The Development of a POCT Multilayer Analytical Film - Based Assay for Detection of Creatine Kinase MB Using CARESIDE Analyzer™
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I N T R O D U C T I O N

Introduction

Each CARESIDE™ CKMB cartridge consists of a CK-MB specific multi-layer reagent film mounted in a plastic base with a hinged lid. The user introduces the patient sample into the cartridge Sample Well, closes the lid, and inserts the cartridge into the CARESIDE Analyzer™. The sample volume is transferred to the test film as an air-tight film-ﬁlm contact. The film is automatically mounted into the reaction chamber of the Analyzer and the sample is automatically dispensed onto the multi-layer enzyme reaction film. The multi-layer reaction ﬁlm consists of a series of reagent layers separated by membrane layers. The layers include the spreading layer, a substrate layer, reaction layers, and a blocking layer. The spreading layer is a thin layer of inert material that helps to spread the sample uniformly over the reaction surface. The substrate layer is a layer of an inert material that helps to support the enzyme reactions. The reaction layers are layers of enzymes and substrates that are used to perform the enzyme reactions. The blocking layer is a layer of an inert material that helps to prevent the diffusion of enzymes and substrates from one layer to another.

Key POC Analyzer Features:

- Fast, easy-to-use, and accurate blood testing device that can be used at the point of patient care.
- Offers a broad menu of the most commonly ordered blood tests in the areas of chemistry, electrolyte, and hematology.
- Submission of results on screen, print cards in electronic file to disk, and to host computer via data port.

Key Test Cartridge Features:

- Requires only semi-quantitative transfer of sample volume to the test cartridge.
- Separates plasma from cells using centrifugal forces.
- Accurate metering and dispensing of sample using air pressure.
- Contains all necessary reagents for testing.
- Protects the user from exposure to biohazardous materials once the cartridge lid is closed.
- Inexpensive electronic and web-based QC for each analyte.
- Dry instrument QC using Rotech, Tachosch, and Testchoc cartridges on all LEDs and electrochemical channels.
- Common exterior design for future technologies of chemistry, electrochemistry, immunochemistry, and hematology.

ASSAY PERFORMANCE

Methodology

The CARESIDE™ CKMB test measures CK-MB activity using the immunometric method. In the spreading and electrochemical layer, the CK-MB activity is inhibited by the antibody to the CK-MB subunit. In the electrochemistry layer, the CK-MB enzyme reacts with adenosine triphosphate (ATP) and ADP yields creatine and ATP. The ATP then reacts with endogenous glucose in a hexokinase (HK) catalyzed reaction...

CLINICAL SIGNIFICANCE

Creatine kinase MB is an isoenzyme of creatine kinase (CK), also known as creatinokinase, is found in the heart muscle and skeletal muscle.

Key Test Carried by Patients:

- Comparison of Whole Blood and Plasma
- Comparison of Serum and Heparin Plasma
- CK-MB activity from sodium heparinized whole blood
- CK-MB activity from serum and heparin plasma

Key Parameters Assessed:

- Assay Validity
- Assay Performance
- Assay Interpretation
- Assay Stability
- Assay Accuracy
- Assay Precision
- Assay Sensitivity
- Assay Specificity
- Assay Linearity
- Assay Recovery

Conclusions

The CARESIDE™ CKMB is a reliable, rapid, and convenient dry film chemistry assay for measurement of Creatine Kinase MB in whole blood, serum, and plasma. The CARESIDE™ CKMB cartridge contains 9.5% of creatine kinase in blood plasma, or serum, and a test cartridge. The assay has a dynamic range of 1.0 to 1,000 U/L and levels of detection of 0.5 U/L. The assay is linear over the assay range as indicated by linear regression analyses of samples with mean slope of 1.00 ± 0.10 and the correlation coefficient within acceptable limits (0.95). The assay has significant lower inter and intra variation compared to other methods. In conclusion, evidence suggests that the CARESIDE™ CKMB assay is suitable for both research and routine use and has a wide range of applications.