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Distribution:

Coagulation Manual

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Next Review: 30 June, 2019

Document Name: CA-1500 Reagents

Approved By:

Jennifer G. Daley Bernier, A/ Manager, Laboratory Services

Status: **APPROVED****PURPOSE:**

To instruct Core Laboratory Staff when it is appropriate and how to change reagents on the Sysmex CA-1500 coagulation analyzer. This procedure will also provide instruction on LIS steps to ensure lot and QC records are accurate.

POLICY:

- A change to the lot number of any reagent, including cleaning agents, require updating the lot records on the instrument. This change may require updating the lot record in the LIS, depending on the reagent in question.
- Additional changes may be required such as:
 - Changes to the following reagents require lot to lot comparison and update of the standard curve on the CA-1500:
 - PT Innovin (INR)
 - FS Actin (PTT)
 - Changes to the following reagents should include a mean determination prior to implementation
 - Ci-Trol 1, 2, 3 Quality Controls
 - Innovance D-Dimer Controls
 - Changes to the following reagents require calibration:
 - Innovance D-Dimer
 - PT Innovin (INR) and FS Actin (PTT) calibration is possible through Sysmex's PT Multicalibrator system not currently in use at Stanton Territorial Hospital
 - LIS registered reagents include Innovance D-Dimer kit, PT Innovin, FS Actin and Calcium Chloride, Innovance D-Dimer Quality Controls, CiTrol 1, 2 and 3 Quality Controls.

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PROCEDURE INSTRUCTIONS:

Follow the steps in the table below to

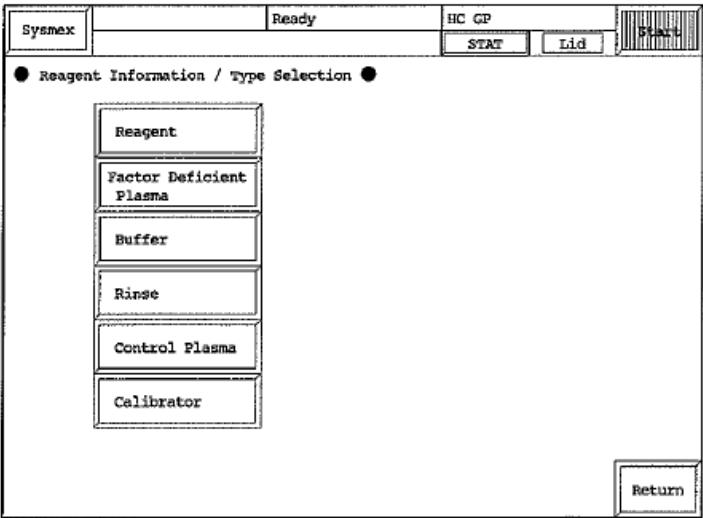
Step	Action	
1	To change lot numbers on the CA-1500 first identify whether a lot to lot comparison, mean determination or calibration is required. Lot to lot comparisons and mean determinations are the responsibility of the MLT II so contact them for assistance.	
	If new lot is:	Then:
	A D-Dimer kit	<ul style="list-style-type: none"> • Follow steps below to enter new lot information. • A D-Dimer calibration will need to be performed
	PT Innovin or FS Actin	<ul style="list-style-type: none"> • Contact MLT II prior to end of lot. • MLT II will confirm the lot to lot comparison has been completed and signed off by hematopathologist. • MLT II will implement new standard curve including ISI and MNPT.
	A QC reagent	<ul style="list-style-type: none"> • Confirm the mean determination has been completed and entered into TQC. • Proceed to “Implementing New Controls”
	A Rinse Solution (Clean 1 or Clean 2)	Proceed to “Enter/Change Lot Information for a Reagent” below.

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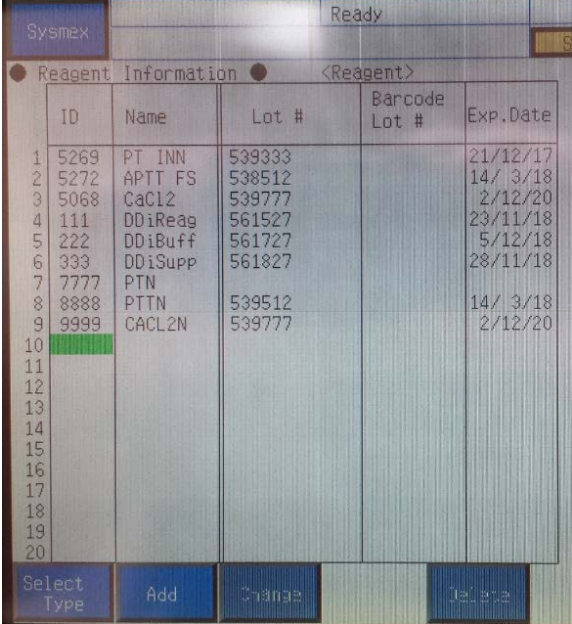
To Enter/Change Lot Information for a Reagent (New Lot)

Due to the need for additional study prior to implementation it is the responsibility of the MLT II to enter new lot information for PT Innovin, FS Actin and controls. Core MLT's will be responsible for entering new lots of D-Dimer kits and Rinse Solution.

1 From the Main Menu go to "Analysis Settings" and then "Reagent Info". Select the appropriate reagent type (Reagent, Rinse or Control Plasma).



2 We will only have one reagent in use at a time. New lots registered on the analyzer but not in use will have names such as PTN, PTTN, CACL2N. These new lot numbers are registered in order to develop a standard curve or have QC data files generated prior to implementation.



ID	Name	Lot #	Barcode Lot #	Exp. Date
1	5269 PT INN	539333		21/12/17
2	5272 APTT FS	538512		14/ 3/18
3	5068 CaCl2	539777		2/12/20
4	111 DDiReag	561527		23/11/18
5	222 DDiBuff	561727		5/12/18
6	333 DDiSupp	561827		28/11/18
7	7777 PTN			
8	8888 PTTN	539512		14/ 3/18
9	9999 CACL2N	539777		2/12/20
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				

3 Using the arrow keys highlight the reagent specific parameters (lot number & expiry) to change and hit "Change". A new window will open.

4 Enter the new data (Date in format: DD/MM/YYYY). Hit "Enter".

5 When all new data entered select "Return"

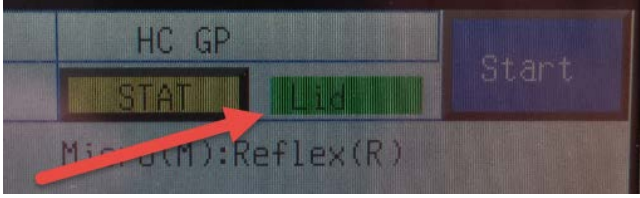
6 The system will give you the options to "Execute Settings"

- "Quit" will exit without saving changes

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- “Continue” will bring you back into the Reagent Info Screen without saving changes
- “Set” will exit Reagent Info Screen after saving changes

Replenishing Reagents (Same Lot)

1	When the system runs out of a needed reagent it will display “Insufficient Reagent” and identify which reagent.
2	Wait for all other testing to complete and/or interrupt the process.
3	From the Main Menu go to “Set Reagents” to view the consumable screen. Fully consumed reagents will be highlighted in red.
4	Confirm the lid signal is green so that you can open the light shield lid
	
5	Set the new reagent in its appropriate position in the reagent tray and close the light shield lid
6	Press the corresponding reagent key to select the pre-set reagent volume. Press Enter and return to sample processing.
7	You can now return to sample analysis. Note: QC should be run again with any new vial of PT Innovin, FS Actin or Innovance D-Dimer.

Setting a New Standard Curve (New PT Innovin)

A standard curve is required for PT Innovin reagent; primarily for the Lot Number, ISI and MNPT settings. It is the responsibility of the MLT II to ensure the standard curve is generated/programmed and signed off prior to implementation. Any MLT can then implement at the moment the new lot is put into use.

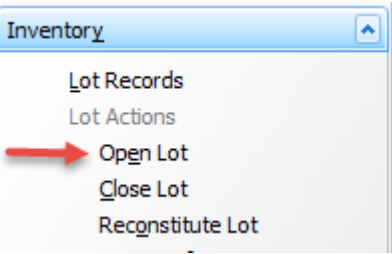
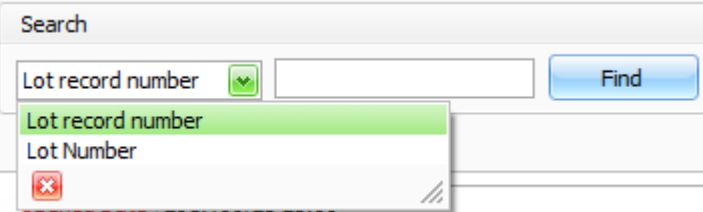
1	To update the standard curve first confirm the new lot is open. Then go to “Standard Curve” from the Main Menu.
2	Select your test “PT” and then “Manual Entry”.
3	Confirm the lot information is correct. Using the arrows and keypad enter the normal patient (MNPT) from hematologist report, ISI from reagent insert. Select “Set” to save.

Implementing New Controls

1	A new lot of control requires a mean determination prior to implementation. MLT II's are responsible for performing the mean study. Once completed and set in TQC any MLT can implement the lot.
2	To switch to new lot in CA-1500 go to the QC screen from the Main Menu.
3	Press "Display Cur/New". Confirm the lot information is accurate. The current lot should be on top and the new lot on the bottom.
	Press "Change Lot". Then Press "Ok" to accept or "Quit" to exit the lot change. This will also update the reagent lot information in the "Reagent Info Section"

Computer steps:

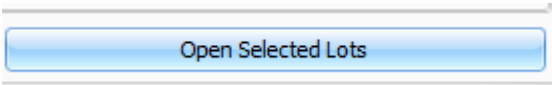
Follow these instructions to change a lot number in Soft Total QC (TQC).

Step	Action
	<p>The reagents for the CA-1500 are registered using the following names:</p> <ul style="list-style-type: none"> • SLAB-INR = PT Innovin • SLAB-PTT = FS Actin • SLAB-CACL – Calcium Chloride • SLAB-DDIM = D-Dimer Reagent • SLAB-QC01 through SLAB-QC05 = various QC solutions
1	<p>Click on "Open Lot" from the "Inventory" section of the main login screen</p> 
2	<p>Either scan the barcode using the "Lot Record Number" option or enter the Lot Number manually. Click on "Find". You can select multiple lots to open at the same time.</p> 

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3 Place a checkmark in the box under the Select column. Then press “Open Selected Lots” in the bottom right corner of the window.


Select	Lot Number	QC Item ID	QC Item Name	Location	De
<input checked="" type="checkbox"/>	4010-0199	CL	Chloride	SLAB	SC



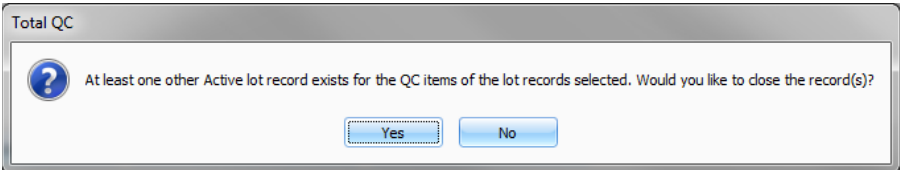
4 If there is a red **X** beside the checkbox hover your mouse pointer over the red **X** to identify what the error is. Troubleshoot the problem prior to opening the lot.

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Select	Lot Number	QC Item ID	QC Item Name	Location	Department	Workstation
<input checked="" type="checkbox"/> 	539203A	SLAB-INR	Innovin	SLAB	SCOA	SCA15



5 Often you will be prompted to close a lot at the same time. This allow the LIS to identify when lot record to attach QC data. Choose “Yes”.



6 The system will switch you to the “Close Lot” tab. Place a checkmark in the box for the lot to close and hit “Close Selected Lots”. Troubleshoot if you get a red **X** similar to Step 4.

CALCULATIONS:

$$INR = (PT Patient/MNPT)^{ISI}$$

REFERENCES:

Operators Manual, CA-1500. Sysmex Corporation. 2006.

REVISION HISTORY:

REVISION	DATE	Description of Change	REQUESTED BY
1.0	30-Jun-17	Initial Release	M. Arbuckle

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Signed by: Jennifer G. Daley Bernier