

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 04D2173838	<b>(X3) Date Survey Completed</b> 04/07/2021
<b>Name of Provider or Supplier</b> Salem Family Clinic P A	<b>Street Address, City, State</b> 507 N Main St, Salem, 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>D2007</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by:                      . Through a review of the form CMS-209 (Laboratory Personnel Report), the testing personnel authorizations to test, a review of proficiency test documentation for 2020 and 2021, as well as interviews with staff, it was determined proficiency testing samples were not tested by all personnel who routinely perform patient testing. Survey findings include: A. A review of the authorizations for testing revealed personnel #2, #3, and #4 ( as listed on form CMS-209) were authorized by the Laboratory Director to perform moderate complexity complete blood counts. B. A review of 2020 and 2021 Proficiency testing attestation statements (four of four events) revealed all proficiency testing in 2020 and 2021 was performed by testing personnel #2. There was no documentation that testing personnel #3, or #4 had performed proficiency testing an any event in 2020 or 2021. C. In an interview at 1:29 p.m. on 4/7/2021 laboratory technical consultant (#5 as listed on the CMS-209) confirmed that laboratory personnel #3, and #4 had not performed proficiency testing in 2020 or 2021.</p>
<b>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p>

This STANDARD is not met as evidenced by:  
. Through a review of temperature records for 2020 and 2021, lack of documentation, as well as interview with laboratory staff, it was determined the laboratory failed to retain refrigerator temperature records for at least two years. Survey findings include: A. A review of temperature records for 2020 revealed the laboratory failed to retain twelve of twelve months of refrigerator temperature records. B. In an interview at 2:38 on 4/7/2021, the technical consultant (as listed on form CMS-209) confirmed the laboratory was unable to produce the temperature records for 2020.

**D5813**

**TEST REPORT**  
CFR(s): 493.1291(g)

The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values.

This STANDARD is not met as evidenced by:  
Through a review of the laboratory panic value policy, a review of the hematology instrument datalog and patient medical records, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to have documentation that the healthcare provider was notified of panic values. Survey findings include: A. The laboratory panic value policy states that a White Blood Cell count (WBC) less than 3.0 and hemoglobin results less than 7 should be treated as panic values. The policy further states all panic value results will be repeated before reporting the results to the provider. B. Two of two panic value results, observed on the instrument datalog, failed to have documentation that the policy was followed. The medical record of Patient #9139 does not include documentation that the provider was notified of the patient's hemoglobin result of 6.2 on 9/1//2020. A patient tested on 7/31/2020 had a WBC reported as 2.7. There was no medical record number recorded on the data log for this patient and the laboratory was unable to determine the identity of the patient in order to provide documentation that the result was immediately reported to the provider There is no documentation of repeat testing on either sample to confirm the panic values. D. In an interview at 2:45 on 4/7/2021, the technical consultant confirmed the lack of documentation that the panic value policy had been followed and the patients healthcare provider had been notified in two of two patients with panic values reported.