

| | | |
|--|--|---|
| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 39D2306204 | (X3) Date Survey Completed 12/10/2025 |
| Name of Provider or Supplier Mt Nittany Hlth Outpatient Endoscopy | Street Address, City, State 164 Greenview Drive, State College, PA | |
| 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 |
|---------------------------|---|
| D3009 | <p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on review of temperature records, and interview with the Technical Consultant (TC), the laboratory failed to monitor and document relative humidity (manufacturer's acceptable range: 10-80 %) for 120 of 169 days to ensure substantial proof of efficacy was provided for reagents and operating conditions were met for reliable test system operation when chemistry testing was performed from 06/25/2025 to 12/10/2025 as required per PA regulations. Findings include: 1. The PA State regulation 5.46 states: "Reagents, procedures or equipment which have been demonstrated to be inadequate for clinical laboratory use as evidenced by reliable data from generally acceptable scientific testing and evaluating sources shall be prohibited for use by clinical laboratories upon specific notification by the Department. Also, reagents, equipment and procedures which do not have substantial proof of efficacy either by trial or extended use experience shall be prohibited for routine use." 2. On the day of the initial survey, 12/10/2025 at 10:01 am, review of the laboratory's temperature logs revealed the laboratory failed to document and define criteria for relative humidity (manufacturer's acceptable range: 10-80 %) for 120 of 169 days to ensure proper storage of reagents and operating conditions were met for the following reagents used in the laboratory from 06/25/2025 to 12/10/2025: - Roche Diagnostics Accu-Chek Inform II test strips 3. Review of the laboratory's chemistry test logs revealed that the laboratory performed 2 Whole Blood Glucose tests from 06/25/2025 to 12/10/2025. 4. The TC confirmed the above findings on 12/10/25 at 11:31 am.</p> |
| D5421 | <p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> |

(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's verification of performance specifications records, lack of documentation, and interview with the Technical Consultant (TC), the laboratory failed to verify the required performance specifications for chemistry and hematology testing performed on 1 of 1 i-STAT system analyzer prior to reporting patient test results from 06/25/2025 to 12/10/2025. Findings Include: 1. The laboratory's Method Validation policy stated, "Normal Patient Values: Since the same patient population is being tested for both Point of Care Testing (POCT) and the Mount Nittany Medical Center Laboratory, the patient reference range for the Mount Nittany Medical Center Laboratory will be used for all POCT unless correlation studies or calibration verification procedures indicate that a modification of the reference range is required." 2. On the day of the initial survey, 12/10/2025 at 10:28 am, review of the laboratory's verification of performance specification records for the 1 of 1 i-STAT system analyzer (s/n 21443425) performed on 01/29/2025, revealed the laboratory failed to perform a reference range/normal value study appropriate for the laboratory's patient population for the following analytes prior to reporting patient test results from 06/25/2025 to 12/10/2025. - pH - Carbon Dioxide Partial Pressure (PCO₂) - Oxygen Partial Pressure (PO₂) - Chloride (Cl) - Sodium (Na) - Ionized calcium (iCa) - Potassium (K) - Glucose (Glu) - Urea Nitrogen (BUN) - Hematocrit (HcT) 3. The laboratory reported 125 chemistry and hematology tests performed in 2025 (CMS 116 estimated annual volume, dated 12/03/2025). 4. The TC confirmed the findings above on 12/10/2025 at 11:31 am.