

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0475237	(X3) Date Survey Completed 10/04/2024
Name of Provider or Supplier Muscogee (Creek) Nation Medical Center	Street Address, City, State 1401 Morris Drive, Okmulgee, 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 10/01,02,03,04/2024. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with lead technologist #1, lead technologist #2, laboratory manager #1, laboratory manager #2, director of laboratory services, acting secretary of health, assistant director of laboratory services, and the laboratory director during an exit conference performed 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 policies and procedures, and interview with the lead technologist</p>

and laboratory director, the laboratory failed to have step-by-step written procedures for one of two procedures reviewed. Findings include: (1) On 10/02/2024 at 4:15 pm, the laboratory director stated Complete Blood Count (CBC) testing which may include a manual differential slide exam were performed using the Cell-Dyn Ruby or Cell-Dyn Emerald analyzers; (2) A review of laboratory procedure manuals identified no evidence of written procedures for how to determine when a manual differential should have a pathology slide review when abnormal (immature) white blood cells that are more immature than a band are seen by the technologist, including but not limited to: (a) Blasts; (b) Promyelocytes; (c) Myelocytes (d) Metamyelocytes (3) A review of patient records revealed the following patients with immature white blood cells more immature than a band: (a) Patient #113656 - Three metamyelocytes, nine myelocytes, and one promyelocyte seen; (b) Patient #1000723447 - Three blasts seen; (c) Patient#332262 - Three metamyelocytes seen; (d) Patient#172502 - 25 Blasts were seen (4) The findings were reviewed with the laboratory director and lead technologist. Both stated on 10/02/2024 at 4:15 pm, the written procedure manual did not include when to refer slides with immature white cells present.

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 and interview with technical supervisor #4, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures on the Abbott Cell-Dyn Emerald 22 analyzer during the review period of January 2024 through August 2024. Findings include: (1) On 10/01/2024 at 09:15 am, technical supervisor #4 stated the laboratory performed CBC (Complete Blood Count) testing using the Abbott Cell-Dyn Emerald 22 analyzer; (2) A review of the manufacturer's instruction manual titled, "Abbott Cell-Dyn Emerald 22 Operator's Manual", section 9 - Preventive Maintenance Schedule showed the following required maintenance procedures: (a) Weekly - Bleach cleaning (b) Quarterly - Lubricating the pistons (3) A review of maintenance logs from January 2024 through August 2024 identified maintenance had not been documented as performed for the following: (a) Weekly: (i) Between 02/01/2024 and 02/15/2024 (ii) Between 02/15/2024 and 02/29/2024 (b) Quarterly: (i) Between 03/06/2024 and 07/09/2024 (4) The records were reviewed with technical supervisor #4 who stated on 10/03/2024 at 04:00 pm, maintenance procedures had not been documented as performed as stated above.