

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  18D1041932	<b>(X3) Date Survey Completed</b>  08/30/2023
<b>Name of Provider or Supplier</b>  Oldham County Pediatrics	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A Recertification Survey was initiated and concluded on 08/30/2023. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
<b>D5421</b>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on observation, policy review, and interview, the laboratory failed to document the verification of accuracy for one (1) of one (1) new instruments used (Sysmex XP-300 hematology analyzer). The findings include: During an observation, on 08/30/2023 at 9:35 AM, a Sysmex XP-300 hematology analyzer was present and available for use. Review of the undated "Laboratory Policy and Procedure Manual," revealed there was not a procedure that defined how to perform and verify accuracy of the hematology analyzer. In an interview on 08/30/2023 at 9:35 AM, Testing Personnel (TP) #1 and TP #2, as listed on the CMS-209, stated the hematology analyzer had been installed on 05/05/2022 and placed into use for patient testing, effective 05/09/2022. Approximately 400 CBCs were performed from the date of installation through the date of the survey. In continued interview on 08/30/2023 at 12:35 PM, TP #1 and TP #2 stated they were unaware of the requirement to perform an accuracy study as part of the test method change.</p>