| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 32D2180846 | 05/12/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Sandia National Laboratories | 1515 Eubank Blvd Ne, Building 897, Albuquerque, NM | |

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 |
|---|---|
| **D0000** | An initial survey and complaint survey were conducted on 05/11/2021 and 05/12 /2021. |
| **D3031** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(3)<br><br>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation of the SARS-CoV-2 laboratory developed test process and interview of Technical Supervisor 2 the laboratory failed to retain all test records. Findings: 1. During observation of the performance of the SARS-CoV-2 test system on 05/12/2021 at 9:45 AM in the building 897 clinical laboratory it was observed that the test person wrote test information onto a laminated plate map then transferred the information to the hard copy plate map and erased the information from the laminated version. 2. An interview of the Technical Supervisor 2 on 05/12/2021 at 9:50 AM confirmed that a copy of the laminated plate map was not retained. |
| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>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.<br><br>This STANDARD is not met as evidenced by: |

| | |
|---|---|
| | Based on a review of competency documentation and an interview of the General Supervisor the laboratory failed to document competencies for the Clinical Consultant, General Supervisor, and 2 of 2 Technical Supervisors. Findings: 1. A review of available competency documents revealed no documented competency assessments for the Clinical Consultant, General Supervisor, or 2 of 2 Technical Supervisors. 2. An interview of the General Supervisor on 05/11/2021 at 11:30 am, 11: 35 am, and 1:15 pm confirmed the above findings. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.<br><br>This STANDARD is not met as evidenced by:<br>I. Based on review of Temperature Control Logs and interview with Technical Supervisor 1 and Technical Supervisor 2, the laboratory failed to document the temperature of the freezers and refrigerators in building 897 and building 6585. Findings: 1. Review of Temperature Control Logs for April 2021 for building 897 revealed -80 degree Centigrade freezers in Room 1262 and Room 1280; -20 degree Centigrade freezers in Room 1262, Room 1280 and Room 1094D; and a 6 degree Centigrade refrigerator in Room 1280. The following products were maintained in cold storage: a. The Room 1262 -80 degree Centigrade freezer stored Human Specimen Control (HSC) Lot 8, expiration date 12/22/2021. The procedure "Preparation of A549 Human Sample Control (HSC) for SNL-NM 2019 nCoV Real Time RT-PCR Diagnostic Assay" states the HSC must be stored at -80 degrees Centigrade. b. The Room 1280 6 degree Centigrade Refrigerator stored Sigma-Aldrich Gentamicin solution 50 mg/mL in deionized water, liquid, sterile-filtered, BioReagent, suitable for cell culture, Batch #0000093345, expiration date April 2022. The manufacturer's Product Information stated a storage temperature of 2-8 degrees Centigrade. c. The Room 1280 -20 degree Centigrade freezer stored the following: (i) Thermo Fisher Applied Biosystems TaqMan Fast Virus 1-Step Master Mix Lot #00904050, expiration date 10/31/2021. The manufacturer product insert stated a storage temperature of -25 to -15 degrees Centigrade. (ii) 2019-nCoV CDC EUA Authorized qPCR Probe assay primer/probe mix, Lot #553336. The manufacturer product insert stated a storage temperature of -15 to -30 degrees Centigrade. (iii) Exact Diagnostics SARS-CoV-2 Standard Lot #20103020, expiration date 04/30 /2022. The manufacturer product insert stated a storage temperature of -20 degrees Centigrade or below. d. The Room 1094D -20 degree Centigrade freezer stored the following: (i) Thermo Fisher Applied Biosystems TaqMan Fast Virus 1-Step Master Mix Lot #00904050, expiration date 10/31/2021. The manufacturer product insert stated a storage temperature of -25 to -15 degrees Centigrade. (ii) 2019-nCoV CDC EUA Authorized qPCR Probe assay primer/probe mix, Lot #553336. The manufacturer product insert stated a storage temperature of -15 to -30 degrees Centigrade. (iii) Exact Diagnostics SARS-CoV-2 Standard Lot #20103020, expiration date 04/30/2022. The manufacturer product insert stated a storage temperature of -20 degrees Centigrade or below. 2. Review of Temperature Control Logs for April 2021 |

| | |
|---|---|
| | for building 6585 revealed -20 degree Centigrade freezers in Room 1410 and Room 1411; a -80 degree Centigrade freezer in Room 1410; and a 6 degree Centigrade refrigerator in Room 1410. The following products were maintained in cold storage: a. The Room 1410 -20 degree Centigrade freezer stored the following: (i) Thermo Fisher Applied Biosystems TaqMan Fast Virus 1-Step Master Mix Lot #00904050, expiration date 10/31/2021. The manufacturer product insert stated a storage temperature of -25 to -15 degrees Centigrade. (ii) 2019-nCoV CDC EUA Authorized qPCR Probe assay primer/probe mix, Lot #553336. The manufacturer product insert stated a storage temperature of -15 to -30 degrees Centigrade. (iii) Exact Diagnostics SARS-CoV-2 Standard Lot #20103020, expiration date 04/30/2022. The manufacturer product insert stated a storage temperature of -20 degrees Centigrade or below. b. The Room 1411 -80 degree Centigrade freezer stored Human Specimen Control (HSC) Lot 8, expiration date 12/22/2021. The procedure "Preparation of A549 Human Sample Control (HSC) for SNL-NM 2019 nCoV Real Time RT-PCR Diagnostic Assay" states the HSC must be stored at -80 degrees Centigrade. 3. During interview on 05/12/2021 at 1:55pm, Technical Supervisor 1 stated the laboratory began documenting refrigerator and freezer temperatures on 04/01/2021. Technical Supervisor 1 stated patient testing began in building 897 on 04/08/2020 and in building 6585 on 04/24/2020. 4. During interview on 05/12/2021 at 2:30pm, Technical Supervisor 2 confirmed the Human Specimen Control (HSC) is prepared in-house and the laboratory established a storage temperature for HSC of -80 degrees Centigrade. 27571 II. Based on observation of the -20 degree Centigrade freezer in the building 701 clinical laboratory and interview of Technical Supervisor 1 the laboratory failed to document the temperature of the freezer. Findings: 1. Observation of the -20 degree Centigrade freezer in the building 701 clinical laboratory on 05/12 /2021 at 11:40 AM revealed the following products being stored in the freezer: a. Bio-Rad One-Step Multiplex Supermix, Lot #64398846 (one box); manufacturer stated storage temperature from the package insert, version A (12010179) 19-0132 0319, was -20 centigrade or colder. b. 2019-nCoV CDC EUA Authorized qPCR Probe assay primer/probe mix, Lot #553336 (one box); manufacturer stated storage temperature from the product insert was -15 to -30 degrees Centigrade. c. Exact Diagnostics SARS-CoV-2 Standard, Lot #20103020 (one box); manufacturer stated storage temperature from the product insert was -20 degrees Centigrade or below. 2. An interview of Technical Supervisor 1 on 05/12/2021 at 11:40 AM revealed that there was no documentation of temperatures for the -20 degree freezer in building 701 clinical laboratory since the beginning of clinical testing on 04/09/2020. |
| **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: |

| | |
|---|---|
| | Based on a review of the performance specifications establishment documentation of the SARS-CoV-2 laboratory developed test and interview of the General Supervisor the laboratory failed to establish the performance specifications for the viral transport medium. Findings: 1. A review of the establishment study for the laboratory developed SARS-CoV-2 test system revealed that it did not include establishment studies for the viral transport medium which was made on-site and the laboratory was using the acceptable transport temperature of 2-8 degrees centigrade and acceptable time from collection to testing of 72 hours. 2. An interview of the General Supervisor on 05/12/2021 at 10:05 AM confirmed the above findings. |
| **D6127** | TECHNICAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1451(b)(9)<br><br>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of testing personnel competency evaluations during the first year of patient testing and an interview of the General Supervisor revealed that the Technical Supervisor failed to perform the evaluations. Findings: 1. A review of competency documentation for testing personnel during the first year of patient testing revealed that personnel that qualified as a General Supervisor performed and documented the evaluations for 15 of 15 testing personnel. 2. An interview of the General Supervisor on 05/11/2021 at 12:00 pm confirmed the above findings. |