HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank (Hormone)		
Document:	Internal Policy and Procedure		
Title:	Analysis of Troponin T hs Level		
Applies To:	All Laboratory Staff		
Preparation Date:	January 06, 2025	**Index No:**	LB-IPP-112
Approval Date:	January 20, 2025	**Version :**	2
Effective Date:	February 20, 2025	**Replacement No.:**	LB-IPP-112(1)
Review Date:	February 20, 2028	**No. of Pages:**	03

1. PURPOSE:

1.1 To illustrate the necessary steps required for performing Troponin T hs Assay By-COBASe411.

2. DEFINITONS:

2.1 Troponin T (TnT) is a component of the contractile apparatus of the striated musculature. Although the function of TnT is the same in all striated muscles, TnT originating exclusively from the myocardium (cardiac TnT, molecular weight 39.7 kD) clearly differs from skeletal muscle TnT. As a result of its high tissue-specificity, cardiac troponin T (cTnT) is a cardio-specific, highly sensitive marker for myocardial damage.

3. POLICY:

3.1 Troponin T (TnT) is a component of the contractile apparatus of the striated musculature. Although the function of TnT is the same in all striated muscles, TnT originating exclusively from the myocardium (cardiac TnT, molecular weight 39.7 kD) clearly differs from skeletal muscle TnT. As a result of its high tissue-specificity, cardiac troponin T (cTnT) is a cardio-specific, highly sensitive marker for myocardial damage.

3.2 Cardiac troponin T increases approximately 3-4 hours after myocardial infarction (AMI) and may persist up to 2 weeks thereafter.2,3 In contrast to ST-elevation myocardial infarction (STEMI), the diagnosis of non-ST elevation myocardial infarction (NSTEMI) heavily relies on cardiac troponin result. According to the new universal definition of myocardial infarction.

3.3 Cardiac troponin T (cTnT) is an independent prognostic marker which can predict the near-, mid- and even long-term outcome of patients with acute coronary syndrome (ACS), In addition, 4 multicentre trials involving more than 7000 patients have shown that cardiac troponin T is also useful to identify patients that benefit from anti-thrombotic therapy (GPIIb/IIIa inhibitors, low molecular weight heparin).10,11,12,13,14 Cardiac troponin is also the preferred marker of myocardial injury in the new guidelines for the diagnosis and treatment of non-ST-segment elevation acute coronary syndromes.

3.4 Elevated levels of troponin T correlate with the severity of coronary artery disease and to poor outcome independent of natriuretic peptide (BNP or NT-proBNP) levels. Low concentrations of troponin T are an independent predictor of cardiovascular events including occurrence and recurrence of atrial fibrillation.

4. PROCEDURE:

4.1 **Principle :** Sandwich principle

4.2 **Specimen collection and preparation:** Serum collected using standard sampling tubes or tubes containing separating gel. K2−EDTA, K3−EDTA, Li−heparin and Na−heparin plasma. Plasma (EDTA, heparin) and serum samples should not be used interchangeably. Stable for 24 hours at 2°-8 °C, 12 months at -20 °C. Freeze only once.

4.3 **Method:** See policy of loading sample on machine (Ref: Operative Manuals' of COBAS e411.

4.4 **Calculation:** The analyzer automatically calculates the analyte concentration of each sample in µIU/mL.

4.5 **Status:** Stat and Routine

4.6 **Reference ranges:** Cut-off (clinical discriminator) value for troponin T is 0.1 µg/L (ng/mL)

4.6.1 The WHO definition of AMI has been recently updated recommending the detection of a rise and/or fall of cardiac troponin in the clinical setting of myocardial ischemia using the 99th percentile troponin cut-off value 4.

4.7 **Limitations- interference:**

4.7.1 The assay is unaffected by icterus (bilirubin < 428 µmol/L or < 25 mg/dL), hemolysis (Hb < 0.062 mmol/L or < 0.1 g/dL; samples showing visible signs of hemolysis may cause interference), lipemia (Intralipid < 1500 mg/dL) and biotin (< 82 nmol/L or < 20 ng/mL). Falsely depressed results are obtained when using samples with hemoglobin concentrations > 0.1 g/dL.

4.7.2 Samples should not be taken from patients receiving therapy with high biotin doses (i.e. > 5 mg/day) until at least 8 hours following the last biotin administration.

4.8 **Measuring range:** 3-10000 ng/L or pg/mL

4.8.1 Values below the Limit of Blank are reported as < 3 ng/L or pg/mL.

4.8.2 Values above the measuring range are reported as > 10000 ng/L.

5. MATERIALS AND EQUIPMENT:

5.1 **Reagent:** For preparation see package insert

5.1.1 **M:** Streptavidin-coated microparticles (transparent cap), 1 bottle, 12 mL: Streptavidin-coated microparticles 0.72 mg/mL, preservative.

5.1.2 **R1:** Anti-troponin T-Ab~biotin (gray cap), 1 bottle, 14 mL:
Biotinylated monoclonal anti-cardiac troponin T-antibody (mouse) 2.5 mg/L; phosphate buffer 100 mmol/L, pH 6.0; preservative; inhibitors.

5.1.3 **R2:** Anti-troponin T-Ab~Ru(bpy) (black cap), 1 bottle, 14 mL: Monoclonal anti-cardiac troponin T-antibody (mouse) labeled with ruthenium complex 2.5 mg/L; phosphate buffer 100 mmol/L, pH 6.0; preservative.

5.2 **Calibration:**

5.2.1 Every Elecsys reagent set has a barcoded label containing specific information for calibration of the particular reagent lot. The predefined master curve is adapted to the analyzer using the relevant CalSet.

5.2.2 Calibration must be performed once per reagent lot. Using fresh reagent (i.e. not more than 24 hours since the reagent kit was registered on the analyzer).

5.2.3 Calibration interval may be extended based on acceptable verification of calibration by the laboratory.

5.2.4 Renewed calibration is recommended as follows:

5.2.4.1 After 8 weeks when using the same reagent lot.

5.2.4.2 After 7 days when using the same reagent kit on the analyzer.

5.2.4.3 As required: e.g. quality control findings outside the defined limits.

5.3 **Quality control:**

5.3.1 For quality control, use PreciControl Troponin. In addition, other suitable control material can be used.

5.3.2 Controls for the various concentration ranges should be run individually at least once every 24 hours when the test is in use, once per reagent kit, and following each calibration.

6. RESPONSIBILITIES:

6.1 Hormone shift on charge is responsible for, running calibration and control and samples of Troponin T hs.

6.2 Hormone staff are responsible for running Troponin T hs samples every morning.

7. APPENDICES:

7.1 N/A

8. REFERENCES:

8.1 Operator's manual for the analyser.
8.2 Company Leaflets of reagents.

9. APPROVALS:

	Name	Title	Signature	Date
Prepared by:	Dr. Talal Abdelgawad	Clinical Pathologist		January 06, 2025
Reviewed by:	Dr. Kawther M. Abdou	Consultant & Lab. Medical Director		January 08, 2025
Reviewed by:	Ms. Noora Melfi Alanizi	Laboratory & Blood Bank Director		January 09, 2025
Reviewed by:	Mr. Abdulelah Ayed Al Mutairi	QM&PS Director		January 12, 2025
Reviewed by:	Dr. Tamer Mohamed Naguib	Medical Director		January 12, 2025
Approved by:	Mr. Fahad Hazam Alshammari	Hospital Director		January 20, 2025