

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0669872	(X3) Date Survey Completed 01/30/2018
Name of Provider or Supplier Sapulpa Indian Health Center	Street Address, City, State 1125 E Cleveland, Sapulpa, 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 findings were reviewed with the laboratory director and testing person #1 at the conclusion of the survey.
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <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).</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, and interview with testing person #1 and the laboratory director, the laboratory failed to evaluate proficiency testing results that had not been evaluated by the proficiency testing program. Findings include: (1) At the beginning of the survey, the laboratory director stated to the surveyor the laboratory performed macroscopic urinalysis testing using the Multistix 10SG reagent strips read on the Clinitek Advantus reader; (2) The surveyor reviewed proficiency testing records for urinalysis testing from the Second and Third events of 2016; and the First, Second, and Third events of 2017. The following was identified: (a) Third 2016 event: (i) Although the laboratory obtained a score of 100% for Urobilinogen, the result for sample UA-05, had not been evaluated by the proficiency testing program, due to "No Consensus" among the participants; (ii) In addition, the laboratory's result was "1.0 or Less than 2.0 mg/dl." The proficiency testing program's acceptable response was "See Data Summary"; (iii) There was no documentation located in the records which verified the laboratory identified the non-graded response, obtained the Data Summary, and performed a self-evaluation of the result to verify the accuracy of testing. (b) Second 2017 event: (i) Although the laboratory obtained a score of 100% for Urobilinogen, the result for sample UA-03, had not been evaluated by the</p>

proficiency testing program, due to "No Consensus" among the participants; (ii) In addition, the laboratory's result was "1.0 or Less than 2.0 mg/dl." The proficiency testing program's acceptable response was "See Data Summary"; (iii) There was no documentation located in the records which verified the laboratory identified the non-graded response, obtained the Data Summary, and performed a self-evaluation of the result to verify the accuracy of testing. (3) The findings were reviewed with testing person #1 and the laboratory director, who verified the laboratory failed to identify the non-graded responses listed above, failed to obtain the Data Summary, and failed to perform a self-evaluation of the results. NOTE: D5215 was cited at the previous recertification survey performed 02/04,05/2016.

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 testing person #1, the laboratory failed to perform maintenance procedures as required by the manufacturer. Findings include: CELL DYN RUBY (1) At the beginning of the survey, the laboratory director 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 Cell Dyn Ruby hematology analyzer; (2) The surveyor reviewed the manufacturer's instructions (operator manual) for maintenance procedures. The manufacturer required the following weekly procedure: (a) Clean Loader Component (3) The surveyor then reviewed the maintenance records from 8 months (May and November 2016; March, August, October, November, and December 2017; and January 2018. During 6 of the 8 months reviewed, the weekly maintenance procedure had not been documented as having been performed, as follows: (a) November 2016: (i) Between 11/04/16 and 11/15/16 (ii) Between 11/15/16 and 11/28/16 (b) March 2017: (i) Between 03/17/17 and 03/27/17 (c) August 2017: (i) Between 08/18/17 and 08/28/17 (d) November 2017: (i) Between 11/02/17 and 11/14/17 (e) December 2017: (i) Between 12/08/17 and 12/18/17 (f) January 2018: (i) Between 01/12/18 and 01/22/18 (4) The surveyor reviewed the records with testing person #1 and the laboratory director who agreed performance of the manufacturer's required weekly maintenance had not been documented as having been performed as listed above. VITROS ECIQ (1) The laboratory director stated to the surveyor the laboratory performed chemistry and endocrinology testing (e.g. TSH-Thyroid Stimulating Hormone, PSA-Prostatic Specific Antigen, FT4-Free Thyroxine, Vitamin D, Vitamin B12, Folate, and Ferritin) using the Vitros ECiQ Immunoassay analyzer; (2) The surveyor reviewed the manufacturer's instructions for the required maintenance. The manufacturer required the following procedures: (a) "Weekly - Date/Initial Boxes": (i) Clean the sample metering proboscis (ii) Clean the tip disposal chute/cup retainer (iii) Clean the sample supply subsystem (iv) Clean the touchscreen monitor (v) Clean the keyboard and keyboard cover (vi) Perform subsystem cleaning (vii) Clean the processing center (b) "Monthly - Date/Initial Boxes": (i) Back up QC, Calibration, and Configuration Files (ii) Inspect the Reagent Cooler Filter (c) Every two months: Change the Vapor Adsorption Cartridge (d) Every three months: Change the Universal Wash Reservoir Filter (3) The surveyor then reviewed maintenance records from 22 months (03/01/16 through 01/31/17) and

identified the maintenance procedures had not been performed as required by the manufacturer. The specific findings follow: (a) Weekly: There was no evidence the weekly maintenance procedures were performed during 5 of the 22 months reviewed: (i) July 2016 - Week 4 (Between 07/18/16 and 08/02/16); (ii) March 2016 - Weeks 1, 2, 3, and 4: Although the boxes for the weekly maintenance had been checked, the dates on which the maintenance was performed had not been documented. Therefore, the surveyor could not determine if the maintenance had been performed on a weekly basis as required; (iii) April 2016 - Weeks 1, 2, 3, and 4: The dates on which the maintenance was performed had not been documented; (iv) May 2016 - Weeks 1, 2, and 3: The dates on which the maintenance was performed had not been documented; (v) April 2017 - Weeks 1, 2, 3, and 4: The dates on which the maintenance was performed had not been documented; (b) Monthly: There was no evidence the monthly maintenance procedures were performed during 16 of the 22 months reviewed, as follows: (i) March 2016 - There was no documentation the "Inspect the Reagent Cooler Filter" procedure had been performed; (ii) June 2016 - There was no documentation the "Inspect the Reagent Cooler Filter" procedure had been performed; (iii) August 2016 - There was no documentation the monthly procedures had been performed; (iv) November 2016 - There was no documentation the monthly procedures had been performed; (v) December 2016 - There was no documentation the monthly procedures had been performed; (vi) January 2017 - There was no documentation the monthly procedures had been performed; (vii) February 2017 - There was no documentation the monthly procedures had been performed; (viii) April 2017 - There was no documentation the "Inspect the Reagent Cooler Filter" procedure had been performed; (ix) May 2017 - There was no documentation the "Inspect the Reagent Cooler Filter" procedure had been performed; (x) June 2017 - There was no documentation the monthly procedures had been performed; (xi) July 2017 - There was no documentation the monthly procedures had been performed; (xii) August 2017 - There was no documentation the monthly procedures had been performed; (xiii) September 2017 - There was no documentation the monthly procedures had been performed; (xiv) October 2017 - There was no documentation the monthly procedures had been performed; (xv) November 2017 - There was no documentation the "Inspect the Reagent Cooler Filter" procedure had been performed; (xvi) December 2017 - There was no documentation the monthly procedures had been performed. (c) Every two months: There was no documentation the maintenance was performed as required, as follows: (i) Had not been performed between 08/29/16 and 12/31/16 (ii) Had not been performed between 01/01/17 and 05/08/17 (iii) Had not been performed between 05/08/17 and 09/13/17 (d) Every three months (i.e. Quarterly): There was no documentation the quarterly maintenance was performed as required, as follows: (i) 2016: Had not been performed during the third quarter (not performed after 06/11/16 and prior to 10/13/16); (ii) 2017: Had not been performed during the first quarter (not performed after 01/01/17 and prior to 04/17/17). (4) The surveyor reviewed the findings with testing person #1 and the laboratory director who verified there was no documentation which showed the maintenance procedures listed above had been performed as required by the manufacturer. NOTE: D5429 was cited at the previous recertification survey performed on 02/04,05/2016.