Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D2180844	05/21/2021
Name of Provider or Supplier	**Street Address, City, State**	
Los Alamos National Laboratory	Ta43, Diamond Drive,Mail Stop M888, Los Alamos, 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 investigation were conducted onsite 05/11/2021 and 05/12/2021. Remote review of documentation continued 05/17/2021 through 05/21/2021. Allegations for complaint intake #NM00051786 were substantiated. The laboratory was found to not be in compliance with the following condition: Testing Personnel High Complexity Testing 42 CFR 493.1487
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, personnel competencies, and in interview with laboratory staff, the laboratory failed to establish all requirements in their written policies and procedures to assess competency of all employees. Findings included: 1. Review of the laboratory's policy for "COVID-19 Assay Technician Demonstration of Competency Assessment" (SAM 959.00, approved 03/09/2021) did not include all six components that must be evaluated and documented by a qualified individual, as specified in 493.1451 (b)(8)(i) through (b)(8)(vi): a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; b) Monitoring the recording and reporting of test results; c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; d) Direct observation of performance of instrument maintenance and function checks; e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and f) Assessment of problem solving skills; The laboratory's policy did not include assessing competency for their

	technical supervisors, general supervisors and clinical consultant. 2. Review of personnel competencies revealed the TS did not ensure all six components were evaluated and documented, as specified in 493.1451 (b)(8)(i) through (b)(8)(vi). Refer to D6127. 3. During an interview on 05/11/2021 at 1:20 pm, General Supervisor - 1 stated the laboratory did not have a policy/procedure for personnel competency prior to 03/09/2021.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on observation, interview, and record review the laboratory failed to record time of collection in order to ensure specimen integrity after collection as established of 96 out of 96 observed sample collections on 05/12/2021. Findings: 1) In review of SOP 1321.03 in section 3.3.2 step 13 states: "Aliquot specimens immediately per Section 3.5 of this document or store at 4C for up to 72 hours after collection. Batches that cannot be processed within that time will be stored at -70C". 2) Review of OSH-ISH-QTG-032 Title: Quick Take Guide COVID -19 Drive- Through Sample Collection under IV. Sample Donor Screening and Registration step 4 states "Testing sample donors will be scheduled in 30 minute blocks during hours of operation". 3) Section V. Preparation for Sample Collection step 4 states "Process Control will print the schedule from the electronic health record, and place the appropriate labels with the LIMS codes on the spreadsheet once the sample donor arrives which will serve as the key to match results with sample donor". 4) The Quick Take Guide did not include recording of collection time as according to SOP 1321.03 to ensure stability of specimen prior to analysis. 5) Observation of sample collection occurred on 5/12/2021 at 0805 hours at collection site Technical Area 33 (TA 33). A collection kit containing swab, barcoded VTM tube and a duplicate barcode label was taken from the Coleman cooler that contained presorted collection kits. As the patient arrived the duplicate barcode corresponding to the barcode on the VTM tubes was placed next to the name as the patient was verified on a list containing names in an appointment block. 6) In interview with process control personnel at 0835 hours on 5/12/2021 at the process control table it was confirmed that sample collection time was not documented. Collection time was considered to be appointment time. 7) Record review of a random sampling of Cordity final result reports from 12/2020 - 3/2021 under Sample Time, 15 out of 15 records reviewed showed no recorded collection time.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL

	CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on record review, observation, and interview the laboratory failed to monitor and maintain temperature (2-8C) of the refrigerator where collected specimens were stored to ensure sample integrity for 7 of 7 days in 2021 (refrigerator) and for 96 of 96 samples 05/12/2021 (in transport box). Findings: 1) Review of SOP 1321.03 Title: Receipt and Handling of Samples for COVID Testing section 3.4.1 titled Time limitations and long-term storage states "Per CDC guidance on March 26, 2020, specimens can be stored at 2-8C for up to 72 hours after collection. If a delay in extraction is expected, specimens must be stored at -70C or lower." 3a) In observation of accessioning and processing of the collected samples on 5/12/2021 at 0945 hours 96 samples were counted. Transport box labeled 4H2V/X20/S/00USA/M4563 was observed with 4 frozen ice packs. No thermometer was observed inside the box for temperature monitoring. b) Based on interview with TP-6 on 5/12/2021 at 0945 hours in the accessioning area confirmed that temperatures inside the transport boxes are not monitored. 4) Samples were accessioned and divided into 8 bundles with 12 samples each then stored in the refrigerator for aliquoting. A sticker was observed on the refrigerator stating 2-8C. 5) Record review of a random sampling of temperature logs from 12/17/2020 through 5/11/2021 for accessioning area refrigerator (where collected specimens were stored) ID: DF68B08813600724 revealed the following temperatures outside the established acceptable range: Temperature C Time Date 8.55 13:15 5/11/2021 8.64 13:00 5/11/2021 8.7 12:15 4/30/2021 9.19 11:00 4/30/2021 9.92 08:00 4/30/2021 9.62 12:30 4/29/2021 9.53 10:00 4/29/2021 9.5 10:45 4/27/2021 10.38 13:00 4/26/2021 10.59 10:15 4/26/2021 10.65 9:00 4/26/2021 10.02 13:30 4/3 /2021 8.48 11:30 3/19/2021 8.48 13:30 3/19/2021 6) The laboratory failed to maintain required refrigerator temperature to ensure sample integrity. 7) In interview with TP-6 on 5/12/2021 at 1035 hours in the accessioning room the question was asked how often temperatures were monitored for the refrigerator. The response was that temperatures were downloaded and reviewed monthly. 8) The question was then asked "How do you know when the temperature is out of range and what do you do about it?" The response was that someone would notice and call QA.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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. This STANDARD is not met as evidenced by: Based on direct observation, review of the laboratory's policies and procedures and staff interview the laboratory failed to have a written policy or procedure for uploading patient test results into the LIMS. 1. On 5/12/2021 at 1145 hours in the Conference Room the Surveyor observed plate one of two (~66 samples) uploaded to the LIMS. 2. CMS requested a policy or procedure for the uploading of patient test results to the LIMS. No policy or procedure was provided. 3. In interview on 5/12 /2021 at 1225 hours, the Technical Supervisor-2 (see CMS-209 form) confirmed the laboratory does not have a written policy or procedure for uploading patient test results to the LIMS. *Acronyms: LIMS=Laboratory Information Management System
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on direct observation, review of the laboratory's policy and procedures, manufacturer's instructions, and interview with staff the laboratory failed to follow manufacturer's instructions for the preparation of 2019-CoV Plasmid Controls. 1. On 05/12/2021 at 0950 AM in the PCR Lab Room 163 the surveyor observed 61 2019 nCoV_N positive controls lot# 0000511398, expiration date 02/27/2022, made 09/14 /2020; 67 HS_RPP30 controls lot# 1100510985, expiration date 02/27/2022, made 09 /14/2020; and 14 NCOV multiplex positive control lot# 20210302, expiration date 02 /27/2020 in a freezer SNWB93539944. 2. A review of the laboratory's procedure SAM 505.01 Preparation of positive controls for 2019-nCoV and RNase P assay, pages 4-5,6.4 "Preparation of Plasmid Control from IDT; 6.4.1 IDT-Dilute and aliquot PC ...IDT provides 2019 CoV Plasmid Controls at 200,000 copies/ L in IDTE pH 8.0 ...1. Thaw, mix and spin down stock PC., 2. Dilute according to Table 1 (final concentration of 200 copies/L)., 3. Aliquot volume indicated on benchsheet into each 0.5 mL labeled tube., 4. Store aliquots per manufacturer instruction in labeled storage box."; and "6.4.2 IDT Dilute combine and aliquot PC ... IDT provides 2019 CoV Plasmid Controls at 200,000 copies/ L in IDTE pH 8.0 ...1. Thaw, mix and spin down stock PC., 2. Dilute according to Table 1 (suggested intermediate concentration of 20,000 copies/ L)., 3. Combine diluted PCs according to Table 2 (final concentration of 200 copies/ L)., 4. Aliquot volume indicated on benchsheet into each 0.5 mL labeled tube., 5. Store aliquots per manufacture instructions in labeled storage box." 3. A review of Integrated DNA Technologies Supplemental information 2019-CoV Plasmid Controls revealed "Supplemental information for use ...Plasmid Controls can

	be diluted to lower concentration using IDTE, pH 8.0 (10mM Tris, 01 mM EDTA, pH 8.0) as needed for experimental requirements. Diluted controls should be prepared fresh at time of use." 4. In interview on 05/12/2021 at 11:15 AM, the General Supervisor-2 confirmed the laboratory does not prepare Plasmid Controls fresh at time of use. *Acronyms: CoV=Coronavirus; PCR= Polymerase Chain Reaction; IDT=Integrated DNA Technologies; DNA=Deoxyribonucleic Acid; L=microliter; mL= milliliter; mM=millimolar
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. This STANDARD is not met as evidenced by: I. Based on direct observation, review of policy and procedures, and interview with staff the laboratory failed to monitor temperatures for storage of reagents and samples. 1. On 5/11/2021 at 2:15 PM in Extraction Room 225, the Surveyor observed three temperature probes: (a) one in a freezer labeled -20 to -35 C containing 29 human sample control (HSC) lot# 20201103-1 and expiration date 03/30/2023; (b) one in a refrigerator labeled 2-8 C; (c) one room temperature; (d) sampling of reagents observed stored at room temperature included (i)one MagMAX Viral/Pathogen Wash lot# 2009105, expiration date 09/07/21, received 10/22/2020, storage temperature 15-30 C (ii)one MagMAX Viral/Pathogen Binding Solution lot# 2008090, expiration date 09/02/2021, received 10/28/2020 storage temperature 15-30 C. 2. A review of Integrated DNA Technologies Supplemental information 2019-CoV Plasmid Controls revealed ..."Storage Conditions ...The Plasmid Controls should be stored at -15 to -30 C in a constant temperature (non-frost-free) freezer through the expiration date provided on the Certificate of Analysis (CoA)." 3. In interview on 05/11/2021 at 3:15 PM, Testing Personel-6 confirmed the refrigerator labeled 2-8 C is for temporary storage of samples prior to extraction and amplification. For all three probes the temperature data is pulled from the probe monitors at approximately monthly intervals, the system does not have an alert or audible alarm, daily temperature checks are not performed by laboratory personnel. 4. CMS requested a policy or procedure for monitoring laboratory temperature. No policy or procedure was provided. 5. In interview on 05/12/2021 at 10:15 AM, the General Supervisor-2 confirmed the laboratory does not have a policy for monitoring temperature, the only way of knowing if temperature is out of range is to review the logs, and the laboratory has not reviewed temperature logs since December 2020. *Acronyms: C= Degree Celsius 41221 II. Based on record review, observation, and interview the laboratory failed to ensure viral transport medium (for COVID-19 collection) integrity of 2-8C for 12 of 12 months (05/2020 through 05/2021). Findings: 1a) Review of Centers for Disease Control and Prevention SOP# SDR-052-05 under Preparation of Viral Transport Medium section 8.17 states "Store at 2-8C (or temperature determined by specific data generated in stability study by manufacturing laboratory)." b) Review of SAM 506.00 Titled Preparation, Dispensing and Quality Assurance of Viral Transport Medium under section 6.3 titled Viral Transport Medium Aliquoting Procedure step 9 states

	"Store large bags of 50 tubes at 2-8C, as well as any medium remaining in the large bottle." c) A random sampling review of the temperature log of viral transport medium storage refrigerator ID: DF68CC5213895425 from 12/23/2020 through 4/5 /2021 showed the following temperatures were outside of established acceptable range: Temperature C Time Date 0.89 0:00 3/24/2021 1.01 18:00 3/23/2021 0.92 12: 00 3/23/2021 1.1 6:00 3/23/2021 1.26 0:00 3/23/2021 1.02 18:00 3/22/2021 0.81 12: 00 3/22/2021 0.89 6:00 3/22/2021 0.86 0:00 3/22/2021 0.76 18:00 3/21/2021 1.12 12: 00 3/21/2021 0.83 6:00 3/21/2021 0.75 0:00 3/21/2021 0.8 18:00 3/20/2021 0.69 12: 00 3/20/2021 0.82 6:00 3/20/2021 0.86 0:00 3/20/2021 1.07 18:00 3/19/2021 1.21 12: 00 3/19/2021 1.51 6:00 3/19/2021 1.28 0:00 3/19/2021 1.09 18:00 3/18/2021 -0.16 12: 00 3/18/2021 1.23 4:58 1/15/2021 -1.57 16:58 1/14/2021 1.4 10:58 1/14/2021 1.65 10: 58 1/11/2021 1.86 4:58 1/11/2021 1.64 22:58 1/10/2021 1.52 16:58 1/8/2021 1.4 10: 58 1/8/2021 1.52 4:58 1/8/2021 1.67 22:58 1/7/2021 1.36 16:58 1/7/2021 1.45 10:58 1 /7/2021 1.61 4:58 1/7/2021 1.44 22:58 1/6/2021 1.84 16:58 1/6/2021 1.39 4:58 1/6 /2021 1.45 22:58 1/5/2021 1.66 16:58 1/5/2021 1.5 4:58 1/5/2021 1.86 22:58 1/4/2021 1.37 4:58 1/5/2021 d) In interview with the accessioning team member at 1415 hours on 5/11/2021 in the conference room it was disclosed that approximately 1000 (100 microliter) viral transport media vials were created each week. e) In interview with the accessioning team member at 1425 hours on 5/11/2021, in the hallway in front of the refrigerator, the question was asked how often the refrigerator temperature was monitored. The answer given was that the temperature log was downloaded and reviewed monthly. 2a) In observation of the collection area (TA 33) refrigerator GE GTH17DBDORWW on 5/12/2021 at 0830 hours 3 boxes containing viral transport media collection kits (labeled: "62110 - 62160", "62161 - 62210", "62061 - 62109") were stored. No thermometer to monitor temperatures was observed. b) In the collection area on 5/12/2021 at 0815 hours it was observed that a Coleman cooler containing viral transport media collection kits had one ice block. No thermometer was seen in the cooler. c) During observation of Occupational Medicine Clinic (TA 3) on 5/12/2021 at 0918 hours, it was noted that additional viral collection kits were stored in the refrigerator labeled Magic Chef, as follows: One bag of 50 viral transport media tubes ("un-kited") labeled "Lot number BATL_506-741-00030, QC passed 02 /12/21" Six boxes of viral transport media kits. The boxes were labeled "62461-62509", "62211-62260", "62261-62310", "62311-62360", "62361-62410", "62412-62460." d) In interview with Occ Health group leader on 5/12/2021 at 1530 hours confirmed that temperatures were not monitored for the collection area or the Occ Health refrigerator.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on direct observation, review of the laboratory's policies and procedures and in interview with staff the laboratory failed to label solutions with storage requirements, and preparation and expiration dates. 1. The Surveyor observed the following: (a) 05 /11/2021 at 1:05 PM in Extraction Room 225-one bottle of 1% Virkon S with no storage requirements on the label; one bottle of 70% ETOH with no storage

	requirements or expiration date on the label; one bucket of 10% Bleach with no storage requirements on the label. (b) 05/12/2021 at 7:45 AM in Pre PCR Room 263-one bucket of 10% Bleach with no storage requirements on the label; one bottle of 70% ETOH with no storage requirements and preparation and expiration date on the label. (c) 05/12/2021 at 9:10 AM in RNA Extraction Room 160-2 bottles of 70% ETOH with no storage requirements or expiration date on the label. 2. CMS requested a policy or procedure for preparation, storage, and labeling of solutions. No policy or procedure was provided. 3. In interview on 5/12/2021 at 3:35 PM, the General Supervisor-1 and General Supervisor-2 (see CMS-209 form) confirmed the laboratory does not have a written policy or procedure for preparation, storage and labeling of solutions. *Acronyms: ETOH=Ethanol; PCR= Polymerase Chain Reaction; RNA=Ribonucleic Acid
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's validation studies and interview with staff the laboratory failed to evaluate the data for the Kingfisher sample extraction modifications made to the EUA approved CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel (CDC-006-00019, Revision 6). 1. CMS requested the Kingfisher sample extraction validation studies. The laboratory provided raw data (Excel document) on a computer screen. 2. In interview on 05/12/2021 at 11: 00 AM, the Technical Supervisor-1, Technical Supervsor-2, and General Supervisor-2 (see CMS-209 form) confirmed the data was not signed and evaluated by the laboratory director. 3. In interview on 05/12/2021 at 11:00 AM, the Technical Supervsor-2 stated the study was completed December 7, 2020 and put in use December 14, 2020. *Acronyms: EUA=Emergency Use Authorization; RT-PCR=Reverse Transcriptase-Polymerase Chain Reaction; COVID-19=Coronavirus Disease 2019
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, temperature records, and interview with

	staff, the laboratory failed to document corrective actions taken when the criteria for proper storage of collection swabs and specimens were not met for 22 of 22 days in 2021. Findings included: 1. Review of SOP 1321.03 Title: Receipt and Handling of Samples for COVID Testing section 3.4.1 titled Time limitations and long-term storage states "Per CDC guidance on March 26, 2020, specimens can be stored at 2-8C for up to 72 hours after collection. If a delay in extraction is expected, specimens must be stored at -70C or lower." 2. Record review of a random sampling of temperature logs from 03/2021 through 5/2021 for accessioning area refrigerator (where collected specimens were stored) ID: DF68B08813600724 revealed the following temperatures outside the established acceptable range of 2-8C: Temperature (C) Time Date 8.55 13:15 5/11/2021 8.64 13:00 5/11/2021 8.7 12:15 4/30/2021 9.19 11:00 4/30/2021 9.92 08:00 4/30/2021 9.62 12:30 4/29/2021 9.53 10:00 4/29/2021 9.5 10:45 4/27/2021 10.38 13:00 4/26/2021 10.59 10:15 4/26/2021 10.65 9:00 4/26/2021 10.02 13:30 4/3/2021 8.48 11:30 3/19/2021 8.48 13:30 3/19/2021 The laboratory did not document corrective actions taken for the above temperatures outside of the criteria. 3. In interview with TP-6 on 5/12/2021 at 1035 hours in the accessioning room the question was asked how often temperatures were monitored for the refrigerator. The response was that temperatures were downloaded and reviewed monthly. 4. The question was then asked "How do you know when the temperature is out of range and what do you do about it?" The response was that someone would notice and call QA. 5. Review of Centers for Disease Control and Prevention SOP# SDR-052-05 under Preparation of Viral Transport Medium section 8.17 states "Store at 2-8C (or temperature determined by specific data generated in stability study by manufacturing laboratory)." 6. A random sampling review of the temperature log of viral transport medium storage refrigerator ID: DF68CC5213895425 from 12/23/2020 through 4/5/2021 showed the following temperatures were outside of the established acceptable range (2-8C): Temperature (C) Time Date 0.89 0:00 3/24/2021 1.01 18:00 3/23/2021 0.92 12:00 3/23/2021 1.1 6:00 3/23/2021 1.26 0:00 3/23/2021 1.02 18:00 3/22/2021 0.81 12:00 3/22/2021 0.89 6:00 3/22/2021 0.86 0:00 3/22/2021 0.76 18:00 3/21/2021 1.12 12:00 3/21/2021 0.83 6:00 3/21/2021 0.75 0:00 3/21/2021 0.8 18:00 3/20/2021 0.69 12:00 3/20/2021 0.82 6:00 3/20/2021 0.86 0:00 3/20/2021 1.07 18:00 3/19/2021 1.21 12:00 3/19/2021 1.51 6:00 3/19/2021 1.28 0:00 3/19/2021 1.09 18:00 3/18/2021 -0.16 12:00 3/18/2021 1.23 4:58 1/15/2021 -1.57 16:58 1/14/2021 1.4 10:58 1/14/2021 1.65 10:58 1/11/2021 1.86 4:58 1/11/2021 1.64 22:58 1/10/2021 1.52 16:58 1/8/2021 1.4 10:58 1/8/2021 1.52 4:58 1/8/2021 1.67 22:58 1/7/2021 1.36 16:58 1/7/2021 1.45 10:58 1/7/2021 1.61 4:58 1/7/2021 1.44 22:58 1/6/2021 1.84 16:58 1/6/2021 1.39 4:58 1/6/2021 1.45 22:58 1/5/2021 1.66 16:58 1/5/2021 1.5 4:58 1/5/2021 1.86 22:58 1/4/2021 1.37 4:58 1/5/2021 The laboratory did not document corrective actions taken for the above temperatures outside of the criteria. 7. In interview with the accessioning team member at 1425 hours on 5/11/2021, in the hallway in front of the refrigerator, the question was asked how often the refrigerator temperature was monitored. The answer given was that the temperature log was downloaded and reviewed monthly. In interview on 05/12/2021 at 10:15 AM, the General Supervisor-2 confirmed the laboratory does not have a policy for monitoring temperature, the only way of knowing if temperature is out of range is to review the logs, and the laboratory has not reviewed temperature logs since December 2020.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where

	the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on direct observation, review of instrument data, final test reports for COVID-19, and interview with staff, the laboratory failed to ensure their patient test reports included all required information (name/address of testing laboratory and correct specimen source) for 27 of 27 random patients from 05/2020, 12/2020, 01/2021, 02 /2021, 03/2021, and 05/2021. Findings included: 1. During an interview on 05/11 /20221 at 9:00 am, Technical Supervisor -1 stated the specimen source for COVID-19 testing was nasopharyngeal. Other specimen sources were not established. During an observation of collection at "Technical Area 33" on 05/12/2021 between 8:11 am and 8:45 am, collectors were obtaining nasopharyngeal specimens. Review of a sampling of patient test reports for specimens collected on 5/12/2021 and reported 05/13/2021 included "Sample Type: Nasal" for the following: Sample ID COVID61983 Sample ID COVID61935 Sample ID COVID61950 Sample ID COVID61964 Sample ID COVID61975 Sample ID COVID61986 Sample ID COVID62000 Sample ID COVID62004 Sample ID COVID62015 Sample ID COVID62027 Further review revealed the reports did not include the name and address of the testing laboratory. (Note: the testing laboratory was the laboratory under survey) 2. A random sampling of patient COVID-19 test reports were selected from Applied Biosystems 7500 Fast Real-Time PCR System instrument data from 05/2020, 12/2020, 01/2021, 02/2021, and 03/2021. Review of final test reports revealed the laboratory did not include the name and address of the testing laboratory and the correct specimen source, as follows (sampling from 17 reports): 05/25/20 (results date) - Sample ID 38622 - Sample Type: Nasal 12/11/20 - Sample ID 52425 - Sample Type: Nasal 01/21/21 - Sample ID 54253- Sample Type: Nasal 02/24/21 - Sample ID COVID57069- Sample Type: Nasal 03/24/21 - Sample ID COVID59969 - Sample Type: Nasal
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on direct observation, review of the laboratory's verification studies and staff interview the laboratory failed to document initial verification and have an ongoing mechanism to monitor the LIMS electronic interpretation of the instrument raw data of patient test results. 1. On 5/12/2021 at 1145 hours in the Conference Room the Surveyor observed plate one of two (~66 samples) uploaded to the LIMS, the Technical Supervisor-2 (see CMS-209 form)stated the LIMS is programmed to interpret results and determine acceptability. 2. CMS requested the laboratory's verification studies. No studies were provided. 3. CMS requested a policy or procedure for monitoring the LIMS electronic interpretation. No policy or procedure was provided. 4. In interview on 5/12/2021 at 1225 hours, the Technical Supervisor-2 confirmed the laboratory does not have verifications studies or a policy or procedure

	for the electronic interpretation of patient test results. *Acronyms: LIMS=Laboratory Information Management System
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on review of the laboratory's validation studies and interview with staff the laboratory director failed to evaluate modifications to the EUA approved CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel (CDC-006-00019, Revision 6) for acceptability. 1. A review the laboratory's validations studies for EUA approved CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel (CDC-006-00019, Revision 6) revealed one initial evaluation and two modification studies not signed and evaluated by the laboratory director. 2. In interview on 05/12/2021 at 11:00 AM, the Technical Supervisor-1, Technical Supervsor-2 and General Supervisor-2 (see CMS-209 form) confirmed the following studies were not signed and evaluated by the laboratory director: (a)Initial Validation-Internal Results Report On Competency Testing and Assay Evaluation, completed April 30, 2020 and put in use May 11, 2020; (b) Modification 1; Diagnostic Testing for COVID-19 Bridging Study for QIAamp Viral RNA Extraction vs Beckman RNAdvance vs Thermofisher MagMAX (LA-UR-21-21730) and Diagnostic Testing for COVID-19 Bridging Study for CDC EUA assays vs CDC Multiplex N1 FAM, N2 SUN, RNAse P ATTO 647 Assays (LA-UR-21-21738),completed September 21, 2020 and put in use October 28, 2020; and (c) Modification 2-Kingfisher extraction, completed December 7, 2020 and put in use December 14, 2020. *Acronyms: EUA=Emergency Use Authorization; RT-PCR=Reverse Transcriptase-Polymerase Chain Reaction; COVID-19=Coronavirus Disease 2019; RNA=Ribonucleic Acid; N=Nucleocapsid
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) 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. This STANDARD is not met as evidenced by: Based on review of the CMS-209 form, personnel competency assessments, and in interview with staff, the Technical Supervisor (TS) failed to evaluate and document all six components for 11 of 11 Testing Persons (TP) competency assessments in 2020. Findings included: 1. Review of the CMS-209 form included 11 TPs who performed high complexity COVID-19 testing. The laboratory began testing 05/11 /2020 and all TPs but one (TP-6 hired 11/2020) had hire dates prior to testing. 2. Review of 11 personnel competency assessments for 2020 included testing blind samples for COVID-19 testing. Further review, revealed the TS did not ensure all six components were evaluated and documented, as specified in 493.1451 (b)(8)(i) through (b)(8)(vi): a) Direct observations of routine patient test performance,

	including patient preparation, if applicable, specimen handling, processing and testing; b) Review of preventive maintenance records; c) Direct observation of performance of instrument maintenance and function checks; d) Assessment of problem solving skills TP-7, TP-8, and TP-10 competency assessments from 06/2020 did not include TS signature. 3. During an interview on 05/11/2021 at 1:30 pm, General Supervisor - 1 confirmed TPs competency assessments did not include all six components.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of the CMS-209 form, personnel credentials, and interview with staff, the laboratory failed to ensure individuals met qualification requirements to perform high complexity testing. The laboratory failed to ensure 2 of 11 Testing Personnel (TP-5, TP-11) met qualification requirements to perform high complexity testing (COVID-19). Refer to D6171.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory

	Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on review of the CMS-209 form, personnel credentials, and interview with staff, the laboratory failed to ensure 2 of 11 Testing Personnel (TP-5, TP-11) met qualification requirements to perform high complexity testing (COVID-19). Findings included: 1. Review of the CMS-209 form listed a total of 11 TPs who perform COVID-19 high complexity testing. 2. Review of personnel credentials (university transcripts) revealed the following: TP-5 had a foreign institution degree without evaluation of U.S. equivalency (CLIA requirement). TP-11 Masters of Science and Ph. D. degree for Comparative Veterinary Medicine semester hours was insufficient to meet 493.1489(b)(2)(ii)(A) through (b(2)(ii)(B)(2). In addition, TP-11 had a foreign institution degree (Bachelor of Veterinary Science and Animal Husbandry) without evaluation of U.S. equivalency in order to evaluate semester hours. TP-5 and TP-11 did not meet the qualification requirements in order to perform high complexity COVID-19 testing. 3. During an interview on 05/11/2021 at 4:10 pm, Technical Supervisor -1 (TS-1) and the Laboratory Director confirmed that TP-5 did not have additional documentation such as a U.S. equivalency to qualify. An electronic mail (email), 05/18/2021 at 12:32 pm (CDT) was sent to TS-1 and the Laboratory Director notifying them that TP-11 credentials were reviewed and it was determined this individual did not qualify to perform high complexity testing. (Email response on 05/18/2021 at 1:35 pm [CDT] included acknowledgement) Word Key: CDT - central daylight time