

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0393798	(X3) Date Survey Completed 06/24/2025
Name of Provider or Supplier Uw Health-Odana Atrium Family Medicine	Street Address, City, State 5618 Odana Rd, Madison, 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
D6070	<p>TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1)</p> <p>(b) Each individual performing moderate complexity testing must-- (b)(1) Follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results;</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of instrument printouts, test results in the electronic medical record (EMR), and procedures, observation of stained hematology slides, and interview with Testing Personnel (Staff A) and the Laboratory Director, Staff A did not follow the laboratory's procedures for performing a manual differential (MDIFF) when indicated for one of four patients test results reviewed. Findings include: 1. Review of patient result printouts from the Sysmex XN-430 analyzer showed the results for Patient 1 from June 24, 2025, at 9:40 AM included the direction to "Perform MDIFF, Refer Abnormal Cells". The report also included a White Blood Cell (WBC) Interpretive Program (IP) Message: "Lymphocytosis". The analyzer result printout showed the absolute lymphocyte count was 12.19 cells x 10³ / microliter (uL). 2. Review of test results in the EMR for Patient 1 showed hematology test results from June 24, 2025, from the Sysmex analyzer. Further review showed no record of results from a manual differential. 3. The 'Sysmex XN-400 Series Hematology Procedure' (effective Date April 7, 2025) in Section VIII, Procedure, step A.2.h., directed testing personnel to review flags and action comments on the result printout to determine whether the sample required repeat or further testing. Appendix 1 of the procedure showed results with an absolute lymphocyte count greater than or equal to 5.0 cells x 10³ / uL required performance of a manual differential and referral to the reference laboratory if personnel saw abnormal cells on the differential. 4. Observation in the laboratory of stained hematology slides on June 24, 2025, at 12:45 PM revealed no evidence testing personnel had made a slide to perform a manual differential for Patient 1. 5. Interview with Staff A on June 24, 2025, at 12:45 PM</p>

confirmed they did not perform a manual differential as required for Patient 1. 6. Interview with the Laboratory Director on June 24, 2025, at 12:45 PM confirmed Staff A did not follow the laboratory's procedures for reviewing results and performing a manual differential when required.

D6072

TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1425(b)(3)

(b)(3) Adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed;

This STANDARD is not met as evidenced by:

Based on surveyor observation of controls in the laboratory, review of procedures and laboratory records, and interview with Testing Personnel (Staff A) and the Laboratory Director, Staff A did not follow the laboratory's quality control policies and did not document all quality control activities for three of three hematology controls vials in use for the Sysmex hematology analyzer. Findings include: 1. Observation of three vials of Sysmex hematology controls in the laboratory refrigerator on June 24, 2025, at 9:15 AM revealed the vials did not include the date opened or the expiration date. 2. Review of the 'Sysmex XN-400 Series Hematology Procedure' in Section VII, Quality Assurance, step 2.c. showed the procedure required: "Label vials with the date opened and the 15 day outdates and tech initials." Step 2.d. showed: "New control vials are started every other Monday morning and discarded at the end of the second week (14 days)." 3. Interview with Staff A on June 24, 2025, at 9:15 AM revealed Staff A opened the three control vials on the morning of Tuesday, June 24, 2025, and confirmed they had not labeled the vials with the open and expiration dates. 4. Review of the 'Maintenance Tasks: Sysmex XN Satellite Series' maintenance log showed the log included, "Every other Monday: open new controls". The log showed controls were opened on June 9, 2024, and showed no indication testing personnel opened new controls on Monday, June 23, or Tuesday, June 24, 2025. 5. Interview with the Laboratory Director on June 24, 2025, at 9:30 AM confirmed Staff A did not follow the laboratory's quality control procedures for opening and labeling controls and did not document the opening of the control vials on the maintenance log.