Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D1095145	12/01/2021
Name of Provider or Supplier	**Street Address, City, State**	
Mednorth Urgent Care	2316 Us Highway 93 North, Kalispell, MT	

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
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of hematology, chemistry, urinalysis and endocrinology procedures, the laboratory failed establish and follow written policies and procedures that ensure positive identification of a patient's specimen (see D5203) and failed establish and follow written procedures to assess testing personnel and technical consultant competency (see D5209).
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on observation, review of procedures, and interview with the Technical Consultant (TC) #1, the laboratory failed to establish and follow written procedures to ensure positive identification of a patient's urine specimens throughout the testing

	process. Findings: 1. Observed two urine specimens in laboratory sink labeled with last name on lid. 2. Review of Specimen Collection Procedures and Policies state "All specimens sent to the laboratory for on-site testing or send out tests must be labeled with the following information: Patient's full name; Patients ID number; Date of birth; Time and Date of collection; Initials of person collecting the specimen." 3. Interview with the TC#1 on December 1, 2021 at 11:25 AM, confirmed the laboratory failed to follow written procedures to ensure positive identification of patient's urine specimens from the time of collection through completion of testing.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a record review, procedures, and an interview with the technical consultant (TC) #1, the laboratory failed to follow procedures and perform competency assessment for the testing personnel and technical consultant listed on the CLIA CMS-209 Personnel Report form. Findings: 1. A record review of the CMS-209 Personnel Report Form revealed four out of four testing personnel listed failed to have competency assessment performed in 2020. 2. No competency assessment documents were available for the technical consultant from January 1, 2019 to December 1, 2021. 3. A review of the laboratory's Quality Assurance Program procedure states, "All personnel are evaluated semi-annually in the first year of employment and annually thereafter." 4. A review of the laboratory's Quality Assurance Program procedure revealed, "As laboratory director some of the responsibilities that may be delegated to the technical consultant include: Training of personnel, assessing competency of the personnel and annual reviews." 5. An interview on December 1, 2021 at 10:00 AM, confirmed the laboratory failed to follow procedure and perform competency for the positions of technical consultant and testing personnel listed on the CMS-209 Personnel Report form.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of hematology, chemistry and endocrinology procedures, the laboratory failed to include reference intervals (normal values) in their hematology procedure (see D5403), failed to ensure immunoassay quality control materials were not used past their expiration date (see D5417), and failed to define, and perform a

	function check protocol to verify the accuracy of pipettes and centrifuge (see D5435) and failed to identify and correct problems to prevent recurrence and failed to document and monitor corrective actions (see D5791).
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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. This STANDARD is not met as evidenced by: Based on record review of hematology and interview with Technical Consultant (TC) #1, the laboratory failed to include in their procedure manuals the reference intervals (normal values) appropriate for the laboratory's patient population for complete blood counts with differentials. Findings: 1.Reveiw of patient results reports listed reference ranges for complete blood counts (CBC) with differentials in the report. 2. No reference intervals (normal values) were available in the hematology procedure for CBC with differentials that have been established and verified for the laboratory's patient population using the Sysmex pocH-100i. 3. Interview with the TC #1 on December 1, 2021 at 12:00 PM confirmed the laboratory failed to include normal values appropriate for the laboratory's patient population for CBC with differentials in the hematology procedure.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on record review, procedures, and an interview with the technical consultant (TC) #1, the laboratory failed to ensure immunoassay quality control (QC) material for the FREND System testing analytes prostate specific antigen (PSA) and thyroid-stimulating hormone (TSH) were not used past their expiration date. Findings: 1. Record review of FREND Quality Control Log revealed QC Lot# 1706904 and

	#17060914 with an expiration date of 2/28/2021 was used to perform the monthly QC for TSH cartridges on 3/9/21, 4/9/21, 5/2/21, and 6/10/21 and PSA Plus cartridges on 3 /25/21, and 4/26/21. 2. Review of procedure CLINIQA Liquid QC Immunoassay Control states, "CLINIQC Liquid QC Immunoassay Control should not be used past the expiration date on the vial label." 3. Interview with the TC #1 on December 1, 2021 at 12:50 PM confirmed the laboratory failed ensure the immunoassay quality control materials were not used past their expiration date.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on observation of pipettes and centrifuge, review of maintenance documentation, procedures and product inserts, and interview with technical consultant (TC) #1 the laboratory failed to define and perform a function check protocol to verify the accuracy of two FREND pipettes and one LabCorp centrifuge. Findings: 1. Observation of the two FREND micro-pipettes available for use showed no calibration label of a pipette function check. 2. Observation of the one LabCorp centrifuge available for use showed no calibration label of revolutions per minute (RPM) and timer function checks. 3. No documentation was found to show the laboratory defined and performed a function check protocol to verify the accuracy of two FREND pipettes and the LabCorp Centrifuge from January 2020 to December 2021. 4. Review of FREND PSA Plus product insert revealed "Specimen Processing (3) Drop the sample (35 L) into the sample inlet on the cartridge using a calibrated micro pipette with a fresh pipette tip." 5. Review of FREND PSA Plus and FREND TSH product inserts revealed "Specimen Collection and Handling ... After allowing the sample to clot for 30 minutes at room temperature, the collection tube should be centrifuged for 10 minutes at 3000 rpm." 6. An interview with the TC#1 on December 1, 2021, at 1:40 PM, confirmed the laboratory failed to perform functions checks for the micro pipettes and centrifuge during January 2020 to December 2021.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on record review, procedures and interview with the technical consultant (TC) #1, the laboratory failed to identify and correct problems to prevent recurrence and

	failed to document and monitor corrective actions. Findings: 1. Review of Hematology Levey Jennings quality control data and the Sysmex pocH-100i CBC Quality Control Log for January 2020 revealed the laboratory failed to retain quality control values for level1, level 2 and level 3 for complete blood counts for 1/4/20, 1/5 /20, 1/13/20 through 1/31/20. 2.Review of FREND Quality Control Log revealed: a. QC Lot# 1706904 and #17060914 with an expiration date of 2/28/2021 was used to perform the monthly QC for TSH cartridges on 3/9/21, 4/9/21, 5/2/21, and 6/10/21 and PSA Plus cartridges on 3/25/21, and 4/26/21. (Cross refer D5417). b. No monthly QC was performed for PSA cartridges for months May and June of 2021. 3. No corrective action documents for the failures listed above were available for review. 4. An interview with the TC#1 on December 1, 2021 at 1:15 PM confirmed the laboratory failed to identify and correct problems to prevent recurrence and failed to document and monitor corrective actions.