


| Manufacturer and Product Information  |  |                        |                             |                      |           |                |                  |                   |           |                |                  |
|---|--|------------------------|-----------------------------|----------------------|-----------|----------------|------------------|-------------------|-----------|----------------|------------------|
| Mission Diagnostics<br>A Division of Diamond Diagnostics, 333 Fiske Street, Holliston, MA.<br><b>For Technical Assistance call:</b><br>Diamond Diagnostics Technical Services at 1-508-429-0450 |  |                        |                             |                      |           |                |                  |                   |           |                |                  |
| <b>Intended Use:</b>  | Mission Slope tHb is used to provide a tHb calibration point for Bayer/Ciba-Corning 288, 280 & 2500 Instruments.   |                        |                             |                      |           |                |                  |                   |           |                |                  |
| <b>Summary And Principle:</b>   | This product is intended to serve as a functional equivalent to pre-existing material distributed by the Original Equipment Manufacturer (OEM).  |                        |                             |                      |           |                |                  |                   |           |                |                  |
| <b>Reagents:</b>  | tHb Slope, CD-478514D, 30 x 2 mL   |                        |                             |                      |           |                |                  |                   |           |                |                  |
| <b>Containing:</b>  | tHb Slope is an aqueous solution containing amaranth and a viscosity adjuster.   |                        |                             |                      |           |                |                  |                   |           |                |                  |
| <b>For in vitro diagnostic use only</b>   |  |                        |                             |                      |           |                |                  |                   |           |                |                  |
| <b>Value Assignment:</b>  | Each reagent is tested for each calibrating analyte. tHb reference is made on the OEM Analyzer.  |                        |                             |                      |           |                |                  |                   |           |                |                  |
|   | <table border="0"> <tr> <td><b>tHb Values for:</b></td> <td><b>LOT R6C148 Exp 02/09</b></td> </tr> <tr> <td>Ciba-Corning 288/280</td> <td>13.9 g/dL</td> </tr> <tr> <td>    Expected Range</td> <td>13.7 - 14.1 g/dL</td> </tr> <tr> <td>Ciba-Corning 2500</td> <td>15.8 g/dL</td> </tr> <tr> <td>    Expected Range</td> <td>15.6 - 16.0 g/dL</td> </tr> </table> | <b>tHb Values for:</b> | <b>LOT R6C148 Exp 02/09</b> | Ciba-Corning 288/280 | 13.9 g/dL | Expected Range | 13.7 - 14.1 g/dL | Ciba-Corning 2500 | 15.8 g/dL | Expected Range | 15.6 - 16.0 g/dL |
| <b>tHb Values for:</b>  | <b>LOT R6C148 Exp 02/09</b>  |                        |                             |                      |           |                |                  |                   |           |                |                  |
| Ciba-Corning 288/280  | 13.9 g/dL  |                        |                             |                      |           |                |                  |                   |           |                |                  |
| Expected Range  | 13.7 - 14.1 g/dL   |                        |                             |                      |           |                |                  |                   |           |                |                  |
| Ciba-Corning 2500   | 15.8 g/dL  |                        |                             |                      |           |                |                  |                   |           |                |                  |
| Expected Range  | 15.6 - 16.0 g/dL   |                        |                             |                      |           |                |                  |                   |           |                |                  |
| <b>Cautions:</b>  | Exercise normal laboratory precautions. If contact occurs with skin, rinse affected area with water. If contact with eyes occurs, immediately rinse with copious amount of clean water or eye rinse. In cases of accidental ingestion, contact a physician immediately. Dye can be removed from clothes and skin by washing with warm soap and water.              |                        |                             |                      |           |                |                  |                   |           |                |                  |
| <b>Stability:</b>   | Product stability is listed on the product label. The product should not be used beyond this date. Store upright at room temperature, 18°- 25 °C. Store away from direct light.  |                        |                             |                      |           |                |                  |                   |           |                |                  |

| Procedure               |  |
|-------------------------|--|
| <b>Procedure:</b>       | The product is manufactured in a ready to use form. It is intended to serve as a direct replacement to pre-existing materials distributed by the OEM. For a detailed description of the use of this reagent, refer to the Instrument's Operator Manual.  |
| <b>Quality Control:</b> | Diamond Diagnostics suggests the use of commercially available control material with results assayed for the instrument used. Controls should be run at Normal and Abnormal levels. Diamond Diagnostics suggests measuring controls before patient samples are run and following instrument maintenance. |

| Limitations  |  |
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| <b>Limitations:</b>  | If the instrument fails calibration or controls do not measure within acceptable range when Diamond Diagnostics products are used, Diamond Diagnostics suggests the following: |
| Verify that the internal calibrators used to standardize the instrument are correct for the instrument, have adequate expiration, and do not contain visually evident contamination. |  |
| Follow the procedures delineated within the Operator's Manual listed under Troubleshooting.  |  |
| Ensure that all appropriate Maintenance Procedures, as listed in the Operator's Manual, have been performed.   |  |
| If problems still exist, contact Diamond Diagnostics' Technical Service Department.  |  |
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