

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0948601	(X3) Date Survey Completed 05/01/2018
Name of Provider or Supplier Jenks Health Team	Street Address, City, State 715 W Main, Suite S, Jenks, 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 laboratory director and testing person #1 at the conclusion of the survey.
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on a review of written policies and procedures, and interview with the testing person #1, the laboratory failed to have complete written policies and procedures. Findings include: (1) At the beginning of the survey, testing person #1 stated the following to the surveyor: (a) CBC (Complete Blood Count) testing was performed on the Beckman Coulter AcT Diff 2 analyzer; (2) Later during the survey, the surveyor</p>

reviewed written hematology policies and procedures. The following could not be located: (a) Reference intervals (normal values) (3) The surveyor reviewed the findings with the quality testing person #1, and asked if the above procedure was available. The testing person #1 stated the procedure had not been written.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on a review of records, observation, and interview with testing person #1, the laboratory failed to ensure materials were being stored as required. Findings include: (1) During the survey, the surveyors observed the following stored at room temperature: (a) Blood Collection tubes used for CBC (Complete Blood Count) testing performed on the Beckman Coulther AcT Diff 2 and collecting reference (send out) specimens: (i) BD Vacutainer SST tubes (75 tubes of lot# 7311874 with a storage requirement of 4-25 degrees Celsius) (ii) BD Vacutainer PST Gel and Lithium Heparin tubes (50 tubes of lot# 7214704 with a storage requirement of 4-25 degrees Celsius) (iii) BD Vacutainer K2 EDTA tubes (25 tubes of lot# 7214632 with a storage requirement of 4-25 degrees Celsius) (2) The surveyor reviewed temperature records from January 2017 through April 2018 and identified daily monitoring of the room temperatures were warmer than 25 degrees Celsius for 4 of 16 months: (a) January 2017 - Days: 9,10,12,17,24 (b) February 2017 - Day 13 (c) November 2017 - Days 2,20 (d) April 2018 - Day 13 (3) The surveyor reviewed the storage requirements with testing person #1, who stated the laboratory was not storing the testing materials as required.