

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0050835	(X3) Date Survey Completed 10/23/2020
Name of Provider or Supplier Wah-Zha-Zhi Health Center	Street Address, City, State 715 Grandview, Pawhuska, 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 on 10/23/2020. The findings were reviewed with the technical consultant at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to review and evaluate proficiency testing results for 2 of 26 events. Findings include: (1) At the beginning of the survey, the surveyor reviewed 2018, 2019, and 2020 proficiency testing records and identified the following biases (the biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program): (a) Third 2019 Hematology Event (i) RDW (Red Cell Distribution Width) - 3 of 5 results exhibited a positive bias (aa) XE-11- SDI of 2.1 (bb) XE-12- SDI of 2.5 (cc) XE-15- SDI of 2.2 (b) First 2020 Hematology Event (i) RDW - 3 of 5 results exhibited a positive bias (aa) XE-01- SDI of 2.0 (bb) XE-03- SDI of 2.0 (cc) XE-05- SDI of 2.8 (2) The surveyor further reviewed the records and could not locate documentation verifying the biases had been identified and addressed; (3) The surveyor then reviewed the records with the technical consultant, and asked if the biases had been addressed. The technical consultant stated on 10/23 /2020 at 04:30 pm the biases had not been addressed.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory</p>

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 technical consultant, the laboratory failed to perform maintenance procedures as required by the manufacturer for 1 of 3 months. Findings include: (1) On the first day of the survey, the technical consultant stated to the surveyor CBC (Complete Blood Count) testing was performed on the Sysmex XS1000i analyzer; (2) The surveyor reviewed the manufacturer's maintenance instructions for the analyzer which were: (a) Daily (i) Perform Shutdown (ii) Verify Background (3) Maintenance records were reviewed by the surveyor for 3 months (April 2020, May 2020 and June 2020). The daily maintenance had not been documented as performed between: (a) 05/13/2020 and 05/15/2020 (4) The surveyor reviewed the records with the technical consultant who stated on 10/23/2020 at 04:15 pm, there was no evidence the above maintenance had been performed as required.

D5807

TEST REPORT

CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:

Based on a review of a patient report and interview with the technical consultant, the laboratory failed to provide normal reference intervals for 1 of 1 Wet Prep test reports. Findings include: (1) At the beginning of the survey, the technical consultant stated to the surveyor Wet Prep testing was performed; (2) Later during the survey, the surveyor reviewed one Wet Prep report for a patient tested on 12/18/2019 at 05:40 pm. The report did not include a normal reference range; (3) The report was reviewed with the technical consultant, who stated on 10/23/2020 at 12:15 pm Wet Prep reports did not include a normal reference range.