

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 02D2007735	(X3) Date Survey Completed 08/27/2024
Name of Provider or Supplier Medical Network Of Alaska	Street Address, City, State 3066 E Meridian Park Loop, Wasilla, AK	
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
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 testing procedures and an interview with the technical consultant, the laboratory failed to include criteria to determine acceptable control results and corrective actions to take when control results fail to meet the laboratory's criteria for acceptability for three of five quantitative test procedures reviewed. Findings include: 1. The procedures for the Beckman Coulter Access 2 Immunoassay System, the Beckman Coulter AU 480 Chemistry Analyzer, and the Sysmex XN-530 CBC Analyzer did not include criteria to determine acceptable control results or what corrective actions to take when control results fail to fall within acceptable ranges. 2.</p>

The technical consultant confirmed these findings in an on-site interview on 8/27/24 at 2:30 PM. 3. The laboratory reports performing 216,000 chemistry tests, and 63,500 hematology tests annually.

D5445

CONTROL PROCEDURES
CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on a review of test procedures, Individual Quality Control Plans (IQCP), Quality Control (QC) records, and an interview with the technical consultant, the laboratory failed to perform and document two levels of Quality Control (QC) monthly, as determined by the IQCP, for Chlamydia and Neisseria gonorrhoeae (CT/NG), Group B Strep (GBS), and MVP (bacterial vaginosis) cartridges on the Cepheid GeneXpert analyzer in 2023 and 2024. Findings include: 1. The test procedures and IQCPs for Group B Strep, MVP (bacterial vaginosis), and CT/NG cartridges on the Cepheid GeneXpert analyzer state that two levels of quality control will be performed monthly, and with each new lot and shipment of cartridges. 2. Quality control records reveal QC was not documented for the following months in 2023 and 2024. a. CT/GN - missing 2/23, 8/23, 9/23, 11/23, 12/23, 1/24, and 5/24. b. GBS - missing 4/23, 7/23, 9/23, 11/23, 12/23, 2/24, and 3/24. c. MVP - missing 5/23, 6/23, 7/23, 10/23, 1/24, 4/24, 5/24, and 6/24. 3. The technical consultant confirmed these findings in an on-site interview on 8/27/24 at 2:30 PM. 4. The laboratory reports performing approximately 1250 tests on the Cepheid annually.

D5781

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
Based on a review of Beckman Coulter AU 480 quality control (QC) records and an interview with the technical consultant, the laboratory failed to document corrective actions taken in May 2024 when the Alkaline Phosphatase QC was out of range for 4 of 22 days, in June 2024 when the Glucose QC was out of range for 16 of 20 days, the

Unsaturated Iron Binding Capacity (UIBC) QC was out of range for 4 of 20 days, the Sodium QC was out of range for 15 of 20 days, the Phosphorous QC was out of range for 8 of 20 days, and in July when the IUBC QC was out of range for 5 of 23 days. Findings include: 1. A request was made to review the corrective actions for the following controls and corrective actions could not be provided: a. Alkaline Phosphatase BioRad Liquid Assayed Multiquel QC Level 1 was outside the acceptable range on 5/6, 5/7, 5/13, and 5/16/2024. b. Glucose BioRad Liquid Assayed Multiquel QC Level 1 was outside the acceptable range on 6/3, 6/4, 6/5, 6/6, 6/7, 6/10, 6/11, 6/12, 6/13, 6/14, 6/17, 6/18, 6/19, 6/20, 6/24, and 6/26/2024. c. UIBC BioRad Liquid Assayed Multiquel QC was outside the acceptable range on 6/3, 6/14, 6/17, 6/20, 7/1, 7/2, 7/3, 7/10, and 7/16/24. d. Sodium BioRad Liquid Assayed Multiquel QC Level 1 was outside the acceptable range on 6/3, 6/4, 6/5, 6/6, 6/10, 6/11, 6/12, 6/14, 6/17, 6/19, 6/20, 6/21, 6/25, and 6/27/24. e. Phosphorous BioRad Liquid Assayed Multiquel QC was outside the acceptable range on 6/6, 6/10, 6/19, 6/20, 6/24, 6/25, 6/26, and 6/27/24. 2. The technical consultant confirmed these findings in an on-site interview on 8/27/24 at 2:30 PM. 3. The laboratory reports performing 213,000 Chemistry tests annually.