

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2040138	(X3) Date Survey Completed 12/08/2021
Name of Provider or Supplier Unique Laboratory Solutions	Street Address, City, State 8560 N Silvery Lane Suite 300, Dearborn Heights, MI	
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 observation, record review, and interviews, the laboratory failed to meet applicable facilities requirements and correct identified problems. Findings include: 1. The laboratory failed to employ a uni-directional workflow for its SARS-CoV-2 Real-Time PCR molecular testing. Refer to D3005.</p>
D3005	<p>FACILITIES CFR(s): 493.1101(a)(3)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on record review, observation, and interview with the General Supervisor, the</p>

laboratory failed to employ a uni-directional workflow for its SARS-CoV-2 Real-Time PCR molecular testing for one 96-well plate observed. Findings include: 1. A review of the laboratory's "SALIVADIRECT COVID-19 PCR Method" procedure revealed a section stating "Dilute the Twist synthetic SARS-CoV-2 RNA standard control to 100 copies/uL in nuclease-free water and store aliquots at -80C" showing the test procedure includes reagent preparation. 2. An interview with the General Supervisor on 12/8/21 at 11:44 am revealed the reagents used in testing are prepared on the bench where specimens are received and accessioned. The reagents are not prepared in a separate area as required. 3. The surveyor observed the General Supervisor perform testing on 12/8/21 from 9:13 am to 12:56 pm. The General Supervisor started pipetting patient sample and initiated preparations with proteinase K in the biosafety cabinet in the main laboratory space. The General Supervisor then moved to another room with a biosafety cabinet to prepare three negative controls and moved back to the main laboratory biosafety cabinet to add remaining reagents to the sample tubes. The General Supervisor then moved the patient samples, positive controls, and a pipette from the main laboratory biosafety cabinet to the other room with the biosafety cabinet to pipette the samples into the 96-well plate. The process observed was not unidirectional and could lead to cross contamination.

D3007

FACILITIES
CFR(s): 493.1101(b)

The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs.

This STANDARD is not met as evidenced by:
 . Based on record review and interview with the General Supervisor, the laboratory failed to have sufficient equipment and supplies for its toxicology testing for 5 (Patients 2109070016, 2111010039, 2108170004, 2009230037, and 2009230030) of 7 patients receiving toxicology testing reviewed. Findings include: 1. A review of patient toxicology test reports revealed the following patients and the time between collection and test report dates: a. Patient 2109070016 collected on 6/23/21 and reported on 11/4/21. b. Patient 2111010039 collected on 10/14/21 and reported on 12/2/21. c. Patient 2108170004 collected on 8/11/21 and reported on 9/9/21. d. Patient 2009230037 collected on 7/31/20 and reported on 10/6/20. e. Patient 2009230030 collected on 9/14/20 and reported on 11/24/20. 2. An interview on 12/8/21 at 1:49 pm with the General Supervisor revealed the laboratory had an extended turnaround on their toxicology samples due to a lack of standards and instrument issues.

D3031

RETENTION REQUIREMENTS
CFR(s): 493.1105(a)(3)

Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.

This STANDARD is not met as evidenced by:
 . Based on record review and interview with the General Supervisor, the laboratory failed to retain temperature monitoring records for at least 2 years for 12 (December 2019 to December 2020) of 24 months reviewed. Findings include: 1. A review of the laboratory's temperature monitoring records revealed a lack of records between

	<p>December 2019 to December 2020. 2. An interview on 12/8/21 at 3:16 pm with the General Supervisor confirmed the laboratory did not retain temperature monitoring records from December 2019 to December 2020.</p>
<p>D5217</p>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the General Supervisor, the laboratory failed to verify the accuracy of its laboratory testing for 2 (December 2019 to December 2021) of 2 years reviewed. Findings include: 1. A review of the laboratory's test menu revealed it performs the following testing on patient specimens: a. COVID-19 RT-PCR with the Biorad CFX 96 b. 6-MAM c. 7-Aminoclonazepam d. Amphetamine e. Benzoylcegonine f. Buprenorphine g. Carisoprodol h. Codeine i. EDDP j. Hydrocodone k. Hydromorphone l. Lorazepam m. MDMA n. Meperidine o. Meprobamate p. Methadone q. Methamphetamine r. Morphine s. Norbuprenorphine t. Nordiazepam u. Norhydrocodone v. Noroxycodone w. O-Desmethyltramadol x. Oxazepam y. Oxycodone z. Oxymorphone aa. Temazepam bb. Tramadol cc. Amobarbital dd. Butabarbital ee. Butalbital ff. Phenobarbital gg. Secobarbital hh. Noroxymorphone 2. The surveyor requested documentation of twice annual verification of accuracy for the tests listed on their test menu on 12/8/21 at 11:22 am and it was not made available. 3. An interview on 12/8/21 with the General Supervisor confirmed the laboratory did not have documentation of twice annual verification of testing from December 2019 to December 2021.</p>
<p>D5301</p>	<p>TEST REQUEST CFR(s): 493.1241(a)</p> <p>The laboratory must have a written or electronic request for patient testing from an authorized person.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the General Supervisor and the owner, the laboratory failed to ensure requests for patient testing came from an authorized person for 7 (Patients 2011160016, 2012160017, 2102100013, 2104070038, 2106230001, 2110050001, and 2111180043) of 8 SARS-CoV-2 test requests reviewed. Findings include: 1. A review of patient test requests for SARS-CoV-2 testing revealed the following test requests did not have an authorized person: a. Patient 2011160016 b. Patient 2012160017 c. Patient 2102100013 d. Patient 2104070038 e. Patient 2106230001 f. Patient 2110050001 g. Patient 2111180043 2. An interview on 12/8/21 at 3:15 pm with the General Supervisor and owner confirmed the patients listed above did not have documentation showing test requests were from an authorized person.</p>
<p>D5305</p>	<p>TEST REQUEST CFR(s): 493.1241(c)</p> <p>The laboratory must ensure the test requisition solicits the following information: (1)</p>

The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.

This STANDARD is not met as evidenced by:
 . Based on record review and interview with the General Supervisor and owner, the laboratory failed to ensure test requests included the test to be performed for 3 (Patients 2106230001, 2108170020, and 2111180043) of 8 patient test requests reviewed. Findings include: 1. A review of patient test requests for patients receiving SARS-CoV-2 testing revealed a lack of indication of the test to be performed for the following patients: a. Patient 2106230001 b. Patient 2108170020 c. Patient 2111180043 2. An interview on 12/8/21 at 3:15 pm with the General Supervisor and owner confirmed the patients listed above did not have documentation showing the test to be performed.

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 record review and interviews, the laboratory failed to meet applicable analytic system requirements and correct identified problems. Findings include: 1. The laboratory failed to have a procedure for the performance of urine drug confirmation testing using the Shimadzu LCMS 8040 CL analyzer. Refer to D5401. 2. The laboratory failed to store reagents according to its policy. Refer to D5413. 3. The laboratory failed to establish performance specifications for the SalivaDirect SARS-CoV-2 RT-PCR Assay. Refer to D5423 A. 4. The laboratory failed to use the software specified in the SalivaDirect SARS-CoV-2 RT-PCR Assay Emergency Use Authorization. Refer to D5423 B. 5. The laboratory failed to perform control procedures for its SARS-CoV-2 RT-PCR assay. Refer to D5445.

D5401

PROCEDURE MANUAL
 CFR(s): 493.1251(a)

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.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the General Supervisor, the laboratory failed to have a procedure for the performance of urine drug confirmation testing using the Shimadzu LCMS 8040 CL analyzer for 14 (October 2020 to December 2021) of 14 months the current laboratory director has been employed by the laboratory. Findings include: 1. A review of the laboratory's procedure manual revealed a lack of procedure for the use of the Shimadzu LCMS 8040 CL analyzer used in urine drug confirmation testing. 2. The surveyor requested the laboratory's approved procedure for toxicology testing on 12/8/21 at 11:03 am and one was not made available. 3. An interview on 12/8/21 at 11:21 am with the General Supervisor confirmed the laboratory did not have a current procedure for toxicology testing using the Shimadzu LCMS 8040 CL analyzer.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

. Based on record review, observation, and interview with the General Supervisor, the laboratory failed to store reagents according to its policy for 13 (November 2020 to December 2021) of 13 months the laboratory has been using the SalivaDIRECT COVID-19 PCR assay. Findings include: 1. A review of the laboratory's "SALIVADIRECT COVID-19 PCR Method" procedure revealed the "Synthetic SARS-CoV-2 RNA Control 2" is to be kept at -80 degrees C and a section titled "SARS-CoV-2 RNA Standard Preparation" stating, "Dilute the Twist synthetic SARS-CoV-2 RNA standard control to 100 copies/uL in nuclease-free water and store aliquots at -80C." 2. The surveyor toured the laboratory on 12/8/21 at 8:57 am and the freezer with the SARS-CoV-2 testing reagents and supplies had a temperature of -18 degrees C. No -80 degrees C freezer was present. 3. An interview on 12/8/21 at 12:39 am with the General Supervisor confirmed the laboratory does not have a -80 degree C freezer and the reagents are kept at -20 degrees C.

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 a record review and interviews with the General Supervisor, the laboratory failed to establish performance specifications for the SalivaDirect SARS-CoV-2 RT-PCR Assay for 13 (November 2020 to December 2021) of 13 months since the laboratory started using the test system. Findings include: 1. An interview on 12/8/21 at 9:39 am with the General Supervisor revealed the laboratory started using the SalivaDirect SARS-CoV-2 RT-PCR Assay in November 2020. 2. The surveyor requested the laboratory's establishment of performance specifications for the SalivaDirect SARS-CoV-2 RT-PCR Assay on 12/8/21 at 10:13 am and was not made available. 3. An interview on 12/8/21 at 2:58 pm with the General Supervisor confirmed the laboratory did not have documentation of the establishment of performance specifications for SalivaDirect SARS-CoV-2 RT-PCR Assay. B. Based on record review, observation, and interview with IT personnel, the laboratory failed to use the software specified in the SalivaDirect SARS-CoV-2 RT-PCR Assay Emergency Use Authorization for 2 (October 2021 to December 2021) of 2 months since the revisions to the Emergency Use Authorization were made. Findings include: 1. A review of the "Yale School of Public Health, Department of Epidemiology of Microbial Diseases SalivaDirect assay EUA Summary - Updated October 29, 2021" Emergency Use Authorization revealed a section titled, "RT-qPCR INSTRUMENTS USED WITH TEST" stating the "CFX96 Touch Real-Time PCR Detection System" is to be used with "Bio-Rad CFX Maestro 1.1 V4.1.2435.1219" software. 2. The surveyor observed the laboratory's CFX96 Touch Real-Time PCR Detection System had the software "CFX Manager 3.1." 3. An interview on 12/8/21 at 12:07 pm with IT personnel confirmed the laboratory was not using the correct software according to the test system's Emergency Use Authorization.

D5433

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

. Based on a lack of documentation and interview with the General Supervisor, the laboratory failed to document maintenance activities for the Shimadzu LCMS 8040 CL toxicology analyzer for 2 (December 2019 to December 2021) of 2 years reviewed. Findings include: 1. A review of the laboratory's documentation revealed a lack of documented maintenance performed for the Shimadzu LCMS 8040 CL toxicology analyzer. 2. An interview on 12/8/21 at 2:08 pm with the General Supervisor revealed the laboratory did not document maintenance performed on the Shimadzu LCMS 8040 CL toxicology analyzer.

D5445

CONTROL PROCEDURES

CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--
(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

. Based on record review, a lack of documentation, and interview with the General Supervisor, the laboratory failed to perform control procedures for its SARS-CoV-2 RT-PCR assay for 1 (11/11/20) of 8 testing dates reviewed. Findings include: 1. A review of patient test records revealed Patient 2011160016 was tested for SARS-CoV-2 on 11/11/20. 2. A review of the laboratory's run data revealed a lack of documentation of quality control performance on 11/11/20 for the SARS-CoV-2 assay. 3. A review of the laboratory's "SALIVADIRECT COVID-19 PCR Method" procedure revealed a section stating, "All test controls should be examined prior to interpretation of patient results. If the controls are not valid, the patient results cannot be interpreted." 4. An interview on 12/8/21 at 3:25 pm with the General Supervisor confirmed documentation was not available for quality control performance on 11/11/20 when patients were reported.

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 record review and interview with the General Supervisor and owner, the laboratory failed to include the test report date and the name and address of the laboratory on test reports for 6 (Patients 2106230001, 2012030079, 2102100013, 20212170044, 2012160017, and 2104070038) of 15 test reports reviewed. Findings include: 1. A review of test reports revealed the patients listed below had a lack of test report date on the test reports: a. Patient 2106230001 b. Patient 2012030079 c. Patient 2102100013 d. Patient 20212170044 e. Patient 2012160017 f. Patient 2104070038 2. A review of test reports revealed the patients listed below had a lack of the laboratory's name and address on the test reports: a. Patient 2012030079 b. Patient 20212170044 3. An interview on 12/8/21 at 3:15 pm with the General Supervisor and owner confirmed the test reports listed above did not include the test report date or name and address of the laboratory.

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 reappoints 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 record review and interview with the General Supervisor, the laboratory director failed to employ sufficient personnel to perform test procedures and report test results in a timely manner for 5 (Patients 2109070016, 2111010039, 2108170004, 2009230037, and 2009230030) of 7 patients receiving toxicology testing reviewed. Findings include: 1. 1. A review of patient toxicology test reports revealed the following patients and the time between collection and test report dates: a. Patient 2109070016 collected on 6/23/21 and reported on 11/4/21 b. Patient 2111010039 collected on 10/14/21 and reported on 12/2/21 c. Patient 2108170004 collected on 8/11/21 and reported on 9/9/21 d. Patient 2009230037 collected on 7/31/20 and reported on 10/6/20 e. Patient 2009230030 collected on 9/14/20 and reported on 11/24/20 2. An interview on 12/8/21 at 1:49 pm with the General Supervisor revealed the laboratory had an extended turnaround on their toxicology samples due to a lack of personnel to perform testing.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the General Supervisor, the laboratory director failed to maintain the quality assessment program for 1 (2020) of 2 years reviewed. Findings include: 1. A review of the laboratory's "BIANNUAL QUALITY ASSURANCE CHECKLIST" documentation revealed it was performed once on 6/5/21. No documentation of other quality assessments was present. 2. A review of the laboratory's "QUALITY ASSURANCE (QA)" policy revealed a section stating, "Problems identified by the plan will be documented along with the corrective action taken by the laboratory personnel and the laboratory director to correct them. The plan will be reviewed annually and revised as necessary, as determined by the laboratory director to accommodate any new procedures introduced to the test menu, or to detect any problems not covered by the original draft of the Quality Assurance Plan." 3. An interview on 12/8/21 at 11:19 am with the General Supervisor confirmed the laboratory had no documentation of quality assessment activities performed in 2020.