FOR COAGUCHEK SYSTEMS

Introduction

The CoaguChek System is a portable, hand-held point-of-care blood coagulation testing system designed to provide accurate, rapid results of prothrombin time (PT) determination.

Test Procedure

The CoaguChek System, used exclusively with the CoaguChek test strips, is intended for the measurement of PT in whole blood. The test procedure involves placing a drop of whole blood on the test strip, followed by the reading of the PT result.

Quality Control

Quality control testing ensures the user’s technique, integrity of the test strips, and performance of the monitor and test strips. Daily quality control testing is good laboratory practice. It is also required by most states and by CLIA ’88 regulations. For one quality control test strip per day, the results must be within the designated range. You should refer to the appropriate licensing or accrediting bodies to ensure your quality control program meets the established standards.

Limitations of Procedure

Blood coagulation is one of the body’s protective responses. Blood clots (thrombi) form as a direct response to vessel injury. Many different substances and conditions are involved in blood coagulation. Thrombin is a key component of this process. Blood coagulation is a complex process involving several steps.

Sources of Error

• The test result may be affected by hematocrit values outside the normal range. For many tests, the hematocrit range is 40% to 55%.
• A normal range may be specified by the laboratory performing the test.

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FOR COAGUCHEK S SYSTEM

Tests

The CoaguChek S System is intended for in-vitro use.

Indications

There is no indication for use with the CoaguChek S System.

Introduction

Proprietary test strips are used with the CoaguChek S and System Monitors to measure a patient's prothrombin time (PT).

Test Strips

Test strips are only suitable for use with Cert. No. 311624748 Test Strips. Other test strips may not provide the expected accuracy.

Performance Characteristics

1. Each test strip lot is accompanied by a Lot Summary, which includes information such as: accuracy, precision, stability, and antigen recovery.

2. The test strip lot number is located in the upper left corner of each test strip. The lot number must be used in the analysis of test results.

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Performance Information

1. Please refer to the CoaguChek S System User’s Manual for additional information on performance characteristics.

2. The CoaguChek S System User’s Manual provides detailed information on performance characteristics, including accuracy, precision, and stability.

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6. The CoaguChek S System User’s Manual provides detailed information on performance characteristics, including accuracy, precision, and stability.

Preparation

1. Before testing, please refer to the CoaguChek S System User’s Manual for detailed instructions.

2. Before testing, please refer to the CoaguChek S System User’s Manual for detailed instructions.


4. Before testing, please refer to the CoaguChek S System User’s Manual for detailed instructions.

5. Before testing, please refer to the CoaguChek S System User’s Manual for detailed instructions.


Specimen Collection

1. Specimen collection is performed using the CoaguChek S System.

2. Specimen collection is performed using the CoaguChek S System.

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4. Specimen collection is performed using the CoaguChek S System.

5. Specimen collection is performed using the CoaguChek S System.

6. Specimen collection is performed using the CoaguChek S System.

Procedures

1. Perform procedures according to the CoaguChek S System User’s Manual.

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4. Perform procedures according to the CoaguChek S System User’s Manual.

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Analysis

1. Analysis is performed using the CoaguChek S System.

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Quality Control

1. Quality Control (QC) is performed using the CoaguChek S System.

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Slope CI (0.89, 0.98) Intercept CI (-0.10, 0.11) Correlation = 0.951

RSquared = 0.904 Std Error = 0.30 CoaguChek S INR

Table 1: Comparison of CoaguChek S INR to Lot 1 on MLA 700/1600

<table>
<thead>
<tr>
<th>Lot</th>
<th>CoaguChek S INR</th>
<th>MLA 700/1600 INR</th>
<th>Bias</th>
<th>T</th>
<th>P Value</th>
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<tr>
<td>1</td>
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<td>0.2</td>
<td>0.08</td>
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<tr>
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<td>3.3</td>
<td>3.1</td>
<td>0.2</td>
<td>0.00</td>
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</tr>
</tbody>
</table>

Additional Information

1. The CoaguChek S System User’s Manual provides additional information about performance characteristics.

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