

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2232953	<b>(X3) Date Survey Completed</b>  05/09/2022
<b>Name of Provider or Supplier</b>  Comprehensive Labs Llc	<b>Street Address, City, State</b>  7543 South Fwy, Houston, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	<p>An initial survey was performed on 05/09/2022. The laboratory was found out of compliance with the CLIA regulations. The condition not met was: 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 Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representatives were given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit.</p>
<b>D3000</b>	<p><b>FACILITY ADMINISTRATION</b> CFR(s): 493.1100</p> <p>Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.</p> <p>This CONDITION is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory and patient test records from 2022, and confirmed in interview, the laboratory failed to report 9539 SARS-CoV-2 positive and negative test results as required by 400.200 for 24 of 24 days reviewed from 4/14/2022 to 5/09/2022. Findings were: 1. Review of the Instructions for Use for the TaqPath (Trademark) COVID-19 Combo Kit (MAN0019181 Revision L.0) under CONDITIONS OF AUTHORIZATION FOR THE LABORATORY revealed "Authorized laboratories using the TaqPath (Trademark) COVID-19 Combo</p>

Kit must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate." 2. Review of the laboratory test records from April and May 2022 revealed the laboratory started SARS-CoV-2 with the TaqPath (Trademark) COVID-19 Combo Kit patient testing on 04/14/2022. 5. Review of the laboratory policies available revealed no documentation of a policy /procedure related to SARS-CoV-2 test reporting. 6. Review of the laboratory SARS-CoV-2 patient test records from 2022 revealed no documentation the laboratory reported 9539 SARS-CoV-2 positive and negative test results as required by 400.200 for 24 of 24 days reviewed from 4/14/2022 to 5/09/2022. Refer to Covid Patient Alias list. 7. An interview with the operational director on 5/09/2022 at 1158 hours in the front lobby confirmed the above findings.

**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 laboratory requisitions and patient test records from 2022 and confirmed in interview, the laboratory failed to establish and follow procedures to ensure positive identification of patient specimens for six of ten patient test results for COVID-19 reviewed. Findings included: 1. Random review of patient test requisition and final test reports from April and May 2022 revealed the following six of ten patient test records with different date and time of collection from their requisition and final reports. Sample ID 1224-56649 Requisition Date and time of collection: 4/18 /2022 1815 hours Final Report Date and time of collection: 4/18/2022 1819 hours Sample ID 1125-1819 Requisition Date and time of collection: 5/03/2022 1226 hours Final Report Date and time of collection: 3/05/2022 1043 hours Sample ID 1126-82867 Requisition Date and time of collection: 5/01/2022 1305 hours Final Report Date and time of collection: 01/05/2022 1250 hours Sample ID 1126-77621 Requisition Date and time of collection: 5/01/2022 1058 hours Final Report Date and time of collection: 01/05/2022 1136 hours Sample ID 1126-7777 Requisition Date and time of collection: 5/04/2022 1557 hours Final Report Date and time of collection: 04/05/2022 1557 hours Sample ID 1126-77631 Requisition Date and time of collection: 5/05/2022 1653 hours Final Report Date and time of collection: 05/05 /2022 1657 hours 2. An interview with the operational director on 5/9/2022 at 1420 hours in the front lobby 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 instructions for use (IFU) for the Taqpath Covid-19 Combo Kit for SARS-CoV-2 testing, manufacturer's instructions for the transport media, laboratory policy, review of laboratory and patient records from 2022, and confirmed in interview, the laboratory failed to meet the requirements for preanalytic systems . Refer to D5311-A, B; and 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:  
A. Based on review of the instructions for use (IFU) for the Taqpath Covid-19 Combo Kit for SARS-CoV-2 testing, manufacturer's instructions for the transport media, laboratory policy, review of laboratory and patient records from 2021 and 2022, and confirmed in interview, the laboratory failed to establish the storage and preservation and specimen acceptability and rejection criteria for one of one test for Covid-19: Taqpath Covid-19 Combo kit. The findings included: 1. Review of the instructions for use for the Taqpath Covid-19 Combo kit (Man0019181, Rev K.o) under Samples and Controls revealed "Patient samples must be collected according to appropriate laboratory guidelines. Positive and negative test controls must be included to accurately interpret patient test results. Store patient samples according to CDC guidelines. See the CDC website: <https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html>." 2. Review of the CDC website referenced in the IFU revealed "Store respiratory specimens at 2-8C for up to 72 hours after collection. If a delay in testing or shipping is expected, store specimens at -70C or below. Store extracted nucleic acid samples at -70C or lower." 3. Random sampling of nasopharyngeal specimens observed on 5/9/2022 at 1040 hours in the laboratory revealed the laboratory accepted 2 types of Universal transport media (UTM): Poyton and Longsee. 4. Review of the Poyton Instructions for USE (PY-B-C-002) revealed "after sampling is completed, the sample within the UTM can be storage temperature for up to 2 days." 5. Review of the Longsee Instructions for Use (LS-C-P-018) revealed "after the sampling is completed, the sample within the UTM can be stored at room temperature for up to 2 days." 6. Review of the laboratory establishment studies performed in May 2022 revealed incomplete preanalytical studies. Cross refer to D5423. 7. Review of the laboratory policy Sample Requirements revealed no documentation of the storage and preservation and specimen acceptability and rejection criteria for one of one test for Covid-19: Taqpath Covid-19 Combo kit. 8. Random sampling of patient test records from 2022 revealed the laboratory received and analyzed the following 14 Poyton UTM samples: Sample ID 1124-46899 Sample ID 1124-46911 Sample ID 1124-46902 Sample ID 1115-97731 Sample ID 1115-97732 Sample ID 1124-46937 Sample ID 1115-97710 Sample ID 1124-46934 Sample ID 1115-97725 Sample ID 1126-82848 Sample ID 1224-56649 Sample ID 1125-1819 Sample ID 1126-82867 Sample ID 1126-77621 9. Random sampling of patient test records from 2022 revealed the laboratory received and analyzed the following Longsee UTM sample Sample ID 1116-78637. 10. An interview with the operational

director on 5/9/2022 at 1035 hours in the front lobby confirmed the above findings. B. Based on review of the laboratory policy, surveyor observations, review of laboratory and patient records from May 2022, and confirmed in interview, the laboratory failed to follow its policy for receiving its specimen in the correct temperature for one of one test for Covid-19: Taqpath Covid-19 Combo kit. Findings included: 1. Review of the laboratory policy Receiving and Acceptance of Samples (Ver 1.0) revealed "samples should be received at optimal temperature between 2-4 degrees...sample remain stable up to 72 hours" 2. Surveyor observations on 5/09/2022 at 1040 hours revealed a Coleman cooler with loose specimens inside UPS and Fedex mailers with a temperature of 5.9 C. 3. Random sampling of patient test records from the above shipment revealed the laboratory received and analyzed the following ten samples: Sample ID 1124-46899 Sample ID 1124-46911 Sample ID 1124-46902 Sample ID 1115-97731 Sample ID 1115-97732 Sample ID 1124-46937 Sample ID 1115-97710 Sample ID 1124-46934 Sample ID 1115-97725 Sample ID 1116-78637 4. An interview with the operational director on 5/09/2022 at 1110 hours in the front lobby confirmed the above findings.

**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 policies, review of patient test records from 2022, and confirmed in interview, the laboratory failed to have written instructions available to the laboratory's clients that included information on specimen collection, preservation with specific viral transport media, storage, and transport for one of one test for Covid-19: Taqpath Covid-19 Combo kit. Findings were: 1. Review of laboratory Sample Requirements revealed no documentation of written instructions for the collection, preservation with specific viral transport media, storage, and transport (with specified acceptable temperature range). 2. Review of the CMS116 signed by the laboratory director on 5/6/2022 revealed the laboratory performed 120,000 Virology tests annually. 3. An interview with the operational director on 5/9/2022 at 1030 hours in the front lobby confirmed the above findings.

**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 review of the instructions for use (IFU) for the Taqpath Covid-19 Combo Kit for SARS-CoV-2 testing, laboratory policy, review of laboratory and patient records from 2022, and confirmed in interview, the laboratory failed to establish the step by step procedure for quality control and interpretation of results for one of one test for Covid-19: Taqpath Covid-19 Combo kit. Findings included: 1. Review of the laboratory records from 2021 and 2022 revealed the laboratory performed Covid-19 testing using the Taqpath Covid-19 Combo kit. 2. Review of the laboratory policy revealed no documentation of the quality control procedures to include: identification of each control, the number and frequency of testing controls; acceptable control limits; and criteria to determine acceptable control results 3. Review of the laboratory policy revealed no documentation of the interpretation of results to include the cutoff values for Ct values for patient results.. 4. Review of the CMS116 revealed the laboratory performed 120,000 Virology tests annually. 5. An interview with the operational director on 5/09/2022 at 1340 hours in the front lobby 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:

A. Based on review of the manufacturer's instructions, laboratory policy, laboratory and patient test records from 2022, and confirmed in interview, the laboratory failed to document complete establishment studies (preanalytical studies) for one of one modified EUA approved Covid test: Taqpath Covid-19 Combo kit. Findings were: 1. Review of the instructions for use for the Taqpath Covid-19 Combo kit (Man0019181, Rev K.o) under Samples and Controls revealed "Patient samples must be collected according to appropriate laboratory guidelines. Positive and negative test controls must be included to accurately interpret patient test results. Store patient samples according to CDC guidelines. See the CDC website: <https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html>." 2. Review of the CDC website referenced in the IFU revealed "Store respiratory specimens at 2-8C for up to 72 hours after collection. If a delay in testing or shipping is expected, store specimens at -70C or below. Store extracted nucleic acid samples at -70C or lower." 3. Random sampling

of nasopharyngeal specimens observed on 5/9/2022 at 1040 hours in the laboratory revealed the laboratory accepted 2 types of Universal transport media (UTM): Poyton and Longsee. 4. Review of the Poyton Instructions for USE (PY-B-C-002) revealed "after sampling is completed, the sample within the UTM can be storage temperature for up to 2 days." 5. Review of the Longsee Instructions for Use (LS-C-P-018) revealed "after the sampling is completed, the sample within the UTM can be stored at room temperature for up to 2 days." 6. An interview with the laboratory manager on 5/9/2022 revealed the laboratory specimens are shipped via FedEx/UPS to another laboratory (CLIA 45D2196313) from their clients. The CLIA 45D2196313 lab will then use a courier for the specimens to be transported via car to this laboratory. No documentation was provided as to the temperature the specimens were shipped prior to other CLIA lab receiving the specimens. 7. Surveyor observations on 5/09/2022 revealed the laboratory received a shipment in a Coleman cooler at about 1040 hours with a temperature of 5.9 C. Random sampling of nasopharyngeal specimens in Poyton Universal transport media (UTM) in the cooler included the following 9 specimens: Sample ID 1124-46899; collected 5/03/2022; elapsed time 6 days Sample ID 1124-46911; collected 5/06/2022; elapsed time 3 days Sample ID 1124-46902; collected 5/03/2022; elapsed time 6 days Sample ID 1115-97731; collected 5/05/2022; elapsed time 4 days Sample ID 1115-97732; collected 5/05/2022; elapsed time 4 days Sample ID 1124-46937; collected 5/06/2022; elapsed time 3 days Sample ID 1115-97710; collected 5/05/2022; elapsed time 4 days Sample ID 1124-46934; collected 5/06/2022; elapsed time 3 days Sample ID 1115-97725; collected 5/05/2022; elapsed time 4 days 8. Surveyor observations on 5/09/2022 revealed the laboratory received a shipment in a Coleman cooler at about 1040 hours with a temperature of 5.9 C. Random sampling of nasopharyngeal specimens in Longsee Universal transport media (UTM) in the cooler included the following specimen. Sample ID 1116-78637; collected 5/05/2022; elapsed time 4 days 9. Review of the laboratory stability study performed on 5/03/2022 revealed documentation of stability studies from when the laboratory RECEIVED specimens for up to 3 days. No documentation was available for review of stability studies from when specimen were collected. 10. Further review of the stability study revealed failures on day 3. No corrective actions were available for review. 11. No documentation of any stability studies were available for the Longsee UTM. 12. Review of the CMS116 signed by the laboratory director on 5/6/2022 revealed the laboratory performed 120,000 Virology tests annually. 13. An interview with the operational director on 5/9/2022 at 1158 hours in the front lobby confirmed the above findings. He stated that the stability studies were ongoing. He was unaware that the stability studies should be performed prior to starting patient testing. B. Based on review of the manufacturer's instructions, laboratory policy, laboratory and patient test records from 2022, and confirmed in interview, the laboratory failed to document complete establishment studies for the modified EUA approved Covid test: Taqpath Covid-19 Combo kit for one of two universal transport media (UTM). Findings included: 1. Random sampling of nasopharyngeal specimens observed on 5/9/2022 at 1040 hours in the laboratory revealed the laboratory accepted 2 types of Universal transport media (UTM): Poyton and Longsee. 2. Surveyor observations on 5/09/2022 revealed the laboratory received a shipment in a Coleman cooler at about 1040 hours with a temperature of 5.9 C. Random sampling of nasopharyngeal specimens in Longsee Universal transport media (UTM) in the cooler included the following specimen. Sample ID 1116-78637 3. No documentation of any establishments studies for the Longsee UTM were available for review. 4. Review of the CMS116 signed by the laboratory director on 5/6/2022 revealed the laboratory performed 120,000 Virology tests annually. 5. An interview with the operational director on 5/9/2022 at 1158 hours in the front lobby confirmed the above findings. He was unaware that studies should include all UTM used in the laboratory.

**D5431**

**MAINTENANCE AND FUNCTION CHECKS**

CFR(s): 493.1254(a)(2)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

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 April and May 2022 and confirmed in interview, the laboratory failed to document the required function checks for the Covid-19 testing on the Taqpath Covid-19 Combo kit for four of four weekly tasks and one of one monthly task reviewed. Findings included: 1. Review of the laboratory test records revealed the laboratory performed Covid-19 testing using the Taqpath Covid-19 Combo kit which uses the QuantStudio 12K Flex Real-Time PCR System for interpretation of the test. 2. Review of the QuantStudio 12K Flex Real-Time PCR System v1.4 Maintenance and Administration Guide revealed "the QuantStudio 12K Flex Real-Time PCR System requires regular calibration and maintenance for proper operation. The following table displays the recommended maintenance that you must perform to ensure optimal instrument performance. weekly maintenance task: "perform an instrument self-test monthly task: perform a background calibration." 3. Random review of the April and May 2022 maintenance records revealed no documentation of the above maintenance for four of four weekly tasks and one of one monthly task reviewed. Weekly: Instrument QS01: 4/30/2022 Instrument QS02: 4/21/2022 Instrument QS01: 5/04/2022 Instrument QS01: 5/07/2022 Monthly: Instrument QS01: 4/2022 Instrument QS02: 4/2022 4. Random sampling of patients performed for the above weeks revealed the laboratory performed the following ten patients with no documentation of the weekly and/or monthly maintenance per the manufacturer's instructions. Weekly: Instrument QS01: 4/30/2022 Sample ID 1126-82848; 117-3617; 1126-82540 Instrument QS02: 4/21/2022 Sample ID 1224-56649 Instrument QS01: 5/04/2022 Sample ID: 1128-87703; 1126-82867; 1125-1819 Instrument QS01: 5/07/2022 Sample ID 1126-7762; 1126-77631; 1126-77777 Monthly: Instrument QS01: 4/2022 Sample ID 1126-82848; 117-3617; 1126-82540 Instrument QS02: 4/2022 Sample ID 1224-56649 5. An interview with the general supervisor on 5/09/2022 at 1430 hours in the front lobby confirmed the above findings.

**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 manufacturer's instructions, laboratory policies, laboratory and patient records from 2022, and confirmed in interview, the laboratory director failed to provide overall management and direction of the laboratory services. Refer to D6082, D6095

**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 instructions for use (IFU) for the Taqpath Covid-19 Combo Kit for SARS-CoV-2 testing, manufacturer's instructions for the transport media, laboratory policy, review of laboratory and patient records from 2022, and confirmed in interview, the laboratory director failed to ensure the laboratory met the requirements for preanalytic systems. Refer to D5311-A, B; and D5317

**D6095**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(6)

The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.

This STANDARD is not met as evidenced by:

Based on review of the manufacturer's instructions, laboratory policy, laboratory and patient test records from 2022, and confirmed in interview, the laboratory director failed to ensure the laboratory documented complete establishment studies for one of one modified EUA approved Covid test: Taqpath Covid-19 Combo kit. Refer to D5423-A, B