Automated Point-of-Care (POC) Test for Uric Acid on the CARESIDE Analyzer™ Utilizing Dry Multi-layer Film and Unprocessed Human Whole Blood
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Introduction

For in vitro diagnostic use in point of care analyzers to detect uric acid from anti-coagulated whole blood, plasma or serum specimen to aid in the diagnosis and treatment of gout.

Objectives

- Developed a dry multi-layer chemistry film assay and the CARESIDE Analyzer™ for the quantitative measurement of uric acid from unprocessed human blood, plasma or serum.
- Uric Acid is hydrolyzed by uricase to generate hydrogen peroxide. The leuco dye is changed to a blue color by oxidation of hydrogen peroxide in the presence of peroxidase (POD).

Analytical Method

- The color intensity, as measured by the amount of light reflected at 655 nm, is directly related to the amount of uric acid in the specimen.

Principle Of The Method

- Uric acid + O₂ + H₂O → Allantoin + H₂O₂ + CO₂

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Analyzer™ for the quantitative measurement of URIC ACID from unprocessed human blood, plasma or serum.
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Automated Point-of-Care (POC) Test for Uric Acid

- Objectives

- Reporting of results on screen, print cards, in electronic file to disk, and to host computer via data port.
- Permits reliable operation by a non-laboratory healthcare professional.
- Automatic calibration.
- Multiple detection technologies (reflectance, transmission, & electrochemical.)
- Onboard auto sample processing, metering, and dispensing; using whole blood, plasma, or serum as samples.
- Fast, easy-to-use, and accurate blood testing device that can be used at the point of patient care.

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, coagulation and immunology.

Key Test Cartridge Features

- Requires only semi-quantitative transfer of sample volume to the test cartridge.
- Separates plasma from cells using centrifugal force.
- Accommodates and disperses of sample 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.
- Protects the user from exposure to biohazards once the cartridge lid is closed.
- Accurate metering and dispensing of sample using air pressure.

Uric Acid Method Comparison

Specimen Type Comparison: CARESIDE - Dry Film Method

- Interferent: Bilirubin, Hemoglobin, Total Protein, Triglyceride, Ascorbic Acid, Triglycerides, Uric Acid
- Uric Acid Linearity Study

- Expected Values (mg/dL)

<table>
<thead>
<tr>
<th>Concentration (mg/dL)</th>
<th>Uric Acid Linearity Study</th>
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<td>20</td>
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Summary

- Dry film assay for plasma or serum URIC ACID 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 analyzer.
- The accuracy and precision of the CARESIDE Uric Acid test are equivalent to those achieved by large chemistry analyzers used in the central laboratory.