

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 35D0409330	(X3) Date Survey Completed 03/12/2019
Name of Provider or Supplier Trenton Community Clinic	Street Address, City, State 331 4th Ave E, Trenton, ND	
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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on record review, policy review, and staff interview, the laboratory failed to enroll in proficiency testing for 1 of 1 regulated immunology tests (rheumatoid factor) performed in 2018. The laboratory performed approximately 11 patient tests since beginning rheumatoid factor testing in the fall of 2018. Findings include: 1. Reviewed at approximately 11:25 a.m. on 03/11/19, the 2018 proficiency testing records indicated the laboratory had not participated in proficiency testing for rheumatoid factor. 2. Reviewed at approximately 12:30 p.m. on 03/11/19, a "2019 Order Confirmation," dated 09/11/18, from the laboratory's proficiency testing vendor failed to include rheumatoid factor testing. 3. Reviewed at approximately 9:20 a.m. on 03/12/19, the undated policies "Proficiency Testing" and "Evaluation of New Equipment, New Test Methods Or Modifications to Test Methods or Procedures" failed to include a requirement to ensure enrollment of regulated analytes in proficiency testing. 4. During interview at approximately 10:00 a.m. on 03/12/19, a testing personnel (#1) stated the laboratory began rheumatoid factor patient testing last fall and did not have evidence of proficiency testing enrollment for rheumatoid factor.</p>
D2009	TESTING OF PROFICIENCY TESTING SAMPLES

CFR(s): 493.801(b)(1)

The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.

This STANDARD is not met as evidenced by:

Based on record review, staff interview, and policy review, the laboratory failed to ensure the testing personnel signed the attestation statements for 3 of 6 (1-2018 and 2-2018 for core chemistry and 2-2018 for coagulation/hematology) proficiency testing events reviewed from 2018. Findings include: 1. Reviewed at 11:25 a.m. on 03/11/19, the 2018 proficiency testing records lacked evidence the testing personnel signed the proficiency testing attestation statements for the following events: 1-2018 and 2-2018 for core chemistry and 2-2018 for coagulation/hematology. 2. During an interview at 1:40 p.m. on 03/11/19, a testing personnel (#1) confirmed the testing personnel had not signed the three proficiency testing attestation statements listed above. 3. Reviewed at approximately 9:20 a.m. on 03/12/19, the undated policy "Proficiency Testing" stated, ". . . Reporting Results . . . 1. Sign the attestation. . . ."

D5407

PROCEDURE MANUAL

CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

Based on policy and procedure manual review and staff interview, the laboratory director failed to approve, sign, and date 1 of 1 policy and procedure manual ("Procedure and General Manual"). Findings include: 1. Reviewed on 03/12/19, the laboratory's "Procedure and General Manual" failed to include evidence the current laboratory director approved, signed, and dated the laboratory's policies and procedures. This manual failed to include a policy requiring the the current laboratory director to approve, sign, and date the laboratory's policies and procedures. 2. During interview at approximately 8:40 a.m. on 03/12/19, a testing personnel (#1) confirmed the current laboratory director had started in October 2018 and had not approved, signed, and dated the laboratory's "Procedure and General Manual."

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE

CFR(s): 493.1253(b)(1)

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.

This STANDARD is not met as evidenced by:

Based on record review, staff interview, and policy review, the laboratory failed to

verify the accuracy for 1 of 1 qualitative immunology test (rheumatoid factor) implemented in 2018 before reporting patient results. The laboratory performed approximately 11 rheumatoid factor patient tests since implementation. Findings include: 1. Reviewed at 8:45 a.m. on 03/12/19, the laboratory's 2018 performance specification verification records for qualitative rheumatoid factor lacked evidence the laboratory evaluated the accuracy data. 2. Reviewed at approximately 9:20 a.m. on 03/12/19, the undated policy "Evaluation of New Equipment, New Test Methods Or Modifications to Test Methods or Procedures," stated, "Purpose: Data from the evaluation of the new instruments or test method/procedure is evaluated and conclusions regarding acceptability of the test method are made based on the data collected. . . ." 3. During interview at approximately 10:00 a.m. on 03/12/19, a testing personnel (#1) confirmed the laboratory began patient testing for rheumatoid factor last fall and the laboratory did not have evidence the laboratory director and/or technical consultant had evaluated and approved the accuracy verification data.

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

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) -- (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 record review, staff interview, and policy review, the laboratory failed to verify calibration for 2 of 2 DCA Vantage non-waived analytes (microalbumin and urine creatinine) at least once every six months in 2018. Findings include: 1. Reviewed at 4:05 p.m. on 03/11/19, the 2018 calibration verification records lacked evidence the laboratory verified microalbumin calibration in 2018 and urine creatinine calibration the second six months of 2018. 2. Upon request on 03/11/19, the laboratory failed to provide additional evidence of calibration verification for microalbumin and urine creatinine in 2018. 3. During interview at approximately 4:35 p.m. on 03/11/19, a testing personnel (#1) stated the laboratory did not have evidence of calibration verification at least twice annually in 2018 for microalbumin and urine creatinine. 4. Reviewed at approximately 9:20 a.m. on 03/12/19, the policy "Calibration and Calibration Verification," revised 03/31/18, stated, ". . . Purpose: . . . To assure analyzer is producing results accurately at lower, middle and high ends to

determine the accuracy of test system throughout the laboratory reportable range. . . .
Policy: . . . Calibration verification will be performed twice a year on all appropriate
quantitative testing systems . . ."

D5481

CONTROL PROCEDURES

CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review, staff interview, and policy review, the laboratory failed to ensure quality control (QC) results met the criteria for acceptability for 1 of 2 patient testing days (07/05/18) in July 2018 for albumin on the DCA Vantage analyzer. The laboratory performed one patient test on 07/05/18. Findings include: 1. Review of the July 2018 quality control results for albumin and urine creatinine on the DCA Vantage analyzer occurred on 03/11/19. On 07/05/18 the albumin low QC result was 41.4 and the high QC result was 276.6. The QC results on 07/05/18 failed to include the manufacturer's acceptable ranges for this lot number of QC (#0052). The laboratory performed one patient test on 07/05/18 without verifying the QC results were in the acceptable range. 2. Upon request on 03/12/19, the laboratory provided the manufacturer's acceptable ranges for albumin QC lot #0052. The acceptable range for the low control was 25.9-38.9 and the high control was 168.0-252.0. The albumin QC results on 07/05/18 were out of the manufacturer's acceptable ranges. 3. During interview at approximately 4:35 p.m. on 03/11/19, a testing personnel (#1) stated the laboratory had misplaced the manufacturer's QC ranges for QC lot #0052 when used on 07/05/18. Upon review of the manufacturer's QC ranges for lot #0052 on 03/11/19, Testing Personnel #1 confirmed the albumin low and high QC results were out of the acceptable ranges on 07/05/18. 4. Reviewed at approximately 9:20 a.m. on 03/12/19, the policy "Policy and Procedure Manual," revised 06/17/15, stated, ". . . Quality Control . . . The purpose of the control program is . . . to identify significant problems as they arise, and to document that the problems are solved. . . . I. Internal Quality Control . . . D. Quality Control - Chemistry - DCA Vantage . . . 2. . . . Results are verified . . ."