

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2176678	<b>(X3) Date Survey Completed</b>  05/17/2021
<b>Name of Provider or Supplier</b>  Ixi Wellness Dallas, Llc	<b>Street Address, City, State</b>  140 Cypress Station Dr, Ste 121, 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 4/27/21, 4/28/21 and 5/10/21 in response to complaint TX00377562 The laboratory was found out of compliance with the CLIA regulations. Immediate jeopardy findings were identified. The conditions not met were: D5300 - 42 C.F.R. 493.1240 Condition: Preanalytic systems; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director; D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director The laboratory voluntarily started to perform patient testing per the manufacturer's instructions on 5/18/21 as evidenced by a letter signed by the laboratory director on 5/17/21. The complaint TX00377562 was substantiated. 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. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider /supplier, the State Survey Agency (SA) should be notified immediately.</p>
<b>D3009</b>	<p><b>FACILITIES</b> CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on review of records and confirmed in interview, the laboratory failed to obtain and possess Pennsylvania State Licensures when specimens were received and tested from state of Pennsylvania as required. Findings included: 1. Review of patient test</p>

	<p>records from January to April 2021 revealed the laboratory performed 171 patient specimens for testing of Covid-19 antibody testing using the Biohit SARS-CoV-2 IgM /IgG Antibody Test Kit from the following location: Pittsburgh International Airport 1000 Airport Blvd Pittsburgh, PA 15231 2. Review of laboratory records revealed no documentation of a Pennsylvania State Licensure. 3. An interview with the COO on 5 /10/21 at 1115 hours in the laboratory confirmed the above findings.</p>
<p><b>D5209</b></p>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of laboratory and personnel records from 2020 to 2021 and confirmed in interview, the laboratory failed to establish a procedure to assess technical supervisor and general supervisor competency. Findings were: 1. Review of the CMS209 revealed the laboratory had 1 technical supervisor and 1 general supervisor. 2. Review of the laboratory records available revealed no documentation of a policy or procedure available to assess the competency of technical supervisor or general supervisor. 3. An interview with the general supervisor on 5/10/21 at 1320 hours in the laboratory confirmed the above findings.</p>
<p><b>D5300</b></p>	<p><b>PREANALYTIC SYSTEMS</b> CFR(s): 493.1240</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory's policy, manufacturer's instructions and patient testing records, and confirmed in interview, the laboratory failed to meet the requirements for the preanalytical phase of testing as evidenced by: The laboratory failed to follow the manufacturer's instructions for specimen collection for Covid-19 antibody testing using the Biohit SARS-CoV-2 IgM/IgG Antibody Test Kit for all Covid antibody tests. Refer to D5311-I</p>
<p><b>D5311</b></p>	<p><b>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL</b> CFR(s): 493.1242(a)</p> <p>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.</p>

This STANDARD is not met as evidenced by:

I. Based on review of the manufacturer's instructions, laboratory training videos, laboratory and patient test records from 2020 to 2021, and confirmed in interview, the laboratory failed to follow the manufacturer's instructions for specimen collection for Covid-19 antibody testing using the Biohit SARS-CoV-2 IgM/IgG Antibody Test Kit for all Covid antibody tests performed at 4 of 4 test locations. Findings were: 1. Review of the test records available revealed the laboratory performed SARS-CoV-2 IgM/IgG Antibody testing from 4 different off site locations: Savannah: 200 Commercial Ct Suite C Savannah, GA 31406 Grand Rapids: Gerald R. Ford International Airport Economy Lot 5500 44th St SE Grand Rapids, MI 49512 Cleveland: Cleveland Hopkins International Airport 5300 Riverside Dr Cleveland, OH 44135 Pittsburgh Pittsburgh International Airport 1000 Airport Blvd Pittsburgh, PA 15231 2. Review of the Instructions for Use for the Biohit SARS-CoV-2 IgM/IgG Antibody Test Kit (Version 03, 16th Jun, 2020) under sample requirements revealed "For whole blood, collect blood specimen into a collection tube (containing heparin, EDTA or Citrate) by venipuncture. The anticoagulative whole blood sample should not be stored for more than 6 hours at normal temperature (18-30C). The sample should not be stored for more than 1 day at 2-8C, do not freeze whole blood specimens.." 3. Review of the Instructions for Use for the Biohit SARS-CoV-2 IgM/IgG Antibody Test Kit (Version 03, 16th Jun, 2020) under limitations revealed "Do not use with blood obtained from a fingerstick procedure." 4. Review of the SARS Covid Antibody training video provided to surveyor via email on 5/17/21 revealed instructions to collect fingerstick blood for the Covid Antibody testing. 5. An interview with a primary testing person at a remote location (Grand Rapids) on 5/17/21 at 1055 hours via phone confirmed that she used finger stick blood for all Covid Antibody testing. 6. Review of the laboratory records available revealed no establishment studies for fingerstick blood for the Covid antibody testing using Biohit SARS-CoV-2 IgM/IgG Antibody Test Kit . 7. Review of the laboratory records from February 2021 to May 2021 revealed the laboratory performed 338 Covid Antibody testing. 8. An interview with the COO via phone on 5/17/21 at 1310 hours confirmed the above findings. II. Review of the laboratory records from 2020 to 2021 and confirmed in interview, the laboratory failed to establish written policies and procedures for 1 of 3 SARS-CoV2 PCR testing on the QuantStudio 6K Flex Real-Time PCR instrument (Nasal Swab). 1. Review of the laboratory records available revealed the laboratory used Beaver for Life Sciences Sample Collection Kit (Cat. #43903) for nasal swab SARS-CoV2 PCR testing on the QuantStudio 6K Flex Real-Time PCR instrument. 2. Review of the laboratory establishment studies revealed no documentation of the preanalytical studies for the lab developed test using the above collection kit. Cross refer to D5423 3. Review of the laboratory policies revealed no documentation of specimen preanalytical requirements for the nasal swabs SARS-CoV2 PCR testing to include: Patient preparation; Specimen collection; Specimen storage and preservation; Conditions for specimen transportation; Specimen processing; and Specimen acceptability and rejection. 4. Random review of the laboratory records from 2021 revealed the following 5 nasal swabs SARS-CoV2 PCR testing. 3/27/21 122M18E5EAA1BFE8ZQ 122M18E5EAA1BD8EFQ 4/6/21 122M18E5EAA1B5806B 122M18E5EAA1B5B2HQ 122M18E5EAA1B59ELQ 5. An interview with the general supervisor on 4/28/21 at 1050 hours in the laboratory confirmed the above findings.

**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 review of the laboratory policy, laboratory and patient test records from January 2021 to April 2021, and confirmed in interview, the laboratory failed to follow its policy for repeat analysis on the Saliva qualitative SARS-CoV2 PCR testing for 1 of 10 patient runs reviewed. Findings were: 1. Review of the laboratory policy EXTRACTION-FREE SALIVA RT-qPCR (version 1.0) under Run Analysis revealed "the RNase P serves as endogenous control. It ensures the sample preparation was successful, and human sample was tested. Expected CT value is no more than 35. If any of the above controls do not exhibit the expected performance as described, the assay may have been set up and/or executed improperly, or reagent or equipment malfunction could have occurred. Invalidate the run and re-test." 2. Random review of the laboratory patient runs from January 2021 to April 2021 revealed 1 of 10 patient that were run that met the laboratory repeat criteria. 4/6/21 SMART00392 RnaseP 36.61 3. Review of the above patient run revealed no repeat analysis of the above patient run. 4. An interview with the general supervisor on 4/28/21 at 1005 in the laboratory confirmed the above findings. He agreed that the patient should have been repeated.

**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 laboratory and patient test records from 2021 and confirmed in interview, the laboratory failed to establish a procedure for 1 of 3 tests (SARS-CoV2 PCR testing for nasal swabs). Findings were: 1. Review of the patient test records from 2020 to 2021 revealed the laboratory started SARS-CoV2 PCR testing for nasal swabs testing on March 2021. 2. Review of the laboratory records revealed no

documentation of a policy to include a step-by-step performance of the procedure for the nasal swab SARS-CoV2 PCR testing. 3. An interview with the laboratory supervisor on 4/27/21 at 1340 hours in the laboratory confirmed the above findings. She stated that the laboratory used the Mag-Bind RNA Saliva Extraction protocol for the nasal swab specimens. No policy was used for the nasal swabs.

**D5423**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

Based on review of the laboratory and patient test records from 2020 to 2021, laboratory policies, and confirmed in interview, the laboratory failed to document all performance characteristic required for test performance on the SARS-CoV2 PCR for 2 of 2 specimen types on 2 of 2 QuantStudio 6K Flex Real-Time PCR instruments using 2 differing extraction methods. A) Extraction Free Saliva B) Saliva Extraction C) Nasal Swab Findings were: 1. Review of the laboratory records available revealed the laboratory performed SARS-CoV2 PCR testing using saliva and nasal swabs. 2. Surveyor observations on 4/27/21 at 1010 hours revealed the laboratory had 2 QuantStudio 6K Flex Real-Time PCR instrument (SN278863171 and 27886163). 3. Review of the laboratory records available revealed the laboratory utilized 2 differing methods for the SARS-CoV2 PCR testing: extraction free and extraction (nasal & saliva). 4. Review of the laboratory policy Method Validation (version 1.0, effective September 30, 2020) under background revealed "the following studies will be performed to verify assay performance for laboratory developed test: Accuracy Precision LOD (Limit of Detection) LLOQ (Lower Limit of Quantitation) Correlation Specificity Sample stability" A) Extraction Free Saliva 5. Review of the establishment studies for the Extraction Free Saliva revealed no documentation of the specificity studies for either QuantStudio 6K Flex Real-Time PCR instrument (SN278863171 and 27886163). B) Saliva Extraction 6. Review of the establishment studies for the Saliva Extraction revealed no documentation of the specificity studies for either QuantStudio 6K Flex Real-Time PCR instrument (SN278863171 and 27886163). 7. Review of the establishment studies for the Saliva Extraction revealed no documentation of the accuracy studies for 1 of 2 QuantStudio 6K Flex Real-Time PCR instrument (SN 27886163). 8. Review of the establishment studies for the Saliva Extraction revealed no documentation of the LOD studies for 1 of 2 QuantStudio 6K Flex Real-Time PCR instrument (SN278863171). C) Nasal Swab 9. Review of the establishment studies for the Nasal Swab revealed no documentation of the LOD or precision studies for either QuantStudio 6K Flex Real-Time PCR instrument (SN278863171 and 27886163). 10. Review of the establishment studies for the Nasal Swab revealed no documentation of the preanalytical studies. 11. An interview with the testing person # 2 at 4/27/21 at 1015 hours revealed the laboratory used both

instruments for SARS-CoV2 PCR testing. 12. An interview with the general supervisor on 4/28/21 at 1053 hours in the laboratory confirmed the above findings. He was unaware the laboratory was required to perform all studies for each instrument and for each specimen type/extraction protocol.

**D5425**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
CFR(s): 493.1253(b)(3)

The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section.

This STANDARD is not met as evidenced by:  
Based on review of laboratory procedures, laboratory and patient records from 2020 to 2021, and confirmed in interview, the laboratory failed to establish and document performance specifications for 3 of 3 QC (quality control) material of the SARS-CoV2 PCR testing using QuantStudio 6K Flex Real-Time PCR instrument (Positive Template control 1 (PTC1), Positive Template Control 2 (PTC2), and human specimen extraction control (HSC)). Findings included: 1. Review of the laboratory records from 2020 to 2021 for the lab developed SARS-CoV2 PCR testing revealed the laboratory used 3 control types: (Positive Template control 1 (PTC1), Positive Template Control 2 (PTC2), and human specimen extraction control (HSC)). 2. Review of the laboratory establishment studies available revealed no documentation of the stability and storage studies nor any statistical data established and documented for the development of the above QC material. 3. Random review of the patient tests performed for the above dates revealed the laboratory performed the following 52 patients for SARS-CoV2. 3/12/21 Patient ID 122M18DEAF2A7CE8KJ 122M18DFEE24B367QE 122M18D7B5D443C0QW SMART20036 SMART20048 SMART20029 SMART20034 SMART20042 SMART20037 2/23/2021 122M18DFEE243D5155 122M18DFEE243D31YI 122M18DFEE243D40VV 122M18DFEE243C45SL 122M18DFEE243C37WL 2/13/2021 122M18DE3B05CAFAYP 122M18D7B5D45514HZ 122M18D7B5D45823JS 122M18D7B5D45613MQ 122M18D7B5D332329W 1/27/2021 122M18DCFEAC3DF8WJ 122M18DCFEAC3DD24E 122M18DCFEAC3E55NB 122M18DCFEAC3E2A0B 122M18DCFEAC3E66YN 122M18DCFEAC3DE7K9 122M18DCFEAC3D9EDF 122M18DCFEAC3DC2RS 1/13/2021 122M18DBF9FF742458 122M18DBF9FF74394P 122M18DBF9FF745F4W 122M18DBF9FF7471JB 122M18DBF9FF7485ZT 122M18DBF9FF7498LI 122M18DBF9FF74A9FD 122M18DBF9FF7598KY 122M18DBF9FF75ABDH 122M18DBF9FF75BDUC 122M18DBF9FF75CFAC 122M18DBF9FF75F7KC 1/3 /2021 122M18D7E36A7EC1AW 122M18D6FC53E563WI 122M18D6FC53E53EHR 122M18D6FC53E52D7V 122M18D7E36A7F14KJ 122M18D6FC53E58EEX 122M18D6FC53E4D60H 122M18D6FC53E5BEZ3 122M18D6FC53E59BS0 122M18D6FC53E520OU 122M18D6FC53E570D1 3/27/21 122M18E5EAA1BFE8ZQ 122M18E5EAA1BD8EFQ 4. An interview with the general supervisor on 5/10/21 at 1330 hours in the laboratory confirmed the above findings.

**D5441**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures

that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the laboratory quality control and patient test records and confirmed in interview, the laboratory failed to establish the number, type, and frequency of testing control that can detect immediate errors that occur for 2 of 3 Sars-CoV 2 PCR testing on the QuantStudio 6K Flex Real-Time PCR instrument (Extraction Free Saliva and Nasal Swab). Findings were: 1. Review of the laboratory policy for EXTRACTION-FREE SALIVA RT-qPCR ASSAY (Version 1.0) under Quality Control revealed "PTC - positive template control with an expected Ct value range. A new 100-200copies/L dilution of 2019-nCoV PTC should be made weekly and kept at -20C" 2. Review of the laboratory policy BIO-TESTING LABS COVID-19 HOME TEST SALIVA qRT-PCR ASSAY (version 1.0) that is currently used as the Nasal Swab policy under Quality Control "PTC - positive template control with an expected Ct value range. A new 100-200copies/L dilution of 2019-nCoV PTC should be made weekly and kept at -20C" 3. An interview with the general supervisor on 4/28 /21 at 1020 hours in the laboratory confirmed that the PTC controls are positive controls. He stated that the PTC2 control is just a dilution of PTC1, but both should provide positive results. 4. Review of the quality control records from January 2021 to April 2021 revealed 5 of 13 patient runs with quality control for either PTC 1 and/or PTC 2 as Negative. 1/3/21 (extraction Free Saliva) PTC 1 Positive PTC 2 Negative 3 /27/21 (Nasal Swab) PTC 1 Positive PTC 2 Negative 4/6/21 (Nasal swab) PTC 1 Negative PTC 2 Positive 1/27/21 (extraction Free Saliva) PTC 1 Positive PTC 2 Negative 3/26/21 (extraction Free Saliva) PTC 1 Negative PTC 2 Positive 5. Random review of the laboratory records from 2021 revealed the following 5 nasal swabs SARS-CoV2 PCR testing. 3/27/21 122M18E5EAA1BFE8ZQ 122M18E5EAA1BD8EFQ 4/6/21 122M18E5EAA1B5806B 122M18E5EAA1B5B2HQ 122M18E5EAA1B59ELQ 6. Random review of the laboratory records from 2021 revealed the following 15 saliva SARS-CoV2 PCR testing. 3/26/21 122M18DFEE249F0A0K 122M18DFEE249F3FLB 122M18DFEE249F4DGP 122M18DFEE249F19JU 122M18CB5A681E4EMB 122M18CB5A67C228PE 122M18CB5A67C4CDVO 3/27/21 MXP011MQM MXP011MWF MXP00RQ33 MXP01BOEF MXP011N56 MXP01BOEP MXP00NM7J MXP011MVN 7. An interview with the general supervisor on 5/10/21 at 1330 hours in the laboratory confirmed the above findings. He stated that sometimes the Ct range for the dilution degrades and illicit the negative result.

**D5449**

CONTROL PROCEDURES  
CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g)

The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of the lab records and quality control (QC) records of the qualitative detection of nucleic acid from SARS-CoV-2 in saliva from 2021 and confirmed in interview, the laboratory failed to include a negative and positive external control material each day of patient testing for 6 of 6 days reviewed for the saliva SARS-CoV-2 PCR testing. Findings were: 1. Review of the laboratory records from 2021 revealed the laboratory performed qualitative PCR testing for SARS-CoV2 using saliva specimens. 2. Review of the quality control records from January to March 2021 revealed no documentation of a negative quality control for 6 of 6 days reviewed. 3/12/21 2/23/2021 2/13/2021 1/27/2021 1/13/2021 1/3/2021 3. Random review of the patient tests performed for the above dates revealed the laboratory performed the following 50 patients for SARS-CoV2. 3/12/21 Patient ID 122M18DEAF2A7CE8KJ 122M18DFEE24B367QE 122M18D7B5D443C0QW SMART20036 SMART20048 SMART20029 SMART20034 SMART20042 SMART20037 2/23/2021 122M18DFEE243D5155 122M18DFEE243D31YI 122M18DFEE243D40VV 122M18DFEE243C45SL 122M18DFEE243C37WL 2/13/2021 122M18DE3B05CAFAYP 122M18D7B5D45514HZ 122M18D7B5D45823JS 122M18D7B5D45613MQ 122M18D7B5D332329W 1/27/2021 122M18DCFEAC3DF8WJ 122M18DCFEAC3DD24E 122M18DCFEAC3E55NB 122M18DCFEAC3E2A0B 122M18DCFEAC3E66YN 122M18DCFEAC3DE7K9 122M18DCFEAC3D9EDF 122M18DCFEAC3DC2RS 1/13/2021 122M18DBF9FF742458 122M18DBF9FF74394P 122M18DBF9FF745F4W 122M18DBF9FF7471JB 122M18DBF9FF7485ZT 122M18DBF9FF7498LI 122M18DBF9FF74A9FD 122M18DBF9FF7598KY 122M18DBF9FF75ABDH 122M18DBF9FF75BDUC 122M18DBF9FF75CFAC 122M18DBF9FF75F7KC 1/3/2021 122M18D7E36A7EC1AW 122M18D6FC53E563WI 122M18D6FC53E53EHR 122M18D6FC53E52D7V 122M18D7E36A7F14KJ 122M18D6FC53E58EEX 122M18D6FC53E4D60H 122M18D6FC53E5BEZ3 122M18D6FC53E59BS0 122M18D6FC53E520OU 122M18D6FC53E570D1 4. An interview with the general supervisor on 4/28/21 at 1057 hours in the laboratory confirmed the above findings. He stated that the laboratory used the NTC (no template control) as a negative and did not use a known negative as a negative control for all saliva testing performed.

**D5791**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1289(a)(c)

(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on review of the laboratory records, quality control records, and confirmed in interview, the laboratory quality assessment policies and procedures failed to to monitor & evaluate the overall quality of the analytic systems, to identify & correct problems for testing performed by the laboratory in the following areas: Test systems (refer to D5423); and Control procedures (refer to D5441, D5449).

**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 patient final results and confirmed in interview, the laboratory failed to document the specimen source for 15 of 15 SARS-CoV-2 IgM/IgG Antibody tests reviewed. Findings were: 1. A random review of SARS-CoV-2 IgM/IgG Antibody final reports from January 2021 to April 2021 revealed 15 of 15 patient results that did not have documentation of the specimen source.

122M18DF4B9D454FGB 122M18DF4B9D44D0WG 122M18C66C9BB330GN 122M18DF4B9D450E7S 122M18DF4B9D350EMV 122M18DF4B9D30F1NO 122M18DF4B9D2FEALS 122M18DF4B9D4890NH 122M18DF4B9D489EB0 122M18CBAF6506BCX3 122M18DF4B9D46C80N 122M18DF4B9D301C0P 122M18DF4B9D4921UE 122M18DF4B9D35320F 122M18CBAF653A8D7W 2. An interview with the general supervisor on 5/10/21 at 1110 hours in the laboratory confirmed the above findings.

**D6000**

**MODERATE COMPLEXITY LABORATORY DIRECTOR**

CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on review of instrument verification records, review of patient final reports, and confirmed in interview, the laboratory director failed to provide overall management and direction of the laboratory. (refer to D6007)

**D6007**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(1)

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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (E) The laboratory director must-- (E)(1) 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:

	<p>Based on a review of laboratory preanalytic systems it was revealed that the laboratory director failed to ensure that testing systems performed in the laboratory provided quality laboratory services for all aspects of test performance in Immunology. Refer to D5311-I</p>
<b>D6076</b>	<p><b>LABORATORY DIRECTOR</b> CFR(s): 493.1441</p> <p>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.</p> <p>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 D6086, D6093)</p>
<b>D6086</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(3)(ii)</p> <p>The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.</p> <p>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 continued to fail to ensure the laboratory documented complete establishment for its test systems before reporting patient test results. Refer to D5423</p>
<b>D6093</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on review of quality control records and interview, the laboratory director failed to ensure that the quality control programs were established to identify failures in quality as they occurred. Refer to D5441, D5449</p>