

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0923388	(X3) Date Survey Completed 06/14/2022
Name of Provider or Supplier Uw Health-Stoughton	Street Address, City, State 1001 Nygaard St, Stoughton, 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
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) records from 2021 and 2022 and interview with the laboratory director, the laboratory did not document the verification of accuracy for ungraded cell identification proficiency test results in one of four PT events. Findings include: 1. Review of the laboratory's hematology PT records for 2021 (events one, two and three) and 2022 (event one) showed no evidence the laboratory evaluated the accuracy of ungraded cell identification challenges in event one in 2022. 2. Interview with the laboratory director on June 14, 2022 at 9:40 AM confirmed the laboratory did not document the evaluation of accuracy of ungraded cell identification PT results from event one in 2022. This is a repeat deficiency previously cited on December 2, 2020.</p>
D6029	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p> <p>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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the</p>

type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on surveyor review of the CMS (Centers for Medicare and Medicaid Services) Form 209 'Laboratory Personnel Report (CLIA)' and laboratory and personnel records, and interview with the laboratory director, the laboratory director did not ensure that four of four staff members who were new to this laboratory had demonstrated they could perform all testing operations reliably prior to testing patients' specimens. Findings include: 1. Review of the CMS Form 209 signed by the laboratory director on June 2, 2022 showed three testing personnel (staff A, B, and C) had not been testing in this laboratory at the time of the last survey. 2. Review of laboratory records showed staff D performed testing on patient one on June 13, 2022. 3. Review of competence and other personnel records showed no evidence that testing personnel A, B, C and D had demonstrated they could reliably perform and accurately report test results at this laboratory prior to testing patient samples. 4. Interview with the laboratory director on June 14, 2022 at approximately 10:30 AM confirmed staff D had performed testing at this location four times since March 2022. Interview also confirmed the director did not ensure testing personnel A, B, C, and D had demonstrated they could perform all testing operations reliably prior to testing patient samples at this laboratory.