The CARESIDE® Analyzer

**Introduction and Principle**

CARESIDE® Analyzer is a single-use disposable in vitro Prothrombin Time (PT) device. It reports the PT, PT Ratio, and the INR. The PT result is reported within 8.5 minutes after starting the test.

**Key CARESIDE Analyzer Features**

- Fast, easy to use in vitro diagnostic device that can be used at the point of patient care
- Offers a broad menu of the most commonly ordered tests in chemistry, electrolysis, and coagulation
- Onboard automatic sample processing, mixing, and dispensing with waste blood, plasma, and reagent from a single cartridge
- Multiple detection technologies (Reflectance, Transmission, and Electrochemistry)
- Automatic calibration
- Performs dry instrument QC using TCHEK QC cartridges
- Protects the user from exposure to biohazards once the cartridge lid is closed
- Results reported on the screen, print card, external printer, in electronic file to disk, and to host computer via a data port

**MATERIALS AND METHODS**

### Precision

Within-run, between-run, and total imprecision were determined using the hPSS, hPSC, Protein, and the hPAC Pathology PT Assay with PT calibrators and PT diluents on the MLA PT Analyzer. The hPSS PT was determined to be linear over the range of 10 to 600 seconds. The hPSC PT was determined to be linear from 0 to 300 seconds. The hPAC PT was determined to be linear from 10 to 500 seconds.

### Interference

Preparations of interfering and control matrices were prepared using platelet poor plasma and diluting it with an equal part of factor deficient plasma. The PT was determined using the CARESIDE PT test to determine the relative accuracy of the CARESIDE PT test to the MLA PT Analyzer. The interference was determined by measuring the relative change in PT of 10% from the control plasma to the factor depleted plasma.

### Method Comparison

The CARESIDE PT method was compared to results determined on the MLA Electra 900C using the Dade Innovin recombinant human tissue factor thromboplastin and following a protocol based upon the NCCLS Guideline EP9-T to determine the relative accuracy of the CARESIDE PT test reagent to the depletion of individual clotting factors in the extrinsic and common coagulation pathways. Interference was defined as a mean difference greater than 10% from the control plasma. No significant interference was observed up to 500 mg/dL hemoglobin, 20 mg/dL bilirubin, or 300 mg/dL triglycerides.

### Reference Interval/Sample Type Validation

The sensitivity of the CARESIDE PT test reagent to the depletion of the vitamin K dependent clotting factors II, VII, and X in the extrinsic and common coagulation pathways was assessed using the Factor Assay Reference samples. Factor deficient samples were prepared in the MLA PT Analyzer and diluted with an equal part of factor deficient plasma. The PT for each test sample was then tested in duplicate on both the MLA PT Analyzer and the MLA Innovin reference system. The logarithm of the PT for each sample was plotted against the logarithm of the PT determined by the MLA PT Analyzer. The first diluent was normally assigned 100% activity. Subsequent % factor activities corresponded to the dilution. The response to vitamin K dependent factor deficiencies for both tests is shown in Figure 5. The sensitivity of the CARESIDE PT test reagent is comparable to that of the reference system.

### PT Test Characteristics

<table>
<thead>
<tr>
<th>Factor Deficiency</th>
<th>MLA PT (Seconds)</th>
<th>CARESIDE PT (Seconds)</th>
</tr>
</thead>
<tbody>
<tr>
<td>II, VII, X</td>
<td>10.0</td>
<td>10.0</td>
</tr>
<tr>
<td>II</td>
<td>9.0</td>
<td>9.0</td>
</tr>
<tr>
<td>VII</td>
<td>8.0</td>
<td>8.0</td>
</tr>
<tr>
<td>X</td>
<td>7.0</td>
<td>7.0</td>
</tr>
<tr>
<td>IX, XI, XII</td>
<td>6.0</td>
<td>6.0</td>
</tr>
</tbody>
</table>

### Summary

The CARESIDE® PT analyzer is a reliable, rapid, and convenient coagulation assay for measurement of anticoagulation time in citrated whole blood and plasma. The test requires 370-350 mL of sample per PT cartridge and will provide a result up to 65% hematocrit. The test performance characteristics of the CARESIDE® PT Analyzer are superior to those of the MLA PT Analyzer and the MLA Innovin reference system. The PT test is sensitive to deficiencies of factors in the extrinsic and common coagulation pathways but is insensitive to those in the intrinsic coagulation pathway. In conclusion, the CARESIDE® PT test is a reliable, rapid, and convenient alternative to the MLA PT Analyzer for use on the CARESIDE® Analyzer.