PROGRAM Standard Operating Procedure – Laboratory Services	
Title: COA20300 Sysmex CA660 Running Quality Control	Policy Number: 15-206-V1
Program Name: Laboratory Services	
Applicable Domain: Lab, DI and Pharmacy Services	
Additional Domain(s): NA	
Effective Date:	Next Review Date:
Issuing Authority: Director, Laboratory and Diagnostic Imaging Services	Date Approved:
Accreditation Canada Applicable Standard: Biomedical Laboratory Services	

GUIDING PRINCIPLE:
Quality Control is performed to obtain high-reliability data over time and to constantly monitor the status of the instrument. This allows for changes to performance to be detected so action can be taken if needed. The Sysmex CA660 analyses control plasma and other standardized samples (QC Samples) and performs statistical control of the results.

PURPOSE/RATIONALE:
This procedure gives instructions on how to perform quality control on the Sysmex CA660.

DEFINITIONS:
QC- Quality Control
LIS- Laboratory Information System

SCOPE/APPLICABILITY:
This procedure applies to Medical Laboratory Technologists (MLT's) who will be performing this procedure.

REAGENTS and/or MEDIA:
Dade Innovin Reagent
Dade Actin-FS Reagent
Calcium Chloride Solution
Dade Thrombin Reagent
Innovance D-Dimer Reagent
CA Clean I
CA Clean II

Dade Owren's Veronol Buffer (OVB)

SUPPLIES:

Sysmex 3.5 mL sample cups
SLD Vials
GW5 (Gewinde- twist top)
PV10 (Push Vial)
Reaction Tubes

EQUIPMENT

Sysmex CA660

EQUIPMENT CALIBRATION AND MAINTENANCE:

Pipettes used must be calibrated yearly based on CSLI QMS23, 2nd edition (June 2019)

ENVIRONMENTAL CONTROLS:

Internal temperatures on the Sysmex CA660 are monitored daily.

SPECIAL SAFETY PRECAUTIONS:

- Ensure proper PPE is used such as gloves, lab gowns and eye protection when possible exposure to splashes.
- Ensure all samples are treated following universal precautions and assume all products as potentially infectious.
- CA Clean II is an acidic cleaning agent. It should not come in contact with skin or clothing, if this happens rinse with plenty of water to avoid damage or injury.
- CA Clean I contains sodium hypochlorite and if directly mixed with an acid solution such as CA Clean II, chlorine gas is produced, which is very dangerous.

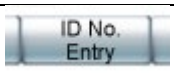
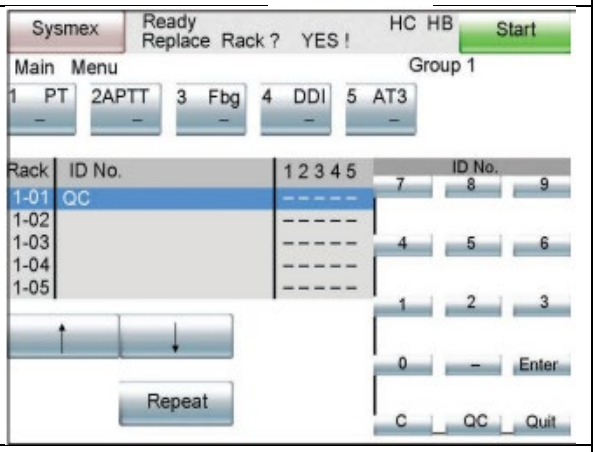
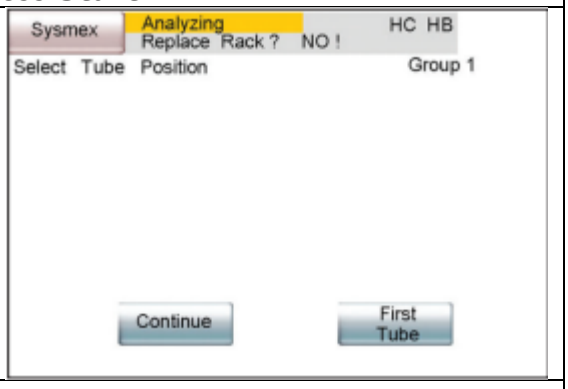
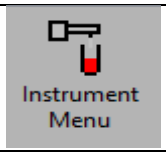
QUALITY CONTROL:

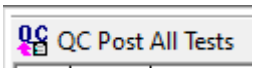
- Dade Ci-Trol
  - Levels 1, 3 and 3
  - Performed every 8 hours
  - Storage 2-8°C: If stored unopen, may be used up until the manufacturer's expiry date
  - Stability when reconstituted:
    - 15-25°C - 8 hours
    - 2-8°C- 16 hours
- Innovance D-Dimer Controls
  - Levels 1 and 2
  - Performed every 8 hours, when patient presents
  - Storage 2-8°C: If stored unopen, may be used up until the manufacturer's expiry date
  - Stability when reconstituted:
    - 15-25°C- 8 hours
    - 2-8°C- 7 days
    - $\leq$-18°C- 4 weeks
- Dade Data-Fi Abnormal Fibrinogen Control
  - One Level

- Performed when patient testing required; QC results valid for 8 hours
- Storage 2-8°C: May be used up until the manufacturers expiry date if stored unopened
- Stability when reconstituted:
  - 15-25°C- 8 hours
  - 2-8°C- 5 days

PROCEDURE INSTRUCTIONS:

Follow the steps in the table below

Step	Action
1	Obtain the appropriate QC vials and reconstitute with 1 mL of Reagent Grade (NERL) water. Allow to stand for 15 minutes at 15-25°C.
2	Place 1 mL of QC material into a 3.5 mL sample cup and place in a sample rack. Since the QC material is being poured from its original container, each sample cup should be labelled as to what it contains.
3	From the Main Menu, Press **ID No. Entry** 
4	Register the QC samples on the analyzer. • Press **QC** and then using the numeric keys enter the file number (i.e. QC01) • Select tests to be run • Press **Enter** • Press **Quit** 
5	Place the rack into the sampler and press **Start**.
6	Select Tube Position: • **First Tube**= start at the first sample reaction tube position • **Continue**= start at the next sample reaction tube position after the last run **Note**: Analysis will not begin until selection is made. 
7	Log into SoftLab to verify results.
8	In the LIS open the Coagulation Instrument Menu: Instrument Menu>SCA1(Sysmex CA 600 #1)/SCA2(Sysmex CA 600 #2) 

9	From your worksheet, locate the QC file you wish to verify and highlight it. Click on **QC Post All Tests.** When the prompt appears "Do you want to verify results with posting?" select **Yes.** Click **OK**	

TROUBLESHOOTING:
Refer to the Sysmex CA660 Operating Manual for general troubleshooting guidance.

CROSS-REFERENCES:
COA20100 Sysmex CA660 Reagent and Quality Control Guidelines

REFERENCES:
Sysmex CA-600 Series Operators Manual, July 2017 Kobe Japan

Sysmex CA-600 Series Application Sheets

Sysmex CA-600 Series Quick Reference Guide, February 4, 2020

Clinical and Laboratory Standards Institute (CSLI). *General Laboratory Equipment Performance Qualification, Use and Maintenance.* 2nd Ed. CSLI guideline QMS23 Wayne, PA: Clinical and Laboratory Standards Institute, 2019.

APPROVAL:

April 24, 2025
Date

Director, Laboratory and Diagnostic Imaging Services

REVISION HISTORY:

REVISION	DATE	Description of Change	REQUESTED BY
1.0	10 Mar 2025	Initial Release	L. Howlett