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

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INTRODUCTION

Objectives
Developed a dry multi-layer chemistry film assay and the CARESIDE Analyzer™ for the quantitative measurement of INORGANIC PHOSPHORUS in human blood, plasma or serum. The method principle is based on enzymatic generation of hydrogen peroxide from inorganic phosphorus. Reaction of chromogen with hydrogen peroxide to form blue dye.

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, electrochemistry and coagulation. (Hematology and immunochemistry to be released later in 2000.)
- Onboard auto sample processing, metering, and dispensing; using whole blood, plasma, or serum as samples.
- Multiple detection technologies (reflectance, transmission, & electrochemical).
- Automatic calibration.
- 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.
- Common exterior design for five technologies:
  - chemistry
  - electrochemistry
  - coagulation
  - hematology
  - immunochemistry
- Protects the user from exposure to biohazards once the cartridge lid is closed.
- Contains all necessary reagents for testing.
- Accurate metering and dispensing of sample using air pressure.
- Separates plasma from cells using centrifugal force.
- No significant interference was observed up to the levels indicated for the above substances.
- No significant interference was observed to Liberase, HEPES柠檬酸, calcium, and heparin.
- The accuracy and precision of the CARESIDE Phosphorus test are equivalent to those achieved by large chemistry analyzers used in the central laboratory.

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 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 analysis.
- Dry instrument QC using R-check, E-check, and T-check QC cartridges on all LED’s and electrochemical channels.
- Common exterior design for five technologies: chemistry, electrochemistry, coagulation, hematology and immunohematology.

Procedures:
- Add approximately three drops of blood or plasma, serum (5 ± 15 µL) into the INORGANIC PHOSPHORUS cartridge.
- Load the test cartridges up to six (cartridges) into the Analyzer.
- During the first 4.5 minutes, the Analyzer warms the cartridges to 37°C and separates plasma from cells using either whole blood or plasma.
- An 8.5 µL sample is precisely metered into the reagent wells.
- The dry reagents react with the sample to generate a colored product that appears within minutes on the film.
- The color intensity of the spot is measured by reflectance photometry.

Key Assay Characteristics:
- Specimen type: Whole blood plasma or serum
- Linear Range: 0.5 to 15 mg/dL
- Sample Volume: 8.5 ± 15 µL
- Incubation Temperature: 37°C
- Reaction Time: 5 min
- Wavelength: 655 nm
- Instrument: CARESIDE Analyzer

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Assay Performance

Inorganic Phosphorus Calibration Curve

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

Inorganic Phosphorus Method Comparison

The POC Inorganic Phosphorus results showed excellent agreement to a large chemistry analyzer, such as the Hitachi 9110 Analyzer.

Specimen Type Comparison

CARESIDE Dry Film Method

No significant interference was observed up to the levels indicated for the above substances.

Interference Physiologic

No significant interference was observed up to the levels indicated for the above substances.

Inorganic Phosphorus Linearity Study

Inorganic Phosphorus films exposed to ordered concentrations of sodium up to 24 hours gave linear results. The instrument for earned passage test cartridges to be used within 24 hours.

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