Extremely clear samples may demonstrate a higher dH with 800 nm

Wavelength switch shown in the Browser screen.



Result Information

Identify key areas of a Normal Reaction Curve

Coagulation Principle

Clotting assays on the CS-2500 use an evaluation method called **Percentage Detection Method**.

The analysis of the reaction is plotted on a graph.

X-axis- Time in seconds

Y-axis- Transmitted light intensity in milli-absorbance units or mA

This graph is called the reaction curve.

The sample/reagent mixture in the reaction cuvette is placed into a 37° C detection well. Light is transmitted through the cuvette. The light transmission in milli-absorbance units is measured over time.

First, the analyzer determines the starting point of the reaction. This is called the **baseline** or **bH**.

The **baseline (bH)** or starting point is called the **0%** point of the curve.

As the sample starts to clot and gets more turbid, the transmitted light intensity decreases, and the reaction curve slopes downward. This should be a constant decrease in transmitted light as the coagulation factors convert to fibrin.

When all the coagulation factors are converted to fibrin and the clotting reaction is complete, the reaction curve levels out and reaches the **endpoint**.

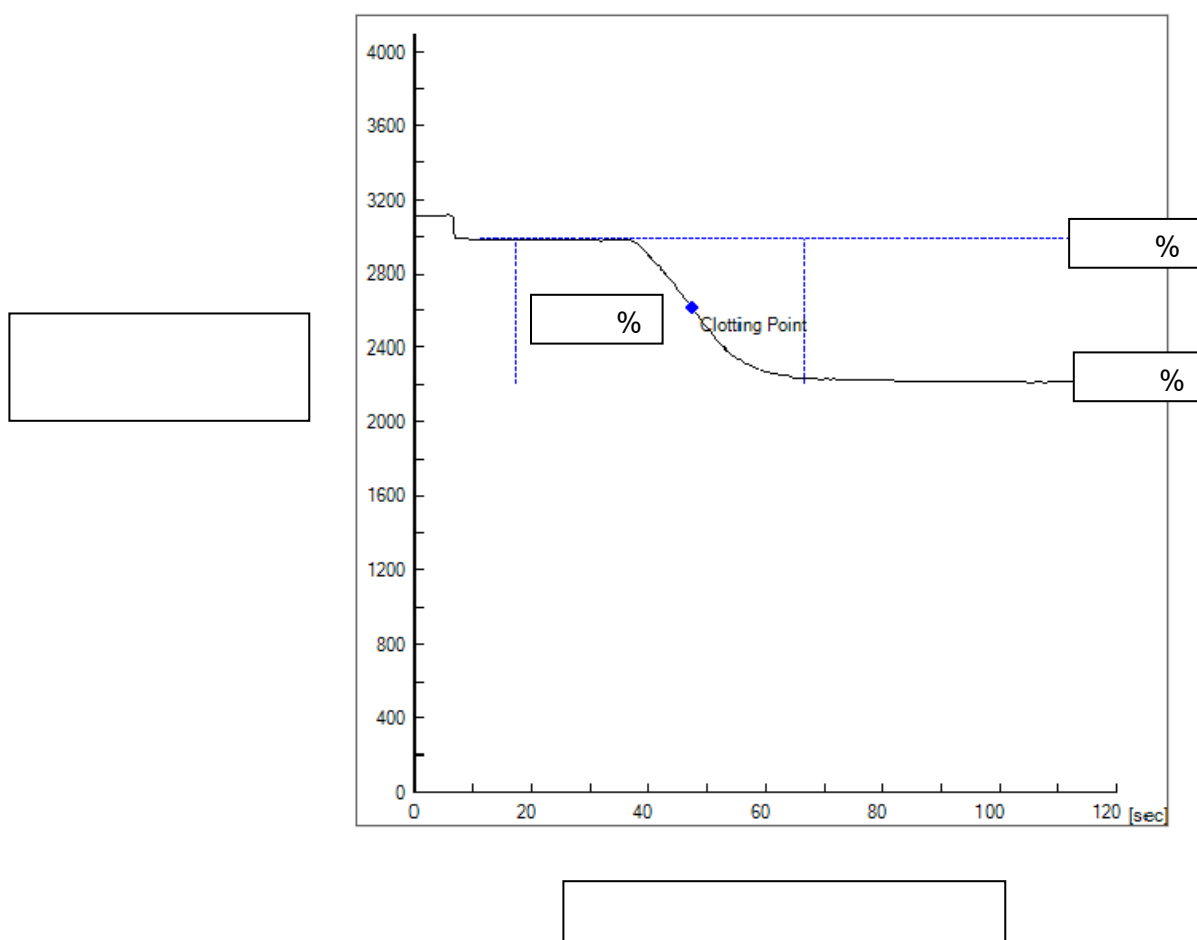
The **endpoint** is called the 100% point of the curve.

The difference in transmitted light between the **baseline** and the **endpoint** is called the **dH**.

The **dH** indicates the intensity of the coagulation reaction.

The **clotting result** is typically taken at the 50% point on the graph. This point is where the greatest change in light intensity occurs.

1. Label the **Normal Reaction** curve for a clotting assay below:



Label the graph with the following items

dH (delta height)

endpoint

bH baseline

100%

0%

50%

Transmitted light

Time in seconds

Resource Material

Chromogenic Principle

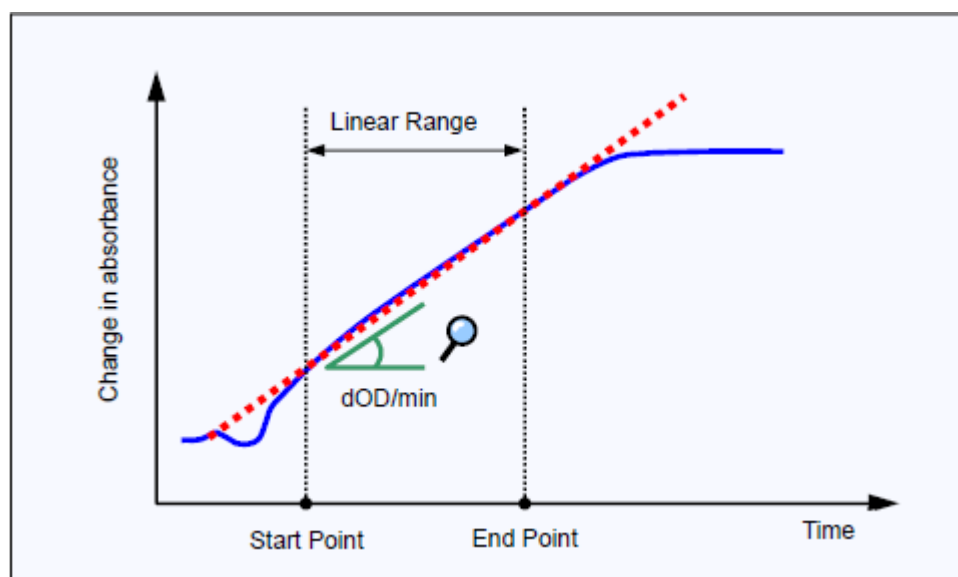
Chromogenic tests on the CS 2500 use the **Rate Method** for evaluation. The Rate method is the process of color emission by a chromogenic synthetic substrate. This method measures the change in absorbance.

Every sample is plotted onto a graph to create a reaction curve. On the X-axis is seconds and on the Y-axis is the Change in absorbance.

When the sample is first introduced into the reaction cuvette the kinetic reaction begins. The system then evaluates a predetermined Start Point and End Point to the reaction curve. The program then calculates the change in absorbance from the Start Point to the End Point.

Example of Chromogenic Assay: INNOVANCE Antithrombin, Heparin

Wavelength used: 405nm



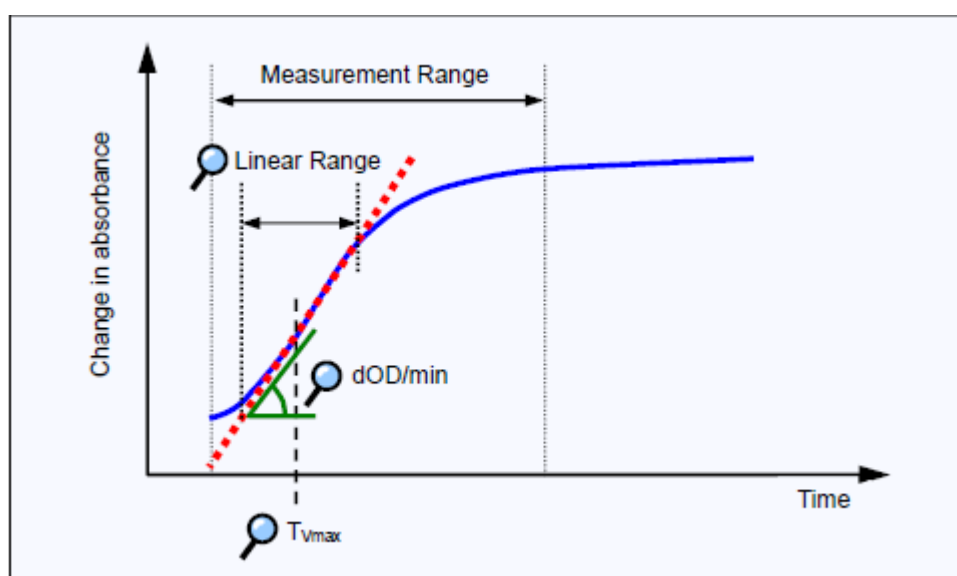
Immunoassay Principle

Immunoassay tests on the CS 2500 use the **VLin Integral Method** for evaluation. This is a process of antibody-sensitive reagent reacting with antibodies. This method measures the change in light absorbance.

Every sample is plotted onto a graph to create a reaction curve. On the X-axis is seconds and on the Y-axis is the Change in absorbance at the time point when the reaction reaches its steepest increase.

Example of Immunologic Assay: INNOVANCE D-Dimer

Wavelength used: 660nm



7 Day 2 Morning Review

Day 2 Morning Review

Resources

- *Sysmex CS-2500 System Quick Reference Guide*

Objectives

Upon completion of this exercise, you will be able to perform the following tasks:

- Perform Daily Maintenance.
- Process QC material.
- Process Patient samples.
- Process sample in Micro mode.
- Process sample with a longer measurement time.

Day 2 Morning Review

Use the **Sysmex CS-2500 System Quick Reference Guide** for this exercise.

1. Login to the system using your personal login and password.
2. Perform all required Daily Maintenance for the Sysmex CS-2500.

Note: Document your Manual Maintenance.

3. View **Reagent** screen and obtain information for chart below. Replace reagents/QC as required.

Reagent	Tests Available:	Remaining stability time
PT Inn		
APTT FSL		
CaCl ₂		
Ci-Trol 1		
Ci-Trol 3		

4. Process PT and aPTT QC. Check QC points on QC Chart screen before running samples.
5. Process samples for PT and aPTT in normal mode.
 - a. Run an underfilled sample tube.
 - b. Run a hemolyzed or lipemic sample.
 - c. Run an abnormal sample.

Process Sample in Micro mode

Use the *Sysmex CS-2500 System Quick Reference Guide, Sample Processing Tab*.

1. Use the sample in a cup for this exercise.

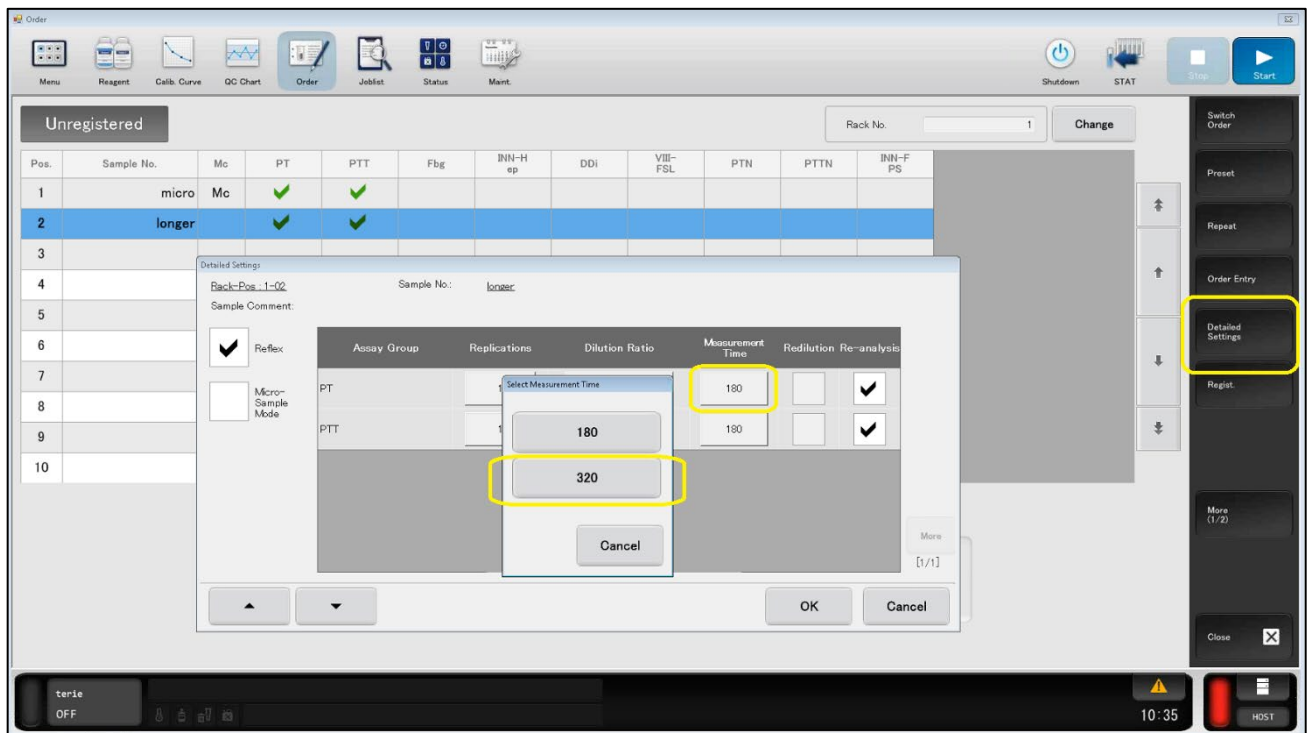
Scenario: The laboratory has just received a CAP proficiency sample that needs to be processed for a PT and PTT. Run in micro mode.

Process Sample with a Longer Measurement time

Use the *Sysmex CS-2500 System Quick Reference Guide, Sample Processing Tab*.

1. Use a sample tube for this exercise.

Scenario: A patient is on an anticoagulant and has a long clotting time. You need to re-run the **PTT** and change the measurement time to the longer time.



8 Calibration

Calibration

Resources

- *Sysmex CS-2500 System Quick Reference Guide*

Objectives

Upon completion of this exercise, you will be able to perform the following tasks:

- Perform a calibration.
- Demonstrate entering reagent information into the Reagent Lot Master.
- Perform a calibration validation.
- Locate the ISI and normal values for the PT assay in the software.

Calibration

Reconstitute Reagents

Siemens Healthineers Job Aid
Sysmex® CS Systems Routine Reagent Preparation Guide

SIEMENS
Healthineers

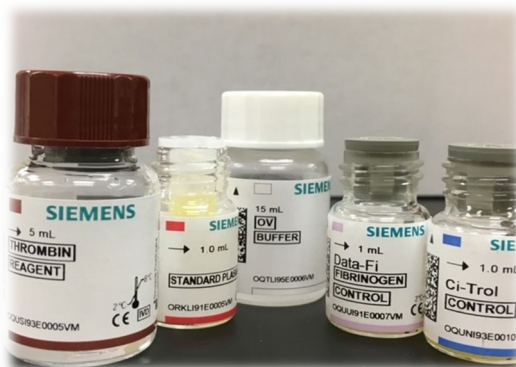
Fibrinogen Dade® Thrombin Reagents

Reagent	Prep	Placement	On-Board Stability (10°C)	Refrigerated Stability (2-8°C)
Dade® Thrombin	Reconstitute with volume of de-ionized water specified on bottle, swirl to mix, allow to clear	Reagent Table	72 hours	5 days
Dade® OVB	Ready to use at room temperature	Buffer Table	24 hours	8 weeks
Dade® Ci-Trol® 1	Reconstitute with 1mL de-ionized water, let stand for 15 mins, swirl to mix	Reagent Table (SLD mini Cup, C rack)	24 hours	16 hours
Data-Fi® Abnormal Fibrinogen Control	Reconstitute with 1mL de-ionized water, let stand for 15 mins, swirl to mix	Reagent Table (SLD mini Cup, C rack)	24 hours	16 hours
CA Clean® I	Ready to Use	Reagent Table	120 hours	1 month
Standard Human Plasma	Reconstitute with 1mL de-ionized water, let stand for 15 mins, swirl to mix	Reagent Table (SLD mini Cup, C rack)	n/a*	n/a*

*Standard Human Plasma is only used for calibration and does not have an on-board stability. Once reconstituted it should stay at room temperature must be used within 4 hours.

1. Reconstitute reagents, QC, calibrator for calibration. Use **Sysmex CS Systems Routine Reagent Preparation** guide for information.

View Application sheet for **Fibrinogen with Dade® Thrombin** or **D-Dimer/INNOVANCE® D-Dimer** for materials needed and for onboard stability.



Enter Reagent Information into Reagent Lot Master

Refer to *Sysmex CS-2500 System Quick Reference Guide*

[Enter Reagent Information Tab](#).

1. **Using Vial barcode/manual entry:** Enter reagent information for your reagents.
2. **Using 2D barcode on Table of Assigned values:** Enter the reagent information for the calibrator.

Perform Calibration

Refer to *Sysmex CS-2500 System Quick Reference Guide*

[Calibration Tab](#)

1. Load Reagents, calibrator, QC.

Note: Calibrator plasma should be transferred into a SLD mini cup and placed in a yellow C-rack

2. Order the calibration.
3. Follow the calibration on the **Joblist** screen.

Perform Calibration Validation

Refer to the *Sysmex CS-2500 System Quick Reference Guide*

[Calibration Tab > Calibration Validation](#)

1. Compare new curve to current curve. Is the new curve similar to the current curve?
2. Validate curve.
3. Print out a copy of the calibration curve.
4. View **Operation Log**. Which username is listed as performing the calibration?
5. Run Quality Control.

Enter the ISI and Normal Values for PT Assay

Refer to the **Sysmex CS-2500 System Quick Reference Guide**

Enter Reagent Information> Using 2D barcode on Table of Assigned values

1. **Scenario:** You have been assigned to lead the lot rollover studies for PT. Your task is to enter the new Dade Innovin reagent lot information into the Reagent Lot Master. This information will be used when you are ready to start using the new lot number on your system.

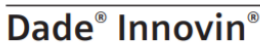
Note: Use the Table of Assigned Values insert included in the box of the PT reagent. Scan the barcode with the 2D barcode reader using the directions in the Quick Reference Guide.

Example of Table of Assigned Values insert.




10873566TU1101 (4554)





CA-600 System¹ CS-2500/CS-5100 System¹




LOT 549779

2023-05-28



ISI Values

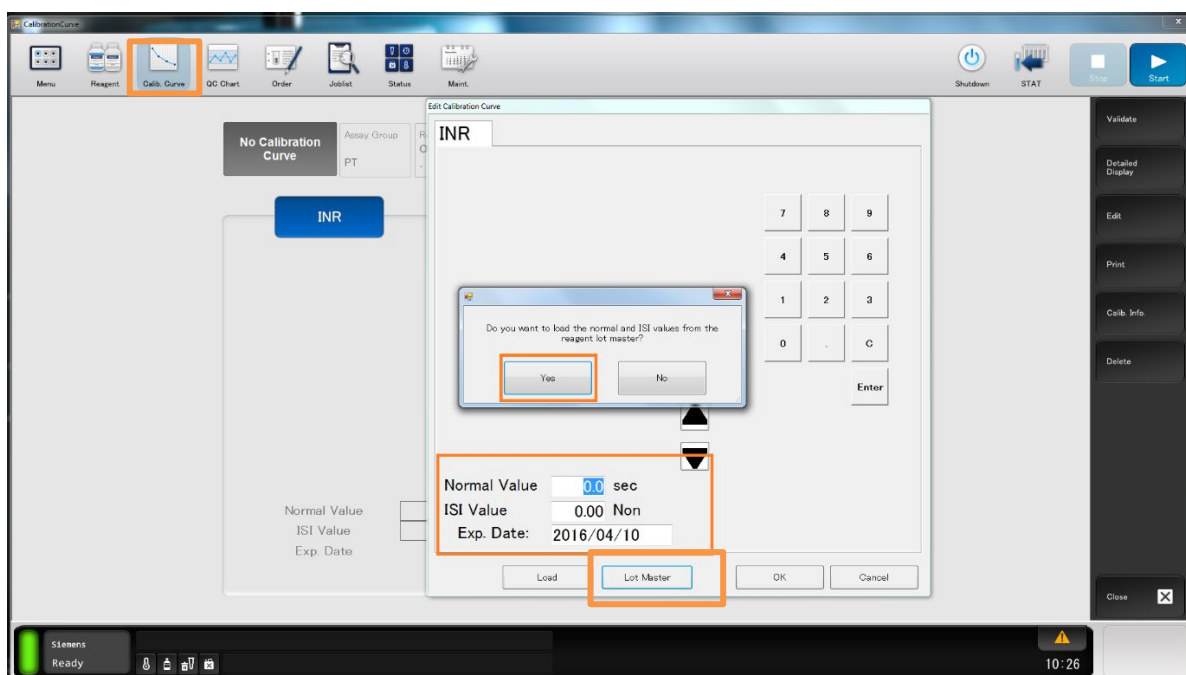
In this table the lot-specific and technique-specific (mechanical and photo-optical) ISI values for the lot of thromboplastin are given.

System	ISI
BFT II ²	0.91
BCS ² / BCS ² XP ²	0.94
CA-500 / CA-600 ²	1.04
CA-1500 ²	1.06
CA-7000 ²	1.10
Sysmex ² CS-2500 ²	1.08
Sysmex ² CS-5100 ²	1.08

¹ Lot data can be read into Sysmex[®] CA-600 System, CS-2500 and CS-5100 System via 2 D barcode.

Master curves for derived fibrinogen

2. Use the Sysmex CS-2500 System Quick Reference Guide > [Enter ISI and Normal Tab](#)
 - a. Navigate to **Calib. Curve** screen to view the ISI and Normal for the current PT reagent.



9 Quality Control

Quality Control

Resources

- *Sysmex CS-2500 System Quick Reference Guide*

Objectives

Upon completion of this exercise, you will be able to perform the following tasks:

- Identify key areas of the QC chart screen.
- Identify QC that is out of range.
- Perform the steps to process D-Dimer QC.

Quality Control

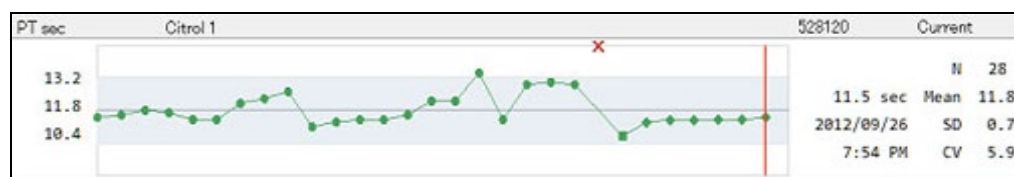
Benefits of Processing Quality Control on the CS-2500 System

1. List the benefits for each feature below.

Feature	Benefit
C-rack with SLD mini cup	Ease of use. Low dead volume.
QC Onboard Stability	Ease of use. No in and out of refrigerator. 24 hours for PT/PTT/Fib/D-Dimer
QC listed with each result	Each result has time of last QC run listed in Measurement Info . Great for troubleshooting results.
Automatic QC with time intervals	Ease of use. QC is performed automatically.
Automatic QC with new reagent vial	Prevents staff from using a vial that is not Quality Controlled.

Identify Key Areas of the QC Chart Screen

1. Answer the following questions based on the QC chart displayed below.



- a. What is the total number of points in this file?
- b. What is the cumulative mean?
- c. What are the upper and lower 2SD limits for this chart?

Identify Out of Control Results

Refer to the *Sysmex CS-2500 System Quick Reference Guide*, Quality Control Tab for assistance.

1. Locate out of range QC results.
2. How are out of range results displayed on the QC chart?
3. Use **Confirm Data** key to comment and exclude unacceptable QC points.
4. How does the QC chart change when a QC point is in range?
5. What does the graph below indicate?



6. What does the below graph indicate?



Enter new D-Dimer QC lots into Reagent Lot Master

Scenario: You have a new lot of INNOVANCE D-Dimer Control 1 and 2 that needs to be entered into the **Reagent Lot Master**.

1. Find the assay value sheet in the box of D-Dimer QC.

SIEMENS

INNOVANCE D-Dimer **CONTROL 1**

INNOVANCE D-Dimer **CONTROL 2**

CS-2500/CS-5100 System¹

CA-600 System¹

CONTROL 1 **CONTROL 2**

2. Press **Menu**.
3. Press **Reagent Lot Master**.
4. Select **Import**.
5. Select **Barcode**.
6. Scan the CS-2500/CS-5100 System barcode with the 2D barcode reader.
7. View **DDiCtl1** information and press **Save**.

Reagent Lot Master Setup

Valid	Reagent ID	Reagent	Reagent Type	Lot No.	Exp. Date	User Definition
☒	5005	SHP	Cal	500275	2021/07/04	☒
☒	5005	SHP	Cal	500275	2022/06/22	☐
☒	5036	AbnFlag	Co	500695	2019/10/20	☐

Barcode Reading Result

Reagent: **DDiCtl1** LotNo: **502252** Exp. Date: **2021/07/07**

Calibrate	Control	Reagent	Management ID	Assay Group	Assay Parameter	Target Value	Unit	Upper Limit	Lower Limit
			2021	INNOVANCE D-Dimer	INN DDI	0.28	mg/L	0.36	0.22

Save **Cancel**

8. View **DDiCtl2** information and press **Save**.
9. Press **Exit**.

10. Press **Close**.**Perform the steps to run D-Dimer Assay QC**

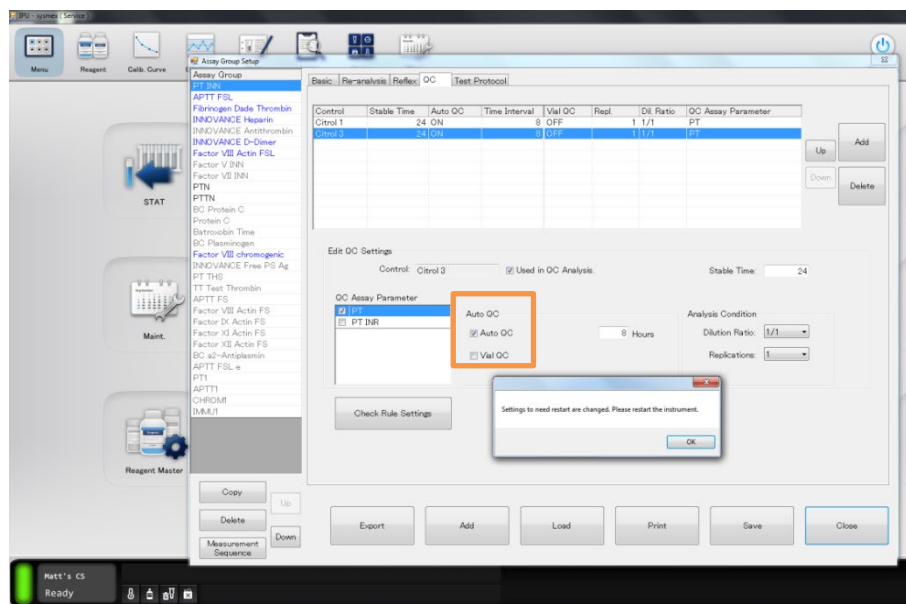
Scenario: There is a Stroke alert in the ED.

1. Load INNOVANCE D-Dimer reagents and order the QC.
2. What is the cutoff value for this assay? **0.5mg/L FEU**

List the Steps to activate Auto QC

Activate Auto QC for PT, PTT, and Fbg.

1. Navigate to **Assay Group Settings**.
2. Select **PT INN** under Assay Group.
3. Select **QC** tab.
4. Highlight Ci-Trol 1.
5. Select **Auto QC** checkbox.
6. Highlight Ci-Trol 3 (AbnFbg for Fibrinogen).
7. Select Auto QC checkbox.
8. Select **Save**.
9. Repeat for PTT and Fbg.
10. **Save and Close**.
11. Restart instrument software.
12. Press **Start**. This will start the first run of QC.



10 Day 3 Morning Review

Day 3 Morning Review

Resources

- *Sysmex CS-2500 System Quick Reference Guide*

Objectives

Upon completion of this exercise you will be able to perform the following tasks:

- Perform Daily Maintenance.
- Process QC Material.
- Process patient samples.
- Perform a calibration.

Day 3 Morning Review

Perform Daily Setup Tasks

Using the *Sysmex CS-2500 System Quick Reference Guide, Sysmex CS-2500* to perform the following tasks.

1. Perform Daily Maintenance.
2. Reconstitute QC and Reagents as needed.
3. Process the following QC.

NOTE: If Auto QC is turned on, press **Start** after the Shutdown.

	PT	aPTT	Fbg
Ci-Trol 1			
Ci-Trol 3			
Data-Fi Abnormal Fibrinogen			

4. Add a comment to a QC point using **Confirm Data** key on **QC Chart** screen.
5. Process samples for PT, aPTT and Fbg in normal mode.
6. Perform a calibration. Validate the calibration. Run QC for the calibration.

11 Analysis Result Errors

Analysis Result Errors

Resources

- *Sysmex CS-2500 System Quick Reference Guide*
- *Sysmex CS-2500 System Evaluation and Check Algorithm*

Objectives

Upon completion of this exercise, you will be able to perform the following tasks:

- Distinguish between a normal and abnormal result on the Joblist.
- Identify corrective action for Analysis Result errors.

Analysis Result Errors

Normal Result

Joblist screen

Status	Rack No. -Pos.	Sample No	End Time	Sample Info.	R	F	Mo de	PT sec	INR -	APTT sec	F se
	000004-03	10025	17.53			F	N	20.4	2.04	39.0	
	000004-04	10026	17.53			F	N	19.7	1.97	38.6	

Browser screen

Final
Remeasure

Hem
Ict
Lip
Vol

HOST

10025 M
2015/03/06 17:45:35
000004-03

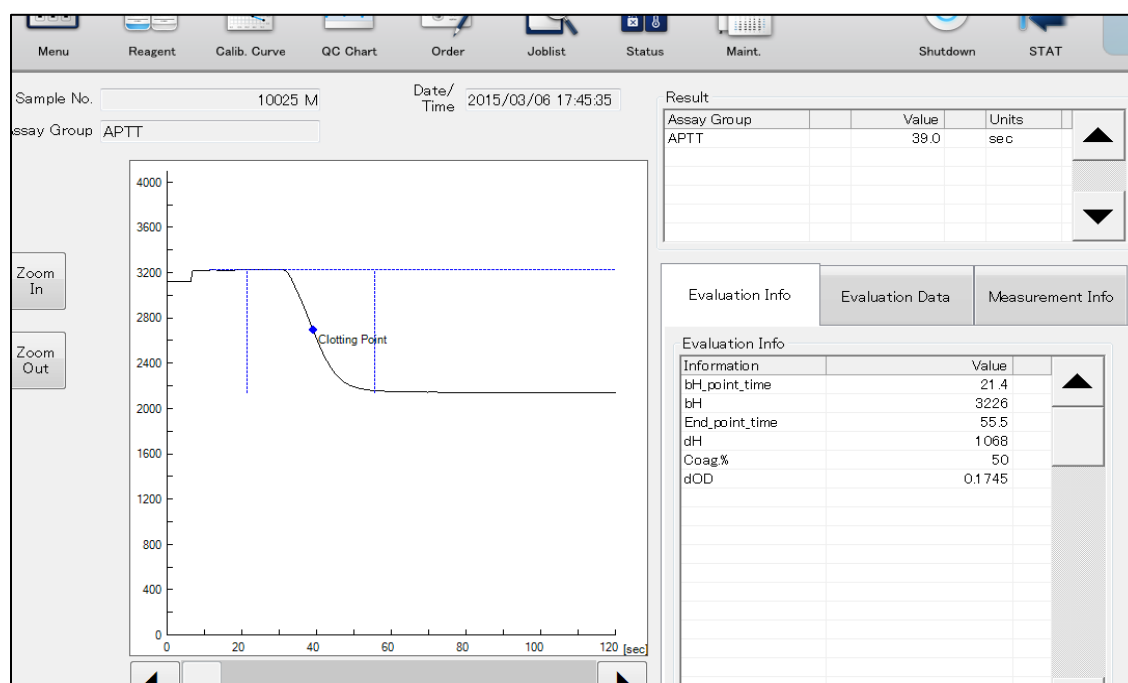
Validated

Clotting Method
Chromogenic Method
Immunoassay Method
Aggregation Method
More

APTT
APTT
39.0
sec
Dilution Ratio
1 / 1

PT
PT
20.4
sec
INR
2.04
-
Dilution Ratio
1 / 1

Reaction Curve



Abnormal Result - Review

Joblist screen: Status is **Review**. Results are displayed as asterisks or flagged with an asterisk. The sample result is abnormal.

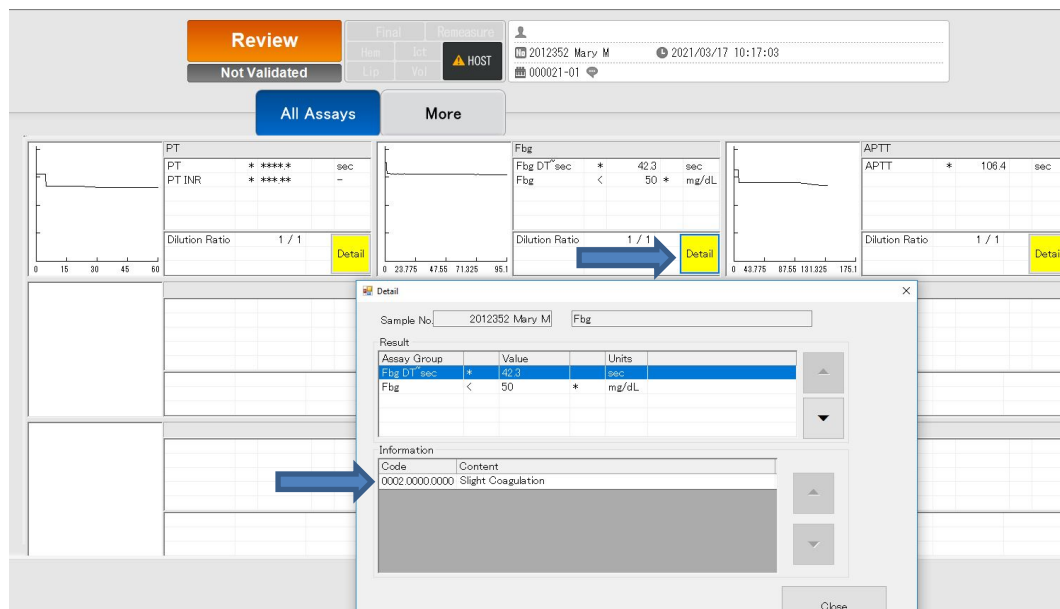


Review	000021-01	2012352 Mary		N	2021/03/17	10:39	*	*****	*	106.4	<	50	*
Review	000021-01	2012352 Mary	R	N	2021/03/17	10:39	*	*****	*	106.6	<	50	
Review	000021-01	2012352 Mary		F	N	2021	*	*****	*	106.6	<	50	



Browser screen: Flagged results have a yellow **Detail** key. Select the **Detail** key for information. Review results are due to sample abnormality.

Detail key: Displays the Analysis Result Error



Review
Not Validated

Final: Pass, Fail, L.Q., No
Temperature:

2012352 Mary M 2021/03/17 10:17:03
000021-01

All Assays More

PT: PT * *****, PT INR * *****, Dilution Ratio 1 / 1, **Detail**

Fbg: Fbg DT * 42.3 sec, Fbg < 50 mg/dL, Dilution Ratio 1 / 1, **Detail**

APTT: APTT * 106.4 sec, Dilution Ratio 1 / 1, **Detail**

Detail

Sample No. 2012352 Mary M Fbg

Result

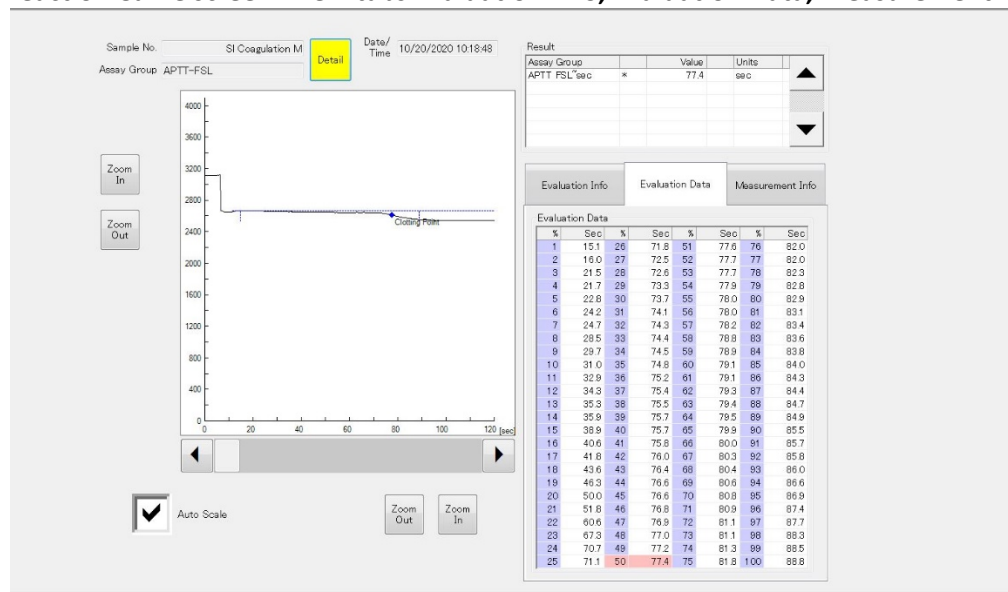
Assay Group	Value	Units
Fbg DT sec	42.3	sec
Fbg	< 50	mg/dL

Information

Code	Content
0002.0000.0000	Slight Coagulation

Close

Reaction Curve screen: View tabs Evaluation Info, Evaluation Data, Measurement Info.



Sample No. SI Coagulation M Date/Time 10/20/2020 10:18:48

Assay Group APTT-FSL **Detail**

Zoom In Zoom Out

Clotting Point

Auto Scale

Zoom Out Zoom In

Result

Assay Group	Value	Units
APTT FSL sec	77.4	sec

Evaluation Info Evaluation Data Measurement Info

Evaluation Data

%	Sec	%	Sec	%	Sec	%	Sec
1	15.1	26	71.8	51	77.6	76	82.0
2	16.0	27	72.5	52	77.7	77	82.0
3	21.5	28	72.6	53	77.7	78	82.3
4	21.7	29	73.3	54	77.9	79	82.8
5	22.8	30	73.7	55	78.0	80	82.9
6	24.2	31	74.1	56	78.0	81	83.1
7	24.7	32	74.3	57	78.2	82	83.4
8	28.5	33	74.4	58	78.8	83	83.6
9	29.7	34	74.5	59	78.9	84	83.8
10	31.0	35	74.8	60	79.1	85	84.0
11	32.9	36	75.2	61	79.1	86	84.3
12	34.3	37	75.4	62	79.3	87	84.4
13	35.3	38	75.5	63	79.4	88	84.7
14	35.9	39	75.7	64	79.5	89	84.9
15	38.9	40	75.7	65	79.9	90	85.5
16	40.6	41	75.8	66	80.0	91	85.7
17	41.8	42	76.0	67	80.3	92	85.8
18	43.6	43	76.4	68	80.4	93	86.0
19	46.3	44	76.6	69	80.6	94	86.6
20	50.0	45	76.6	70	80.8	95	86.9
21	51.8	46	76.8	71	80.9	96	87.4
22	60.6	47	76.9	72	81.1	97	87.7
23	67.3	48	77.0	73	81.1	98	88.3
24	70.7	49	77.2	74	81.3	99	88.5
25	71.1	50	77.4	75	81.8	100	88.8

Abnormal Result - Error

Joblist screen: Status is **Error**. Results are displayed as asterisks only.



	000004-01	MDA sample	16.44		F	N				
Error	000004-01	10023	17.29	-	F	N	*	*****	* *****	* *****

Browser screen: Error results have a red Detail key. Select the Detail key for information. Errors are due to a system error. These are not due to sample abnormalities.



Error

Validated

Final

Remeasure

Hem

Lot

Lip

10023 M

2015/03/06 17:29:58

000004-01

HOST

Clotting Method

Chromogenic Method

Immunoassay Method

Aggregation Method

More

APTT

APTT

Dilution Ratio

* *****

sec

1 / 1

Detail

PT

PT

INR

Dilution Ratio

1 / 1

Detail

Detail

Sample No.

10023 M

APTT

Result

Assay Group	Value	Units
APTT	*	*****

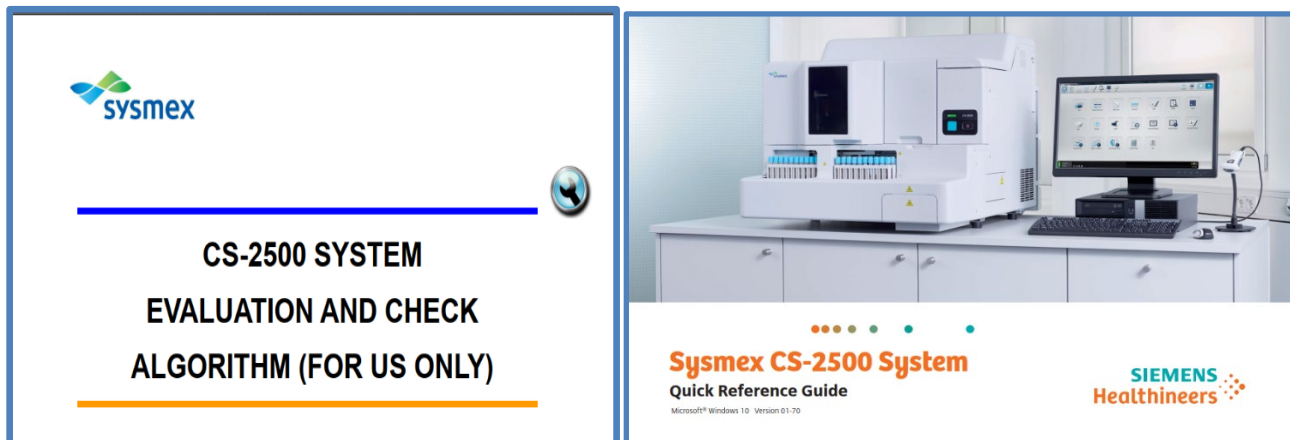
Information

Code	Content
37742	Failure in CA Clean II priming (During analysis)

Exercise

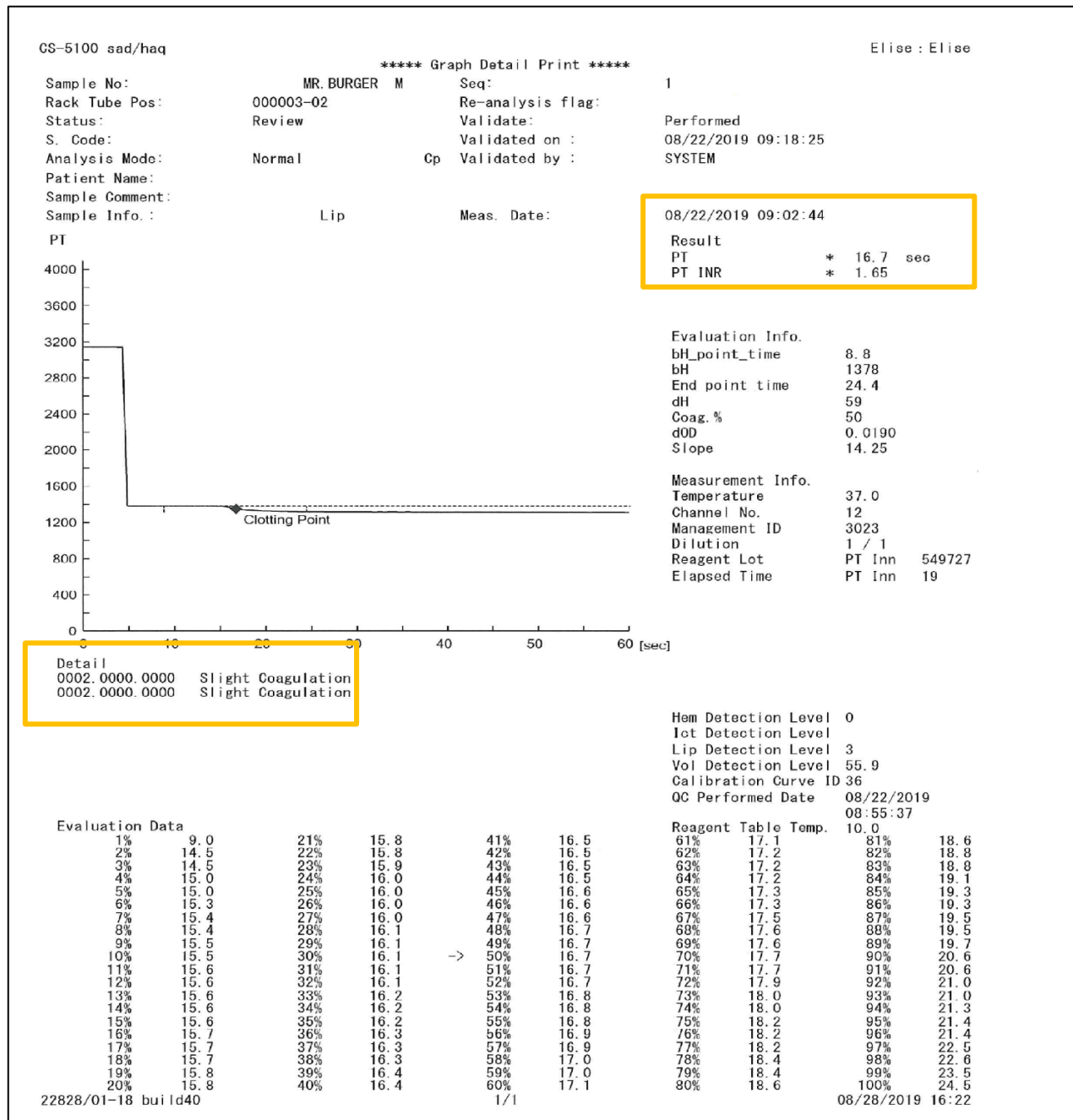
1. Draw and label all the parts of a Normal reaction curve.
2. Using the *Sysmex CS-2500 System Quick Reference Guide*, complete the following with a partner.
 - a. Draw the reaction curve of the assigned error.
 - b. Describe how the result is displayed on the Joblist.
 - c. List possible causes of the error.
 - d. List corrective action for the error.
3. Circle your assigned error
 - Slight Coagulation
 - No Coagulation
 - Analysis Time Over
 - Noise Error
 - Coagulation Curve Error
 - Early Reaction Error
 - Flat Curve
 - Turbidity Level Over

Resources to use for Troubleshooting Analysis Errors:



Coagulation Curve Scenario 1

1. What test? Which error? Will it be automatically reanalyzed?

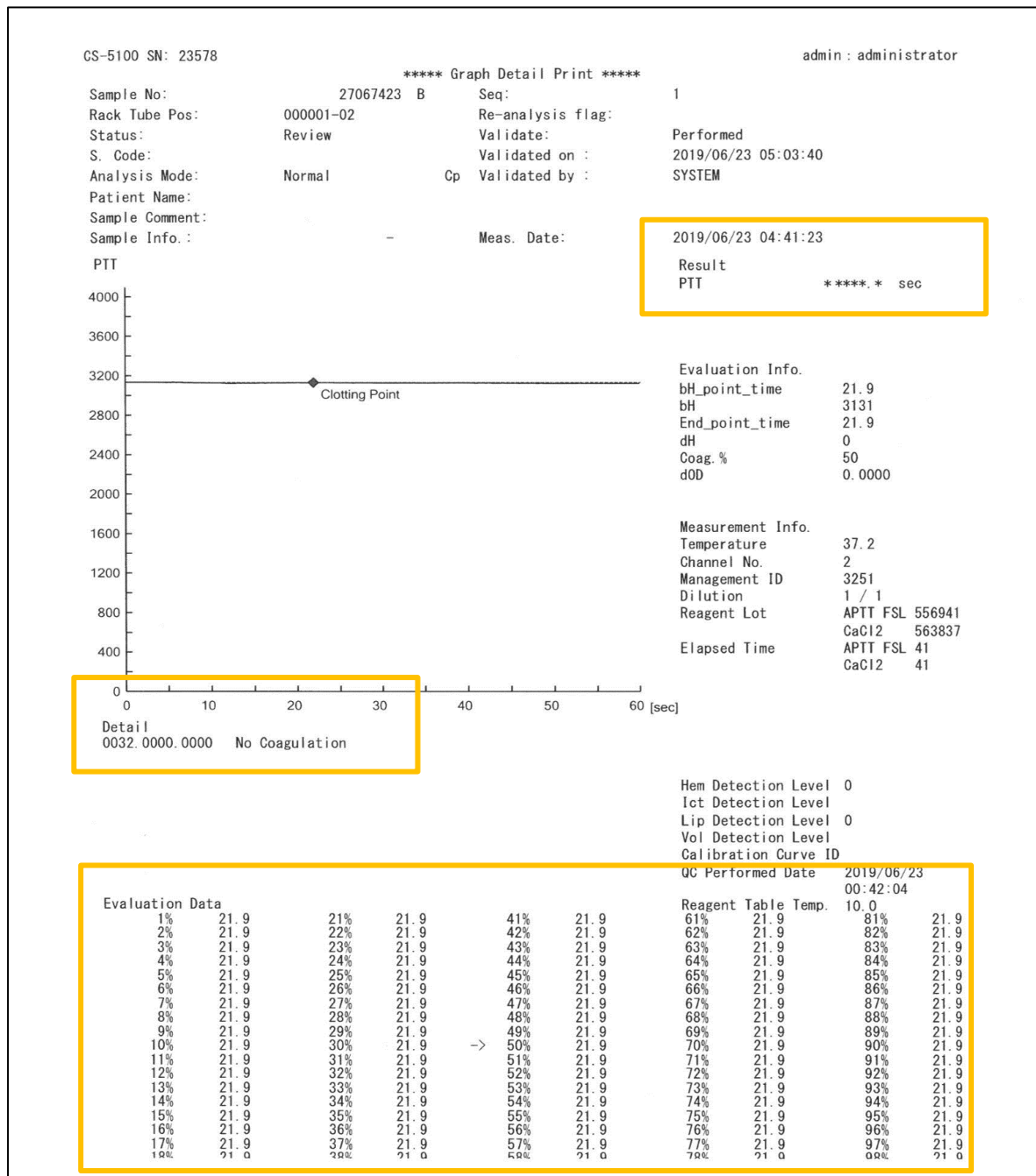


2. List Action steps

3. Is this reportable?

Coagulation Curve Scenario 2

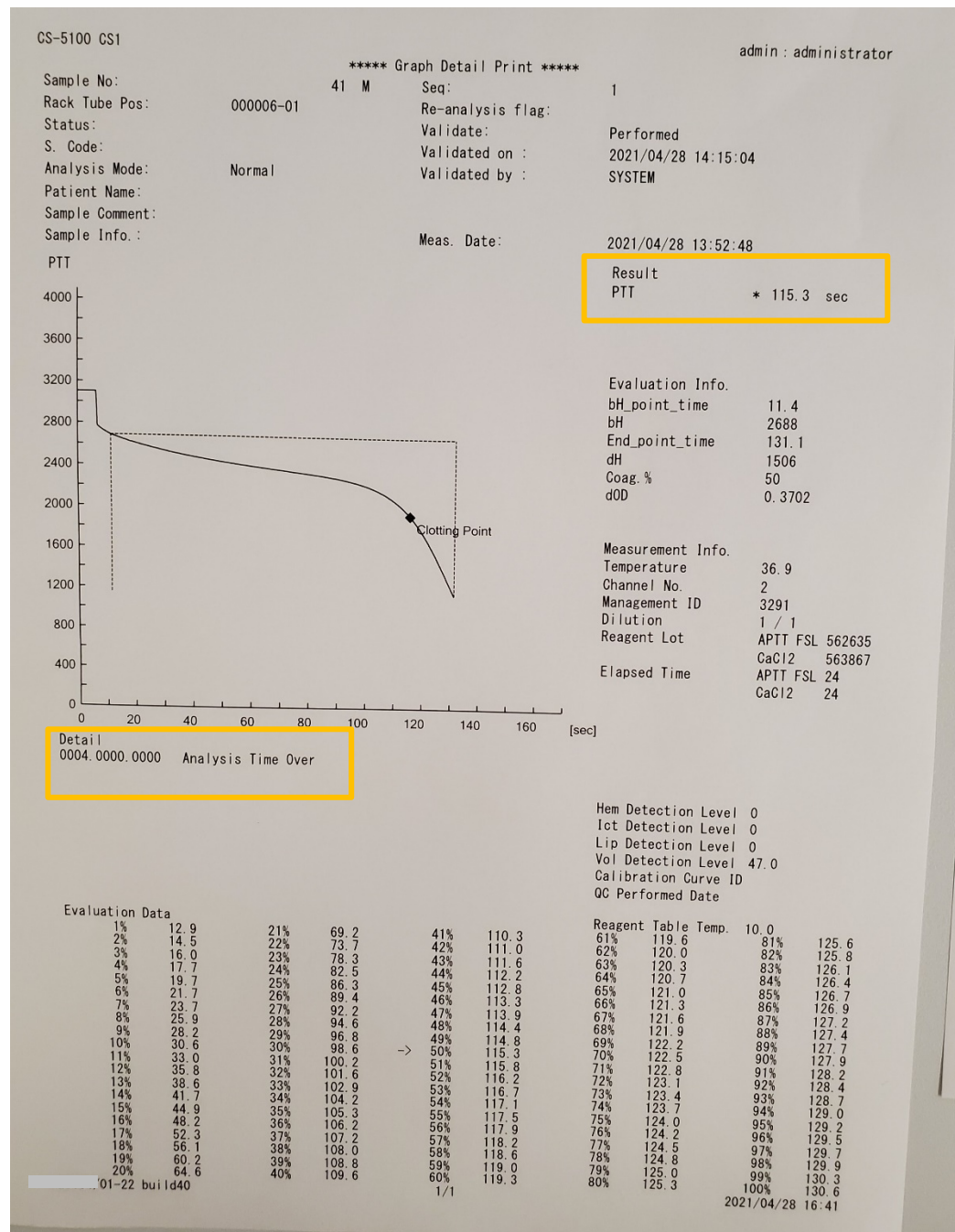
1. What test? Which error? Will it be automatically reanalyzed?



2. List Action steps.
3. Can the **Evaluation data** be used?
4. Is this reportable?

Coagulation Curve Scenario 3 – Initial Run

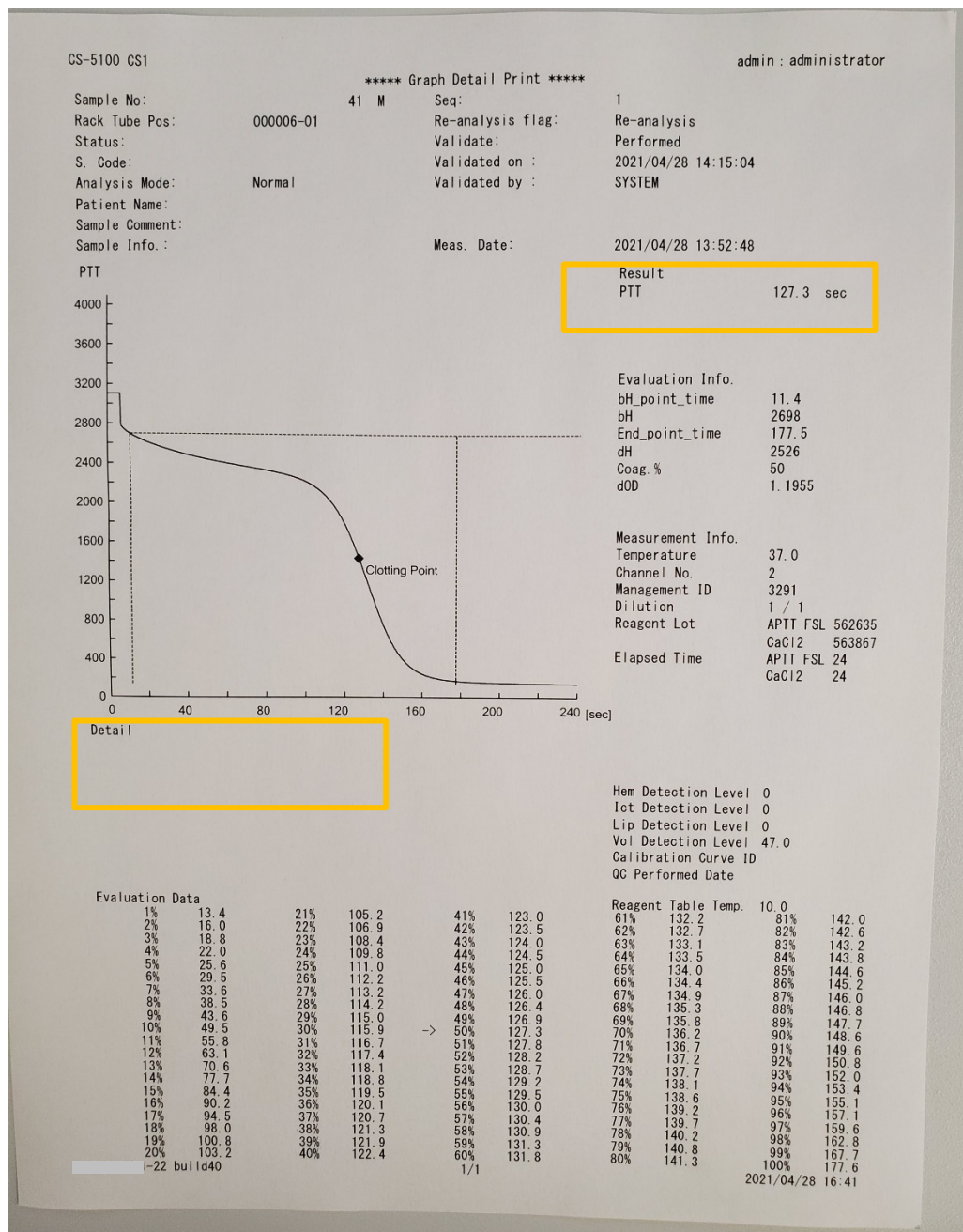
1. What test? Which error? Will it be automatically reanalyzed?



2. List the action steps:

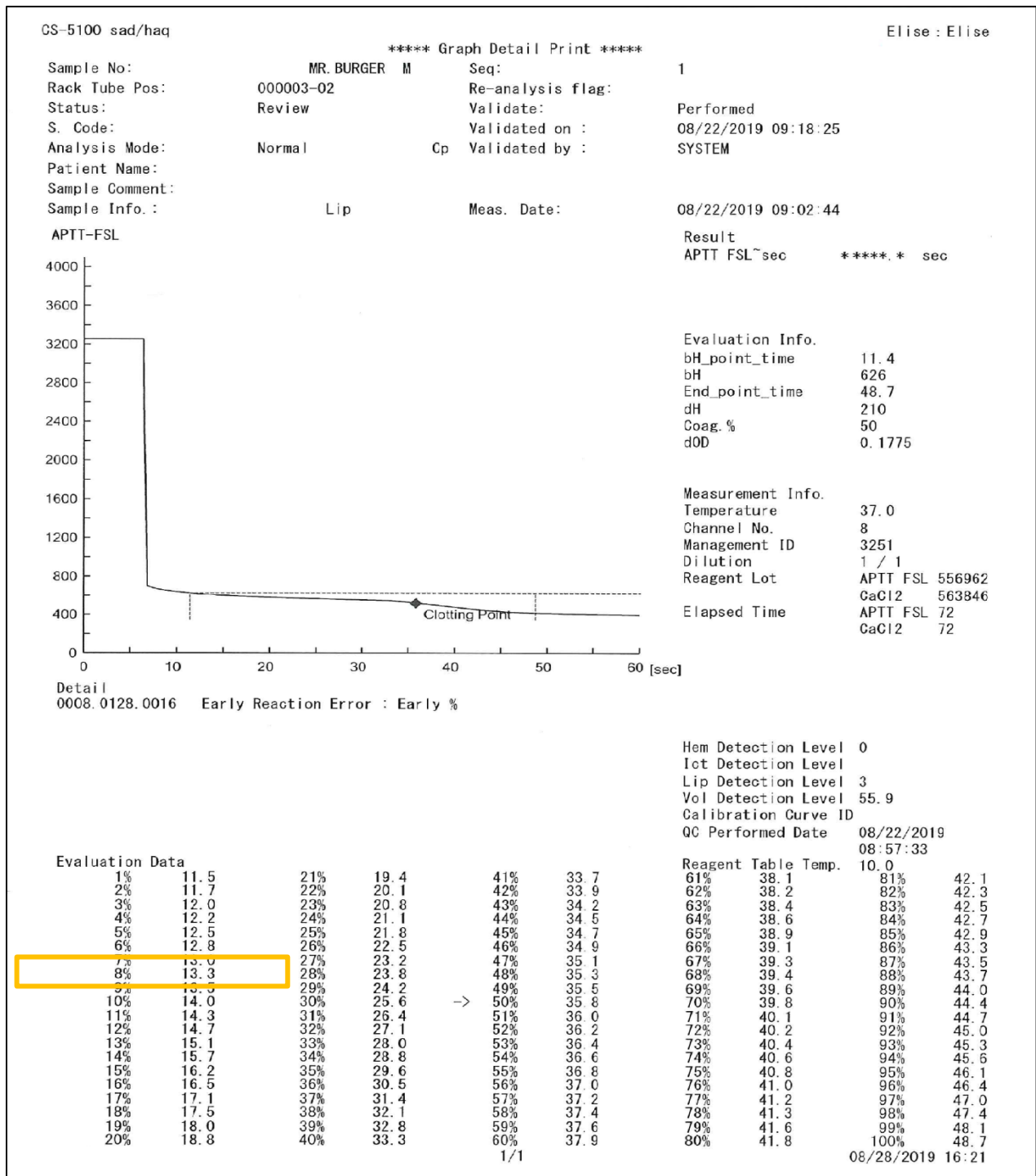
Coagulation Curve Scenario 3 – Reanalysis at longer measurement time.

1. Result? Is there an error? Can this be reported?



Coagulation Curve Scenario 4

1. What test? Which error? Will it be automatically reanalyzed?

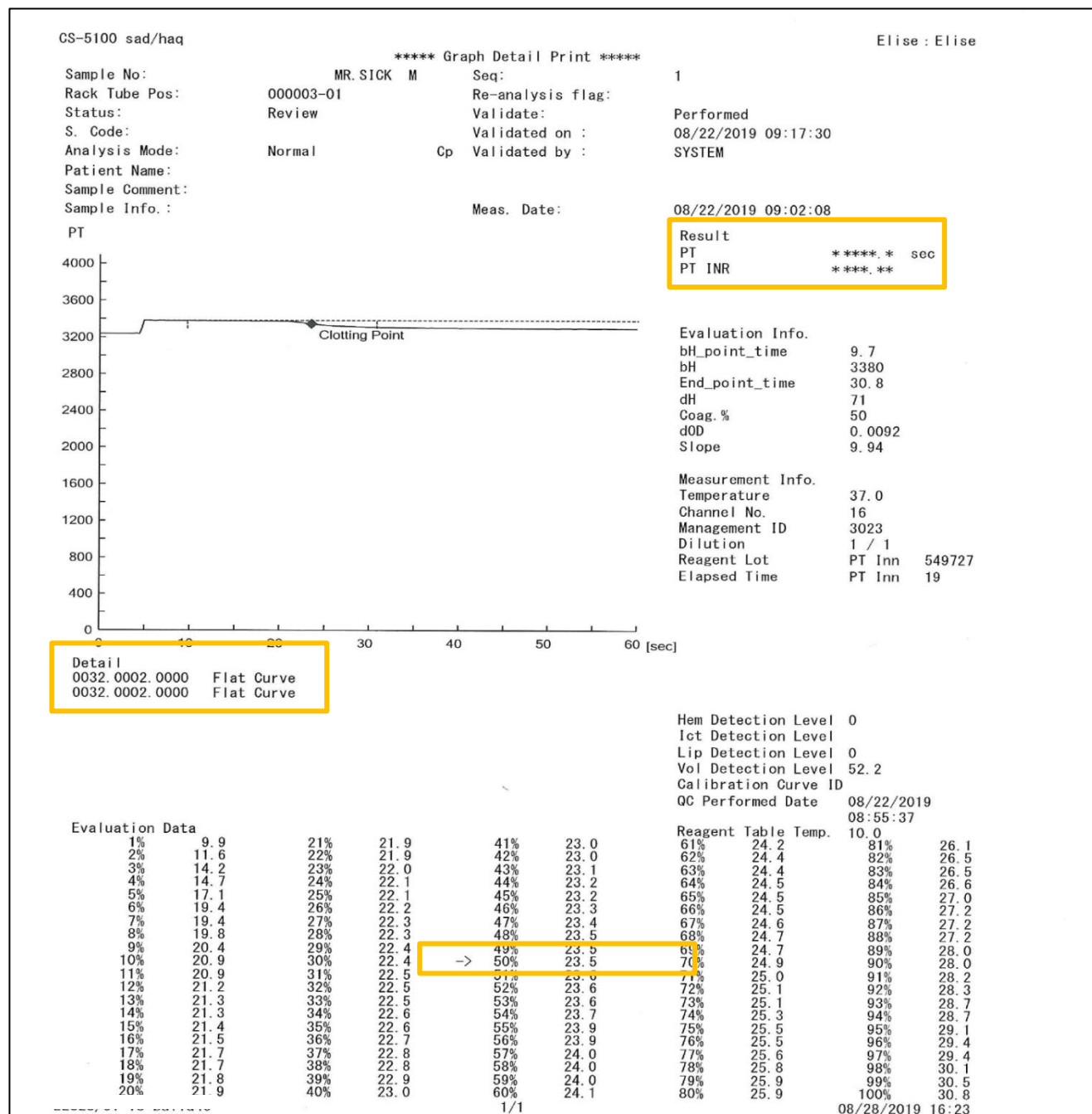


2. List Action steps.

3. Is this reportable?

Coagulation Curve Scenario 5

1. What test? Which error? Will it be automatically reanalyzed?

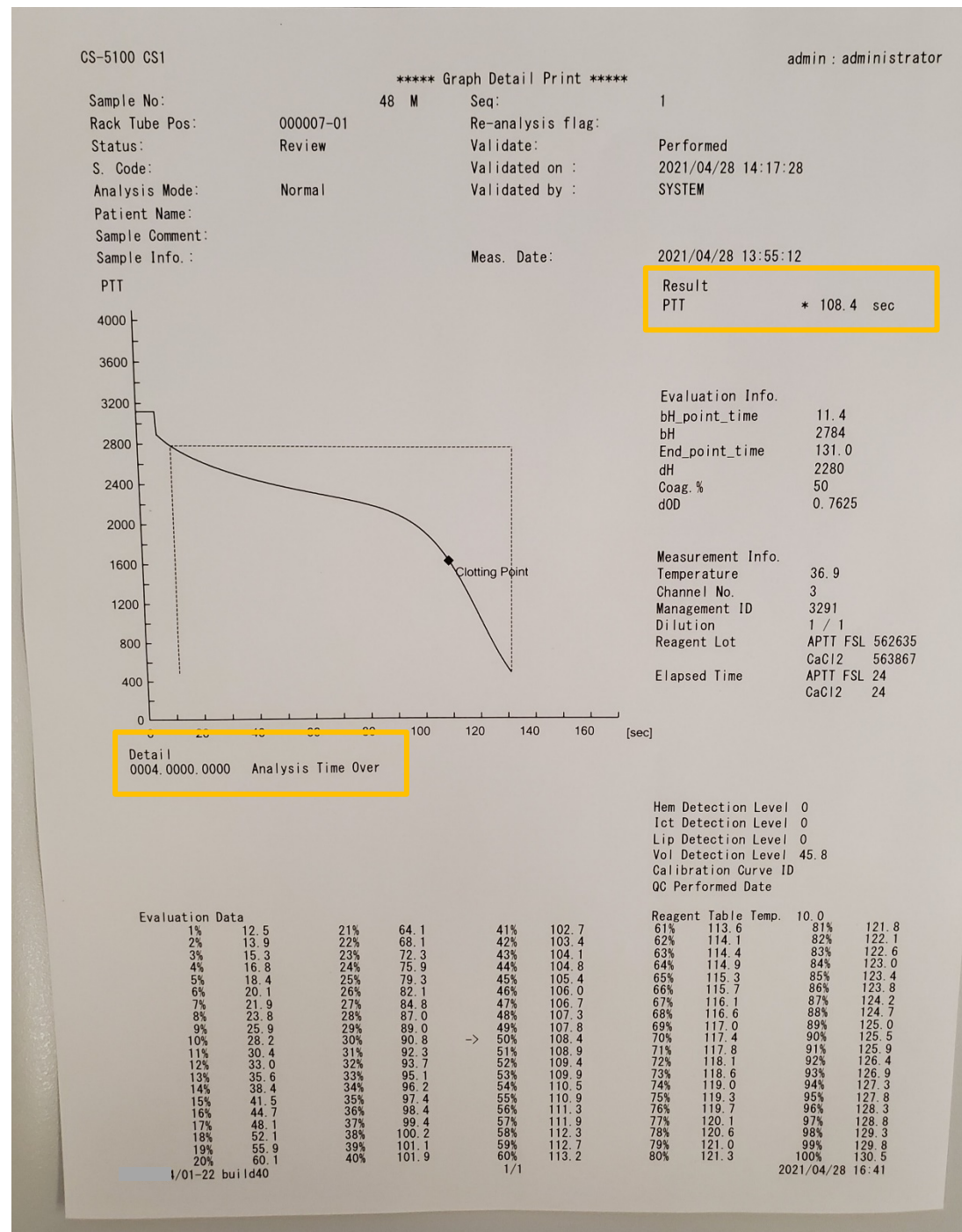


2. List Action steps.

3. Is this reportable?

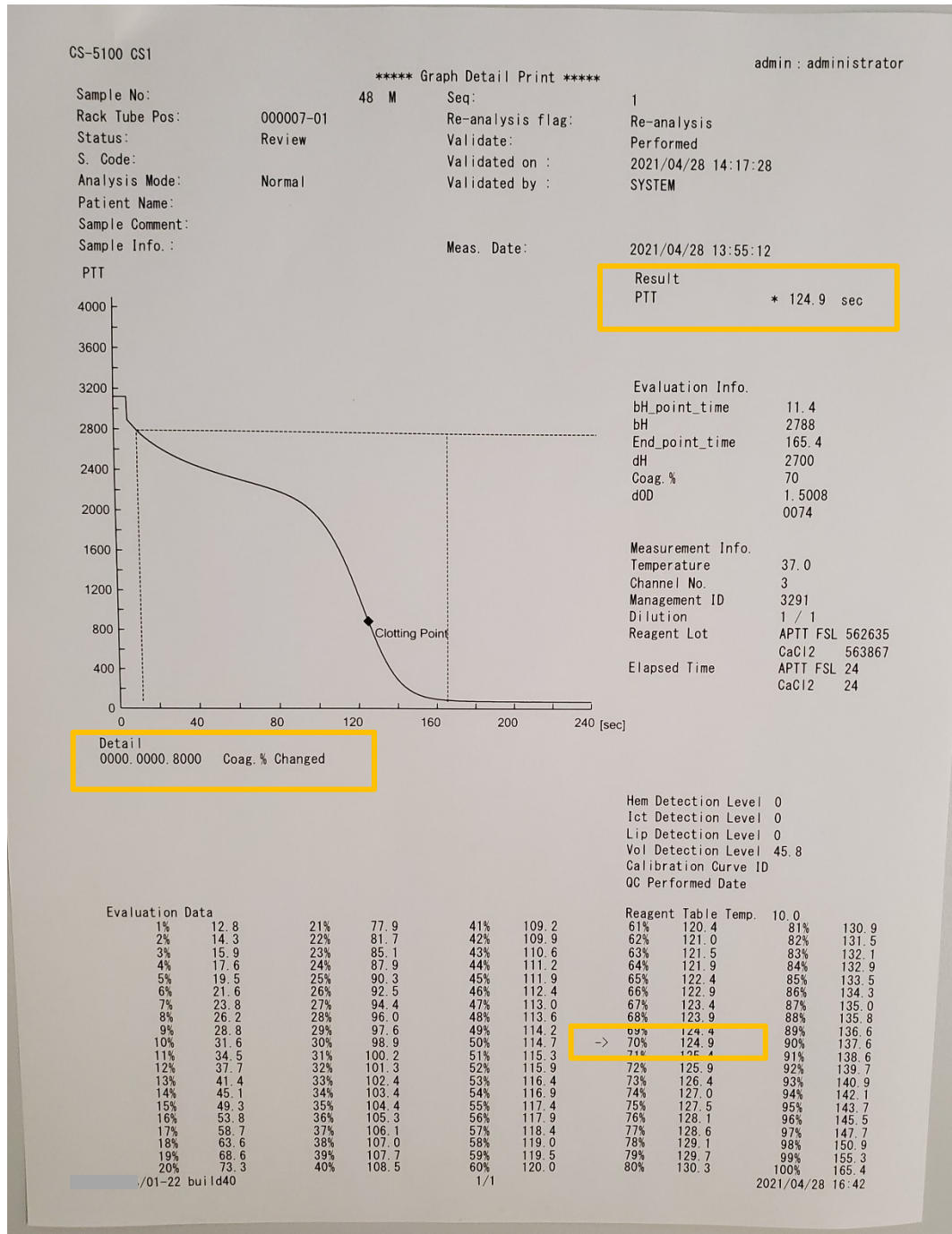
Coagulation Curve Scenario 6- Initial Run

1. What test? What error? Will it be automatically reanalyzed?



Coagulation Curve Scenario 6-Reanalysis at longer measurement time

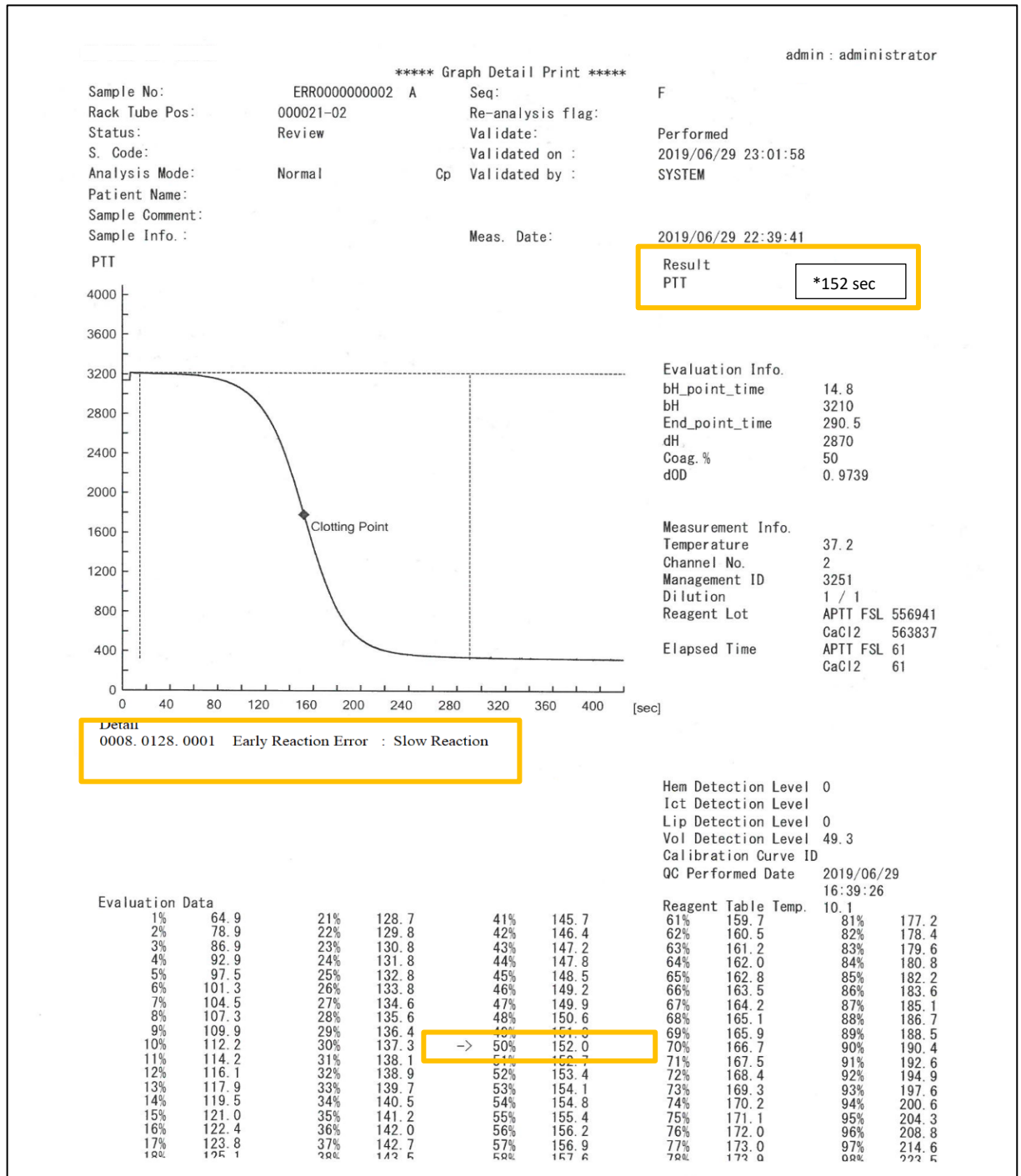
Coag % Changed: This error occurs on samples that have a biphasic reaction curve. The coagulation time is corrected and the Coagulation detection % is changed.



1. What is the error message?
2. What % is being used for the clot time?
3. Can this be reported?

Coagulation Curve Scenario 7

1. What test? Which error? Will it be automatically reanalyzed?



2. List the Action steps.

3. Is this reportable?

Answer Key for Scenarios

Coagulation Curve Scenario 1

Test- PT

Result- *16.7 sec, 1.68 INR

Error- Slight coagulation

Automatic reanalysis- Yes

Action steps- Verify reagent and sample integrity. Verify QC. An automatic reanalysis will be performed.

Reportable result- If reanalysis produces a result without an error, it may be reported. If reanalysis produces a Slight Coagulation error again with comparable results, it may be reported.

Coagulation Curve Scenario 2

Test-PTT

Result-***.* No numerical result

Curve- no baseline, no clotting phase, no endpoint. A straight line.

Error-No Coagulation

Automatic reanalysis- Yes

Action steps- Verify reagent and sample integrity. Verify QC. An automatic reanalysis at a longer measurement time will be performed.

Reportable result-If reanalysis produces result without error, it may be reported. If reanalysis produces No Coagulation again, determine if result is plausible. Check sample integrity. It may be reported as greater than your Reportable limit.

Coagulation Curve Scenario 3

Test-PTT

Result-*115.3 sec

Error-Analysis Time Over

Automatic reanalysis-Yes

Action steps-Check sample for possible anticoagulant contamination. Verify reagent and sample integrity. Check patient history-are they on heparin. Verify QC. An automatic reanalysis at a longer measurement time will be performed.

Coagulation Curve Scenario 3-Reanalysis at longer measurement time

Test-PTT

Result-127.3 sec

Error- no error

Reportable result-The Reanalysis result does not have an error. Report the result.

Coagulation Curve Scenario 4

Test-PTT

Result-***.* No numerical result

Error-Early Reaction Error-Early %

Automatic reanalysis- Yes

Action steps- Verify reagent and sample integrity. Verify error code. (Early %) An automatic reanalysis will be performed. Check the Evaluation data- the 8% value is less than 16.8 sec- Do not report.

Reportable result- Do not report. Recollect specimen.

Coagulation Curve Scenario 5

Test-PT

Result-***.* No numerical result

Error- Flat Curve

Automatic reanalysis- Yes

Action steps- Verify reagent and sample integrity. Verify QC. An automatic reanalysis at a longer measurement time will be performed. Check the reaction curve for a normal baseline, clot phase, and endpoint. Compare the Evaluation data results at the 50% for both the first run and the reanalysis.

Reportable result-If reanalysis result is without an error, it may be reported. If the reanalysis at the longer measurement time produces Flat Curve again, and the results are comparable, it may be reported as per your laboratory policy. Use the PT Calib. Curve for the current lot to calculate the INR for the result.

Coagulation Curve Scenario 6

Test-PTT

Result- *108.4 sec

Error- Analysis Time Over

Automatic reanalysis- Yes

Action steps- Check sample for possible anticoagulant contamination. Verify reagent and sample integrity. Check patient history. Verify QC. An automatic reanalysis at a longer measurement time will be performed.

Coagulation Curve Scenario 6-Reanalysis at a longer measurement time

Test- PTT

Result- *124.9 sec

Error- Coag % Changed: This error occurs on samples that have a biphasic reaction curve. The coagulation time is corrected and the Coagulation detection % is changed.

Action steps- Verify reagent and sample integrity. View the reaction curve. View the Evaluation data to view the detection % used.

What % is being used- 70%

Can this be reported? Yes, this may be reported.

Coagulation Curve Scenario 7

Test-PTT

Result-*152 sec

Error- Early Reaction Error- Slow Reaction

Automatic reanalysis- Yes

Action steps- Result is >100 sec. An automatic reanalysis at a longer measurement time will be performed. Check the reaction curve. Reaction curve has a normal baseline, clot phase, and endpoint.

Reportable result- Yes, this may be reported.

12 Maintenance and Troubleshooting

Maintenance and Troubleshooting

Resources

- *Sysmex CS-2500 System Quick Reference Guide*
- *Sysmex CS-2500 Instructions for Use*

Objectives

Upon completion of this exercise, you will be able to perform the following tasks:

- Locate the chapters of the ***Sysmex CS-2500 Instruction for Use***.
- Review Weekly Maintenance tasks.
- Perform a data backup of the system.
- Review Monthly Maintenance tasks.
- Review As Needed Maintenance tasks.

Maintenance and Troubleshooting

Weekly Maintenance

Using the *Sysmex CS-2500 System Quick Reference Guide*, perform the following tasks.

1. What should I use to clean the exterior/interior of my instrument?
2. Document manual maintenance in the **Maint.** Screen under **Manual Maintenance** in the operation panel.

Perform a data backup of the system

1. Save a backup using the **Backup** icon on the desktop.
2. Locate the saved backup in the **IPU_Backup** folder on the desktop.
3. Save the backup file to a flash drive.

Note: Backup should be performed weekly or monthly.

Monthly Maintenance

Using the *Sysmex CS-2500 System Quick Reference Guide*, perform the following tasks.

1. Locate the 4 filters on the analyzer. Clean the filters and document the maintenance with **Manual Maintenance** key.

As Needed Maintenance

Pressure and Vacuum Adjustment

Using the *Sysmex CS-2500 System Quick Reference Guide, As Needed Maintenance* tab to perform the following tasks.

1. Scenario: You received the following error messages on your instrument.
2. Troubleshoot the problem. Adjust the pressures on the instrument.
3. It will be documented on the Maintenance screen with the date.

18001	Pressure Error (0.22MPa) (Start)
Probable Cause	• The pressure adjustment is incorrect. • The pneumatic or hydraulic system has failed • The pneumatic unit power supply is suspended. • The tube is kinked or blocked.

18003	Pressure Error (0.1MPa) (Start)
Probable Cause	• The pressure adjustment is incorrect. • The pneumatic or hydraulic system has failed • The pneumatic unit power supply is suspended. • The tube is kinked or blocked.

Lamp Replacement

Lamp should be replaced when:

- a. **Lamp has been illuminated for 1000 hours.** The lamp usage time is listed on the Maintenance screen.
- b. Receive error message “Replace the Lamp”

Note: “Replace the Lamp” message will appear when instrument has sensed that the lamp has decreased in intensity.

13702	Replace the Lamp
Probable Cause	• The lamp intensity declines. • The lamp intensity exceeds the adjustment range. • The detective unit has failed.
Corrective Action	Replace the lamp. Select the “Lamp Calibration” button in the “Maintenance” screen.

1. Watch the video for Lamp Replacement.

Use the **Sysmex CS-2500 System Quick Reference Guide, As Needed Maintenance** tab to perform the following tasks.

2. **Scenario:** You received an error message stating **Replace the Lamp**. You look in the Maintenance screen and find that your lamp has been burning for 1,300 hours.

- a. Practice removing and replacing the lamp.

Note: A new halogen lamp must **burn in for 30 minutes** before performing a lamp calibration

- b. Perform a lamp calibration. Update the setting.
- c. **Quality control must be performed** before processing patient samples.

3. Listed below are additional error messages for the halogen lamp.

13704	Calibrate the lamp
Probable Cause	The lamp intensity exceeds the upper or lower limit of the set range.
Corrective Action	Calibrate the lamp.

0008.0256.0000	[Noise]
Probable Cause	The coagulation reaction may have been contaminated with noise.
Corrective Action	Calibrate the lamp. If this does not resolve issue, replace the lamp and calibrate the lamp.

Clean the Sysmex racks

Refer to *Sysmex CS-2500 System Quick Reference Guide, As Needed Maintenance Tab, Clean the Sysmex racks* for instructions.

1. Wipe racks with a soft cloth.
2. Document this task using the **Manual Maintenance** key.

Wiping the Piercer Clean

Refer to *Sysmex CS-2500 System Quick Reference Guide, As Needed Maintenance Tab, Wipe the piercer clean* for instructions.

1. Wipe piercer clean. It will be documented automatically.

Note: Never touch the piercer tip. Handle it with care and make sure to use the jig when cleaning the piercer. Wear proper PPE.

Removing Jammed Cuvettes

1. Refer to **Maintenance Chapter, As-needed maintenance**, in the *Sysmex CS-2500 System Instruction for Use*, to remove jammed cuvettes.
2. Open Hopper lid and loosen the screw. Pull hopper cover open. Look into the small hopper for cuvettes. Remove cuvettes. Close the hopper cover before resuming processing.
3. Document this task using **Manual Maintenance** key.

13202	Cuvette Jammed (Small Hopper)
Probable Cause	• The cuvette is jammed in the small hopper. • The operation of the guide is defective. • The small hopper sensor has failed. • The rail sensor has failed.
13203	Cuvette Jammed (Rail Rotor)
Probable Cause	• The cuvette is jammed on the rail. • The cuvette is jammed in the rotary feeder. • The motor for the rotary feeder is defective. • The rotary feed sensor failed.

4. Other possible messages for jammed cuvettes are listed below. Perform the necessary steps to remove obstruction.

13201	Cuvette Jammed (Conveyor)
Probable Cause	The cuvette is jammed in the conveyor. The conveyor sensor has failed. The conveyor mechanism has failed.

13 Preanalytical Sample Integrity

Preanalytical Sample Integrity

Resources

- *Sysmex CS-2500 System Quick Reference Guide*

Objectives

Upon completion of this exercise, you will be able to perform the following tasks:

- Identify hemolysis and lipemia checks on the Joblist.
- Identify volume errors on the Joblist.

Preanalytical Sample Integrity

Effects of Hemolysis and Lipemia

Hemoglobin, bilirubin, and lipids have photometric, turbidimetric, and biochemical properties that can cause interferences in assays measured. The hemolytic sample, with breakdown products of red cells and platelets, can alter or compromise the coagulation proteins that may lead to erroneous test results (biochemical interference). Hemolytic specimens have always been a major concern for clinical laboratories world-wide in that they are the leading cause of pre-analytical variability, multiple testing, and can also have a negative impact on medical care. In the case of hemolysis, the absence of red color does not exclude its presence, because it is not seen by the naked eye until it reaches approximately 300 mg/L.

The Effect of Hemolysis on Most Commonly Used Routine Tests

Test	Result	Effect
APTT	Decreased	Release of thromboplastic substances
Antithrombin	Decreased	Analytical interference
D-Dimer	Increased	Release of thromboplastic substances
Fibrinogen	Decreased	Release of thromboplastic substances
PT	Increased	Release of thromboplastic substances

Seventy percent (70%) of errors in testing are from pre-analytical variables.

References

1. G. Lippi et al., Haemolysis: An overview of the leading cause of unsuitable specimens in clinical laboratories, *Clinical Chemistry Lab Med* 2008; 46 (6) 764-772
2. Clinical Laboratory Standards Institute. Collection, Transport and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays: Approved Guideline-Fifth Edition. CLSI Publication H21-A5. Wayne, PA, January 2008.
3. G. Lippi et al., Interference of Blood Cell Lysis on Routine Coagulation Testing *Arch Pathol Lab Med*. 2006; 1 30:181-1842.

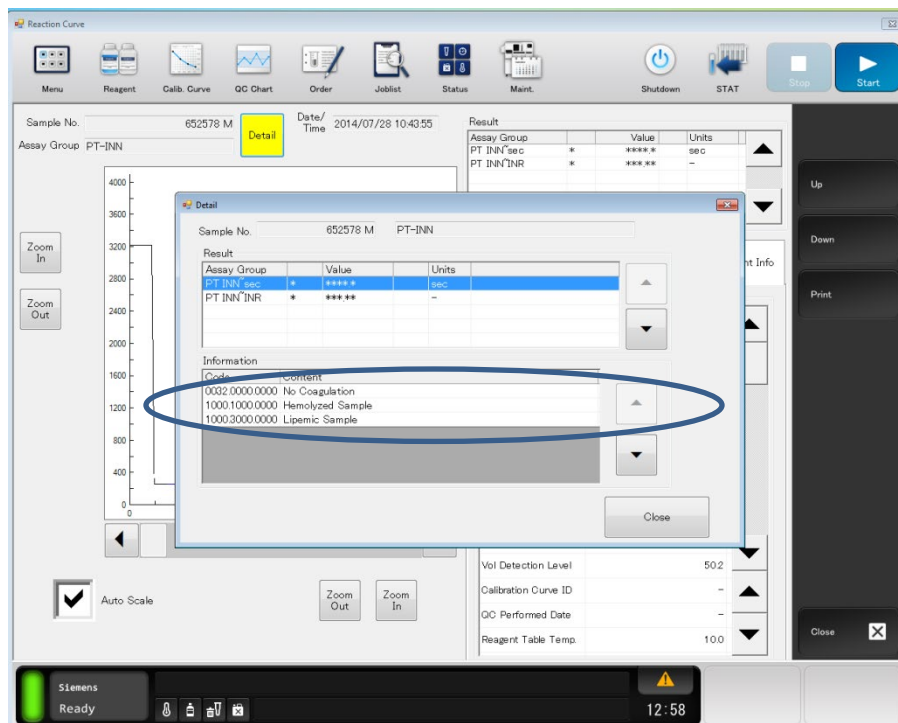
HL Detection System

The HL Check System requires 100uL of plasma and a cuvette.

Absorbance measurements at 575, 660 and 800 nm are used to classify interferences into a negative or positive judgement before ordered sample measurement begins.

If the absorbance is greater than any of the criteria, the flag is displayed on the Joblist and Browser based on the setting of the system.

Status	Rack No. -Pos.	Sample No.	Sample Info.	Mo de	R	F	End Time	PT INN ^{sec} sec	PT INN ^{INR} -	APTT FSL ^{sec} sec	Fbg DT mg/dL
	REAG00	QCControl 528110		M		F	10:45	11.2	1.04	25.0	
	REAG00	QCControl 548405		M		F	10:45	48.5	4.56	55.0	
	000002-01	152854		N		F	10:50	18.2	1.69	41.6	
	000002-02	525645		N		F	10:50	17.9	1.67	41.9	
Review	000002-03	252145		N		F	10:51	* 49.5	* 4.65	* ****	
Processing	000002-04	652578	H* L*	N			10:59	* ****	* ****	* ****	
Processing	000002-04	652578	H* L*	N	R		10:59	⊙	⊙		
Processing	000002-04	652578	H* L*	N	F		10:59	⊙	⊙	* ****	
Review	000002-05	930201	H* Lip	N		F	10:51	* 17.1	* 1.59	* ****	
Review	000002-06	925649	H*	N		F	10:52	* 19.1	* 1.78	* 40.0	
	000002-07	974152		N		F	10:52	17.5	1.65	41.8	
	000002-08	933251		N		F	10:52	17.5	1.63	41.3	
Error	000002-09	541254	Lip	N		F	10:53	* ****	* ****	* 44.4	
	000002-10	482215		N		F	10:53	17.4	1.62	40.7	
Processing	000001-01	548251		N			10:54	18.1	1.68	⊙	
Processing	000001-02	154852		N			10:54	18.8	1.75	⊙	
Processing	000001-03	958474	Hem	N			10:54	* 17.4	* 1.62	⊙	
Processing	000001-04	945142		N			10:55	⊙	⊙	⊙	
Processing	000001-05	872214		N			10:55	⊙	⊙	⊙	
Processing	000001-06	142577		N			10:55	⊙	⊙	⊙	



Setting up HL Check Path:

Settings> System Settings > Operational Settings > HIL Check

There levels are 0-5 for both Hemolysis and Lipemia.

The instrument will flag a sample if it is equal to or above the check level selected.

The screenshot displays the 'HIL Check' settings window. It is organized into three main sections, each with a checkbox, a 'Check Level' spinner, and a 'Display Method of Analysis Results' dropdown menu.

- Hemolysis Check:** The checkbox is checked. The 'Check Level' is set to 1. The 'Display Method of Analysis Results' dropdown is open, showing four options: 'Output values with low-reliability flags.' (selected), 'Output numeric values.', 'Output values with low-reliability flags.' (highlighted in blue), and 'Output masked values.'
- Icterus Check:** The checkbox is unchecked. The 'Check Level' is set to 1. The 'Display Method of Analysis Results' dropdown is set to 'Output values with low-reliability flags.'
- Lipemia Check:** The checkbox is checked. The 'Check Level' is set to 2. The 'Display Method of Analysis Results' dropdown is set to 'Output values with low-reliability flags.'

NOTE: Icterus check is not used. Icterus levels of 0-5 do not interfere with most Hemostasis assays.

Display Method Analysis Results

Define Result Output Settings

Result Output	Analysis Status	Sample Information	Analysis Result	Flag sent to Host
Output numeric values	<None>	Hem or Lip	17.5	Yes
Output values with low-reliability flags	Review	Hem or Lip	*17.5	Yes
Output masked values	Review	Hem or Lip	***.*	Yes

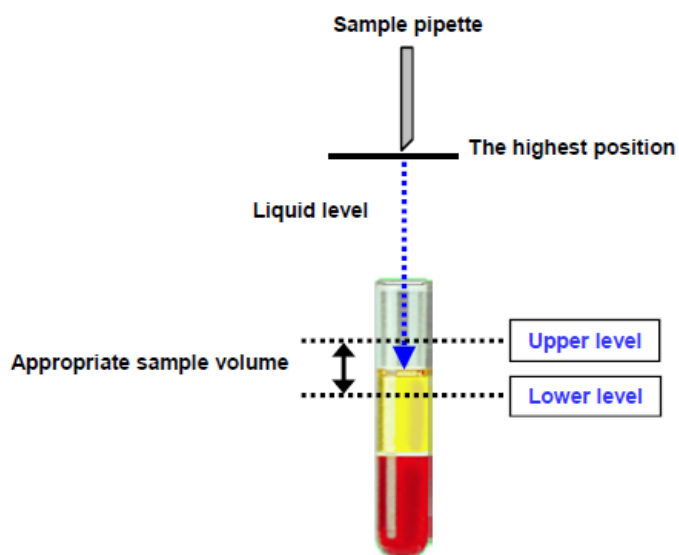
- **Hem-** flag for hemolysis
- **Lip-** flag for lipemia
- **H*** interference in Hemolysis reading. Check tube manually
- **L*** interference in Lipemia reading. Check tube manually

NOTE: In the case of Range Over, a H* or L* is displayed on the Joblist. This indicates that a Hemolysis or Lipemic reading could not be obtained.

Sample Volume Check

The Cap piercing probe aspirates from the sample tube and takes a liquid level reading to determine if the volume is in the correct range for the tube. When the liquid level is out of range, a “Vol” or volume message is displayed under the Sample Information column of the Joblist. The ranges are tube type specific.

The sample volume check is set up at installation.



Setting up Sample Volume Check

Path: System Settings > Operational Settings > Sample Volume Check

The screenshot shows the 'System Settings' dialog box. On the left, a tree view lists various settings categories. 'Operational Settings' is expanded, and 'Sample Volume Check' is selected. The main area on the right displays configuration options for three types of sample volume checks.

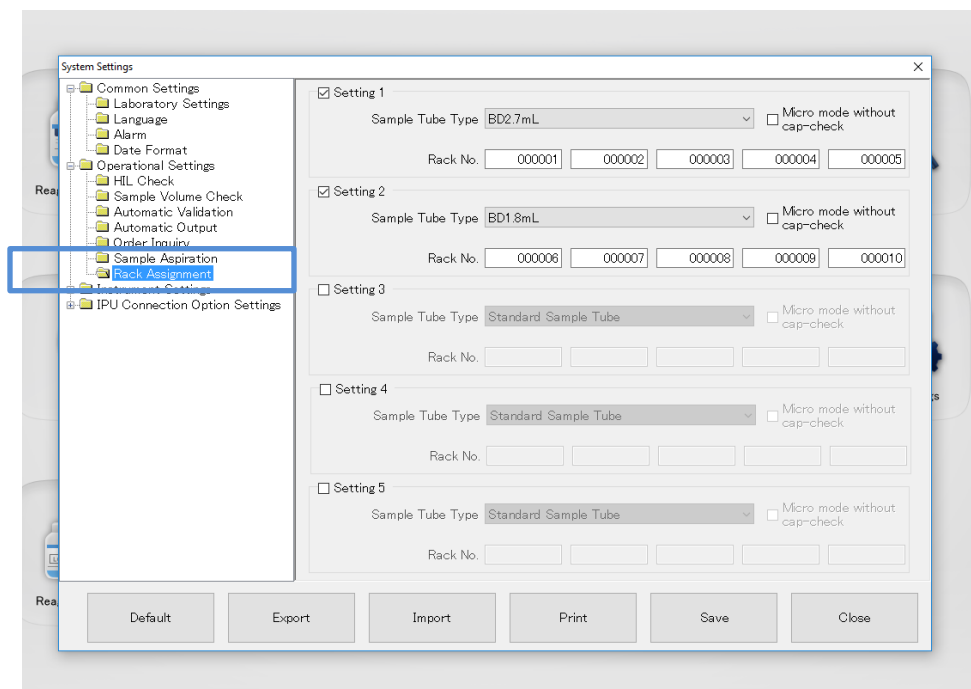
Type	Rack No	Uncapped (mm)	Capped (mm)
☒ Type1	11 - 20	43.0 - 55.0	44.7 - 55.9
☒ Type2	1 - 10	45.0 - 56.5	51.0 - 63.0
☐ Type3	0 - 999999	0.0 - 0.0	0.0 - 0.0

At the bottom of the dialog, there are six buttons: Default, Export, Import, Print, Save, and Close.

Setting up Rack Assignment

Path: System Settings > Operational Settings > Rack Assignment

Identify racks as a specific sample tube type.



This is setup during installation by the Application Specialist.

1. Run a PT on 5 capped and 5 uncapped blue top tubes.
2. Calculate the average of the volume detect levels for both capped and uncapped.
3. Create a range for capped and uncapped: average +/- 5mm.
4. Go to Sample Volume Check, enter ranges and racks numbers used.

Navigate to a sample with H L and Vol Flag

Use the *Sysmex CS-2500 System Quick Reference Guide*.

Preanalytical Sample Integrity

1. Locate a sample with a Hem or Lip flag.
2. Navigate to the Measurement Info tab.
3. What is the level?

4. Locate a sample with a Vol flag.
5. Navigate to the Measurement Info tab.
6. How many millimeters down did the probe detect liquid in the tube?