**Coag-Sense Prothrombin Time (PT)/INR Professional Test Strip Kit- 50**

**Test Principle**

The Coag-Sense PT/INR system uses an in vitro diagnostic test to determine the Prothrombin Time (PT) results, expressed in seconds and

**Information**

**Warnings and Precautions**

1. Gather supplies: • Coag-Sense Meter • Coag-Sense PT Test Strip • Sample Transfer Tube or MiniTips and • Single-use Auto Lancet

2. Insert the low control strip and the meter will detect that it is a low control strip and prompt you to enter the control value in the Professional User's Manual.

3. Apply a drop of control activation (calcium chloride) solution to the sample well in the strip warming process changing the display to: "Ready Insert Strip." The time for completion of the warming process is approximately 50 seconds. The meter will beep to let you know it is ready for a sample and display the message "Apply Control Solution" and then "Apply Control Solution..." when it is ready for the control activation solution.

4. Testing has confirmed that PT/INR test results are not affected by: • Lactose up to 3000 mg/dL and Hemolysis up to 500 mg/dL.

5. The Coag-Sense PT/INR system is suitable for use in patients with the following medical conditions; Anemia, Polycythemia, Patients who are vitamin K-dependent and within range. It is important to store control strips with or in the same manner as test strips. The Coag-Sense PT/INR system should not be used if the patient is on heparin or Low Molecular Weight Heparin or any direct thrombin or Factor Xa inhibitor.

6. Very Low or Very High Test Results

   The Coag-Sense test strips provide test results if the INR value is between 0.8 and 8.0. Results between these ranges may not be confirmed using an alternate test method.

   The Coag-Sense PT/INR system uses direct clot detection technology to directly determine prothrombin time and INR. The test sample undergoes a series of reactions that result in a reaction with the thromboplatelet. The sample is applied to the test strip and rotate across a light beam. As the sample transforms into a solid clot, it is picked up by a spoke interrupting the light beam. This elapsed time from when the sample is applied to the test strip to when the clot is detected is the actual prothrombin time. No curve fitting algorithms or look-up tables are used.

   **Limitations of Procedure**

   The measuring range for the Coag-Sense PT/INR system is between 0.8 to 8.0. Results outside this range can not be confirmed using an alternate test method.

   The Coag-Sense PT/INR system should not be used if the patient is on heparin or Low Molecular Weight Heparin or any direct thrombin or Factor Xa inhibitor.

   The very low or very high ranges between 15-90 do not significantly affect results.

   Testing has confirmed that PT/INR test results are not affected by: • Bilirubin up to 20 mg/dL, Lipemia up to 3000 mg/dL and Hemolysis up to 500 mg/dL.

   In reagents, magnets, and pins, and pin analytic variables may affect prothrombin time test results. These factors should be considered when comparing results from different test methods. CoagSense can provide additional information regarding results.

   **Quality Control**

   Quality control is an important part of PT testing. The Coag-Sense Meter has been designed with multiple internal systems to ensure proper system function. When turned-on, the meter runs an extensive self-check protocol to assure, for example, that room temperature, timing, batteries, and INR calculations are correct. The meter is sensitive to deficiencies in vitamin K-dependent test methods. CoaguSense can provide additional information regarding results.
5. The meter will display “TESTING PLEASE WAIT” while the test is being performed.

6. In less than a minute the test will be complete and the meter will display “LO CONTL OK” and display PT results in seconds.

7. Repeat steps 2 through 6 using a High Control strip, display will read “HI CONTROL OK” and display PT results in seconds.

If control results are outside of the range for that level of control, the Coag-Sense Meter will display “CONTROL OUT OF RANGE.” If this occurs, repeat the test with a new control strip. If it is still outside the recommended range, it is usually an indication that the test strips have not been stored properly and have deteriorated. Refer to the Professional/Client’s Manual for further troubleshooting information or contact Technical Service at 1-866-903-0890.

Service and Support
The Professional User’s Manual contains more information about product use. If you need technical assistance or encounter unusual results, call Technical Service at 1-866-903-0890 24 hours a day.

Performance Characteristics
Reportable Range: The Coag-Sense PT/INR System has a PT reportable range of 0.8–8.0 INR. If the INR is outside the reportable range, 0.8 < INR > 8.0, an error message is displayed.

Capillary Accuracy and Precision Data: A clinical study was conducted across three different point-of-care sites where the Coag-Sense PT/INR system was compared against a Diagnostica Stago STA Compact Analyzer using Dade Innovin. The results comparison is as follows:

<table>
<thead>
<tr>
<th>Site</th>
<th>N</th>
<th>Slope</th>
<th>Intercept</th>
<th>Correlation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site 1</td>
<td>88</td>
<td>1.060</td>
<td>0.142</td>
<td>0.946</td>
</tr>
<tr>
<td>Site 2</td>
<td>187</td>
<td>1.078</td>
<td>0.050</td>
<td>0.947</td>
</tr>
<tr>
<td>Site 3</td>
<td>266</td>
<td>0.958</td>
<td>0.286</td>
<td>0.900</td>
</tr>
<tr>
<td>All Sites</td>
<td>541</td>
<td>1.015</td>
<td>0.179</td>
<td>0.924</td>
</tr>
</tbody>
</table>

Duplicate measurements obtained by Healthcare professionals across the three study sites using the Coag-Sense PT/INR system produced the following precision results:

<table>
<thead>
<tr>
<th>Sample</th>
<th>N</th>
<th>Mean INR</th>
<th>95% CI</th>
<th>Ave. CV%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capillary</td>
<td>220</td>
<td>2.55</td>
<td>2.12-2.94</td>
<td>2.53</td>
</tr>
</tbody>
</table>

Limited Warranty
CoaguSense, Inc. warrants that your Coag-Sense PT test strips will be free from defects in materials and workmanship until the product expiration date printed on the label if the test strips are stored and used in the manner described in this package insert and in your Professional/Client’s Manual. If, prior to the expiration date of the test strips, there is a defect in materials or workmanship, CoaguSense will replace the test strips free of charge. Your sole and exclusive remedy with respect to the strips shall be replacement. Any warranty claim should be directed to the CoaguSense Technical Service Center at 1-866-903-0890.

The above warranty is exclusive of all other warranties, and CoaguSense makes no other warranties, express or implied, including without limitation the implied warranty of merchantability or fitness for a particular purpose. In no event shall CoaguSense be liable to the purchaser or any other person for any incidental, consequential, indirect, special or punitive damages arising from or in any way connected with the purchase or use of the test strips, no warranty of merchantability or fitness for a particular purpose, if any, is implied for the sale of the test strips, shall extend for a longer duration than the expiration date of the test strips.

References

Elements of the Coag-Sense System (meter and test strips) and its use are covered by the following U.S. Patent: 7,235,213. Additional Patents pending. All product names and trademarks are the property of their respective owners.

Manufactured by:
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www.coagusense.com

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