

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0723896	(X3) Date Survey Completed 09/01/2021
Name of Provider or Supplier Uw Health-Yahara	Street Address, City, State 1050 E Broadway, Monona, 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
D6019	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv)</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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the hematology proficiency testing (PT) 'Evaluation Report' from College of American Pathologists (CAP) for the FH9-C 2020 event and laboratory PT records and interview with the laboratory director, the director did not ensure an approved corrective action plan was followed for one of one unacceptable result reported by the laboratory for cell identification. Findings include: 1. Review of the CAP 'Evaluation Report' for event FH9-C 2020 showed the laboratory reported "Lymphocyte" for image BCP-23. The expected result was Lymphocyte, Large Granular Lymphocyte, or Reactive. The result was graded "unacceptable". 2. Review of the laboratory's PT records for the event showed no evidence of review of the unacceptable result reported for BCP-23. 3. Interview with the laboratory director on September 1, 2021 at 1:00 PM confirmed the laboratory director did not ensure a corrective action plan was followed when the unacceptable result was received.</p>
D6054	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.</p>

This STANDARD is not met as evidenced by:

Based on surveyor review of competence evaluation records from 2019 and 2020 and interview with the laboratory director, two of the three primary testing personnel's records were not complete. Findings include: 1. Review of competence evaluation records for the three primary testing personnel showed the following records were not available: Staff A: Direct observation of automated hematology testing and manual white blood cell differentials were not documented in 2019. Staff B: Paper records showed the 2020 annual evaluation results were available on-line. On-line records for Staff B did not include the 2020 annual review. 2. Interview with the laboratory director, who is also a technical consultant, on September 1, 2021 at 3:15 PM confirmed the missing records for Staff A and Staff B were not available.