

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 18D1041932	(X3) Date Survey Completed 09/02/2025
Name of Provider or Supplier Oldham County Pediatrics	Street Address, City, State 9710 Park Plaza Suite 107, Louisville, KY	
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
D0000	A recertification survey was initiated on 09/02/2025. The facility was found to not be in compliance with the laboratory requirements of 42 CFR Part 493 with standard deficiencies cited.
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, review of Sysmex XP-300 Hematology Analyzer instructions for use, laboratory maintenance records, and staff interview, the laboratory failed to document weekly maintenance for 3 of 5 months reviewed. During a tour of the laboratory on 9/2/2025 at 2:40 PM, a Sysmex XP-300 Hematology Analyzer (Serial Number C2776) was observed to be in use. Review of the Sysmex XP-300 instructions for use stated, "to ensure proper functioning of the instrument, it is necessary to periodically clean and service the instrument. Perform maintenance according to the schedule below. And record the results in the Maintenance checklist." The laboratory maintenance logs stated, "Weekly - Clean SRV tray." Further review of the laboratory maintenance records revealed the laboratory failed to document performance of the weekly maintenance for the following: December 2024 - Week 1,2,3,4 March 2025 - Week 1,2,3,4 July 2025 - Week 2,3,4 In an interview on 9/2/2025 at 3:30 PM in the office area, the Testing Personnel 1 (TP1) was asked to provide documentation of weekly maintenance for the Sysmex XP-300. No documentation was provided. This confirmed the findings.</p>
D6018	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</p>

(e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; and

This STANDARD is not met as evidenced by:

Based on review of laboratory policy, quarterly assessment checklist, proficiency testing (PT) documents, and staff interview, the laboratory failed to review 6 of 12 proficiency testing events in Microbiology and Hematology from 2023, 2024, and 2025. Review of the Laboratory Policy and Procedure Manual, section Quality Assurance Plan, stated, "The laboratory reviews all proficiency testing results to identify any problems that require remedial action." Review of Quarterly Assessment Checklist 2023/2024/2025, stated, "Proficiency tests results were evaluated, failures were investigated, and corrective action was taken on all results that were not 100%." Review of Proficiency Testing (PT) from the American Proficiency Institute (API) for 2023, 2024, and 2025 for Hematology/Coagulation and Microbiology revealed the following: 2023 Microbiology 3rd Event - no evaluation 2024 Hematology/Coagulation 2nd Event - no evaluation 2024 Microbiology 3rd Event - no evaluation 2024 Hematology/Coagulation 3rd Event - no evaluation 2025 Microbiology 1st Event - no evaluation 2025 Hematology/Coagulation 1st Event - no evaluation In an interview on 09/02/2025 at 3:15 PM, the Testing Personnel 1 stated the PT reports were not signed or otherwise noted as being reviewed by the Laboratory Director and/or their designee. This confirmed the findings.