Specimen Collection and Storage

All specimens used in this test should be considered potentially infectious. Universal precautions as they apply to your facility should be used for handling and disposal of materials during and after testing. Clear unhemolyzed serum is the specimen of choice. No special additives or preservatives are required. Whenever possible specimens should be separated and analyzed on the day of collection. Store serum in capped tubes. CK-MB activity in serum is reportedly stable for 4 weeks, when stored in a dark area at -20°C. Since serum isothermally temperatures will result in a loss of activity, after 24 hours at 2-8°C, < 10%; after one hour at 15-30°C, < 10%. Extremely hemolyzed samples are not suitable for the test since they may contain high levels of adenylate kinase, ATP, and glucose-6-phosphate, which interfere with the assay to yield false results.

Interfering Substances: Ascorbic acid up to 30 mg/dL, conjugated bilirubin up to 10 mg/dL. 

Limitations

If the ∆% CK-MB Activity Activity is > 100%, then the CK-MB assay should not be used since it may contain high levels of adenylate kinase, ATP, and glucose-6-phosphate, which interfere with the assay to yield false results.

Materials Provided

CK-MB Liqui-UV® Buffer (R1) and CK-MB Liqui-UV® Enzyme (R2)

Material Required But Not Provided

Spectrophotometer capable of absorbance reading at 340 nm and 1 cm light path. 

Accuracy pipetting devices 

Automated Procedure

Applications for automated analyzers are available by contacting Stanbio’s Customer Service Department.

Manual Procedure

1. Allow reagents and specimens to equilibrate to ambient room temperature prior to use. 

2. Prepare CK-MB Working Reagent according to instructions (see Reagent Preparation section). 

3. Zero spectrophotometer at 340 nm with distilled water. 

4. For each sample and control, add 1.0 mL Working Reagent to cuvette or test tube and incubate at 37°C for 4 minutes. 

5. Add 40 μL of serum to its respective tube and mix gently. 

6. Read and record absorbance at 5 minutes. Continue incubating at 37°C and record absorbance again at 6, 7, 8, and 9 minutes. Rate should be nearly linear. 

7. Determine the average absorbance per minute (ΔA/min), multiply by the factor 8360 (4180 x 2) for results in U/L.

NOTE: If cuvette is not temperature controlled, incubate samples at 37°C between readings.

Calibration

Calibration is not required. If calibration is required by the instrument manufacturer, follow the calibration guidelines to calibrate your analyzer.

Quality Control: Stanbio recommends the use of commercially available controls with CK-MB values assayed by this method for verifying accuracy and precision. Controls containing non-human CK-MB fractions are not suitable to be applied with this test due to the monoclonal antibody used in the reagent. Use controls containing exclusively human CK-MB. CK-MB activity determined in these materials, by this procedure should fall within the ranges for the corresponding controls (Normal/Abnormal) of controls should be analyzed each day of the run.

Results

CK-B Activity: Values are derived based on the absorbivity micromolar extinction coefficient of NADP at 340 nm (0.0062). A unit per liter (U/L) of CK-B activity is that amount of enzyme that oxidizes one μmol/L of NADP per minute.

% CK-MB Activity = CK-MB Activity (U/L) x 100 

Total CK Activity (U/L)

Limitations

If the AA/min. is greater than 0.345, dilute 1 part sample with 9 parts saline and re-assay. Multiply the results by 10. CK values for neonatal patients have not been established with this procedure.

Expected Values

< 24 U/L (37°C) CK-MB activity is between 6 and 25% of total CK activity.

This range should serve only as a guideline. It is recommended that each laboratory establish its own range of expected values, since differences exist between instruments, laboratories, and local populations.

Performance Characteristics

Comparison: A group of 90 sera were assayed by the described CK-MB method and by a similar commercially available CK-MB reagent. Comparison of the results yielded a correlation coefficient of 1.00 and the regression equation was y = 1.00x + 0.28. Comparison studies were performed according to NCCLS Tentative Guideline, EP9-T.

Precision

Within-Run 

Total Precision

0.8 in 100 patients have not been established with this procedure.

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