Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0668319	08/03/2021
Name of Provider or Supplier	**Street Address, City, State**	
Centers For Disease Control And Prevention I	1600 Clifton Road Ne, Buildings 17,18 And 23, Atlanta, GA	

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 unannounced complaint survey was conducted at the Centers for Disease Control and Prevention I Lab on 8/03/2021. Based on the survey findings, the laboratory failed to meet the following CLIA conditions: D5300 493.1240 Condition: Preanalytic Systems D5400 493.1250 Condition: Analytic Systems
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on direct observations, review of laboratory procedures, test directory, stability data, test requisitions (50.34 forms), stability data summary, and in interview with staff, the laboratory failed to meet the preanalytic system requirements, as evidenced by: 1. The laboratory failed to ensure written policies and procedures included all preanalytic requirements (defined specimen storage, rejection criteria, conditions for transportation) for 1 of 1 assay observed (Fungal Identification) on 08/03/2021. Refer to D5311, I. 2. The laboratory did not have supporting documentation to ensure shipping methods used by outside submitters to the laboratory maintained transport conditions and specimen integrity for 2 of 2 test procedures (Fungal Identification and Respiratory Virus Molecular Detection) in 2021. Refer to D5311, II. 3. The laboratory failed to have a system in place to ensure specimens received in the STAT room included documentation of their disposition (specimen vial conditions) for 1 of 1 specimen observed on 08/03/2021. Refer to D5311, III. 4. The laboratory failed to

	ensure the test directory (client services manual) included all preanalytic requirements (defined specimen storage, preservation, stability and indicate conditions for transport) for their submitters sending specimen for 1 of 1 test reviewed. Refer to D5317, I. 5. The laboratory failed to ensure all Preanalytic requirements were included in the test directory for submitters for test procedures missing conditions for transportation information for 2 of 2 test (Enteric Isolation -Primary Specimen and Fungal identification). Refer to D5317, II. 6. The laboratory failed to ensure their test directory (client services manual) included all preanalytic requirements (defined specimen storage, rejection, and conditions for transportation) for their submitters sending specimens for 1 of 1 assay reviewed (Fungal Identification). Refer to D5317, III. 16410 7. The laboratory failed to have consistent policy that included specific instructions for Preanalytic specimen storage, transportation and stability studies for testing branches. refer to D5391
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: I. Based on direct observations, review of laboratory procedures, test directory, stability data, test requisitions (50.34 forms), and in interview with staff, the laboratory failed to ensure written policies and procedures included all preanalytical requirements (defined specimen storage, rejection criteria, conditions for transportation) for 1 of 1 assay (Fungal Identification) observed on 08/03/2021. Findings included: 1. Review of Fungal Identification (ID) (test code: 10179) procedures, "Procedure for MALDI-ToF-based Identification of Yeast" (Doc.No. RES-400-P09) and "DNA-Based Identification of Molds and Yeasts, Test Procedure fpr [sic] BSL2 lab" (Doc. No. FL-0017) did not include the following preanalytical requirements: specimen storage (defined temperature); conditions for specimen transportation (defined temperature); and specimen rejection. 2. Review of the test directory (client services manual) for Fungal ID stated, "Isolates can be refrigerated or kept at an ambient temperature" for "collection, storage, and preservation of specimen prior to shipping" and "shipping instructions" were not provided. The test directory did not define "refrigerated" and "ambient" temperatures for storage; conditions for specimen transportation; and specimen rejection. Preanalytic requirements had not been established and defined in the laboratory's procedures to ensure submitters sent specimens within acceptable conditions. 3. Review of "Specimen Stability Summary" for "Fungal Identification, Yeasts" did not include defined temperature of "ambient" for storage of isolates. The study also included "4C" for storage but was not included in the laboratory's procedures and test directory; and a temperature range was not included. 4. During a tour of the STAT room on 08/03/2021 at 10:20 am, Package ID 2021007750 was observed being received and accessioned. It was an isolate on a Sabouraud Dextrose Agar (SDA) slant (specimen 3002863528 collected 07/21/21, no collection time) in a biohazard bag in a SAFTPAK box in a FedEx bag. The Team Lead documented "RT" (room temperature) on the 50.34 form for specimen container. Room temperature was not defined in the laboratory's policies. 5. Review of the

testing laboratory's 2020 annual test volume for "Fungal ID, Yeasts" was 108. 6. During an interview on 08/03/2021 at 11:50 am in the STAT room, the STAT team and laboratory director were asked what is the definition of "Room Temperature" (temperature range/gradient), as observed documented on the 50.34 forms; they were unable to provide a definition. 7. During a telephone interview on 08/23/2021 at 3:22 pm, the laboratory director confirmed the above findings. Word Key: MALDI-ToF - Matrix-Assisted Laser Desorption-Ionisation-Time of Flight (Mass Spectrometry) DNA - deoxyribonucleic acid BSL - biosafety level C- degree Celsius II. Based on direct observations, test directory, laboratory procedures, stability data summary, and in interview with staff, the laboratory did not have supporting documentation to ensure shipping methods used by outside submitters to the laboratory maintained transport conditions and specimen integrity for 2 of 2 test procedures (Fungal Identification and Respiratory Virus Molecular Detection) in 2021. Findings included: 1. During a tour of the STAT room on 08/03/2021 at 10:20 am, observations of processes included the following packages with specimens received from outside submitters: Package ID 2021007750 from Pennsylvania included an isolate on a SDA slant (specimen 3002863528 collected 07/21/21, no collection time) in a biohazard bag in a SAFTPAK box in a FedEx bag for Fungal ID. The Team Lead documented "RT" (room temperature) on the 50.34 form for specimen container. Results were reported 08/10/2021. Note: on 08/03/2021, one sample/test procedure was observed for this CLIA number. The above test was 1 sampling of 90 offered by the testing laboratories (units). 2. The test directory for Fungal ID did not include all preanalytical requirements to ensure submitters shipped specimens within acceptable conditions. Refer to D5317. The laboratory policies and procedures for Fungal ID did not include the following preanalytical requirements: defined specimen storage and preservation and conditions for specimen transportation to ensure specimen integrity. Refer to D5311, I. 3. The laboratory was unable to provide supporting documentation /studies to demonstrate the shipping methods observed above did not affect specimen integrity/results and maintained specimen transportation conditions, as follows: a) "room temperature" (not defined) per documentation on the 50.34 forms; b) "ambient temperature" (not defined) per the test directory and stability summary; and c) "4C" per their stability summary (a range was not provided) 4. Further review of the test directory for Respiratory Virus Molecular Detection (Non-Influenza) (test code: 10401) stated, "Collection, Storage, and Preservation of Specimen Prior to Shipping: Refrigerate all specimens promptly after collection. If specimens can be shipped to CDC within 72 hours of collection, they should be kept refrigerated at 4C and shipped on gel ice-packs. Freezing should be avoided if possible, as this will reduce virus infectivity. Specimens for virus culture should not be frozen at -20 C. If specimens must be held for >72 hours, they should be promptly frozen at -70 C and shipped on dry ice ...Shipping Instructions which Include Specimen Handling Requirements: Frozen specimen should be shipped on dry ice. Refrigerated specimen should be shipped on cold packs." The test directory included conflicting information for freezing specimens, "Freezing should be avoided if possible, as this will reduce virus infectivity" and later stated, "If specimens must be held for >72 hours, they should be promptly frozen at -70 C and shipped on dry ice." In addition, it could not be determined how the laboratory ensured shipping methods maintained a "4C" temperature, a temperature range was not provided. The laboratory was unable to provide supporting documentation/studies to demonstrate the shipping instructions above did not affect specimen integrity/results and maintained the transport conditions of "-70C" or "4C." 5. During the exit conference via phone call on 09/09/2021 at 2:00 pm, the laboratory director confirmed the above findings. III. Based on observations, review of the laboratory's procedures, test requisitions (50.34 forms), and in interview with staff, the laboratory failed to have a system in place to ensure specimens received

	in the STAT room included documentation of their disposition (specimen vial condition) for 1 of 1 specimen observed on 08/03/2021. Findings included: 1. Review of the STAT room's "Specimen Processing" (SOP#: D10-200-004-04) procedure (page 4) stated, "Cold pack or room temperature shipments: ...8.11 record the following information on the CDC Form 50.34 in the CDC USE ONLY box located on the lower left corner of page 1 ...8.11.5 Outer package condition at STAT; 8.11.6 Specimen container at STAT; 8.11.7 Specimen (Vial condition) at STAT." The procedure did not list the options for documenting conditions on the 50.34 forms. Review of 50.34 forms included documentation of "RT" (room temperature), "CP" (cold pack), or "FR" (frozen) for "Specimen Container" on the first page (container was the shipping container). The forms for 1 specimen (Fungal ID) received in the STAT room did not include documentation for "Specimen (Vial condition)." Refer to the findings below. Note: room temperature, "cold pack", and "frozen" were not defined in laboratory procedures (temperature gradient). 2. During the tour of the STAT room on 08/03/2021 at 10:20am, the following specimen was observed being received and accessioned without documentation of the "Specimen (Vial condition) at STAT" on page 1 on the 50.34 forms: Specimen 3002863528 (Fungal ID) - isolate collected 07/21/2021 on an SDA slant, packaged in a biohazard bag in a SAFTPAK box in a FedEx bag. The Team Lead documented "G" (good) for the "Outer Package" (condition) and "RT" (room temperature) for the "Specimen Container" but did not document anything for "Specimen" (vial condition). 3. In an email on 08/25/2021 at 7: 30 am, the laboratory director sent the STAT team responses for questions asked by the surveyor, as follows: the surveyor asked, "On the 50.34 form, what does 'G' mean for 'Outer Package' and what is supposed to be documented for 'Specimen'?" and the laboratory responded, "G stands for good. Meaning the outer shipping container was intact and not damaged or wet. We only document under specimen on the 50.34 if something is wrong with the specimen such as mislabeled or leaking. If that is left blank 'good' is documented in ELIMS." The process for documenting "G" was not outlined in the laboratory's procedure. Specimen vial conditions were not documented as the specimen container conditions were documented on the 50.34 forms upon receipt ("RT," "CP," "FR"). The laboratory did not have a system in place to ensure specimens conditions/dispositions were documented upon receipt in the STAT room. The laboratory did not have a system in place to ensure specimen conditions were documented upon receipt in the STAT room. Word Key: ELIMS - enterprise laboratory information management system
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: I. Based on record review, interview with laboratory director and policies and procedures, the laboratory failed to ensure the test directory (client services manual) included all preanalytic requirements (defined specimen storage, preservation, stability and indicate conditons for transport) for their submitters sending specimen for 1 of 1 test reviewed. Findings include: 1. Review of (test code: 10181) Procedure for Fungal Study, test directory found the "Collection, Storage, and Preservation of Specimen prior to Shipping and Transport Medium," states, "To be determined". Review of procedure for "Antifungal Susceptibility Testing for Yeasts following M27-

A4 guidance (Doc. No. FRL-100-PO9, Rev No.: 01, Effective Date: 5/9/19), does not include specimen shipping information. Review of the procedure for "Basic Procedures and Guidelines for Identification of Yeast Cultures" in 10.12 "Sample Information/Processing," provides information for specimens, which states "Store original samples in the refrigerator (2-8C) until start of testing. Review of the "Specimen Stability Data Summary," stated "Our laboratory receives yeast isolates at ambient temperature on agar slants. The laboratory failed to include defined specimen shipping information for their Fungal Study. 2. During the exit conference via conference call on 9/9/2021 at 2:00pm, the laboratory director confirmed the above findings. II. Based on record review and interview with laboratory director, the laboratory failed to ensure all Preanalytic requirements were included in the test directory for submitters for test procedures missing conditons for transportation information for 2 of 2 test (Enteric Isolation -Primary Specimen and Fungal identification). Findings include: 1. Review of the laboratory test directory found the (test code:10106) - Enteric Isolation-Primary Specimen instructs the submitter to contact the CDC Consultant. Review of the laboratory procedure for FilmArray Gastrointestinal Panel, (Doc. No. PROS.TE.C.065, Ver. No. 04, Effective Date:7/22 /2019) revealed the laboratory failed to include instructions on how the condition of laboratory transport to the submitter. 2. Review of the (test code:10179) Fungal Identification, the test directory section for "Collection, Storage and Preservation" states " Isolates can be refrigerated or kept at an ambient temperature". The "Shipping Instructions" states "Specimen should be shipped at ambient temperature". Review of the Procedure for Isolation and identification of Candida auris (Doc. No. FRL-100-P04, Rev. No. 02, Effective Date:8/1/2018), section 9.1(a) states "Eswab collection and transportation...After the specimen is collected the swab should be placed into tube containing modified liquid Amies medium and stored at 4-25C, and shipped with an ice pack to the laboratory for processing within 96 hours of specimen collection. The test directory failed to include the 96-hour shipment timeline as documented in the laboratory procedure. The Test Directory did not define refrigerated or ambient temperature and Eswab collection requirement. 3. During the exit conference via conference call on 9/9/2021 at 2:00pm, the laboratory director confirmed the above findings. 43232 III. Based on direct observations, review of test requisitions (50.34 forms), final test reports, test directory, laboratory policies and procedures, stability summary, and interview with staff, the laboratory failed to ensure their test directory (client services manual) included all preanalytic requirements (defined specimen storage, rejection, and conditions for transportation) for their submitters sending specimens for 1 of 1 assay reviewed (Fungal Identification). Findings included: 1. During a tour of the STAT room on 08/03/2021 at 10:20 am, observations of processes included the following package with a specimen received from an outside submitter: Package ID 2021007750 from Pennsylvania included an isolate on a Sabouraud Dextrose Agar (SDA) slant (specimen 3002863528 collected 07/21/21, no collection time) in a biohazard bag in a SAFTPAK box in a FedEx bag for Fungal ID. The Team Lead documented "RT" on the 50.34 form for specimen container. Results were reported 08/10/2021. 2. Review of the test directory (client services manual) for Fungal ID stated, "Isolates can be refrigerated or kept at an ambient temperature" for "collection, storage, and preservation of specimen prior to shipping" and "shipping instructions" were not included. The test directory did not define "refrigerated" and "ambient" temperatures for storage; conditions for specimen transportation; and specimen rejection. Review of Fungal Identification (ID) (test code: 10179) procedures, "Procedure for MALDI-ToF-based Identification of Yeast" (Doc.No. RES-400-P09) and "DNA-Based Identification of Molds and Yeasts, Test Procedure fpr [sic] BSL2 lab" (Doc. No. FL-0017) did not include the following preanalytic requirements: specimen storage (defined temperature); conditions for specimen

	transportation (defined temperature); and specimen rejection. Preanalytic requirements had not been established and defined in the laboratory's procedures to ensure submitters sent specimens within acceptable conditions. 3. Review of the "Specimen Stability Summary" for "Fungal Identification, Yeasts" did not include a defined temperature of "ambient" for storage of isolates. The study also included "4C" for storage, but was not included in the the above laboratory procedures and test directory. The test directory did not include instructions to ensure shipping conditions maintained "ambient", "refrigerated" or "4C." 4. During the exit conference via phone call on 09/09/2021 at 2:00 pm, the laboratory director confirmed the above findings.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of laboratory Quality Assessment (QA) policies and staff interview, the laboratory's QA program was not effective to identify their laboratory's failure to establish specimen storage, preservation, and transport criteria for 90 Laboratory Developed Tests (LDTs). Findings include: 1. Review of the CLIA Consolidated Laboratory Compliance Manual, (Doc. No. CCP.060, Rev 01, Effective 3/10/2020, found the laboratory's did not address establishing specimen storage, preservation and transportation requirements to ensure specimen integrity, in "Section - 15. Analytic - Test Procedure". 2. Review of the Poxvirus and Rabies Branch (PRB) Quality Manual (Doc No. CDC-007-0024), section 5.3.2 General, found the procedure did not address establishing specimen storage, and transportation to ensure specimen integrity. 3. Review of the Enteric Diseases Laboratory Branch (EDLB) - Quality Assurance Plan (Doc. No. EDLB.AS.A.001) found the procedure did not address establishing specimen storage, and transportation to ensure specimen integrity. 4. Review of Clinical and Environmental Microbiology Branch (CEMB) - CEMB Quality Assurance and Assessment Plan (Doc. No. CEM.QMA.A.001) found the procedure did not address establishing specimen storage, and transportation to ensure specimen integrity. 5. During the exit conference via conference call on 9/9/2021 at 2:00pm, the laboratory director confirmed the above findings
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory procedures, test directory, specimen stability data summary report, and interview with staff, the laboratory failed to establish conditions for specimen storage and transport for their laboratory developed tests. 1. The

	laboratory failed to include specimen specimen storage and transportation policies and procedures reviewed on 09/09/21. Refer to D5403 2. The laboratory failed to complete specimen stability studies for 73 of 90 laboratory developed tests reviewed on 09/09/2021. Refer to D5423
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 record review of laboratory procedures and interview with the laboratory staff, the laboratory failed to include all required criteria in their test procedure. Findings include: 1. Review of the CLIA Compliance Manual for CDC I, (Doc. No.. CCP .060, Rev. 01, revealed a process for drafting laboratory procedures. Section 15, Analytic Test Procedures, states the following: 15.1. Technical Procedures - Technical procedures must contain all of the elements outlined in the CLIA Procedure Guidance." 2. Review of a sampling of test procedures found the following procedures do not include specimen storage and transportation criteria. a) Review of the test procedure FilmArray Gastrointestinal Panel, (Doc. No. PROS.TE.C.065, Ver. No. 04, Effective Date:7/22/2019), found the laboratory procedure failed to include specimen storage and transportation criteria. b) Review of the procedure for Isolation and identification of Candida auris (Doc. No. FRL-100-P04, Rev. No. 02, Effective Date: 8/1/2018), found the laboratory procedure failed to include specimen storage and transportation criteria. 3. During the exit conference via conference call on 9/09 /2021 at 2:00pm, the laboratory director confirmed the above findings.
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 specimen stability data summary report, test method validation records, laboratory test procedures, the laboratory test directory and interview with staff, the laboratory failed to establish any other performance characteristics (conditions for specimen storage and transportation) for 74 out of 90 laboratory developed tests (LDTs). Findings Include: 1.The laboratory failed to performed a total 74 of 90 specimen stability studies for tests performed in their branches. On 8/19/2021, the laboratory provided by email an Excel spreadsheet titled "Initial Stability Data Call Summary_ 11D0668319. The spreadsheet identified 90 test systems performed in 12 laboratory branches that contained columns titled: a. Branch Name b. Test System (test name) c. Test Code (CDC Test Directory Code) d. LDT (Laboratory Developed Tests) e. Stability Data Review of the laboratory specimen stability studies revealed for 2 of 16 did not have data documented in excel spreadsheet for (Detection of poxvirus or rabies lyssavirus nucleic acid and Detection of viable virus by Tissue Culture). Review of the specimen stability studies found the laboratory documentation failed to include Preanalytic specimen storage and temperature requirements in the Method Validation Summary Report (Qualitative Laboratory Developed Test) (Doc. No.: OCCP.036, Revision No.: 02, Effective Date: 11/16/2018 and laboratory test procedures. 2. The laboratory provided the test procedure titled "2019 Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel, Document Number: RVB.RD.METHOD.006, Version: 04, Effective Date: 06/01/2021; "Method Validation Summary Report (Qualitative Lab Developed Test), Method Validation Report for: 2019-nCoV Real-Time RT-PCR Diagnostic Panel", an excel spreadsheet titled "NCIRD_DVD_RVB_SARS-CoV-2 Stability Study VTM and Saline.XLS", " Evaluating the Effect of Freeze Thaws on Specimens Study Plan & Results Summary", Document Number: NCIRD.DVD. QRECORD.001, Version: 1, Effective Date:16 APR 2020, and the Food and Drug Administration (FDA) Emergency Use Authorization (EUA) Instructions for Use (IFU) for CDC 2019 nCoV Real-Time RT-PCR Diagnostic Panel (CDC-006-00019). The EUA original issue date is February 2, 2020. This laboratory test is listed as test code CDC-10401 on the" Initial Stability Data Call Summary_11D2030855" spreadsheet. A. Review of "2019 Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel" procedure found the following: "9. ACCEPTABLE SPECIMENS" "a. As described in CDC-006-00019. b. Basis for Rejected Specimens 1) Specimen not appropriately refrigerated or frozen 2) Incomplete specimen labeling or documentation 3) Inappropriate specimen type 4) Insufficient specimen volume" "10. SPECIMEN COLLECTION, HANDLING, AND STORAGE" "a. Specimens will be collected, handled, and stored as described in CDC-006-00019." B. Review of "Method Validation Summary Report (Qualitative Lab Developed Test), Method Validation Report for: 2019-nCoV Real-Time RT-PCR Diagnostic Panel" found the laboratory did not include studies to determine conditions for storage and transport of clinical specimens. This validation summary report was not signed nor dated. The test procedure "2019 Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel", Document No: RVB.RD.METHOD.006, Revision No: 01, Effective date: 1.18.2020 was approved by the laboratory director January 18, 2020. C. Review of "NCIRD_DVD_RVB_SARS-CoV-2 Stability Study VTM and Saline.XLS" revealed data for testing of Viral Transport Media (VTM) and Saline for three consecutive days

	with specimens stored at 4 C and room temperature. Room temperature was not defined in the study. D. Review of "Evaluating the Effect of Freeze Thaws on Specimens Study Plan & Results Summary" found the laboratory performed repeat testing on primary specimens and extracted total nucleic acid (TNA) subjected to 4 freeze thaw cycles. The study did not define the temperature of the freeze cycle or the timeframe of the 4 freeze thaw cycles. E. Review of the FDA EUA IFU for CDC 2019 nCoV Real-Time RT-PCR Diagnostic Panel (CDC-006-00019) found the following: "Transporting Specimens" "Store specimens at 2-8C and ship overnight to CDC on ice pack. If a specimen is frozen at -70C or lower, ship overnight to CDC on dry ice." "Storing Specimens" Specimens can be stored at 2-8C for up to 72 hours after collection. If a delay in extraction is expected, store specimens at -70C or lower. Extracted nucleic acid should be stored at -70C or lower. F. Review of test code CDC-10401 Respiratory Virus Molecular Detection (Non-Influenza) in the CDC Test Directory (https://www.cdc.gov/laboratory/specimen-submission/list.html.) found the following instructions: "Collection, Storage, and Preservation of Specimen Prior to Shipping" "Refrigerate all specimens promptly after collection. If specimens can be shipped to CDC within 72 hours of collection, they should be kept refrigerated at 4 C and shipped on gel ice-packs. Freezing should be avoided if possible, as this will reduce virus infectivity. Specimens for virus culture should not be frozen at -20 C. If specimens must be held for >72 hours, they should be promptly frozen at -70 C and shipped on dry ice." Based on review of the above documents, the laboratory failed to establish conditions for frozen storage and frozen transport of clinical isolates and extracted TNA for the LDT titled "2019 Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel". 3. Review of the laboratory Validation Method Summary Report (Qualitative Laboratory Developed Test) found the laboratory failed to ensure stability studies for use in the Preanalytical specimen storage and transportation for the submitter and laboratory staff to follow. The laboratory provides documentation of completed stability studies by using the Validation Method Summary Reports (Qualitative Laboratory Developed Test) for 12 of 16 tests performed to identify specimen storage and transportation requirements. Review of the Validation Method Summary (Qualitative Laboratory Developed Test) Reports found the document did not have a section or documentation on form for specimen stability studies for verification of specimen storage or transportation. 4. During the exit conference via conference call on 9/09/2021 at 2:00pm, the laboratory director confirmed the above findings. .