

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  27D1095145	<b>(X3) Date Survey Completed</b>  08/06/2025
<b>Name of Provider or Supplier</b>  Mednorth Urgent Care	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a record review and an interview with technical consultant (TC) #1, the laboratory failed to establish and perform competency assessment for the technical supervisor listed on the CMS-209 Laboratory Personnel Report from August 6, 2023 to August 6, 2025. Findings: 1. A review of the CMS-209 Form revealed one of one personnel listed as the technical consultant. No competency assessment based on the technical consultant position was available for review from August 6, 2023, to August 6, 2025. 2. A record review of the laboratory's procedure manual revealed the laboratory failed to have a policy or procedure to assess the technical consultant position. 3. An interview on August 6, 2025, at 11:30 AM with TC #1 confirmed the laboratory failed to perform competency assessment for the position of technical consultant listed on the CMS-209 form from August 6, 2023 to August 6, 2025.</p>
<b>D5311</b>	<p><b>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL</b> CFR(s): 493.1242(a)</p> <p>(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral.</p>

This STANDARD is not met as evidenced by:  
 Based on observation, procedures, and an interview with technical consultant (TC) #1, the laboratory failed to follow their written procedures to label two of two patient urine specimens with either the patient's full name and date of birth, or at least two patient identifiers on August 6, 2025. Findings: 1. Observed on August 6, 2025, at 12:00 PM, two patient specimen cups containing urine in the sink with just initials, the specimen cups lacked either a patient label or two patient identifiers. 2. A review of the "Specimen Collection Procedure and Policies" revealed laboratory staff failed to label the urine specimen cups with either the patient's full name and date of birth or at least two patient identifiers. 3. An interview with TC #2 on August 6, 2025, at 12:05 PM confirmed the laboratory staff failed to label two of two patient urine specimens with either the patient's full name and date of birth, or at least two patient identifiers on August 6, 2025.

**D5469**

**CONTROL PROCEDURES**  
 CFR(s): 493.1256(d)(10)(g)

(d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters.

This STANDARD is not met as evidenced by:  
 Based on a record review, product inserts, and an interview with the technical consultant (TC #1), the laboratory failed to verify the acceptability of each new lot of immunoassay quality control (QC) for two of two analytes performed on the FRENDD Immunoassay System from August 6, 2023, to August 6, 2025. Findings: 1. The laboratory failed to follow the manufacturer's instructions to "establish its own mean and standard deviation" of each new lot of CLINIQA Liquid QC immunoassay control performed on the FRENDD Immunoassay System. 2. QC records lacked verifications studies for new immunoassay control lots for Prostate Specific Antigen (PSA) and Thyroid Stimulating Hormone (TSH) analytes performed on the FRENDD Immunoassay System. 3. A review of the annual test volume report revealed that 34 PSA and 9 TSH patient tests were performed in the last 12 months. 4. An interview with TC #1 on August 6, 2025, at 1:23 PM confirmed the laboratory failed to verify the acceptability of each new lot of immunoassay QC for analytes PSA and TSH performed on the FRENDD Immunoassay System from August 6, 2023, to August 6, 2025

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
 CFR(s): 493.1413(b)(8)

(b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to--

This STANDARD is not met as evidenced by:

Based on a record review, Laboratory Personnel Report CMS-209 Form, and an interview with the technical consultant (TC #1), the technical consultant failed to perform their responsibility to evaluate the competency of three of three testing personnel (TP) for eight moderate complexity tests performed in the laboratory from August 6, 2023, to August 6, 2025. Findings: 1. A review of the CMS-209 form dated August 2, 2025, listed one technical consultant (TC #1) and three testing personnel (TP #1, #2, #3). 2. TC #1 failed to perform the competency assessments for each moderate test semi-annually during the first year that laboratory personnel test patient specimens and annually thereafter for the years 2024 and 2025. a. A review of the "Competency Assessment" worksheets lacked the six procedures for each moderate test: complete blood counts (CBC), troponin, creatinine, myoglobin, D-Dimer, brain natriuretic peptide (BNP), Prostate Specific Antigen (PSA) and Thyroid Stimulating Hormone (TSH). b. A review of the "New Employee Checklist" and "Competency Assessment" worksheets revealed that TP #1 performed the assessment for TP #2 on May 22, 2025, and May 23, 2025, and for TP #3 on June 6, 2025, and June 26, 2025. TP #1 had not been qualified as the technical consultant. c. TP #1 failed to have a competency assessment performed for the years 2024 and 2025. 3. An interview with TC #1 on August 6, 2025, at 11:30 AM revealed that TC #1 was not aware of the need to perform competency assessments for each moderate complexity test and confirmed the findings listed above from August 6, 2023, to August 6, 2025.