Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2196313	02/09/2022
Name of Provider or Supplier	**Street Address, City, State**	
Texas Diagnostic Laboratories, Llc	12000 Westheimer Road Suite 309, Houston, TX	

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 onsite complaint survey was performed in response to TX00408055, TX00406980, TX00406981, TX00407176, TX00407212, TX00407215, TX00407273, TX00407348, TX00407401, TX00410454 on 2/8/2022 and 2/9/2022. All allegations were substantiated. The laboratory was found out of compliance with the CLIA regulations. The conditions not met were: D5200 - 42 C.F.R. 493.1230 Condition: General laboratory systems; D5300 - 42 C.F.R. 493.1240 Condition: Preanalytic systems; D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director; D6168 - 42 C.F.R. 493.1487 Condition: Laboratories performing high complexity testing; testing personnel; The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit.
D3005	FACILITIES CFR(s): 493.1101(a)(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation. This STANDARD is not met as evidenced by: Based on review of the laboratory records from 2021 and 2022, surveyor observations, and confirmed in interview, the laboratory failed to establish procedures to monitor for cross-contamination of patient specimens for two of two Covid PCR tests (BioGx Xfree Covid-19 Direct RT-PCR and LumiraDx FastLab Solutions SARS). Findings included: 1. Surveyor observations on 2/8/2022 at 1040 hours revealed the laboratory used a robot to uncap specimen tubes in the preamplification room. Afterwards, the rack with specimen tubes that are uncapped are brought to a table where laboratory personnel manually processed the specimens onto a specimen plate. Observations included laboratory personnel who walked in and out of the pre-amplification room with the same laboratory coats and worked in both the uncapping

	and processing of specimens. 2. Review of the laboratory policies for both BioGx Xfree Covid-19 Direct RT-PCR and LumiraDx FastLab Solutions SARS revealed no documentation of procedures to monitor for cross-contamination of patient specimens. 3. Review of the laboratory CMS116 revealed the laboratory performed 25000 Covid tests annually. 4. An interview with the the director of laboratory operations on 2/9 /2022 at 1120 hours in the office confirmed the above findings. key: PCR: polymerase chain reaction RT-PCR: Reverse transcription PCR
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on review of records from 2021 and confirmed in interview, the laboratory failed to obtain and possess Pennsylvania (PA), Maryland (MD), and California (CA) State Licensure when specimens were received and tested from those three states as required. Findings included: 1. Random review of laboratory patient test records from 2021 revealed the laboratory collected and performed patient testing from the following three states: Pennsylvania, Maryland, and California. Refer to patient alias list. A random sampling of patients from PA, MD, and CA include: Requisition 1326904: MD Requisition 1326652: MD Requisition 1229655: PA Requisition 1229653: PA Requisition 1229655: PA sample ID 223220: CA sample ID 223221: CA sample ID 339596: CA 2. Surveyor requested documentation of the licenses to perform patient testing from the above states on 2/8/2022 at 1330 hours and again 2/09 /2022 at 1040 hours. The facility representative provided correspondence regarding their PA license, but no license was provided for any states. 3. An interview with the director of lab operations on 2/9/2022 at 1400 hours in the office confirmed the above findings.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: The facility failed to have an effective mechanism by which to monitor and evaluate the overall quality of the general laboratory systems, to identify and correct problems in the following areas: competency assessments (refer to D5209) or verify the accuracy of specimen identity (refer to D5203)
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure

	positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on review of the laboratory and patient test records from 2021 and 2022, laboratory policies, and confirmed in interview, the laboratory failed to establish and follow procedures to ensure positive identification of patient specimens from collection, testing, and reporting of test results for one of ten patients reviewed for both Covid PCR tests (BioGx Xfree Covid-19 Direct RT-PCR and LumiraDx FastLab Solutions SARS). Findings included: 1. Review of the 2021 and 2022 patient final reports revealed one of ten patients that had conflicting specimen label and requisition name and date of birth. Both specimens (ID 392295 and 392290) had the same barcode label (1111-55075) with same patient names. 2. Review of the requisition for specimen ID 392295 included the picture of the specimen tube which revealed the specimen had a different name and date of birth as the requisition. 3. Review of the laboratory policies revealed no documentation of a policy to ensure positive identification of patient specimens for two of two Covid PCR tests (BioGx Xfree Covid-19 Direct RT-PCR and LumiraDx FastLab Solutions SARS). 4. Review of the laboratory CMS116 revealed the laboratory performed 25000 Covid tests annually. 5. An interview with the director of lab operations on 2/10/2022 at 1330 hours in the office confirmed the above findings.
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 the laboratory's policies, review of laboratory's Centers for Medicare and Medicaid (CMS) Form 209, Laboratory Personnel Report, review of the laboratory's personnel records and staff interview, it was determined the laboratory failed to have documentation of competency assessment for 1 of 1 Technical Supervisor and 3 of 3 General Supervisors. Findings included: 1. Review the laboratory's policies revealed there was no policy for assessing competencies for the technical or general supervisor. 2. Review of the laboratory's CMS Form 209 (signed by Laboratory Director on 02/08/2022) revealed the laboratory identified 1 Technical Supervisor (TS) and 3 General Supervisors (GS). 3. Review of the laboratory's personnel records revealed there was no documentation of competency assessment for the TS, GS#1, GS#2 and GS#3, as listed on CMS Form 209. 4. In an interview on 02 /08/2022 at 1435 hours in the interview room the General Supervisor #1 confirmed the above findings.
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 review of the manufacturer's instructions, review of the laboratory's preanalytical studies, review of the laboratory policy, and review of patient records, the laboratory failed to meet the requirements for preanalytic systems. Refer to D5311-I, II, III; D5317
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 review of the manufacturer's instructions, review of laboratory and patient test records from 2021 and 2022, and confirmed in interview, the laboratory failed to establish the patient preparation; specimen collection; specimen storage and preservation and/or conditions for specimen transportation and processing of two of two specimen types (nasopharyngeal and oropharyngeal specimens) for the Covid PCR testing. Findings included: 1. Review of laboratory records from 2021 and 2022 revealed the laboratory performed Covid PCR testing using nasopharyngeal and oropharyngeal specimens in two types of viral transport media: Copan Universal Transport Media (UTM) and Beaver Viral Transport Media (VTM). 2. Review of the instructions for use for the BioGx Xfree Covid-19 Direct RT-PCR and LumiraDx FastLab Solutions SARS-CoV-2 RNA Star Complete revealed no documentation that the Beaver VTM was a compatible viral transport media for the test. BioGx Xfree Covid-19 Direct RT-PCR (500-003-XMP US Rev 04.4-11Oct2021) LumiraDx FastLab Solutions SARS-CoV-2 RNA Star Complete (SD-COM-ART-00023 Rev 16 Nov2021) A. BioGX Xfree Covid-19 3. Review of the laboratory policy for the BioGx Xfree Covid-19 Direct RT-PCR (SOP 002) revealed no documentation of the patient preparation; and specimen collection for the Beaver VTM. No preanalytical studies for either the nasopharyngeal and oropharyngeal specimens in Beaver VTM were available for review. Cross refer to D5423-A B. LumiraDx FastLab Solutions SARS 4. Review of the instructions for use for the LumiraDx FastLab Solutions SARS-CoV-2 RNA Star Complete (SD-COM-ART-00023 Rev 16 Nov2021) under limitations revealed "Samples must be collected, transported, and stored using appropriate procedures and conditions. Improper collection, transport, or storage of specimens may hinder the ability of this test to detect the target sequences." 5. Further review of the instructions for use for the LumiraDx FastLab Solutions SARS-CoV-2 RNA Star Complete (SD-COM-ART-00023 Rev 16 Nov2021) under Conditions of Authorization for the Laboratory revealed "authorized laboratories using LumiraDx SARS-CoV-2 RNA STAR Complete must use the product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control

	materials, authorized other ancillary reagents and authorized materials required to use this product are not permitted." 6. Review of the laboratory policy for LumiraDx FastLab Solutions SARS-CoV-2 RNA Star Complete (SOP 007) revealed no documentation of the patient preparation; specimen collection; specimen storage and preservation and conditions for specimen transportation and processing for the Beaver VTM. No preanalytical studies for either the nasopharyngeal and oropharyngeal specimens in Beaver VTM were available for review. Cross refer to D5423-B 7. Review of the laboratory CMS116 revealed the laboratory performed 25000 Covid PCR tests annually. 8. An interview with the director of laboratory operations on 2/9 /2022 at 1000 in the office confirmed the above findings. II. Based on review of the laboratory and patient test records from 2022 and confirmed in interview, the laboratory failed to follow its policy for specimen acceptability for one of twenty specimens reviewed for Covid PCR testing using the LumiraDx FastLab Solutions SARS test kit. 1. Review of the validation report for LumiraDx PCR kit revealed specimen stability at room temperature (temperature range not defined) for 7 days. 2. Random review of patient test records from January 2022 revealed the laboratory received and performed patient testing for one of twenty specimens after the seven day stability. Patient requisition: 1433508, collected 1/6/2022, received 1/14/2022; elapsed time 8 days 3. An interview with the director of lab operations on 2/9/2022 at 1400 hours in the office confirmed the above findings. III. Based on surveyor observations, review of the laboratory records from 2021 and 2022, and confirmed in interview, the laboratory failed to ensure specimens were received per their preanalytical studies for two of two specimen types (nasopharyngeal and oropharyngeal specimens in Copan UTM and Beaver VTM for LumiraDx FastLab Soultions SARS). Findings included: 1. Surveyor observations on 2/8/2022 at 1000 hours in the specimen processing area revealed the laboratory received 50 nasopharyngeal and oropharyngeal specimens in two types of viral transport media: Copan Universal Transport Media (UTM) and Beaver Viral Transport Media (VTM) in various FedEx boxes; FedEx mailers; and regular brown box mailers and envelopes. Refer to patient alias list 2/8/2022. 2. Review of the validation report for LumiraDx PCR kit revealed specimen stability at room temperature (room temperature not defined) for 7 days. 3. Review of the laboratory records available revealed no mechanism to monitor the temperature of specimens received. No studies were performed to verify the FedEx boxes; FedEx mailers; and regular brown box mailers and envelopes kept specimens at room temperature (temperature range undefined) per the validation studies performed. 4. Review of the laboratory CMS116 revealed the laboratory performed 25000 Covid tests annually. 5. An interview with the the director of laboratory operations on 2/9/2022 at 1120 hours in the office confirmed the above findings. key: PCR: polymerase chain reaction RT-PCR: Reverse transcription PCR
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: Based on review of the laboratory's client service manual and confirmed in interview, the laboratory failed to provide the appropriate specimen handling for nasopharyngeal and oropharyngeal specimens for two of two Covid PCR tests (BioGx Xfree Covid-19

	Direct RT-PCR and LumiraDx FastLab Solutions SARS). (specimen preservation, storage, transport) Findings included: 1. Review of the Collection Process Manual provided on 2/9/2022 revealed no documentation of the specimen storage and preservation; conditions for specimen transportation and specimen acceptability and rejection for two of two specimens types: nasopharyngeal and oropharyngeal specimens for two of two Covid PCR tests (BioGx Xfree Covid-19 Direct RT-PCR and LumiraDx FastLab Solutions SARS). 2. An interview with the director of lab operations on 2/9/2022 at 1340 hours in the office 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 the laboratory's policy and staff interview, the laboratory's quality assurance program failed to detect problems in preanalytic systems. 1. The laboratory failed to establish criteria for specimen acceptability and rejection. (Refer to D5311-I, II, III) 2. The laboratory failed to establish a complete client service manual. (Refer to D5317)
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 surveyor observations, review of the laboratory policies and records from 2020 and 2021, and confirmed in interview, the laboratory failed to document written procedures to include requirements for specimen preparation for two of two Covid PCR tests (BioGx Xfree Covid-19 Direct RT-PCR and LumiraDx FastLab Solutions SARS). A. BioGx Xfree Covid-19 Direct RT-PCR B. LumiraDx FastLab Solutions SARS Findings included: 1. Surveyor observations on 2/8/2022 at 1000 hours in the

	specimen processing area revealed the laboratory received 50 nasopharyngeal and oropharyngeal specimens in two types of viral transport media: Copan Universal Transport Media (UTM) and Beaver Viral Transport Media (VTM). Refer to patient alias list 2/8/2022. A. BioGx Xfree Covid-19 Direct RT-PCR 2. Review of the laboratory policy BioGx Xfree Covid-19 Direct RT-PCR SOP 2 revealed no documentation of the patient preparation using the Copan UTM or Beaver VTM specimen transport media. B. LumiraDx FastLab Solutions SARS 3. An interview with the director of lab operations on 2/9/2022 at 1020 hours revealed the laboratory performed the Lumira covid assay with the Beaver swab using an extraction kit (Magbead Viral DNA/RNA kit) prior to performing the assay. 4. Review of the laboratory policy LumiraDX Procedure SOP 007 revealed no documentation for the step by step procedure for patient preparation using the extraction kit nor any documentation of the acceptance criteria and patient preparation for the Beaver VTM transport media. 5. Review of the CMS116 revealed the laboratory performed 25000 Covid tests annually. 6. An interview with the director of lab operations on 2/9/2022 at 1000 hours in the office confirmed the above findings.
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 review of the manufacturer's instructions, review of the laboratory and patient test records from 2021 and 2022, and confirmed in interview, the laboratory failed to follow the manufacturer's instructions for specimen shipment for two of two Covid PCR tests (BioGx Xfree Covid-19 Direct RT-PCR and LumiraDx FastLab Solutions SARS). Findings included: 1. Review of the instructions of use for the BioGx Xfree Covid-19 Direct RT-PCR (500-003-XMP US Rev 04.4-11Oct2021) under Specimen Collection, Storage and Handling revealed "Shipping: Specimens must be packaged, shipped, and tranpsorted according to the current edition of the International Air Transport Association (IATA) Dangerous Goods Regulation. Store specimens at 2-8 C and ship overnight to the lab on ice pack. Specimens frozen at -70 C are shipped overnight to the lab on dry ice." 2. Review of the instructions of use for the LumiraDx FastLab Solutions SARS-CoV-2 RNA Star Complete (SD-COM-ART-00023 Rev 16 Nov2021) under Specimen Collection, Handling, and Storage revealed "transporting specimens: specimens must be packaged, shipped, and transported according to the current edition of the International Air Transport Association (IATA) Dangerous Goods Regulation. Follow shipping regulations for UN3373 Biological Substance, Category B when sending potential SARS-CoV-2 specimens." 3. Surveyor observations on 2/8/2022 at 1000 hours in the specimen processing area revealed the laboratory recieved Covid PCR specimens that were not packaged and labeled as required by the manufacturer. 4. Review of the laboratory CMS116 revealed the laboratory performed 25000 Covid PCR tests annually. 5. An interview with the the director of laboratory operations on 2/9/2022 at 1120 hours in the office 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 manufacturer's instructions, review of laboratory and patient test records from 2021 and 2022, and confirmed in interview, the laboratory failed to document preanalytical studies to support specimen requirements for two of two specimen types for the modified EUA approved COVID PCR tests. Findings included: 1. Review of laboratory records from 2021 and 2022 revealed the laboratory performed Covid PCR testing using nasopharyngeal and oropharyngeal specimens in two types of viral transport media: Copan Universal Transport Media (UTM) and Beaver Viral Transport Media (VTM) at ambient temperature (temperature range undefined). 2. An interview with the director of lab operations on 2/9/2022 at 1010 hours in the office confirmed the laboratory began Covid PCR testing using the BioGx Xfree Covid-19 Direct RT-PCR in April 2021 and LumiraDx FastLab Solutions SARS in 12/2021. 3. Surveyor observations on 2/8/2022 at 1340 hours revealed the laboratory performed Covid testing using the CFX Opus 384 Touch (SN 786BR02407) and CFX 384 (SN 796BR02381) thermocylcers. A. BioGx Xfree Covid-19 Direct RT-PCR 4. Review of the instructions for use for the BioGx Xfree Covid-19 Direct RT-PCR (500-003-XMP US Rev 04.4-11Oct2021) under Specimen Collection, Storage and Handling revealed "nasopharyngeal/oropharyngeal swab specimens should be collected according to the manufacturer's instructions for use. Swab specimens should be collected using only swabs with a synthetic tip, and an aluminum or plastic shaft...place swabs immediately into sterile tubes containing either 3 mL of viral transport media (UTM/VTM)..specimens may be stored at 2-8 C for up to 72 hours after collection. If a delay in testing or shipping is expected store specimens at -70 C or below." 5. Review of the package insert for the Copan Universal Tranpsort Medium (UTM-RT) System Instructions for Use revealed "using the UTM-RT System, collected specimens can be stored for up to 72h [hours] at 2-8 C." 6. Review of the package insert for the Beaver Sample Collection Kit under storage revealed "after use, the sample can be stored at room temperature for 1 week or for a longer time storage, please place it at -20 C and below." Room temperature range was undefined by the manufacturer and/or laboratory. 7. Review of the laboratory records revealed no documentation of the preanalytical studies for either the nasopharyngeal and oropharyngeal specimens in Beaver VTM or Copan UTM at ambient temperature (temperature range undefined). Note: laboratory provided preanalytical studies for the BioGx Xfree Covid Direct RT-PCR test on the ABI7500 Fast thermocyler on 2/9/2022. Review of those studies revealed a 5 day room temperature stability (room temperature undefined) for Copan UTM. However, no preanalytical studies were documented for the CFX Opus 384 Touch (SN 786BR02407) and CFX 384 (SN 796BR02381) thermocylcers. B. LumiraDx FastLab Solutions SARS 7. Review of the instructions of use for the LumiraDx FastLab Solutions SARS-CoV-2 RNA Star Complete (SD-COM-ART-00023 Rev 16

	Nov2021) under Specimen Collection, Handling, and Storage revealed "if wet swab is expressed in a compatible buffer (i.e. viral transport media (VTM), 0.85% saline solution, or phospate buffer saline (PBS - calcium and mangesium free) store specimens at 2 to 8 C for up to 72 hours after collection. If a delay in testing or shipping is expected, store specimens at -70 C or below and ship on dry ice...wet swab specimens are stable either at room temperature for up to 48 hours or refrigerated for up to 72 hours before processing. If a delay in testing is expected, store specimens at -20 C or below." Room temperature range was undefined by the manufacturer and/or laboratory. 8. Review of the package insert for the Copan Universal Tranpsort Medium (UTM-RT) System Instructions for Use revealed "using the UTM-RT System, collected specimens can be stored for up to 72h [hours] at 2-8 C." 9. Review of the package insert for the Beaver Sample Collection Kit under storage revealed "after use, the sample can be stored at room temperature for 1 week or for a longer time storage, please place it at -20 C and below." Room temperature range was undefined by the manufacturer and/or laboratory. 10. Review of the laboratory records revealed no documentation of the preanalytical studies for either the nasopharyngeal and oropharyngeal specimens in Beaver VTM were available for review. 11. Preanalytical studies for the Copan UTM were performed on 2/8/2022, after patient testing began in 12/2021. No documentation of the specimen type used for those studies were provided. 12. Review of the CMS116 revealed the laboratory performed 25000 tests annually. 13. An interview with the director of lab operations on 2/9/2022 at 1100 hours in the office confirmed the above findings.
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 review of the laboratory and patient test records from 2021 and 2022 and confirmed in interview, the laboratory failed to document the correct information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability for three of ten specimens reviewed for Covid PCR testing. Findings included: 1. Review of laboratory final reports from 2021 and 2022 revealed the following three of ten specimens with the incorrect disposition on the final report. The laboratory final report states the laboratory specimen status as having received the specimen but were reported as 'no specimen received'. Specimen Requisition: 1427329; 1427335; 1427335 2. An interview with the director of laboratory operations on 2/9/2022 at 1110 hours in the office confirmed the above findings. He acknowledged that if the specimen were not received it should not have a received date and time.
D5815	TEST REPORT CFR(s): 493.1291(h)

	When the laboratory cannot report patient test results within its established time frames, the laboratory must determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual(s) of the delayed testing. This STANDARD is not met as evidenced by: Based on review of the laboratory and patient test records from 2021 and 2022, laboratory policy, and confirmed in interview, the laboratory failed to establish procedures to notify the appropriate individual(s) for any delay in Covid PCR testing for 7 of 20 patient test records reviewed. Findings included: 1. Review of the laboratory policy Collection Process Manual revealed "the results of this test will be emailed to you within 24-48 hours, excluding weekends and holidays." 2. Random review of the laboratory records revealed the following 7 of 20 specimens that were collected and the corresponding results were beyond the 48 (2 day) hour turnaround time. Specimen Requisition: 1391965, collected 1/2/22, received 1/6/22, reported 1/9 /22; elapsed time 5 days (excluding weekend) Specimen Requisition: 1433508, collected 1/6/22, received 1/14/22, reported 1/14/22; elapsed time 6 days (excluding weekend) Specimen Requisition: 1311523, collected 12/23/21, received 12/27/21, reported 12/30/21; elapsed time 5 days Specimen Requisition: 1326904, collected 12 /27/21, received 12/28/21, reported 1/1/22; elapsed time 4 days Specimen Requisition: 1427329, collected 1/6/22, received 1/9/22, reported 2/7/22; 'no specimen received' elapsed time 22 days Specimen Requisition: 1427335, collected 1/6/22, received 1/9 /22, reported 2/7/22; 'no specimen received' elapsed time 22 days Specimen Requisition: 1427335, collected 12/29/21, received 1/1/22, reported 2/7/22; 'no specimen received' ; elapsed time 32 days 3. Review of the laboratory records available revealed no documentation of the laboratory notifying the above patients and /or provider of the delay of test results. 4. No documentation of a policy to notify patients and/or providers of a delay in testing. 5. An interview with the laboratory of lab operations on 2/9/22 at 1010 hours in the office confirmed the above findings.
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 review of policies and procedures, patient records, and confirmed in interview of facility personnel, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems in post-analytic systems. Refer to D5805, D5815
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by:

	Based on review of the laboratory's records and staff interview, it was revealed the laboratory director failed to provide overall management for the laboratory. (Refer to D6082, D6086, D6101, D6102)
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on review of the laboratory records, patient records, and confirmed in interview, the laboratory director failed to ensure the laboratory provided quality laboratory services for all aspectes of test performance. Refer to D5311-I, II, III
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 a review of the laboratory's test system records and interview of facility personnel, the laboratory director failed to ensure the laboratory documented complete establishment of all modified EUA approved Covid testing for its test systems before reporting patient test results. (Refer to D5423)
D6101	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(11) The laboratory director must employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart. This STANDARD is not met as evidenced by: Based on review of the laboratory's Centers for Medicare and Medicaid (CMS) Form 209, Laboratory Personnel Report, review of the laboratory's personnel records, and staff interview it was determined the Laboratory Director failed to ensure laboratory personnel education/qualifications were documented for high complexity testing laboratory for 1 of 1 Technical Supervisor (TS) and 2 of 3 General Supervisors (GS). Findings included: 1. Review of the laboratory's CMS Form 209 (signed by Laboratory Director on 02/08/2022) revealed the laboratory identified 1 TS and 3 GS. 2. Review of the laboratory's personnel records revealed there was no documentation of education available to qualify the following individuals: TS - had no documentation of education necessary to qualify for this position. GS #1 - had documentation of completing education in Surrey, England. There was no foreign equivalency

	evaluation of the diploma available for review, necessary to qualify the individual for this position. GS #3 - had no documentation of education necessary to qualify for this position. 3. The laboratory was repeatedly asked to provide documentation required to qualify its personnel. Requests for documentation were submitted on 02/08/2022 at 1015 hours, 1230 hours, and 1400 hours. No such documentation was provided by the end of the survey. 4. An interview with the General Supervisor #1 on 02/08/2022 at 1605 hours in the interview room confirmed the findings.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of the laboratory's Centers for Medicare and Medicaid (CMS) Form 209, Laboratory Personnel Report, review of the laboratory's personnel records, review of instructions for use for the for the BioGx Xfree Covid-19 Direct RT-PCR (500-003-XMP US Rev 04.4-11Oct2021) and the LumiraDx FastLab Solutions SARS-CoV-2 RNA Star Complete (SD-COM-ART-00023 Rev 16 Nov2021), and staff interview it was determined the Laboratory Director failed to ensure 9 of 9 Testing Personnel (TP) had documentation of training prior to patient testing to demonstrate they can perform testing reliably and provide accurate results. Findings included: 1. Review of the laboratory's CMS Form 209 (signed by Laboratory Director on 02/08 /2022) revealed the laboratory identified 9 TP as follows: TP#1 -hired 08/19/2021 TP#2 -hire date not provided TP#3 -hired 12/24/2021 TP#4 -hired 01/17/2022 TP#5 -hired 12/16/2021 TP#6 -hired 12/29/2021 TP#7 -hired 12/27/2021 TP#8 -hired 01/18 /2021 TP#9 -hired 08/18/2021 2. Review of the laboratory's personnel records revealed there was no documentation of training or documentation of evaluation of testing reliability and accuracy of results for 9 of 9 TP employed by the laboratory. 3. Review of the laboratory's instructions for use for the BioGx Xfree Covid-19 Direct RT-PCR (500-003-XMP US Rev 04.4-11Oct2021) under Conditions of Authorization for the laboratory revealed: "All laboratory personnel using the BioGx Xfree Covid-19 Direct RT-PCR assay must be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use the BioGx Xfree Covid-19 Direct RT-PCR assay in accordance with the authorized labeling." 4. Review of the laboratory's instructions for use the LumiraDx FastLab Solutions SARS-CoV-2 RNA Star Complete (SD-COM-ART-00023 Rev 16 Nov2021) under Conditions of Authorization for the laboratory revealed: "All laboratory personnel using the LumiraDx SARS-CoV-2 RNA Star Complete must be appropriately trained in nucleic acid amplification techniques and use appropriate laboratory and personal protective equipment when handling this Test and use this product in accordance with the authorized labeling." 5. In an interview on 02/08/2022 at 1235 hours in the interview room the General Supervisor #1 confirmed the above findings.
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 submitted Centers for Medicare and Medicaid (CMS) Form 209 Laboratory Personnel Report, review of personnel records and staff interview, it was determined the laboratory's Technical Supervisor failed to have documentation semiannual competency assessments within the first year of employment for one of nine Testing Personnel employed by the laboratory. Findings included: 1. Review of CMS Form 209 form revealed 9 Testing Personnel (TP) performing high complexity testing. 2. Review of the laboratory's personnel records revealed one of nine TP (TP#8, hire date 1/18/21) had no semiannual competency assessment for 2021. 3. In an interview on 02/08/2022 at 1435 hours in the interview room the General Supervisor #1 confirmed the above findings.
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 submitted Centers for Medicare and Medicaid (CMS) Form 209 Laboratory Personnel Report, review of personnel records and staff interview it was determined the laboratory failed to ensure testing personnel meet qualifications to perform high complexity testing. 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 laboratory's Centers for Medicare and Medicaid (CMS) Form 209, Laboratory Personnel Report, review of the laboratory's personnel records, and staff interview it was determined the laboratory failed to ensure 3 of 9 Testing Personnel (TP) meet qualifications to perform high complexity testing. Findings included: 1. Review of the laboratory's CMS Form 209 (signed by Laboratory Director on 02/08/2022) revealed the laboratory identified 9 TP. 2. Review of the laboratory's personnel records revealed there was no documentation of education available to qualify the following individuals: TP#2 - no foreign equivalency evaluation of the diploma available for review, necessary to qualify the individual for this position. TP#8 - had no documentation of education necessary to qualify for this position. TP#9 - had no documentation of education necessary to qualify for this position. 3. The laboratory was repeatedly asked to provide documentation required to qualify its personnel. Requests were submitted on 02/08/2022 at 1015 hours, 1230 hours, and 1400 hours. No such documentation was provided by the end of the survey. 4. An interview with the General Supervisor #1 on 02/08/2022 at 1605 hours in the interview room confirmed the findings.