

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 28D0455722	(X3) Date Survey Completed 09/06/2023
Name of Provider or Supplier Franciscan Healthcare	Street Address, City, State 430 North Monitor Street, West Point, NE	
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 new instrumentation list, list of tests performed, lack of documentation, and interview with the technical consultant, the laboratory failed to verify precision on the laboratory's new sedimentation rate analyzer, Mini Sed. 1. Review of new instrumentation list revealed the laboratory started patient testing on February 2022 on the new sedimentation rate analyzer, Mini Sed. 2. Review of the laboratory's list of test performed revealed the laboratory had tested 608 patients using the new sedimentation rate analyzer. 3. Review of the validation of performance specifications for the new sedimentation rate analyzer revealed no run to run precision studies had been performed. 4. Interview with the technical consultant on 9/6/2023 at 2:28 PM confirmed run to run precision was not performed prior to patient testing.</p>
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)</p>

-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on review of laboratory's quality control, lack of calibration verification records, list of tests performed, and an interview with the technical consultant the laboratory failed to perform calibration verification every six months for urine sodium and urine creatinine tested on the chemistry instrument. Findings are: 1. The laboratory's quality control records for September 2023 revealed the laboratory performed two levels of controls for urine sodium and urine creatinine. 2. Review of calibration verification records for the chemistry instrument in use revealed, no calibration verification records for urine sodium and urine creatinine. 3. Review of the laboratory's list of tests performed revealed, the laboratory performed fourteen urine sodium tests and thirty-eight urine creatinine tests. 4. Interview with the technical supervisor on 9/6/2023 at 2:09 PM, confirmed the laboratory did not perform calibration verification for urine sodium and urine creatinine.