

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0887547	(X3) Date Survey Completed 09/06/2024
Name of Provider or Supplier Dexter Medical Clinic	Street Address, City, State 610 North One Mile Road, Dexter, MO	
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
D5421	<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 review of the performance verification procedures for the Alcor Scientific mini iSED erythrocyte sedimentation rate (ESR) analyzer, patient results and interview with the laboratory director (LD), the laboratory failed to verify performance specifications prior to reporting patient test results. Findings: 1. Review of the performance specifications for the Alcor Scientific mini iSED ESR analyzer showed the laboratory failed to verify that the manufacturer's reference intervals (normal ranges) were appropriate for the laboratory's patient population prior to the beginning of patient testing in June 2024. 2. Review of patient results from June 2024 to date September 3, 2024 showed approximately ten ESR patient results were reported. 3. Interview with the LD on September 3, 2024 at 11:30 AM confirmed the laboratory failed to verify performance specifications prior to reporting patient test results.</p>
D5807	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests</p>

and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's reference range procedure, patient reports and interview with the laboratory director (LD), the laboratory failed to ensure the procedure manual reference ranges matched the references ranges on the patient reports. Findings: 1. Review of the laboratory's "Laboratory Reference Ranges" procedure showed the reference ranges as: Glucose 74 - 110 mg/dL Blood Urea Nitrogen (BUN) 7 - 18 mg/dL Creatinine 0.55 - 1.30 mg/dL Sodium 136 - 145 mmol /L Potassium 3.5 - 5.1 mmol/L Chloride 98 - 107 mmol/L ECO2- Enzymatic Carbonate 21.0 - 32.0 mmol/L Calcium 8.5 - 10.1 mg/dL Total Protein 6.4 - 8.2 g/dL Albumin 3.4 - 5.0 g/dL Aspartate Aminotransferase (AST/SGOT) 15 - 37 U/L Bilirubin, Total 0.2 - 1.0 mg/dL Alkaline Phosphatase 46 - 116 U/L Alanine Aminotransferase (ALT/AST) 12 - 48 U/L 2. Review of the patient reports showed the reference ranges as: Glucose 75 - 109 mg/dL Blood Urea Nitrogen (BUN) 8 - 17 mg/dL Creatinine 0.56 - 1.29 mg/dL Sodium 137 - 144 mmol/L Potassium 3.6 - 5.0 mmol/L Chloride 99 - 106 mmol/L ECO2- Enzymatic Carbonate 21.1 - 31.9 mmol/L Calcium 8.6 - 10.0 mg/dL Total Protein 6.5 - 8.1 g/dL Albumin 3.5 - 4.9 g/dL Aspartate Aminotransferase (AST/SGOT) 16 - 36 U/L Bilirubin, Total 0.3 - 0.9 mg /dL Alkaline Phosphatase 47 - 115 U/L Alanine Aminotransferase (ALT/AST) 13 - 47 U/L 3. Interview with the laboratory director (LD) on September 3, 2024 at 11:30 AM confirmed that the laboratory's procedure reference ranges did not match the patient report reference ranges.