HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank (Chemistry)		
Document:	Internal Policy and Procedure		
Title:	Analysis of CKMB Level		
Applies To:	All Laboratory Staff		
Preparation Date:	January 06, 2025	**Index No:**	LB-IPP-159
Approval Date:	January 20, 2025	**Version :**	2
Effective Date:	February 20, 2025	**Replacement No.:**	LB-IPP-159(1)
Review Date:	February 20, 2028	**No. of Pages:**	04

1. PURPOSE:

1.1 The purpose of this policy and procedure is to provide all information related to the analysis of CKMB level in blood (serum/plasma) on DimensionEXL200 and SynchronDXC600 machines.

2. DEFINITONS:

2.1 CKMB appears to support the diagnosis of suspected myocardial infarction through its serial measurements.

3. POLICY:

3.1 This policy provides instructions for performing the quantitative determination of MB in human serum or plasma on Dimension EXL200 and SynchronDXC700 machines.

3.2 Creatine kinase (CK) includes three isoenzymes which are dimers composed of two types of monomer subunits. The isoenzymes comprise all three combinations of monomers, M (for skeletal muscle derived) and B (for brain derived), as represented by the notations MM, MB, and BB. Many organs contain CK, but the distribution of isoenzymes is different in each one. Skeletal muscle is very rich in the MM isoenzyme, whilebrain, stomach, intestine, bladder, and lung contain primarily the BB isoenzyme.

3.3 The MB isoenzyme has been found in appreciable amounts (15-20 %) only in myocardial tissue. Therefore, total serum CK activity is elevated in several diseases. This decreases the specificity of total CK and limits its diagnostic value. However, the striking difference in the CK isoenzyme patterns from different organs has made CK one of the most useful enzymes for diagnostic purposes in acute myocardial infarction. CKMB appears in serum reflecting its unique presence in myocardial tissue. It helps in supporting the diagnosis of suspected myocardial infarction by serial determinations of CK isoenzymes.

3.4 Serum or plasma CKMB level is increased in myocardial infraction, extensive rhabdomyolysis, cardiomyopathy, myocarditis and pericarditis.

4. PROCEDURE:

4.1 **Specimen:**

4.1.1 Type:

4.1.1.1 Serum, or plasma

4.1.2 Tube Type:

4.1.2.1 Gel tube, Plain tube, Li-Heparin

4.1.3 Amount Required:

4.1.3.1 2.0 to 3.0 ml.

4.1.4 Delivery Arrangements:

4.1.4.1 Sample to be delivered to the lab as soon as possible.

4.1.5 If the sample is serum should be ensuring complete clot formation before centrifugation. Some specimens, especially those from patients receiving anticoagulant or thrombolytic therapy, may exhibit increased clotting time. If the specimen is centrifuged before a complete clot forms, the presence of fibrin may cause erroneous results.

4.1.6 Temperature Restrictions:
4.1.6.1 At room temperature.
4.1.7 Unacceptable Specimen:
4.1.7.1 See sample rejection criteria policy.
4.1.8 Specimen Retention:
4.1.8.1 Period of retention: up to one week after separation of the sample
4.1.8.2 Storage condition: store at 2-8° t
4.1.9 Safety Precaution:
4.1.9.1 Treat all samples material as infectious and handled in accordance with the OHSA standard on blood borne pathogens.

4.2 **Principle:**

Creatine phosphate+ADP ------CKMB----- Creatine+ATP
ATP+D-glucose ---------HK------- ADP + G6P
G6P+ NADP+ ---------G6PDF------- D-6-phosphogluconate+ NADPH + (H+)

4.2.1 The rate of the NADPH formation is directly proportional to catalytic CKMB Activity and is measured bio chromatically at 340 and 540 nm by measuring the change in absorbance photometrically.

4.3 **Method:**
4.3.1 See policy of loading sample on machine (Ref: Operative Manuals' of Dimension ExL200 and SynchronDXC700.

4.4 **Calculation:**
4.4.1 Instrument system automatically calculates the Analytic activity and gives results in the form of printout.

4.5 **Format:**
4.5.1 Numeric

4.6 **Status:**
4.6.1 Stat and Routine

4.7 **Reference ranges:**
4.7.1 Serum/plasma 7 — 25 U/L

4.8 **Dilution information:**
4.8.1 Specimens with values exceeding the linearity range are flagged and may be diluted with automatic dilution either automated or manual dilution. Manual Dilution should be performed as follows:
4.8.1.1 Use saline (0.85% to 0.90%) to dilute the sample.
4.8.1.2 The operator must enter the dilution factor in the patient order screen. The system dilution factor to automatically correct the concentration by multiplying the result by factor
4.8.1.3 If the operator does not enter the dilution factor, the result must be multiplied appropriate dilution factor before reporting the result.
4.8.1.4 If a diluted sample result generates a Linear Low (LL) result error code. do result. Prepare an appropriate dilution/concentration and rerun.

4.9 **Linearity:**
4.9.1 CKMB is leaner up to 125U/L

4.10 **Limit of Detection:**
4.10.1 The Limit of Detection is 3 U/L

5. MATERIALS AND EQUIPMENT:

5.1 **Reagents:**
5.1.1 Refer to CKMB reagent leaflet of DimensionEXL200 and SynchronDXC700..
5.1.2 Reagents retention:
5.1.2.1 The unopened reagents are stable until the expiration date when stored at 2-8 °C. Reagent stability is 30 days if the reagent is unopened and for 2 days if the reagent is opened properly for 5 days if the reagent is opened wells (1 — 3) and 15 days for well (6).

5.2 **Calibration:**

5.2.1 Calibration is stable approximately 30 days and required with each change in reagent lot number. Verify calibration curve with at least two levels of controls according to the established Quality Control requirements for your laboratory. Calibration must be done when:

5.2.1.1 A compete change of reagents that affects the range used to report patient results or QC value.

5.2.1.2 A reagent kit with new lot number is used .

5.2.1.3 A new assay file that requires a calibration is installed.

5.2.1.4 QC fails to meet the established criteria.

5.2.1.5 After major maintenance or service.

5.2.1.6 When recommended by the manufacturer.

5.2.1.7 Documentation accompanying a new version of an existing file states calibration is required.

5.2.1.8 At least every 6 months.

5.2.2 Calibrator retention:

5.2.2.1 At 2-8 °C for 24 h. Instability or deterioration should be suspected if there are visible signs of leakage, extreme turbidity microbial growth or if calibration does not meet the appropriate package insert and/or instrument operation manual criteria.

5.2.3 Calibration Procedure:

5.2.3.1 Verify that the correct calibrator values have been entered into the calibration file. For details refer to Operator Guide of Dimension EXL200.

5.2.3.2 Allow calibrator to come to room temperature.

5.2.3.3 Mix bottle 10 times by inversion.

5.2.3.4 Open the bottle, place a minimum of 300 ul of each level in separate sample cup, and place on the assigned positions.

5.2.3.5 Cap the bottle tightly and store at 2-8°C. Immediately after use.

5.2.3.6 Perform calibration as indicated in Operator Guide of DimensionEXL200 and SynchronDXC700.

5.2.4 Calibration Expected Values:

5.2.4.1 Refer to CKI/MBI calibrator for Dimension

5.2.4.2 Refer to synchron operator manual

5.3 **Quality control:**

5.3.1 Normal and pathological control. one time in 24 hours. If more frequent control monitoring is required, the established quality control procedures is followed If quality control results do not fall within an acceptable range defined by laboratory, patient be affected and corrective action should be taken.

5.3.2 Quality Control retention:

5.3.2.1 Unopened control vial is stable up to expiry date printed on the label when stored at cold room.

5.3.2.2 Opened control vial for all analytes will be stable for 7 days except Bilirubin (Direct) for 4 days at 2 — 8 °C, all analytes will be stable for 30 days at -10 to -20 °C.

5.3.2.3 Instability or deterioration should be suspected if there are visible signs of leakage, extreme microbial growth or if calibration does not meet the appropriate package insert and/or instrument operation manual criteria.

5.3.3 QC Procedure:

5.3.3.1 Verify that the correct QC values have been entered into the QC file. For details refer to Operator Guide of Dimension.

5.3.3.2 Allow QC to come to room temperature.

5.3.3.3 Gently remove the stopper to avoid loss of the lyophilized pellet and add exactly 5.0 ml distilled or de-ionized water.

5.3.3.4 Leave to stand for 20 minutes.

5.3.3.5 Mix bottle several times by inversion to allow homogeneity.

5.3.3.6 Gently invert just prior to use. Avoid foaming

5.3.3.7 Open bottle, place a minimum of 1000 ul of each level in separate sample cup, and place on the assigned positions.
5.3.3.8 Cap bottle tightly and store at 2-8°C. Immediately after use
5.3.3.9 Perform QC as indicated in Operator Guide of DimensionEXL200 and SynchronDXC600 machines Refer to synchron operator manual.

5.3.4 QC Expected Values:

5.3.4.1 Refer to the Bio-Rad Lyphochek assayed chemistry controls value sheet for Dimension and Synchron.

6. RESPONSIBILITIES:

6.1 Chemistry shift in charge is responsible for, running calibration and control and samples of CKMB
6.2 Chemistry staff are responsible for running CKMB samples all over the day.

7. APPENDICES:

7.1 N/A

8. REFERENCES:

8.1 Tietze Text Book of clinical chemistry and molecular diagnostics 4th Edition,2006
8.2 Company Leaflets of reagents

9. APPROVALS:

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