

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0682080	(X3) Date Survey Completed 04/12/2023
Name of Provider or Supplier Uw Milwaukee Student Health And Wellness Center	Street Address, City, State 2025 E Newport Ave, Milwaukee, WI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the verification studies completed for one of one new test system and interview with the technical consultant, the studies performed by the laboratory for the Horiba ABX Micros ES60 (ES60) hematology analyzer did not verify the manufacturer's reference intervals were appropriate for the laboratory's patient population and did not evaluate the accuracy and precision of the automated differential. Findings include: 1. Review of the verification studies for the ES60 analyzer showed no evidence of evaluation of the automated differential results produced by the analyzer and did not show evaluation of the reference ranges for any testing performed on the ES60. 2. Interview with the technical consultant on April 12, 2023 at 1:45 PM confirmed the ES60 validation study did not show the laboratory evaluated the reference ranges for any testing on the ES60. Further interview confirmed the laboratory also did not evaluate the automated differential results from the analyzer for accuracy or precision.</p>
D5447	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations</p>

Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on surveyor review of laboratory procedures and quality control (QC) records and interview with the technical consultant, the laboratory did not assay two control materials of different concentrations on twenty-one of twenty-one days of refractometer testing in October 2022. Findings include: 1. Review of laboratory procedures showed the laboratory referenced use of the refractometer for measuring urine specific gravity in the 'OSOM Card Pregnancy Test' Procedure. The procedure directed testing personnel to perform quality control once per day by placing a drop of distilled water (specific gravity 1.000) on the measuring prism. Review of other procedures showed the laboratory also referenced refractometer use in the procedure for urinalysis. The reviewed procedures showed no requirements for additional control testing with the refractometer. 2. Review of twenty-one QC records from October 2022 showed the laboratory obtained one QC result (1.000) each day on twenty-one days. 3. Interview with the technical consultant on April 12, 2023 at 11:30 AM confirmed the laboratory did not test two control materials of different concentrations prior to testing patient samples each day of testing.

D6013

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(3)(ii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:

Based on surveyor review of the verification studies performed for the Horiba ABX Micros ES60 (ES60) hematology analyzer and interview with the technical consultant, the laboratory director did not document review of the verification testing performed for the ES60 to ensure the analyzer was adequate for patient testing. Findings include: 1. Review of verification studies for the ES60 analyzer showed Verified Medical Research (VMR) evaluated the laboratory's collected data and identified three parameters (Hemoglobin, Hematocrit, and Platelet) with "Review Risks for Exceeding Limits". The report showed no indication the director reviewed the indicated parameters, and the laboratory director or technical consultant did not sign or date the report. 2. Further review showed the verification studies did not evaluate the ES60 automated differential testing. See D5421. 3. Interview with the technical consultant on April 12, 2023 at 1:45 PM confirmed the laboratory director did not approve and sign the verification report and confirmed the director did not ensure the verification procedures were adequate to determine the accuracy and precision of the ES60 test system.