| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number**<br><br>34D2234962 | **(X3) Date Survey Completed**<br><br>06/22/2022 |
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| **Name of Provider or Supplier**<br><br>Bethany Medical Center | **Street Address, City, State**<br><br>495 Arbor Hill Rd Suite N, Kernersville, NC | |
| 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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| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory procedure and interview with testing personnel (TP) #1 6/22/22, the laboratory procedure for reporting SARS-CoV-2 results failed to include the specific method used by the laboratory for reporting SARS-CoV-2 results to state and/or local public health authorities. Findings: Review of laboratory procedure "REPORTING COVID-19 LABORATORY RESULTS" revealed under section 5.1 "How to report...Laboratory data elements may be reported in the following ways:... Submit laboratory testing data directly to state or local public health departments according to state/or local law or policy....Submit laboratory testing date to state or |

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| | local public health departments through a centralized platform, where the data will then be routed to the appropriate state and local authorities and routed to CDC.... Submit laboratory testing data through a state or regional Health Information Exchange to the appropriate state or local public health department and then to CDC...". The procedure failed to state the specific method used by the laboratory for reporting SARS-CoV-2 results to state and/or local public health authorities. During interview with TP #1 at approximately 2:00 p.m., TP #1 stated that each day of testing she batch faxes all negative results and all positive results along with the demographics to the state. She also stated that she maintains the fax transcript to ensure the results were received. |
| **D5423** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(2)<br><br>Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory procedure, review of laboratory performance verification records, review of stability study records, and interviews with testing personnel (TP) #1 and test manufacturer representative 6/22/22, the laboratory failed to verify specimen stability requirements for the SARS-CoV-2 "Saliva Now", testing performed. Findings: Review of laboratory procedure "SLP ... COVID_Saliva Now_384_Sal" revealed under section 1 "SAMPLE COLLECTION...1.10....The virus RNA in saliva remains stable at room temperature for at least 7 days....1.11 Store samples at 2-8 degrees C (Celsius) until sample transport or processing up to 3 days or at -90 to -70 degrees C for up to 30 days." Review of laboratory performance verification records for the SARS-CoV-2 "Saliva Now" testing revealed a procedure for a stability study which included testing aliquots exposed to a "Winter Cycle" and "Summer Cycle". The performance verification records failed to include any raw data or documentation of the stability study. During interview at approximately 12:30 p.m., TP #1 stated all patient specimens are tested within 3 days of receipt and if not tested immediately they would be refrigerated until testing was performed. Review of stability study, "SAMPLE STABILITY STUDY", submitted by test manufacturer representative at time of survey revealed a summary of a stability study for "Testing Upon Receipt - 0 hours, Shipment Stability - Overnight shipping (2-8 degrees C)" and "Post-Extraction Stability - 1 hour (2-8 degrees C) and 48 hours (-70 to -90 degrees C)". The stability study summary failed to include the raw data obtained from the study. The stability study summary also failed to meet the criteria of specimen stability stated in the laboratory procedure "SLP ... COVID_Saliva Now_384_Sal", failed to meet the criteria of a stability study as outlined in the validation procedure, and failed to meet the criteria for specimen stability used by the laboratory performing the test. Interview with test manufacturer representative at approximately 2:00 p.m. confirmed the "SAMPLE STABILITY STUDY" failed to include the raw data for the |

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| | study. The representative also confirmed the stability study failed to meet the criteria specified by the test procedure and the validation procedure, and failed to meet the specimen storage requirements of the laboratory performing the test. |
| **D6094** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's quality assessment plan, review of 2021 and 2022 quality assessment records, and interview with the laboratory manager 6/22/22, the laboratory director failed to ensure that the quality assessment program was maintained to assure the quality of laboratory services provided. Findings: The laboratory's quality assessment plan states "... Implementation Quality Assessment Reviews are conducted at the frequency specified. The calendar indicates which monitors will be reviewed each month. The Quality Assessment Forms associated with the monitor are completed. If a problem is identified, corrective action is implemented, and a follow up review is conducted to assure that the corrective actions have resolved the problem. The QA Review forms are signed and dated by the reviewer and laboratory director and retained in the Quality Assessment folder for a minimum of two years. Annual Calendar of QA Reviews ... 1. Review the monitor (s) assigned for each month. Document the review on the appropriate form and attach all supporting data and information. 2. Biannually, complete the Analytical, Proficiency, Personnel, and Procedure Manual checklists. The Analytical Checklist includes Maintenance, Calibration/Calibration Verification, Quality Control, Temperatures, and Reagents. Review as applicable. 3. Quarterly, complete the Patient Test Management Checklist of the Post-Analytical Phase as part of the routine laboratory operation. ..." Review of 2021 and 2022 quality assessment records revealed the following monitors were not performed at the frequency specified: 1. Proficiency Testing monitor scheduled for biannual review in May and November not documented during 2021 or 2022. 2. Personnel monitor scheduled for biannual review in January and July not documented during 2021 or 2022. 3. Procedure manual monitor scheduled for biannual review in April and October not documented during 2021 or 2022. During the exit conference at approximately 2:55 p.m., the laboratory manager confirmed that the quality assessment monitors had not been performed as specified in the quality assessment plan. |