The Development of a POCT Multilayer Analytical Film - Based Assay for Detection of Magnesium for Use on the CARESIDE Analyzer™

Ashok K. Sawhney, Mirasol C. Conde, and Thomas H. Grove
CARESIDE Inc., 6100 Bristol Parkway, Culver City, CA. 90230.

Introduction
The CARESIDE™ Mg is a single-use disposable in vitro diagnostic test cartridge for assay of magnesium in whole blood, plasma, or serum. The Mg film slides, manufactured by E&G Plastics, are transparent support film mounted in a plastic base with a lanced lid, and are intended for point of care testing environments as well as professional laboratory use. The user introduces 70-100 mL of specimen into the cartridge sample well, closes the lid and inserts the cartridge into the analyzer.

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, electrophoresis, and coagulation. (Hematology and immunochemistry to be released later in 2000.)
- Reporting of results on screen, print cards, in electronic file to disk, and to host computer via data port.
- 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.
- Permits reliable operation by a non-laboratory healthcare professional.
- Automatic calibration.

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/real time control for each analyze.
- Dry instrument based on current microcontroller technology.
- Common exterior design for five technologies: chemistry, electrophoresis, coagulation, hematology and immunochemistry.

Materials and Methods

Principle of the Method
A. Reaction Sequence
Mg + ATP + Glycerol + ICE → MgATP + Glycerol
POD → ΔOD/min

MATERIALS AND METHODS

Expected Values (Reference Interval)

Table 1. Expected Values

<table>
<thead>
<tr>
<th>Component</th>
<th>Expected Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mg</td>
<td>1.0 - 2.2 mg/dL</td>
</tr>
</tbody>
</table>

Conclusion
The dry film assay for Magnesium in hemepurified whole blood, plasma, or serum has been developed for use in the CARESIDE™ analyzer that is suitable for point of care and alternative testing environments.

The non-clinical and clinical data provided demonstrate that the CARESIDE™ Mg product is as safe, effective, and performs as well or better than the large chemistry instruments used in the central laboratory.