

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  23D0036143	<b>(X3) Date Survey Completed</b>  12/14/2020
<b>Name of Provider or Supplier</b>  University Health Service	<b>Street Address, City, State</b>  207 Fletcher Street, Ann Arbor, 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: . Based on record review and interview with the General Supervisor, the laboratory failed to ensure all authorized Fact Sheets were included with patient test result reports as required by the manufacturer for 1 (November 2020 to December 2020) of 1 month the laboratory has been testing COVID-19 specimens. Findings include: 1. A review of the laboratory's "Xpert Xpress SARS-CoV-2/Flu/RSV" package insert revealed a section stating, "Authorized laboratories using your product will include with test result reports, all authorized Fact Sheets." 2. An interview on 12/14/20 at 1: 15 pm with the General Supervisor revealed the laboratory did not distribute the authorized fact sheets with patient test result reports.</p>
<b>D5411</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(a)</p>

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the General Supervisor, the point-of-care (POC) laboratories failed to implement, monitor, and document the room temperature and humidity readings for 2 (December 2018 to December 2020) of 2 years reviewed. Findings include: 1. During a tour of the four POC laboratories on 12/14/2020 at 9:36 AM, the surveyor noted the use of the following microscopes in the four laboratories: a. Treatment Center - Olympus CX 21 (room temperature 5 degrees to 40 degrees C (41 degree to 104 degree F); maximum relative humidity - 80%) b. Medical Center - Nikon Eclipse E200 (room temperature -0 to 40 degree C; maximum relative humidity 85%) c. Quick Clinic - Olympus CX 21 (room temperature 5 degrees to 40 degrees C (41 degree to 104 degree F); maximum relative humidity - 80%) d. Gynecological and Sexual Health - 2 Olympus CX 21 and a AO One-Ten (Olympus - room temperature 5 degrees to 40 degrees C (41 degree to 104 degree F); maximum relative humidity - 80%) 2. A record review for 2 (December 2018 to December 2020) of 2 years revealed a lack of documentation to show the POC laboratories had implemented, monitored, and documented the room temperature and humidity readings for the proper operation of the microscopes in use. 3. An interview on 12/14 /2020 at 9:40 AM, the General Supervisor confirmed the POC laboratories had not implemented the monitoring and documenting of the room temperature and humidity readings.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the General Supervisor, the Technical Consultant failed to assure personnel performing Potassium Hydroxide (KOH) and Wet Mount Preparations maintained their competency for 20 (Testing Personnel #1, 2, 3, 4, 5, 7, 8, 9, 10, 11, 13, 19, 20, 21, 22, 23, 24, 25, 26, and 27) of 27 testing personnel listed on the CMS-209 form. Findings include: 1. A review of the laboratory's competency assessments revealed the following testing personnel did not have documented competency assessments performed in 2019: a. Testing Personnel #1 b. Testing Personnel #2 c. Testing Personnel #3 d. Testing Personnel #4 e. Testing Personnel #5 f. Testing Personnel #7 g. Testing Personnel #8 h. Testing Personnel #9 i. Testing Personnel #10 j. Testing Personnel #11 k. Testing Personnel #19 l. Testing Personnel #20 m. Testing Personnel #21 n. Testing Personnel #22 o. Testing Personnel #23 p. Testing Personnel #24 q. Testing Personnel #25 r. Testing Personnel #26 s. Testing Personnel #27 2. A review of the laboratory's "PPM Competency Assessment" policy revealed a section stating, "Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. Annually, a designated observer will observe each PPM

provider perform testing. KOH and Wet Preps are the PPM testing done in UHS clinics. All steps of the procedures are observed and evaluated. Evaluation is recorded on the Provider Performed Microscopy Competency Checklist. 3. An interview on 12/14/20 at 10:17 am with the General Supervisor confirmed competency assessments had not been performed for the testing personnel listed above.