

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2232232	(X3) Date Survey Completed 02/16/2023
Name of Provider or Supplier Us Health Laboratories	Street Address, City, State 15260 Ventura Blvd Ste 1200, Sherman Oaks, CA	
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
D3000	<p>FACILITY ADMINISTRATION 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 Surveyor review of laboratory's policy & procedure, workflow, and interview with the laboratory testing person on February 16, 2023, at 11:50 am, it was determined that the laboratory did not meet the requirement under 493.1103 and 493.1105 to fulfil the facility administration condition. The laboratory's failure to meet the condition may have potential to harm and affect patient care. The findings include: 1. The laboratory failed to minimize patient sample contamination, see D3003. 2. The laboratory failed to follow a unidirectional workflow for the PCR amplification procedure, see D3005. 3. The laboratory's testing declaration form, signed by the laboratory director on 2/7/2023 stated that the laboratory performs approximately 24,000 tests, annually.</p>
D3003	<p>FACILITIES CFR(s): 493.1101(a)(2)</p> <p>The laboratory must be constructed, arranged, and maintained to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is</p>

minimized.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's workspace and workflow, and interview with the laboratory testing person on February 16, 2023, at 11:50 am, the laboratory failed to minimize sample contamination. The findings include: 1. The laboratory performed PCR test for SARS-CoV-2. The test method utilizes manual sample preparation, RNA extraction and signal detection with the PCR instrument. The laboratory re-uses the deep plate for RNA extraction. Moreover, the laboratory's equipment and spaces are poorly organized and prevents a unidirectional workflow to minimize contamination. Therefore, patients' sample may potentially cross contaminated and affected patient care. 2. The laboratory testing person on February 16, 2023, at 11:50 am, affirmed that the laboratory's work process has the potential of sample cross contamination. 3. The laboratory's testing declaration form, signed by the laboratory director on 2/7/2023 stated that the laboratory performs approximately 24,000 tests, annually.

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 Surveyor review of laboratory's workflow, and interview with the laboratory testing person on February 16, 2023, at 11:50 am, the laboratory failed to maintain a uni-directional workflow and use separate areas for specimen preparation, PCR amplification, product detection, and reagent preparation. The findings include: 1. The laboratory used PhoenixDx PCR method to detect SARS-CoV-2 in the patients swab sample. The method includes nucleic acid extraction, reagent preparation, PCR amplification and signal detection. The laboratory performed all the steps in a single room that measured approximately 144 sq. ft. It utilized Tecan liquid handler to transfer the sample into a deep plate, then extracted RNA with the Kingfisher semi-automated instrument. It used the extracted RNA with the amplification reagents to make PCR plate in a hood that lies in the middle of the room. Then, it amplified the PCR plate using 7900HT instrument from ABI. The laboratory personnel moved the sample back and forth within the room throughout the procedure and did not maintain a unidirectional workflow. Unidirectional workflow refers to the manner in which testing personnel and patient specimens move through the molecular testing process to prevent cross-contamination, and consists of separate areas for the reagent preparation, pre-amplification area for specimen preparation and amplification reaction set up, and post-amplification area for specimen amplification, product detection, and storage or disposal of amplified products. Therefore, the quality of the patients' test results rendered by the laboratory cannot be assured and may have harmed patient. 2. The laboratory testing person on February 16, 2023, at 11:50 am, affirmed that the laboratory did not follow a unidirectional workflow for the PCR amplification procedure. 3. The laboratory's testing declaration form, signed by the laboratory director on 2/7/2023 stated that the laboratory performs approximately 24,000 tests, annually.

<p>D5400</p>	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, patient testing records, and interview with the laboratory testing person on February 16, 2023, at 12:15 pm, it was determined that the laboratory did not meet the requirement under 493.1251 and 493.1253 to fulfil the analytic systems condition. The laboratory's failure to meet the condition may have potential to harm and affect patient care. The findings include: 1. The laboratory testing personnel did not follow the laboratory's procedure in reporting the patients test results, see D5401. 2. The laboratory failed to establish and verify the test performance specifications for the SARS-CoV-2 PCR test, see D5423. 3. The laboratory's testing declaration form, signed by the laboratory director on 2/7/2023 stated that the laboratory performs approximately 24,000 tests, annually.</p>
<p>D5401</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, patient testing records, and interview with the laboratory testing person on February 16, 2023, at 12:15 pm, the laboratory personnel failed to follow the laboratory's procedure for the SARS-CoV-2 PCR test. The findings include: 1. The laboratory used PhoenixDx PCR method to detect SARS-CoV-2 in the patients swab sample. The method includes nucleic acid extraction, PCR amplification and signal detection. The method uses RNase P as an internal control for the proper sample collection and integrity. According to the method, a negative SARS-CoV-2 sample must give a positive Ct value for the internal control to ensure that sample material of suitable quality was present. However, 57 SARS-CoV-2 negative samples (include sample ID NOVWZ4250 and many others) data review showed RNase P was undetectable and the results were reported. According to the method these samples should have been repeated from the extraction step. Therefore, the accuracy of the negative test results rendered by the laboratory cannot be assured and might have harmed patients. 2. The laboratory testing person on February 16, 2023, at 12:15 pm, affirmed that the laboratory reported negative results even though RNase P was undetectable. 3. The laboratory's testing declaration form, signed by the laboratory director on 2/7/2023 stated that the laboratory performs approximately 24,000 tests, annually.</p>
<p>D5423</p>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE</p>

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 Surveyor review of laboratory's SARS-CoV-2 test validation records, and interview with the laboratory testing person on February 16, 2023, at 12:25 pm, the laboratory failed to establish the performance characteristics when reusing the deep plates for the RNA extraction. The findings include: 1. The laboratory performed PCR test for SARS-CoV-2. The test method includes RNA extraction, PCR amplification and signal detection with the PCR instrument. The laboratory reused the deep plate several times after washing for the RNA extraction. However, the laboratory did not investigate the effect of reuse of the extraction plate and did not establish any performance specification, i.e., how many times the plate can be reused etc. Therefore, the accuracy of the patients' test results rendered by the laboratory cannot be assured and might have harmed patients. 2. The laboratory testing person on February 16, 2023, at 12:25 pm, affirmed that the laboratory did not investigate and establish the test performance specification when reusing the extraction plate. 3. The laboratory's testing declaration form, signed by the laboratory director on 2/7/2023 stated that the laboratory performs approximately 24,000 tests, annually.

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 Surveyor review of laboratory's policy & procedure, workflow, patient test records and interview with the laboratory testing person on February 16, 2023, at 11:50 am, and the severity and the number of deficiencies found and cited herein, it was determined that the laboratory director failed to provide effective direction over the operation of the laboratory, hence the Condition: Laboratories performing high complexity testing; laboratory director was not met. The laboratory director's failure to provide direction over the laboratory operation has a consequence of potential erroneous test result reporting and patient harm. The findings include: 1. The laboratory director failed to assure compliance with the applicable regulations. (See D6079) 2. The laboratory director failed to ensure that the physical plant and environmental conditions of the laboratory are appropriate for the PCR amplification and detection of test SARS-CoV-2 test. (See D6083) 3. The laboratory director failed to ensure that verification procedures used are adequate to determine the pertinent

performance characteristics of the SARS-CoV-2 test. (See D6086) 4. The laboratory director failed to ensure that the laboratory personnel are performing the test methods as required for accurate and reliable results of the SARS-CoV-2 test. (See D6087)

D6079

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(a)(b)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reappropriates performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's policy & procedure, workflow, patient test records and interview with the laboratory testing person on February 16, 2023, at 11:50 am, the laboratory director failed to assure laboratory's compliance with the applicable regulations and potentially harmed patients. The findings include: See D3000, D5400 and D6175.

D6083

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(2)

The laboratory director must ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's workflow and interview with the laboratory testing person on February 16, 2023, at 11:50 am, the laboratory director failed to ensure that the physical plant and environmental conditions of the laboratory are appropriate for the SARS-CoV-2 test. The findings include: See D3005.

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 Surveyor review of laboratory's SARS-CoV-2 test validation records, and interview with the laboratory testing person on February 16, 2023, at 12:25 pm, the laboratory director failed to ensure that the performance characteristics of the SARS-CoV-2 test was established. The findings include: See D5423.

D6087

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(3)(iii)

The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's policy & procedure, patient testing records, and interview with the laboratory testing person on February 16, 2023, at 12:15 pm, the laboratory director failed to ensure that the laboratory personnel are performing the SARS-CoV-2 test methods as required for accurate and reliable results. The findings include: See D5401 and D6175.

D6175

TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1495(b)(1)

Each individual performing high complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's policy & procedure, patient testing records, and interview with the laboratory testing person on February 16, 2023, at 12:15 pm, the laboratory personnel failed to follow the laboratory's procedure for the SARS-CoV-2 PCR test. The findings include: The testing person #1 reported negative results even though the sample had undetectable RNase P without repeating the extraction. According to the method these samples should have been repeated from the extraction step. Therefore, the accuracy of the negative test results rendered by the laboratory cannot be assured and might have harmed patients. See D5401.