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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 52D2171289 | (X3) Date Survey Completed 03/05/2024 |
| Name of Provider or Supplier Oakleaf Clinics- Chippewa | Street Address, City, State 855 Lakeland Drive, Chippewa Falls, WI | |
| 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 surveyor review of laboratory records and interview with the Laboratory Supervisor (Staff A), the laboratory did not evaluate two of the four required performance characteristics (precision and reference intervals) and did not evaluate the remaining performance characteristics (accuracy and reportable range) prior to reporting patient test results with the Diesse MINI-CUBE ESR (Erythrocyte Sedimentation Rate) analyzer used for patient testing starting on October 12, 2022. Findings include: 1. Review of the verification documentation for the MINI-CUBE ESR analyzer showed the laboratory performed comparison studies that the laboratory director approved on November 10, 2022. The documentation showed no evidence the laboratory evaluated precision or the reference intervals (normal values) of the analyzer. 2. Interview with Staff A on March 5, 2024, at 1:00 PM confirmed the verification studies did not show evaluation of precision or reference ranges. Email communication with Staff A on March 8, 2024, at 10:58 AM confirmed the laboratory reported patient test results with the MINI-CUBE ESR analyzer starting on October 12, 2022.</p> |