TITLE: Cobas h232 Operating Procedure	**Doc #:** 23237
Section: \\Management System\PLM\Point of Care Testing\Troponin\	**Version:** 1.0 Current
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Purpose

This procedure provides instructions to perform troponin analysis using the *ROCHE Cobas H232* in a point of care setting.

Abbreviations

RT Room Temperature
QC Quality Control
IQC Internal Quality Control

Materials

Note: Refer to Quality Control section for information on QC materials

Equipment
Pipette (able to measure 150 ul)
Pipette tip
Roche CARDIAC pipettes CAT# 11622889190
Roche Cardiac T Quantitative strips Cat # 11894307193
10 % bleach solution or approved cleaning solution
Point of Care Test Results (Chemistry/Hematology) - form CD2532MR

Equipment
Roche Cobas h232
Citizen Mobile Thermal Printer CMP-10 Cat # 05412951001 (SAP # 167112)
Roche Handheld Base Unit
Roche Cardiac Reader IQC (low and high) Cat# 04880668190
Roche Cardiac Control Troponin T Cat # 04890515190
*CARDIAC T Quantitative Rapid Assay with coding chip

Sample

If samples are required for laboratory analysis refer to: *Laboratory Test Catalogue Collection & Shipping Requirements*

Sample type	Amount required	Storage	Stability
lithium heparin (green top)	• For **collection**- fully evacuated tube • For **analysis**- 150 µL	18 - 25°C	8 hours

Note: Do not refrigerate. Do not freeze.

Sample retention:
Store sample in rack provided for laboratory retrieval and disposal

Specimen Rejection Criteria

• Insufficient amount of blood	• Clotted samples
• Greater than 8 hours at room temperature	

Special Safety Precautions

"Routine Practices" as directed by Health Canada, must be considered as the level of care provided for all patients. Use Health Canada Guidelines for "Routine Practices" to avoid exposure to blood, body fluids and contaminated surfaces. All patient samples, as well as the materials they contact, are to be considered biohazardous and therefore capable of transmitting infection or cross contamination.

Maintenance

Complete *Cobas H232 QA Log* for all maintenance performed

1. Weekly Maintenance

Step	Action
1	**Clean instrument surface** 1.1 Turn off meter and remove from base unit if required 1.2 Wipe all exterior surfaces with a lint-free cloth moistened in 10% bleach solution 1.3 Dry meter with fresh dry cloth **Note:** • Do not spray anything on or into the meter • Refer to Cobas h 232 System Operator's Manual for alternative cleaning solutions (Virox wipes can be used)
	Clean test strip and measurement chamber cover 2.1 Remove measurement chamber cover by pulling cover horizontally from the meter 2.2 Wipe easily accessible areas with a lint-free cloth moistened in 10% bleach solution 2.3 Allow strip guide area to dry for 10 minutes 2.4 Replace chamber cover **Note:** • Do not insert any objects into test strip guide as this may damage the meter Refer to H232 Operator's Guide for alternative cleaning solutions
3	**Enter cleaning task in meter**

Calibration Calibration is automatic. No intervention required.

Quality Control

IQC controls (reusable strips) - checks the optical system**.**

IQC Control	Level	Storage	Stability	Frequency
Cardiac control Troponin T	**Low**	**2 to 30°C**	**The first of:** **Labeled expiration date or 6 months of use**	**Once every 24 hours**
Cardiac control Troponin T	**High**			
CARDIAC T Quantitative Rapid Assay with coding chip		**w/control**	**w/ @ Lot # control**	**w/ @ Lot # control**

Note: -IQC control coding chip is required only when a new bottle of IQC strips is opened.
- **Record the date on each container when opening**

1. Procedure for IQC control strips

Step	Action
1	**Obtain IQC** stored next to instrument
2	**Prepare meter** **2.1** Press **[On/Off]** button for longer than 5 seconds if meter is not already turned on **2.2** Press (√) **2.3** Scan Operator ID or manually enter ID Note: For manually entered ID press (√) to complete entry **2.4** Select **[QC Test]** from [Main Menu]
3	**Run control strip** **3.1** **Insert Low IQC strip** into test strip guide when prompted on screen -**Run IQC code chip (**if prompted) by inserting **IQC code chip** into **code chip slot** at the back of meter. **Note:** Meter will proceed immediately to analyzing IQC strip after reading code chip. No intervention is required 3.2 **Wait for analysis** to complete (about 30 sec) 3.3 **Remove IQC strip** from meter 3.4 **Analyze High IQC strip** by repeating steps above
4	**Store control strips and code chip** **4.1** **Return** code chip, High and Low control strips **to original container**

5	**Record controls** **5.1 Obtain *Cobas h232 QA log*** **5.2 Check and initial IQC section** on log **Note**: If problems were identified while analyzing controls, give a brief description in comment area on log.

2. Liquid Quality control samples will be run by laboratory.

Note: Lab staff enter test strip coding chip when a new Lot # of test strips are opened

Procedure

Note: - Use strip within **15 minutes** of removing from foil pouch.

1 Sample PROCEDURE (Analysis Time- 8-12 minutes)

Step	Action
1	**Collect** sample 1.1 **Collect** lithium heparin whole blood **sample** (green tube) • Mix sample by gentle inversion 8-10 times **Note:** Mix the sample **promptly** after the blood is drawn. 1.2 **Label** Specimen with • Patient name, Patient MRN and/or HCN number (Star label can be used) • Time and date of collection • Initials of staff drawing blood
2	**Prepare** materials 2.2 **Remove** required **test strips** from refrigerator 2.3 **Obtain** meter and place on level, vibration free surface 2.4 **Obtain** pipette and tip located next to instrument. **Note**: Roche Cardiac pipette can be used
3	**Analyze sample** **3.1 Press [On/Off] for longer than 5 seconds** if meter is not already turned on **3.2 Run IQC if required** (e.g. Meter states IQC lock out). **OR** Proceed to step 3.3 if the IQC has already been run **Note**: ***Procedure for IQC control Strips*** is listed above. 3.3 **Select [Patient test]** from **[Main Menu]** 3.4 **Scan** bar code from patient's Star label **or** manually **enter MRN** or HCN **Note:** For manually entered patient information press **[√]** to complete entry. **3.5 Remove** test strip **from foil pouch** **3.6 Insert test strip** into test strip guide when prompted on screen **3.7 Obtain** 150 ul of **specimen** by inserting pipette into collection tube (Ensure sample has been properly mixed before sampling) **3.8 Apply Sample**" to the sample well when prompted **Note**: The **pipette must be held in an upright position** when adding the sample. **3.9 Press the [√]** button to confirm sample has been applied correctly. **3.10 Wait for analysis** to complete (about 12 minutes) **3.11 Request print** by selecting icon resembling a printer**.** **3.12 Remove test strip** from meter **3.13 Place test strip and pipette tip** in biohazardous waste container **3.14 Return pipette** to storage area (if using a **disposable pipette**, discard in biohazard waste)
4	**Record results** 4.1 **Review results** to identify if repeat or lab collection is required 4.2 **Attach** results to ***Point of Care Test Results (Chemistry/Hematology)*** *form*

	4.3 **Fill** patient, collection and user information on form.

Calculation	All required calculations are performed by the instrument.

Result	**Reference Values**: Troponin < or = 50 ng/L in healthy individuals.

Interpretation	A negative result within the first hours of onset of symptoms cannot rule out myocardial infarction with certainty due to the release kinetics of Troponin T. The test should be repeated at appropriate intervals. The initial appearance of elevated Troponin T in the blood of those who have suffered AMI is variable, from 3-24 hours, depending on factors such as infarct size. *<50 ng/L =TROP T (low cardiac risk)* *50-100 ng/L =TROP T LOW 100 ng/L (medium cardiac risk)* *100-2000 ng/L =TROP T "X" ng/L (high cardiac risk)* *>2000 ng/L =TROP T HIGH <2000 ng/L (massive cardiac damage)*
Limitations	Erroneous findings may be obtained from samples taken from patients who have been treated with monoclonal mouse antibodies.
Principle	The Roche Cardiac H232 System is an instrument for the quantitative evaluation of immunoassays using the gold-labeling technique. Two lines (signal and control line) in the detection zone of the test strip indicate whether the marker to be determined is present in the sample. The cardiac reader detects those lines by means of a charge – coupled device photosensor with imaging lens. The test signal (signal line) increases in intensity in proportion to the concentration of the individual marker. The system software converts the signal intensity to a quantitative result which is then displayed on the screen.
Clinical Utility	The rapid diagnostic TropT test is used to improve the diagnosis of Myocardial Ischemia.
Related Procedures and Documents	• *Laboratory Test Catalogue Collection & Shipping Requirements* • *Point of Care Test Results (Chemistry/Hematology)* • *Cobas H232 QA Log*
Reference	• Roche Cardiac Troponin T Quantitative insert • Cobas h 232 System Operator's Manual