

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  23D0375684	<b>(X3) Date Survey Completed</b>  12/08/2020
<b>Name of Provider or Supplier</b>  Kathleen Knapp, Do Pc	<b>Street Address, City, State</b>  1320 Byron Rd, Howell, 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>
<b>D1000</b>	<p><b>CERTIFICATE OF WAIVER TESTS</b> CFR(s): 493.15(c)</p> <p>Certificate of waiver tests. A laboratory may qualify for a certificate of waiver under section 353 of the PHS Act if it restricts the tests that it performs to one or more of the following tests or examinations (or additional tests added to this list as provided under paragraph (d) of this section) and no others: (1) Dipstick or Tablet Reagent Urinalysis (non-automated) for the following: (i) Bilirubin; (ii) Glucose; (iii) Hemoglobin; (iv) Ketone; (v) Leukocytes; (vi) Nitrite; (vii) pH; (viii) Protein; (ix) Specific gravity; and (x) Urobilinogen. (2) Fecal occult blood; (3) Ovulation tests-visual color comparison tests for human luteinizing hormone; (4) Urine pregnancy tests - visual color comparison tests; (5) Erythrocyte sedimentation rate-non-automated; (6) Hemoglobin-copper sulfate-non-automated; (7) Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use; (8) Spun microhematocrit; and (9) Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout.</p> <p>This STANDARD is not met as evidenced by:</p> <p>. A. Based on record review and interviews, the laboratory failed to use the analyzer portion of the BD Veritor SARS-CoV-2 test system while testing for 1 (12/8/20) of 7 testing days. Findings include: 1. During a tour of the laboratory on 12/8/20 at 9:38 am, the surveyor requested to see the laboratory's BD Veritor System analyzer. 2. An interview on 12/8/20 at 9:38 am with Testing Personnel #1 revealed the analyzer was not in the office and the test system can be used without the analyzer. 3. A review of the laboratory's BD Veritor System For Rapid Detection of SARS-CoV-2 instructions for use revealed a section stating, "When specimens are processed and added to the test device, SARS-CoV-2 antigens present in the specimen bind to antibodies conjugated to detector particles in the test strip. The antigen-conjugate complexes migrate across the test strip to the reaction area and are captured by a line of antibodies bound on the membrane. A positive result is determined by the BD Veritor</p>

Plus Analyzer when antigen-conjugate is deposited at the Test "T" position and the Control "C" position on the assay device. the instrument analyzed and corrects for non-specific binding and detects positives not recognized by the unaided eye to provide an objective result." and a section stating, "The test is not intended to be interpreted visually." 4. An interview on 12/8/20 at 10:29 am with the Laboratory Director revealed she had brought the analyzer home and performed testing on a family member, but did not use the analyzer to read the result. Instead, the result was read visually from the test cartridge. B. Based on record review and interviews, the laboratory failed to use the BD Veritor SARS-CoV-2 test system in a laboratory certified under the Clinical Laboratory Improvement Amendments for 1 (12/8/20) of 7 testing dates. Findings include: 1. During a tour of the laboratory on 12/8/20 at 9:38 am, the surveyor requested to see the laboratory's BD Veritor System analyzer. 2. An interview on 12/8/20 at 9:38 am with Testing Personnel #1 revealed the analyzer was not in the office. 3. An interview on 12/8/20 at 9:50 am with the Laboratory Director revealed she brought the test system home to test a family member. 4. A review of the laboratory's BD Veritor System For Rapid Detection of SARS-CoV-2 instructions for use revealed a section stating, "In the USA, testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C 263a, that meet the requirements to perform moderate, high, or waived complexity tests." C. Based on record review and interview with Testing Personnel #1, the laboratory failed to issue authorized Fact Sheets with the BD Veritor System for Rapid Detection of SARS-CoV-2 test results for 10 of 10 patients tested. Findings include: 1. A review of the laboratory's BD Veritor System For Rapid Detection of SARS-CoV-2 instructions for use revealed a section stating, "Authorized laboratories using your product will include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media." 2. An interview on 12/8/20 at 10:51 am with Testing Personnel #1 revealed the laboratory does not give authorized Fact Sheets with test result reports.