Automated Point-of-Care (POC) Test for Glucose on the CARESIDE Analyzer™

Utilizing Dry Multi-layer Film and Unprocessed Human Whole Blood

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I N T R O D U C T I O N

Objectives

- Developed a dry multi-layer chemistry film assay and the CARESIDE Analyzer™ for the quantitative measurement of GLUCOSE from unprocessed human blood, plasma or serum.
- The method principle is based on glucose oxidase generation of hydrogen peroxide from glucose. Reaction of chromogen with hydrogen peroxide to form red dye.

Key POC Analyzer Features

- Fully automated, no standardization or calibration 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, electrolyrochemistry and coagulation.
- Requires only semi-quantitative transfer of sample volume to the test cartridge.
- Separates plasma from cells using centrifugation.
- Multi-technique detection technology (immunoassays, electrochemistry, & enzymatic chemistry).
- Automatically calibrated.
- Permits reliable operation by a non-laboratory healthcare professional.
- Reporting of results on screen, print cards, in electronic file to disk, and to host computer via data port.
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Key Test Cartridge Features

- Requires only semi-quantitative transfer of sample volume to the test cartridge.
- Separates plasma from cells using centrifugal force.
- Accurate metering and dispensing of reagents using air pressure.
- Contains all necessary reagents for testing.
- Protects the user from exposure to biohazards once the cartridge lid is closed.
- Incorporates electronic & wet/reagent QC for each analyte.
- Dry Instrument QC using Roche, Echog and Theraspec QC cartridges on all LED and electrochemicals.
- Common exterior design for five technologies: chemistry, electrolyrochemistry, coagulation, hematololgy and immunochemistry.

Procedure

1. The user doses the disposable cartridge directly with whole blood.
2. The assay kit contains the necessary detecting device, reagents, and disposable cartridge. The disposable cartridge contains a reagent and a chromogen to generate a colored product as measured by reflectance.
3. The assay cartridge is sealed and placed in a reader.
4. The reader interprets the color intensity of the sample and reports results.

INTRODUCTION ASSAY PERFORMANCE

ASSAY PERFORMANCE

Glucose Calibration Curve

The assay performance was determined with the following standard solutions: 20, 40, 80, 160, 320, and 640 mg/dL. The coefficient of determination was R² = 0.9976.

The results of two dry film assays, CARESIDE and J&J Vitros, showed excellent agreement throughout the reportable range.

Glucose Method Comparison

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Glucose Linearity Study

The glucose film exposed to ambient temperature and humidity up to 24 hours gave similar results. We recommend for opened package test cartridge to be used within 30 minutes.

Summary

- Dry film assay for plasma or serum GLUCOSE has been developed for use at the point of care on the CARESIDE Analyzer™.
- The user doses the disposable cartridge directly with whole blood and loads the cartridge into a small, automated device.
- The accuracy and precision of the CARESIDE Glucose test is equivalent to those achieved by large chemistry instruments used in the central laboratory.

ASSAY PERFORMANCE

Glucose Specimen Type Comparison

The POC glucose results showed excellent agreement to a large chemistry analyzer, such as the Hitachi Systems, using central and/or hospital laboratories.

Glucose Package Stability at Room Temperature

No significant interference was observed upon the blood specimens used for the above substances.

Glucose Stability at Room and Refrigerated Temperatures

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Interferent

- No significant interference was observed upon the blood specimens used for the above substances.

Precision

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