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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>23D0365956      | <b>(X3) Date Survey Completed</b><br><br>12/18/2019 |
| <b>Name of Provider or Supplier</b><br><br>Steven D Trombly Md   | <b>Street Address, City, State</b><br><br>5195 15 Mile Rd, Sterling Heights, MI |   |
| For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency. |   |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>  |
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| <b>D5415</b>              | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br/>CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by:<br/>. Based on observation and interview with Testing Personnel #1 (TP1), the laboratory failed to label the hematology reagent with the name, contents, lot #, open date, and expiration date for the current reagent cube on the Beckman Coulter AcT diff hematology analyzer. Findings include: 1. During a tour of the laboratory on 12/18/19 at approximately 9:16 am, the surveyor observed a cube of reagent on a shelf below and connected to the Beckman Coulter AcT diff hematology analyzer. 2. The cube of reagent lacked documentation of the name of the reagent, contents, lot #, open date, and expiration date. 3. On 12/18/19 at approximately 9:16 am when queried, TP1 confirmed the reagent on the analyzer to be the Coulter diff Act Pak Reagent Kit which is "put on the analyzer at the beginning of each month." 4. During the interview on 12/18/19 at approximately 9:16 am, TP1 confirmed the hematology reagent cube on the hematology analyzer had no identification of it's name, contents, lot#, open date, and expiration date.</p> |