

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0906177	(X3) Date Survey Completed 04/15/2019
Name of Provider or Supplier Absentee Shawnee Tribal Health System -	Street Address, City, State 15951 Little Axe Drive, Norman, OK	
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
D0000	The recertification survey was performed 04/15/19. The laboratory was found to be in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory manager and the laboratory director at the conclusion of the survey.
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager and the laboratory director, testing persons failed to indicate the proficiency samples they tested. Findings include: (1) At the beginning of the survey, the laboratory manager stated to the surveyor the laboratory performed CBC (Complete Blood Count) testing (i.e. WBC (White Blood Count), RBC (Red Blood Count), Hemoglobin, Hematocrit, Platelet Count, etc.) using the Sysmex XS-1000i analyzer; (2) The surveyor reviewed Hematology proficiency testing records for the First, Second, and Third 2018 Events; and the First 2019 Event. From the review, the surveyor identified 3 of the 3 testing persons (laboratory manager, testing person #3, and testing person #4) who performed the proficiency testing, had not indicated the proficiency samples they tested on the attestation statement for the Third 2018 Hematology Event; (3) The surveyor reviewed the findings with the the laboratory manager and the laboratory director, who stated to the surveyor, the 3 testing persons listed above, failed to sign the attestation statements for the proficiency testing event listed above.</p>
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p>

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the laboratory manager and the laboratory director, the laboratory failed to evaluate the accuracy of testing when proficiency results had not been graded by the proficiency program. Findings include: (1) On the first day of the survey, the surveyor reviewed 2018 and 2019 proficiency testing records and identified the following results had not been graded by the proficiency testing program: (a) First 2018 Core Chemistry Event: (i) LDL (Low Density Lipoprotein): 1 of 5 samples had not been graded by the proficiency testing program due to no appropriate peer group being available; (aa) Sample CH-02 (i) The laboratory reported, "1;" (ii) The proficiency testing program's expected result was, "See Data Summary"; (iii) There was no evidence found in the records that the laboratory reviewed the data summary to evaluate their result. (b) First 2018 Miscellaneous Chemistry Event: (i) Urine Microalbumin: 2 of 2 samples had not been graded by the proficiency testing program due to no consensus among the participants: (aa) Sample MA-01 (i) The laboratory reported, "30 mg/L;" (ii) The proficiency testing program's expected result was, "See Data Summary"; (iii) There was no evidence found in the records that the laboratory reviewed the data summary to evaluate their result. (bb) Sample MA-02 (i) The laboratory reported, "10 mg/L;" (ii) The proficiency testing program's expected result was, "See Data Summary"; (iii) There was no evidence found in the records that the laboratory reviewed the data summary to evaluate their result. (ii) Urine Drug Screen: 1 of 1 sample had not been graded for Opiates by the proficiency testing program due to no consensus among the participants: (aa) Sample 01 (i) The laboratory reported, "Negative;" (ii) The proficiency testing program's expected result was, "See Data Summary"; (iii) There was no evidence found in the records that the laboratory reviewed the data summary to evaluate their result. (2) The surveyor asked the laboratory manager and the laboratory director if the laboratory obtained the data summary, reviewed and evaluated the proficiency testing results listed above. The laboratory manager and the laboratory director stated the non-graded results listed above had not evaluated for accuracy with the data summary.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on a review of records, manufacturer's instructions, and interview with the laboratory manager and the laboratory director, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Findings include: VITROS 350 (1) At the beginning of the survey, the laboratory manager stated to the surveyor the laboratory performed Chemistry testing (i.e. Albumin, Glucose, Potassium, etc.) using the Vitros 350 analyzer; (2) The surveyor reviewed the

manufacturer's maintenance requirements, as stated on the manufacturer's maintenance log and identified the following procedures were required on a weekly basis: (a) Clean tray platform and transport arm (b) Clean cup retainer (c) Clean diluent bottles (d) Clean tip locator assembly (e) Clean control unit screen (f) Clean keypad cover (g) Inspect, clean, and/or replace air filter (h) Back up QC/Config/Calibration Data (3) The surveyor reviewed the maintenance records from 08/01/17 through 3/31/19. There was no documentation found which showed the weekly maintenance procedures had been performed during 3 of 15 months reviewed: (a) Between 11/22/17 and 12/08/17 (b) Between 01/19/18 and 01/29/18 (4) The surveyor reviewed the findings with the laboratory manager and the laboratory director, who stated to the surveyor there was no documentation the manufacturer's required weekly maintenance procedures had been performed as listed above. SYSMEX XS-1000i (1) At the beginning of the survey, the laboratory manager stated to the surveyor the laboratory performed CBC (Complete Blood Count) testing (i.e. WBC (White Blood Count), RBC (Red Blood Count), Hemoglobin, Hematocrit, Platelet Count, etc.) using the Sysmex XS-1000i analyzer; (2) The surveyor reviewed the manufacturer's maintenance requirements, as stated on the manufacturer's maintenance log and identified the manufacturer required the IPU (Internal Processor Unit) be powered down on a weekly basis; (3) The surveyor reviewed the maintenance records from 08/01/17 through 3/31/19 and identified there was no documentation which showed the weekly maintenance procedure had been performed during 2 of 15 months reviewed: (a) Between 10/23/18 and 11/05/18 (4) The surveyor reviewed the findings with the laboratory manager and the laboratory director, who stated to the surveyor there was no documentation the manufacturer's required weekly maintenance procedure had been performed as listed above.