

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D0857041	<b>(X3) Date Survey Completed</b>  03/27/2025
<b>Name of Provider or Supplier</b>  Andalusia Family Practice	<b>Street Address, City, State</b>  712 East Three Notch Street, Andalusia, AL	
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>D2009</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Wisconsin State Laboratory of Hygiene (WSLH) Proficiency Testing (PT) records and an interview with Testing Personnel 1 (TP1), the surveyor determined the Laboratory Director (or Designee) failed to sign the Attestation statements for six out of the six survey events. The findings include: 1. A review of the 2023-2024 WSLH PT records revealed the TP examining the PT samples had signed the Attestation statements but were not signed by the Laboratory Director (or Designee) for the following PT events: A) 2023 Hematology Events #1, #2, and #3 B) 2024 Hematology Events #1, #2, and #3 2. A further review of the WSLH PT Handbook under General Information, Ten Steps to Successful Proficiency Testing, page 5, revealed the following instructions: 7. Resulting PT samples: "Have the attestation statement signed by the testing personnel and the laboratory director." 3. TP1 confirmed the above findings during the exit conference on 03-27-2025 at 12:30 PM.</p>
<b>D5211</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on a review of the Wisconsin State Laboratory of Hygiene (WSLH) Proficiency Testing (PT) records and an interview with the Testing Personnel 1 (TP1), the laboratory failed to ensure review and evaluation of PT performance results for the Hematology specialty. This was noted for six out of the six events reviewed from 2023 through 2024. The findings include: 1. A review of the 2023-2024 WSLH PT records revealed no documentation of the Hematology PT results review from the Laboratory Director, or designee, for the following surveys. A) 2023 Hematology Events #1, #2, and #3 B) 2024 Hematology Events #1, #2, and #3 2. A further review of the WSLH PT Handbook under General Information, Ten Steps to Successful Proficiency Testing, page 5, revealed the following instructions: 9. When your report comes back: Review the entire report (evaluation, event notes...) 3. TP1 confirmed the above findings during the exit conference on 03-27-2025 at 12:30 PM.

**D5417**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(d)

(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:  
Based on direct observation and an interview with the Testing Personnel 1 (TP1), the surveyor determined the laboratory utilized expired EDM3 Solutions HealthLink Potassium Hydroxide (KOH) 10 percent reagent for the Provider Performed Microscopy (PPM). The expired date was noted on the reagent bottle to the current date of the survey on 03-27-2025. The surveyor noted the reagent had been expired since before the previous survey on 2-8-2023. The findings include: 1. During the laboratory tour with TP1 at approximately 8:30 AM, the surveyor observed KOH reagent, Lot 0310 with Expiration date of 11-05-2022. No open date was written on the bottle. 2. A further review revealed the laboratory did not have any unexpired KOH solution on site. TP1 stated the volume for the KOH patient testing was so low during the past years, the laboratory had not ordered any new reagent. 3. An interview with TP1 revealed 20 KOH preps on patients had been performed since the previous survey on 2-8-2023. No patient log was available for review at the time of the survey. 4. TP1 confirmed the above findings during the exit conference on 03-27-2025 at 12:30 PM.

**D5431**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(a)(2)

(a)(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturers established limits before patient testing is conducted. (b) Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer. The laboratory must do the following:

This STANDARD is not met as evidenced by:  
Based on review of maintenance records and an interview with Testing Personnel 1 (TP1), the laboratory failed to perform and document maintenance on the microscope the Laboratory Director (LD) utilized for Provider Performed Microscopy (PPM). The

surveyor noted there was no documentation of microscope maintenance from the date of the previous survey on 2-8-2023 to the date of the current survey on 3-27-2025. The findings include: 1. A review of maintenance records revealed no documentation of microscope maintenance from 2023 to 2025. 2. During the interview with TP1 on 03-27-2025 at 11:37 AM, she stated the LD performed the microscope maintenance and function checks whenever needed, however the LD had not recorded them. 3. TP1 confirmed the above findings during the exit conference on 03-27-2025 at 12:30 PM.