

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  04D2284065	<b>(X3) Date Survey Completed</b>  05/13/2025
<b>Name of Provider or Supplier</b>  Westside Family Clinic, Llc	<b>Street Address, City, State</b>  3812 W Main St, Russellville, AR	
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>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based upon observation, review of policy and procedure, review of quality control (QC) reports for complete blood cell analysis (CBC), lack of documentation, and interview with laboratory staff, the laboratory procedures for QC and corrective action to take when QC results fail to meet the laboratory's criteria for acceptability were not followed and did not accurately reflect the laboratory's practice. Findings follow: A) During a tour of the laboratory on 5.13/25 at 10:05 a.m., a Coulter DxH 520 Hematology analyzer was observed in the laboratory room and was the only instrument in the laboratory capable of performing CBC analysis. B) Review of the manufacturer's user manual revealed that tri-level Coulter 6C Cell Control was to be used for performing QC. C) Review of the laboratory's policy and procedure manual revealed the "Quality Control Evaluation Process" policy stated that two levels of QC material are to be run daily and both levels must be within acceptable range before releasing patient results. Steps for corrective action to be taken if one or both levels were outside acceptable range were described, that the steps taken must be "recorded in the daily QC data or occurrence log". D) Review of QC records for the months of July 2024, November 2024, and March 2025 revealed that three levels of QC material were performed daily and there occurrences of a single level having recorded ranges outside the range for acceptability, indicated by a "H" or "L" flag, the unacceptable levels were not repeated and recorded as acceptable, and a hand-writtten notification was on the record stating "other 2 levels OK" on three of three months reviewed . E) Upon request, the laboratory could not provide additional policies and procedures that</p>

defined unacceptable quality control results and corrective actions to take in the event of control failures for CBC analysis. F) In an interview on May 13, 2025, at 1:43 p.m. the laboratory staff member (# 3 on form CMS 209) stated when only one level of the tri-level control material was outside acceptable range and the other two levels are acceptable, that she releases patient results, that she was instructed during her initial training to do so, and that written policies and procedures to that effect were not available.