

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D1060221	(X3) Date Survey Completed 01/25/2024
Name of Provider or Supplier White River Health Family Care	Street Address, City, State 2200 Malcolm Avenue Suite B, Newport, AR	
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
D5779	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(a)</p> <p>Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.</p> <p>This STANDARD is not met as evidenced by: Through a review of laboratory policies and procedures, review of quality control (QC) results for Blood Urea Nitrogen (BUN) for May 2023, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to follow written policies and procedures for corrective actions when chemistry quality control results failed to meet acceptable criteria. Survey findings follow: A) A review of the laboratory general policies and procedures revealed that when chemistry quality controls failed to meet the acceptable criteria "if repeated result is still out of range documented corrective action should be initiated". B) A review of QC results for BUN assays performed in May 2023 revealed that on 5/1/23 MAS Chem TRAK QC material lot # 24083 was resulted above acceptable range at 07:43 a.m., repeated at 08:27 a.m. and, 08:35 a.m. before being acceptable at 08:44 a.m. C) Upon request, the laboratory was unable to provide the corrective action taken to bring the controls identified above into acceptable range. . D) In an interview at 01:17 p.m. on 1/25/24, laboratory staff member (#2 as listed on the form CMS-209) confirmed the lack of written corrective action for the chemistry quality control failure identified above.</p>
D5783	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test</p>

results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

Through review of the Total Bilirubin (TBil) quality control (QC) summary reports for May 2023, the laboratory policy and procedure for quality control of chemistry assays lack of documentation and interview with laboratory staff it was determined that the laboratory failed to evaluate patient results since the last successful QC performance in one of one occasions when QC results failed to meet the laboratory's criteria for acceptability and corrective action required making changes in the laboratory's test systems. Findings follow: A) Review of QC results for TBil testing for May 2023 revealed that on 5/30/23 level 1 MAS ChemTRAK lot # 24081 QC material with acceptable limits for TBil assay of (.54 to 1.14) was resulted as 1.3 at 07:44 a.m., as 1.3, at 08:24 a.m. before being acceptable as 0.7 at 08:27 a.m..The note of corrective action stated "end of cup will switch" which represented a change in the test system. The last successful QC for TBil was recorded on 5/25/23 at 08:18 a.m. , B) Review of the laboratory policy for quality control of chemistry assays states previous patient results must be evaluated to determine if the reason for the QC failure may have had an adverse impact on patient results since the last successful QC run. C) Review of patient results for TBil revealed nine patients (identified as numbers 1 through 9 on a separate patient identification list had TBil assays performed since the last acceptable QC. D) Upon request, the laboratory was unable to provide documentation that the tests results identified above had been evaluated. E) In an interview in 1/25/23 at 01:17.p.m. the laboratory staff member (# 2 on the CMS 209 form) confirmed that the consecutive QC failures identified above did not have previous result evaluation documented and should have had as per laboratory policy.