| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 35D0408575 | 11/18/2025 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Unity Medical Center | 164 W 13th St, Grafton, ND | |

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 |
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| **D2006** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)<br><br>(b)The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review, staff interview, and policy review, the laboratory failed to report the results from the Laboratory Information System (LIS) or testing personnel worksheets to American Proficiency Institute (API) for 3 of 6 events (Chemistry Core and Hematology/Coagulation Event 3 2024, Event 1 2025, and Event 2 2025) in 2024 and 2025. Findings include: 1. Review of API proficiency testing records on the afternoon of 11/17/25 revealed the following: - Chemistry Core Second Event 2025 GLY-06 Hemoglobin A1C [A1C] LIS result was 10.0. The result reported to API was 9.7. - Chemistry Core Third Event 2024 CH-15 Aspartate Aminotransferase [AST] LIS result was 132. The result reported to API was 131. - Hematology/Coagulation Second Event 2025 Blood Cell ID testing personnel worksheet for specimen BCI-06 was "Basophil, all stages", BCI-07 was "Neutrophil, segmented", BCI-08 was "Dacrocyte (tear-drop cell)", BCI-09 was "Eosinophil, all stages", and BCI-10 was "Platelets (giant/large)". The results reported to API for specimen BCI-06 was "Polychromatophilic RBC", BCI-07 was "Neutrophil, band", BCI-08 was "Lymphocyte, normal", BCI-09 was "Basophil, all stages", and BCI-10 was "Neutrophil, segmented". 2. During an interview at 3:14 p.m. on 11/17/25, the Laboratory Manager (#1) indicated the discrepancies in results reported to API were |

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| | due to clerical error. 3. Reviewed at 3:30 p.m. on 11/18/25, the policy "Unity Medical Center Clinical Laboratory Services Quality Control Program," revised 07/2018, stated, "Proficiency Testing Performance . . . Report all results same as patient results. . . . Keep all data together for manager to review and send in. . . ." |
| **D5429** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(1)<br><br>(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation, record review, and staff interview, the laboratory failed to perform required quarterly maintenance on the GeneXpert PCR [Polymerase Chain Reaction] analyzer for 1 of 4 quarters (maintenance due April 2025) reviewed. The laboratory performed 5,899 patient tests on the GeneXpert PCR analyzer the past year. Findings include: 1. Reviewed the morning of 11/18/25, the manufacturer's GeneXpert System Maintenance Log from "GeneXpert GX Dx Operator Manual (302-8378, Rev. C)", showed the following requirements: "Quarterly Maintenance Clean plunger rod and cartridge bays Clean instrument surfaces Replace air filters Replace fan prefilters" 2. Reviewed at 11:45 a.m. on 11/18/25, the April 2025 maintenance records for the GeneXpert PCR analyzer lacked evidence of quarterly maintenance performance. 3. During an interview at 11:50 a.m. on 11/18/25, the Laboratory Manager (#1) confirmed the laboratory had not documented the performance of quarterly maintenance after 01/10/25 and before 06/02/25 for the GeneXpert. |
| **D5435** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(b)(2)<br><br>(b)(2)(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. (b)(2)(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on observations, record review, and staff interview, the laboratory failed to perform required function checks on 4 of 4 expired timers (Serial Number [SN] 181524192, SN 181524235, SN 181524243, SN 181524322) observed. Findings include: 1. Observed at 10:30 a.m. on 11/17/25 on a counter in the main laboratory, a Traceable timer with SN 181524192 [used for gram stains] showed a manufacturer tag indicating a function check due date of 08/15/20. 2. Observed at 3:30 p.m. on 11/18/25 on counters throughout the main laboratory, Traceable timers with SN 181524235 [used for calibration material thawing], SN 181524243 [used for Clostridium Difficile testing], and SN 181524322 [used for kit testing] showed a manufacturer tag indicating function check due dates of 08/15/20. 3. Reviewed at 2:05 p.m. on 11/18/25, the preventative maintenance records lacked evidence of timer function checks. 4. During an interview at 3:30 p.m. on 11/18/25, the Laboratory Manager (#1) confirmed the laboratory had not performed function checks on 4 of 4 timers since 08/15/20 and there was no policy related to timer function checks. |

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| **D5481** | CONTROL PROCEDURES<br>CFR(s): 493.1256(f)(g)<br><br>(f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review, staff interview, and policy review, the laboratory failed to ensure quality control (QC) results met the criteria for acceptability for 3 of 31 patient testing days (05/28/25, 05/29/25, and 05/31/25) in May 2025 for one analyte (lactate) on the Dimension EXL200 chemistry analyzer. The laboratory performed six lactate patient tests on 05/28/25, 05/29/25, and 05/31/25. Findings include: 1. Review of the May 2025 QC results for analytes on the Dimension EXL200 chemistry analyzer occurred on 11/18/25. The following lactate QC did not meet the laboratory's criteria for acceptability before reporting patient test results: - 05/28/25 level 3 QC was 3.0 standard deviations (SD) - 05/29/25 level 1 QC was 2.5 SD and level 3 QC was 3.0 SD - 05/31/25 level 1 QC was 2.5 SD and level 3 QC was 5.0 SD, excluded and not repeated The laboratory reported results for lactate when the QC was out of the acceptable range for two patient tests on 05/28/25, three patient tests on 05/29/25, and one patient test on 05/31/25. 2. During an interview at 11:30 a.m. on 11/18/25, a Laboratory Manager (#1) confirmed the laboratory reported patient test results for lactate on 05/28/25, 05/29/25, and 05/31/25 when the QC was not in acceptable range. 3. Reviewed at 3:30 p.m. on 11/18/25, the policy "Unity Medical Center Clinical Laboratory Services Quality Control Program," revised 07/2018, stated, "Chemistry . . . Dimension . . . a) . . . Acceptable limits are the manufacturer's assayed ranges and established peer data. . . . b) Review all data . . . prior to reporting patient results. Note all control values not meeting acceptance criteria. Document the cause for any out-of-control situation, the disposition of patient samples, and remedial action taken. . . . B. Acceptance, Rejection Troubleshooting: 4. If one control is outside 3 SD, re-run the control immediately. . . . If one or both controls are still "out" . . . DO NOT REPORT PATIENT DATA!" |
| **D6102** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(12)<br><br>(e)(12) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;<br><br>This STANDARD is not met as evidenced by:<br>Based on record review, staff interview, and policy review, the laboratory director failed to ensure 2 of 2 new testing personnel in 2024 (Testing Personnel #2 and #3) received appropriate training and demonstrated reliable performance of all testing operations before reporting patient results. Findings include: 1. Reviewed at 11:15 a.m. on 11/17/25, the 2024 testing personnel records failed to include documentation ensuring appropriate training and demonstration of reliable performance of MedTox Scan Drugs of Abuse, Alere Triage D-Dimer, GeneXpert MPV, and GeneXpert CT /NG testing before reporting patient results for Testing Personnel (#2) and Testing Personnel (#3). 2. Reviewed at 11:15 a.m. on 11/17/25, the 2024 testing personnel |

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| | records showed Testing Personnel (#2) started patient testing in April 2024 and Testing Personnel (#3) started February 2024. 3. During an interview at 11:56 a.m. on 11/17/25, the Laboratory Director (#1) confirmed the laboratory did not have documented performance of MedTox Scan Drugs of Abuse, Alere Triage D-Dimer, GeneXpert MPV, and GeneXpert CT/NG training for Testing Personnel (#2) and Testing Personnel (#3). 4. Reviewed at 3:30 p.m. on 11/18/25, the policy "Unity Medical Center Laboratory Services General Policies," revised 06/2019, stated, "I. Personnel Descriptions, Requirements, Responsibilities: A. Laboratory Director: . . . 3. The Laboratory Director's responsibilities include, but are not limited to the following: . . . e. The director assures that any procedures and/or tests outside the scope of education, training, and experience of the testing personnel in the Laboratory are not performed in UMC's [Unity Medical Center's] laboratory services. . . . II. Staff Competency Assessment and Maintenance A. Orientation: . . . 2. The laboratory orientation program includes an 'Orientation Checklist' . . . which is designated to help new employees become familiar with the policies, procedures and equipment in the laboratory. . . ." |