| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 45D2191410 | 06/29/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Formula Wellness Park Cities | 4342 Lovers Ln, Dallas, TX | |

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

| (X4) ID Prefix Tag | Summary Statement of Deficiencies |
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| **D0000** | On 06/29/2021, an unannounced onsite visit to Formula Wellness, 4342 Lovers Lane, Dallas, TX, 75225, CLIA number 45D2191410 was conducted to investigate complaint TX00386501 and to perform an initial survey for compliance with CMS 42 CFR regulations. The entrance conference was held on 06/29/2021 at 10:25 am with the laboratory director, the Chief Executive Officer of Formula Diagnostics, the Minnesota state agency surveyor conducting the complaint investigation on this laboratory's temporary site located in Jackson, Minnesota, Testing Person-2 (as listed on the submitted Center for Medicare and Medicaid Services (CMS) 209 form) from the Minnesota temporary testing site, and two Texas state agency CLIA surveyors. The survey process was discussed, and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be NOT in compliance with the CLIA conditions for specialties/subspecialties surveyed for 42 CFR and Complaint TX00386501 was substantiated. 493.1100 Facility Administration, 493.1250 Analytic Systems 493.1403 Laboratory Director, (moderate complexity) 493.1409 Technical Consultant The laboratory's failure to be in compliance with these regulations was found to pose IMMEDIATE JEOPARDY to the patients served by the laboratory 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. |
| **D1001** | CERTIFICATE OF WAIVER TESTS<br>CFR(s): 493.15(e) |

Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.

This STANDARD is not met as evidenced by:
I. Based on review of the initial Centers for Medicare and Medicaid (CMS) 116 application, direct observation, review of the FDA emergency use authorization instructions for use for SARS-CoV-2 waived test kits, manufacturer's instructions for waived test kits, the Centers for Medicare and Medicaid (CMS) 116 form, laboratory records, and confirmed by the laboratory director, the laboratory failed to provide documentation of following the manufacturer's instructions for specified storage requirements to ensure accurate and reliable results for 9 of 9 months. Findings included: 1. Review of the CMS-116 application revealed the laboratory's initial application for a certificate of waiver was processed on 08/26/2020. 2. A tour of the laboratory and storage areas was conducted 06/29/2021 at 10:07 am. The following waived test kits were observed: a. In a main common area with several reclining chairs: BD Veritor SARS-COV-2 rapid antigen testing Lot number 1117210; Expiration 09/28/2021 Testing cartridges and collection swabs were observed. These cartridges and swabs were NOT contained in the original test kit box. Lucira COVID-19 All-in-One molecular in-vitro diagnostic test Lot number KO7A111706214M2; Expiration 01/21/2022; 1box b. In a storage room adjacent to the common area, the following test kits were observed: BD Veritor Group A Strep Lot number 0069339, Expiration 12/22/2022; 1 box Lot number 9307940; Expiration 09/10/2022; 2 boxes BD Veritor Flu A/B Lot number 0076570; Expiration 12/18/2022; 2 boxes CareStart COVID-19 Antigen Lot number CH20M15, Expiration 05/2021; 6 boxes Ecotest COVID IgG/IgM Rapid Test Device Lot number 12005023; Expiration 05/2022; 1 box Lucira COVID-19 All-in-One molecular in-vitro diagnostic test Lot number KO7A111706214M2; Expiration 01/21/2022; 21 boxes No temperature monitoring devices were observed. 3. Review of the FDA emergency use authorization instructions for use for each SARS-CoV-2/COVID-19 test system stated the following: a. BD Veritor SARS-COV-2 rapid antigen testing (REF 256082 2021-03): "Warnings and Precautions: ...Do not use components from any other BD Veritor test with the BD Veritor system for Rapid Detection of SARS-CoV-2. While components from other BC Veritor tests may appear similar, they are not the same ...Storage: Kits may be stored at 2-30C. DO NOT FREEZE. Reagents and devices must be at room temperature (15-30C) when used for testing. b. Lucira COVID-19 All-in-One molecular in-vitro diagnostic test (INST011 Rev. 1): "Storage and Handling: Test kits must always be stored at an ambient temperature (15-30C/59-86F)" c. CareStart COVID-19 Antigen (IFU-RCHM71-E) "Storage and Stability: Store the test kit as packaged between 1-30C" d. Ecotest (Assure) COVID IgG/IgM Rapid Test Device (1110032033 Rev1.4) "Storage and Stability: Store the Assure COVID-19 IgG/IgM Rapid Test Device at 2-30C when not in use ...Test Procedure: Allow the test device, specimen, buffer, and/or controls to reach room temperature (15-30C) prior to testing." 4. Review of the manufacturer's instructions for other observed waived test systems stated the following: a. BD Veritor Group A Strep (8087675(12); 2020-04) "Storage and Handling: Kits may be stored at 2-30C. DO NOT FREEZE. Reagents and devices must be at room temperature (15-30C) when used for testing." b. BD Veritor Flu A/B (808667(15); 2020-04) "Storage and Handling: Kits may be stored at 2-30C. DO NOT FREEZE. Reagents and devices must be at room temperature (15-30C) when used for testing." The laboratory was asked to provide documentation of room temperature monitoring in all areas where waived test kits were stored. No documentation was provided. The laboratory failed to follow manufacturer's

instructions for ensuring proper room temperature test kit storage. 5. Review of the CMS-116 form requested on 06/11/2021 prior to the survey and received 06/16/2021, revealed the laboratory had an annual waived test volume of 5000 tests. 6. During the exit conference on 06/29/2021 at 02:20 pm in the laboratory area, the laboratory director confirmed that the laboratory did not monitor the room temperatures where waived test kits were stored. II. Based on review of the submitted Center for Medicare and Medicaid Services (CMS) 209 form, FDA emergency use authorization instructions for use for SARS-CoV-2 test kits, laboratory records, the Centers for Medicare and Medicaid (CMS) 116 form, and confirmed by the laboratory director, the laboratory failed to provide documentation of operator training for 2 of 2 testing persons. Findings included: 1. The CMS-209 form submitted by the laboratory and signed by the laboratory director 06/29/2021 listed 2 testing persons (Testing Person -1 and Testing Person -2) that performed laboratory testing. 2. A tour of the laboratory and storage areas was conducted 06/29/2021 at 10:07am. The following waived test kits were observed: In a main common area with several reclining chairs: BD Veritor SARS-COV-2 rapid antigen testing Lot number 1117210; Expiration 09/28/2021 Testing cartridges and collection swabs were observed. These cartridges and swabs were NOT contained in the original test kit box. In a storage room adjacent to the common area, the following test kits were observed: CareStart COVID-19 Antigen Lot number CH20M15, Expiration 05/2021; 6 boxes Ecotest(Assure) COVID IgG /IgM Rapid Test Device Lot number 12005023; Expiration 05/2022; 1 box 3. Review of the FDA emergency use authorization instructions for use for each SARS-CoV-2 /COVID-19 test systems stated the following: a. BD Veritor SARS-COV-2 rapid antigen testing (REF 256082 2021-03): "Conditions of Authorization for the Laboratory (Applicable in the USA) ...All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling ..." b. CareStart COVID-19 Antigen (IFU-RCHM71-E) "Conditions of Authorization for the Laboratory ...All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling ..." c. Ecotest (Assure) COVID IgG/IgM Rapid Test Device (1110032033 Rev1.4) "Conditions of Authorization for the Laboratory (Applicable in the USA) ... All operators using your product must be appropriately trained in immunoassay techniques and use appropriate personal protective equipment when handling this kit and use your product in accordance with the authorized labeling. All laboratory personnel using this assay must also be trained in and be familiar with the interpretation of results of this product ..." 4. During the entrance conference on 06/29 /2021 at 10:25 am, Testing Person -2 was asked what tests were performed at the Minnesota temporary testing site. She stated that SARS-CoV-2 waived antigen and antibody tests were performed in Minnesota. 5. Review of laboratory records revealed the laboratory failed to document training for TP-1 and TP-2 for the test systems listed above. The laboratory was asked to provide documentation of training. No documentation was provided. The laboratory failed to follow manufacturer's instructions for testing persons training and documentation of training. 6. Review of the CMS-116 form requested 06/11/2021 prior to the survey and received 06/16/2021, revealed the laboratory had an annual waived test volume of 5000 tests. 7. During the exit conference on 06/29/2021 at 02:20 pm in the laboratory area, the laboratory director confirmed that the laboratory did not document testing person training. III. Based on direct observation, review of the FDA emergency use authorization instructions for use for SARS-CoV-2 test kits, manufacturer's instructions for waived test kits, laboratory records, and confirmed by the laboratory director, the laboratory

failed to ensure 6 of 6 boxes of SARS-CoV-2 test kits were not used beyond their expiration date. Findings included: 1. A tour of the laboratory and storage areas was conducted on 06/29/2021 at 10:07am. The following waived test kits were observed: In a storage room adjacent to the common area, the following test kits were observed: CareStart COVID-19 Antigen Lot number CH20M15, Expiration 05/2021; 6 boxes 2. Review of the FDA emergency use authorization instructions for the CareStart COVID-19 Antigen (IFU-RCHM71-E) test system stated the following: "Storage and Stability .... The reagents and materials in the CareStart COVID-19 Antigen are stable until the expiration date printed on the outer packaging. Do not use beyond the expiration date." 3. During the exit conference on 06/29/2021 at 02:20 pm in the laboratory area, the laboratory director confirmed that the CareStart COVID-19 test kit was expired. IV. Based on entrance interview with Testing Person-2 (in Minnesota), review of FDA emergency use authorization instructions for the CareStart COVID-19 Antigen (IFU-RCHM71-E) test system and Ecotest (Assure) COVID IgG/IgM Rapid Test Device (1110032033 Rev1.4), it was revealed the laboratory failed to provide documentation of external quality control performance for each new lot number of COVID-19 test kits for 2 of 2 lot numbers. Findings included: 1. During the entrance conference on 06/29/2021 at 10:25am in the laboratory area, Testing Person -2 was asked what tests were performed at the Minnesota temporary testing site. She stated that SARS-CoV-2 waived antigen and antibody tests were performed in Minnesota. The Minnesota state surveyor on site at the Minnesota temporary testing site confirmed that the location used the following test kits: CareStart COVID-19 Antigen test kit; Lot number CH21A22 Ecotest (Assure) COVID IgG/IgM Antibody Rapid Test kit; Lot number 12005023 Testing Person -2 stated that the Minnesota temporary site performs the waived COVID tests and takes a picture of the test cartridge after completion of patient testing. The picture is sent to the CEO of Formula Diagnostics for review. She further stated she performs external controls with each new test kit lot. She stated that she also sends photos of the test cartridges after the performance of external quality control material. She stated that she sends these photos to the CEO of Formula Diagnostics. 2. The FDA emergency use authorization instructions for the CareStart COVID-19 Antigen (IFU-RCHM71-E) test system stated the following: "External Control: External Control is used to demonstrate that the test device and test procedure perform properly. It is recommended that positive and negative external control swabs are run once with every new lot, shipment, and each new user. External positive and negative control swabs are provided in the kit ...6. Assess BIO, Inc, authorized distributors, and authorized laboratories using your product must ensure that any record, associated with this EUA are maintained until otherwise notified by the FDA. Such records will be made available to FDA for inspection upon request." 3. The FDA emergency use authorization instructions for the Ecotest (Assure) COVID IgG/IgM Rapid Test Device (1110032033 Rev1.4) stated the following: "External Positive and Negative Controls: Good laboratory practice suggests testing positive and negative external controls to ensure that the test reagents are working and that the test is correctly performed ....7. Assure Tech (Hangzhou Co., Ltd), authorized distributors, and authorized laboratories using your product must ensure that any record, associated with this EUA are maintained until otherwise notified by the FDA. Such records will be made available to FDA for inspection upon request." 4. These photos and review of quality control performance documents were not retained at the Formula Wellness location. On 06/29/2021, the Executive Assistant texted the Chief Executive Officer (CEO) of Formula Diagnostics. It was communicated to the surveyor that all documentation was saved digitally and could be emailed. Requested documentation was emailed to the Executive Assistant, but she was unable to open the attachment. The Executive Assistant then emailed the documentation directly to the surveyor. The

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| | surveyor was unable to open the attachment. The CEO of Formula Diagnostics was requested by an email sent on July 1, 2021 at 09:40 am to fax the requested documentation. The email was acknowledged at Monday, July 5, 2021 at 3:05 pm. No documentation was received. This confirmed the above findings. Word Key: BD= Becton Dickinson USA = United States of America |
| **D3000** | FACILITY ADMINISTRATION<br>CFR(s): 493.1100<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of the facility records, the facility administration failed to meet the requirements specified in 493.1101 through 493.1105, as evidenced by: 1. The laboratory failed to ensure the space and temperature requirements specified for the MobileDetect BIO BCC19 Polymerase Chain Rection (PCR) test system. Refer to D3001. 2. The laboratory failed to have a unidirectional workflow for virology PCR testing using the MobileDetect BIO BCC19 Polymerase Chain Rection (PCR) test system to ensure contamination prevention of patient specimens, equipment, reagents, and supplies. Refer to D3005. 3. The laboratory failed to retain test requisitions for 13 of 13 patients tested using the MobileDetect BIO BCC19 Test Kit for SARS-CoV-2 Detection. Refer to D3027. 4. The laboratory failed to retain the operator's manual for the Thermal Cycler used for the MobileDetect-Bio BCC19 Test Kit for SARS-CoV-2 Detection. Refer to D3031. 5. The laboratory failed to retain testing data related to the laboratory's "Analytical Method Validation Report" for the MobileDetect-BIO BCC19 Test Kit. Refer to D3033. |
| **D3001** | FACILITIES<br>CFR(s): 493.1101(a)(1)<br><br>The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process.<br><br>This STANDARD is not met as evidenced by:<br>Based on direct observation, review of the MobileDetect BIO BCC19 Instructions for Use, review of provided MobileDetect BIO BCC19 Test Kit for SARS-CoV-2 Detection Standard Operating Procedure, and confirmed by the laboratory director, the laboratory failed to ensure the laboratory met the space and temperature requirements specified for the MobileDetect BIO BCC19 Polymerase Chain Rection (PCR) test system. Findings included: 1. Observed in the laboratory area on 06/29 /2021 at 10:07 am was a Roche Hitachi C311 and a Roche Hitachi C411 that were currently not in use. The laboratory area had one stainless steel workbench area. Also, in the laboratory area was a Frigidaire Frost Free household refrigerator/freezer. No |

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| | biological safety hood was observed. No temperature monitoring devices for room temperatures or refrigerator/freezer temperatures were observed. 2. The MobileDetect BIO BCC19 Instructions for Use-Ver 2.1 for Emergency Use Authorization only, dated June 17, 2020, stated the following: "Precautions-General ...The MD-Bio BCC 19 test kit has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories; laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) of 1988, 42 U.S.C 263a, that meet requirements to perform high or moderate complexity test ...Precautions -BCC19 Test and Sample Handling ...Perform sample collection, reagent preparation, and sample addition in three different locations..... BCC 19 Test Kit Storage Conditions: Store the unopened BCC 19 reagents at -20C. Thaw reagents on ice for approximately 30 minutes after taking out of storage conditions ...BCC 19 Testing Conditions: Run a BCC 19 test at room temperature. This test should not be used outdoors and has not been tested at high temperatures or humidity ..." 3. The MobileDetect BIO BCC19 Test Kit for SARS-CoV-2 Detection Standard Operating Procedure (no documentation of laboratory director approval) stated the following: "Materials: Lab Coat, Black Sharpie Marker, Gloves, BSL II Hood ..."Precautions-General ...The MD-Bio BCC 19 test kit has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories; laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) of 1988, 42 U.S.C 263a, that meet requirements to perform high or moderate complexity test ... Precautions - BCC19 Test and Sample Handling ...Perform sample collection, reagent preparation, and sample addition in three different locations per the user manual ..." NOTE: This standard operating procedure, provided by the facility, indicated the source of the procedure as "Formula Diagnostics". The laboratory did not provide documentation that this procedure was reviewed or approved by the Formula Wellness laboratory director. 4. During the exit conference on 06/29/2021 at 02:20 pm in the laboratory area, the laboratory director confirmed that the laboratory only used the one stainless steel workbench for testing, did not have a biosafety Level (BSL) II hood, and did not monitor room temperature or freezer temperatures. Word Key: FDA= Federal Drug Administration BSL= Biosafety Level |
| **D3005** | FACILITIES<br>CFR(s): 493.1101(a)(3)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on direct observations, review of the MobileDetect BIO BCC19 Instructions for Use, review of the provided MobileDetect BIO BCC19 Test Kit for SARS-CoV-2 Detection Standard Operating Procedure, and confirmed by the laboratory director, the laboratory failed to have a unidirectional workflow for virology PCR testing using the MobileDetect BIO BCC19 Polymerase Chain Rection (PCR) test system to ensure contamination prevention of patient specimens, equipment, reagents, and supplies. Findings included: 1. Observed in the laboratory area on 06/29/2021 at 10:07 am was a Roche Hitachi C311 and a Roche Hitachi C411 that were currently not in use. The laboratory area had one stainless steel workbench area. 2. The MobileDetect BIO BCC19 Instructions for Use-Ver 2.1 for Emergency Use Authorization only, dated June 17, 2020, stated the following: "Precautions-General ...The MD-Bio BCC 19 test |

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| | kit has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories; laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) of 1988, 42 U.S.C 263a, that meet requirements to perform high or moderate complexity test ... Precautions-BCC-19 Test and Sample Handling ...Avoid microbial and cross contamination of the kit reagents. Follow Good Laboratory Procedures. Perform sample collection, reagent preparation, and sample addition in three different locations per the user manual." 3. The MobileDetect BIO BCC19 Test Kit for SARS-CoV-2 Detection Standard Operating Procedure (nodocumentation of laboratory director approval) stated the following: "Precautions-General ...The MD-Bio BCC 19 test kit has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories; laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) of 1988, 42 U.S.C 263a, that meet requirements to perform high or moderate complexity test ... Precautions -BCC19 Test and Sample Handling ...Ensure that bench spaces used for all test steps have been properly cleaned with 10% bleach and followed with 70% alcohol. Perform sample collection, reagent preparation, and sample addition in three different locations per the user manual ..." NOTE: This standard operating procedure, provided by the facility, indicated the source of the procedure as "Formula Diagnostics". The laboratory did not provide documentation that this procedure was reviewed or approved by the Formula Wellness laboratory director. 4. During the exit conference on 06/29/2021 at 02:20 pm in the laboratory area, the laboratory director confirmed that the laboratory only used the one stainless steel workbench for testing. The laboratory failed to have a unidirectional workflow for virology PCR testing using the MobileDetect BIO BCC19 Polymerase Chain Rection (PCR) test system to ensure contamination prevention of patient specimens, equipment, reagents, and supplies |
| **D3027** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(1)<br><br>Test requisitions and authorizations. Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory test logs (02/10/2021 through 04/20/2021) and laboratory patient reports, the laboratory failed to retain test requisitions for 13 of 13 patients tested using the MobileDetect BIO BCC19 Test Kit for SARS-CoV-2 Detection. Findings included: 1. Review of laboratory records (a patient testing log) revealed the laboratory performed the MobileDetect BIO BCC19 for SARS-CoV-2 patient testing on 22 days from 02/10/2021 through 04/20/2021 for a total of 187 patients. A random review of the following 13 patient reports revealed the following information: a. Patient Test ID: CVD-HN18FWD8 Collection date: 02/09/2021; Resulted date: 02/10/2021 Result: Sars-CoV-2 Not Detected b. Patient Test ID: CVD-7FF62CCD Collection date: 02/11/2021; Resulted date: 02/11/2021 Result: Sars-CoV-2 Detected c. Patient Test ID: CVD-RJ1FULLQ Collection date: 03/26/2021; Resulted date: 03/26/2021 Result: Sars-CoV-2 Not Detected d. Patient Test ID: CVD-EGPW5CN4 Collection date: 03/26/2021; Resulted date: 03/26/2021 Result: Sars-CoV-2 Not Detected e. Patient Test ID: CVD-BUKKDYSN Collection date: 03/26 /2021; Resulted date: 03/26/2021 Result: Sars-CoV-2 Not Detected f. Patient Test ID: CVD-7WPVUMFO Collection date: 03/27/2021; Resulted date: 03/27/2021 Result: |

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| | Sars-CoV-2 Not Detected g. Patient Test ID: CVD-GCGEM18E Collection date: 04 /05/2021; Resulted date: 04/06/2021 Result: Sars-CoV-2 Not Detected h. Patient Test ID: CVD-5PTQAEQI Collection date: 04/05/2021; Resulted date: 04/06/2021 Result: Sars-CoV-2 Not Detected i. Patient Test ID: CVD-NBIBV4Q7 Collection date: 04/06 /2021; Resulted date: 04/06/2021 Result: Sars-CoV-2 Not Detected j. Patient Test ID: CVD-PR5RTTTG Collection date: 04/08/2021; Resulted date: 04/08/2021 Result: Sars-CoV-2 Not Detected k. Patient Test ID: CVD-YLIIOQVU Collection date: 04/09 /2021; Resulted date: 04/09/2021 Result: Sars-CoV-2 Not Detected l. Patient Test ID: CVD-PVN6P46T Collection date: 04/09/2021; Resulted date: 04/09/2021 Result: Sars-CoV-2 Not Detected m. Patient Test ID: CVD-AUJFA77V Collection date: 04/09 /2021; Resulted date: 04/09/2021 Result: Sars-CoV-2 Not Detected 3. On July 08, 2021 at 11:51 am, test requisitions for the 13 patients listed above were requested by email from the CEO of Formula Diagnostics. The documentation was requested to be sent by July 9, 2021. No documentation was received. This confirmed the above findings. |
| **D3031** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(3)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the MobileDetect BIO BCC19 Instructions for Use, review of provided MobileDetect BIO BCC19 Test Kit for SARS-CoV-2 Detection Standard Operating Procedure, and confirmed in staff interview, the laboratory failed to retain the operator's manual for the Thermal Cycler used for the MobileDetect-Bio BCC19 Test Kit for SARS-CoV-2 Detection. Findings included: 1. The MobileDetect BIO BCC19 Instructions for Use-Ver 2.1 for Emergency Use Authorization only, dated June 17, 2020, stated the following: " ....Step 6 Heat Cycle: For an approved Thermal Cycler: Utilize the operators manual and instructions of the chosen thermal cycler. Set the well plate temperature to 65C and lid temperature to 95C ..." 2. The provided MobileDetect BIO BCC19 Test Kit for SARS-CoV-2 Detection Standard Operating Procedure (no documentation of laboratory director approval) stated the following: "Step 6 Heat Cycle: For an approved Thermal Cycler: Utilize the operator's manual and instructions of the chosen thermal cycler. Set the well plate temperature to 65C and lid temperature to 95C ..." NOTE: This standard operating procedure, provided by the facility, indicated the source of the procedure as "Formula Diagnostics". The laboratory did not provide documentation that this procedure was reviewed or approved by the Formula Wellness laboratory director 3. In an interview on 06/29 /2021 at 12:53 pm in the laboratory area, the Executive Assistant was asked to provide the operator's manual for the Thermal Cycler used with MobileDetect-Bio BCC19 Test Kit for SARS-CoV-2 Detection. No operator's manual was provided. This confirmed the above findings. |
| **D3033** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(3)(i)<br><br>In addition, the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years. |

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| | This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's "Formula Wellness LDT for MobileDetect-Bio BCC19 Test Kit for SARS-CoV-2 Detection, Analytical Method Validation Report" and staff communications, the laboratory failed to retain testing data and information related to the verification studies for the MobileDetect-BIO BCC19 Test Kit. Findings included: 1. The verification studies titled, "Formula Wellness LDT for MobileDetect-Bio BCC19 Test Kit for SARS-CoV-2 Detection, Analytical Method Validation Report", reviewed and approved by the laboratory director on 02/02/2021, stated the following: "Introduction: This document details the analytical method validation for Formula Wellness COVID Detection test using the MobileDetect-Bio BCC19 Test Kit. Formula Wellness internally validated the MobileDetect-Bio BCC19 Test Kit to perform as a Laboratory Developed Test (LDT). All tests performed by Formula Wellness undergo analytical method validation before use in clinical testing. The Method Validation is used to evaluate the quality, reliability, and consistency of assay performance characteristics. Assay performance characteristics described in this assay validation report are specific to Formula Wellness. The MD-Bio BCC-19 test kit is a simpler test than Real Time PCR needing only a static-timed incubation cycle to detect the SARS-CoV-2 virus. This validation is for a kit that utilizes an isothermal incubation heat cycle. The test is designed to use the MD-Bio Heater along with various other Thermal Cyclers that are capable of performing this assay ...Clinical Comparisons: Clinical correlation studies were completed using clinical positive and negative samples ..." 2. The laboratory was asked to provide raw data collected during the" validation" studies, identity of persons performing the "validation" study, lot numbers of MobileDetect-Bio BCC19 Test Kits used for the "validation" study, specific dates in which the "validation" study was conducted and specific manufacturer and serial number of the thermo cycler used to perform the "validation" study. The requested "validation" study documents were not retained at the Formula Wellness location. On 06/29/2021, the Executive Assistant texted the Chief Executive Officer (CEO) of Formula Diagnostics. It was communicated to the surveyor that all documentation was saved digitally and could be emailed. Requested documentation was emailed to the Executive Assistant, but she was unable to open the attachment. The Executive Assistant then emailed the documentation directly to the surveyor. The surveyor was unable to open the attachment. The CEO of Formula Diagnostics was requested by an email sent Monday, July 5, 2021 at 1:05 pm to fax the requested documentation. The email was acknowledged at Monday, July 5, 2021 at 3:45 pm. No documentation was received. This confirmed the above findings. |
| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's submitted Centers for Medicare and Medicaid Services (CMS) 209 form and review of laboratory policies, it was revealed the laboratory failed to have documentation of a policy to assess competency, based on the position responsibilities, for 1 of 1 Technical Consultants (TC-1). Findings included: 1. Initial review of the submitted Centers for Medicare and Medicaid |

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| | Services (CMS) 209 form revealed the laboratory did not list a technical consultant. The laboratory was asked to provide the name of the technical consultant. On 06/29 /2021 at 12:17 pm, the executive assistant, after conferring with the Chief Executive Officer of Formula Diagnostics, stated that the laboratory did not have a technical consultant. On 06/29/2021 at 1:39 pm, the executive assistant provided an email stating the name of the technical consultant. The executive assistant added this individual's name on the submitted CMS-209 form as the technical consultant (TC-1). At the exit conference on 06/29/2021 at 2:13 pm, surveyors were given a curriculum vitae (CV) for another individual not listed on the submitted CMS-209 form. The executive assistant stated that the person listed as TC-1 performed the MobileDetect validation studies and that the other individual was the laboratory's technical consultant. 2. A review of the laboratory's policies revealed the laboratory failed to have documentation of a policy of when and how a competency assessment was to be performed on the technical consultant. The laboratory was asked to provide a documentation policy of when and how a competency assessment was to be performed on the technical consultant. No documentation was provided. This confirmed the above findings. |
| **D5313** | SPECIMEN SUBMISSION, HANDLING, AND REFERRAL<br>CFR(s): 493.1242(b)<br><br>The laboratory must document the date and time it receives a specimen.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of specimen test logs, patient final reports, and staff communications, the laboratory failed to document a specimen received date and time for 13 of 13 patients (random sampling from 02/10/2021 through 04/20/2021). Findings included: 1. Review of the laboratory submitted PCR test log revealed areas for the following information to be documented: "Date/Time; Test performed; Patient Last Name; Patient First Name; Tester's initials; Results/Initials" 2. A random review of patient final reports revealed the following 13 of 13 patients in which the specimen received date and time was NOT documented on the specimen test log or on the patient final report: a. Patient Test ID: CVD-HN18FWD8 b. Patient Test ID: CVD-7FF62CCD c. Patient Test ID: CVD-RJ1FULLQ d. Patient Test ID: CVD-EGPW5CN4 e. Patient Test ID: CVD-BUKKDYSN f. Patient Test ID: CVD-7WPVUMFO g. Patient Test ID: CVD-GCGEM18E h. Patient Test ID: CVD-5PTQAEQI i. Patient Test ID: CVD-NBIBV4Q7 j. Patient Test ID: CVD-PR5RTTTG k. Patient Test ID: CVD-YLIIOQVU l. Patient Test ID: CVD-PVN6P46T m. Patient Test ID: CVD-AUJFA77V The laboratory failed to document a specimen received date and time. 3. On 07/08/2021 at 11:51 am, test requistions for the patients listed above was requested by email from the CEO of Formula Diagnostics. On 07/08/2021 at 02:43 pm, the CEO responded, "On it." No documentation was provided. This confirmed the above findings. |
| **D5400** | ANALYTIC SYSTEMS<br>CFR(s): 493.1250<br><br>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 |

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| | 493.1289 for each specialty and subspecialty of testing performed.<br><br>This CONDITION is not met as evidenced by:<br>Based on direct observation, review of FDA emergency use authorizations, laboratory records, and confirmed by the laboratory director, it was revealed the laboratory failed to meet analytic systems requirements, as evidenced by: 1. The laboratory failed to provide a procedure for the laboratory (Formula Wellness) that included all required components for 1 of 1 moderate complexity laboratory tests (MobileDetect BIO BCC19 Test Kit for SARS-CoV-2 Detection). Refer to D5403. 2. The laboratory failed to ensure that Formula Wellness procedures were approved, signed, or dated by the laboratory director before use. Refer to D5407. 3. The laboratory failed to ensure room temperature, freezer temperatures, and Thermal Cycler plate and lid temperatures were within operating specifications for the MobileDetect BIO BCC19 Test Kit for SARS-CoV-2 Detection for 69 of 69 days. Refer to D5413. 4. The laboratory failed to document a negative and positive control each day patient specimens were analyzed for 22 of 22 days of patient testing on the MobileDetect BIO BCC19 Test Kit. Refer to D5449. |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory and patient test records from 02/10/2021 through 04/20/2021, and confirmed by the laboratory director, the laboratory failed to provide a procedure for the laboratory (Formula Wellness) that included all required components of a procedure for 1 of 1 moderate complexity laboratory tests (MobileDetect BIO BCC19 Test Kit for SARS-CoV-2 Detection). Findings included: 1. Review of the test records revealed the laboratory started SARS-CoV-2 polymerase chain reaction (PCR) patient testing using the EUA approved MobileDetect BIO BCC19 Test Kit for SARS-CoV-2 Detection on 02/10/2021. 2. A laboratory procedure manual was requested for the laboratory, Formula Wellness. A procedure titled "Mobile Detect-BIO BCC-19 Test Kit for SARS CoV-2 Detection Standard Operating Procedure" from Formula Diagnostics was provided. The procedure failed |

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| | to document Formula Wellness laboratory director review or approval. 3. Review of the laboratory procedure provided by the Chief Executive Officer of Formula Diagnostics revealed no documentation of: a. Specimen acceptability and rejection criteria b. Reagent and control material storage and stability requirements c. Quality Control procedures d. Corrective action to take when control results fail to meet the laboratory's criteria for acceptability e. The laboratory's system for entering results in the patient record and reporting patient results The laboratory was asked to provide documentation of a procedure manual for MobileDetect BIO BCC19 Test Kit for SARS-CoV-2 Detection that included the criteria listed above. The laboratory provided a document titled "2019-Novel Cornavirus Specimen Rejection Procedure". This document was NOT specific to Formula Wellness and failed to show documentation of Formula Wellness laboratory director review or approval. The laboratory failed to provide a procedure for this laboratory (Formula Wellness) that included all required components of a procedure for 1 of 1 moderate complexity laboratory tests (MobileDetect BIO BCC19 Test Kit for SARS-CoV-2 Detection). 4. During the exit conference on 06/29/2021 at 02:20 pm in the laboratory area, the laboratory director confirmed the above findings. |
| **D5407** | PROCEDURE MANUAL<br>CFR(s): 493.1251(d)<br><br>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of provided laboratory procedures and confirmed by the laboratory director, the laboratory failed to ensure that Formula Wellness procedures were approved, signed, or dated by the laboratory director before use. Findings included: 1. A laboratory procedure manual was requested for the laboratory, Formula Wellness. A procedure titled "Mobile Detect-BIO BCC-19 Test Kit for SARS CoV-2 Detection Standard Operating Procedure" from Formula Diagnostics was provided. The procedure failed to document Formula Wellness laboratory director review or approval. 2. The laboratory was asked to provide documentation of any other procedures for MobileDetect BIO BCC19 Test Kit for SARS-CoV-2 Detection. The following was provided: a. The laboratory provided a document titled "2019-Novel Coronavirus Specimen Rejection Procedure". This document was NOT specific to Formula Wellness and failed to show documentation of Formula Wellness laboratory director review or approval. b. The laboratory also provided a procedure for proficiency testing (PT) or twice annual accuracy assess for SARS-CoV-2 PCR testing using the MobileDetect-BIO BCC-19 Test Kit for SARS CoV-2 titled "Formula Diagnostics Proficiency Testing" (Policy # FDXPO-1104) was provided. The procedure failed to document Formula Wellness laboratory director review or approval. c. The laboratory provided a procedure titled, "SARS-CoV-2 Specimen Receiving and Accessioning Training & Competency Assessment". The procedure failed to document Formula Wellness laboratory director review or approval. 3. During the exit conference on 06/29/2021 at 02:20 pm in the laboratory area, the laboratory director confirmed that he failed to review or approve laboratory procedures. This confirmed the above findings |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>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 review of the MobileDetect BIO BCC19 Instructions for Use, review of provided MobileDetect BIO BCC19 Test Kit for SARS-CoV-2 Detection Standard Operating Procedure, direct observation, laboratory records (02/10/21 - 04/20/2021), and confirmed by the laboratory director, the laboratory failed to ensure room temperature, freezer temperatures, and Thermal Cycler plate and lid temperatures were within operating specifications for the MobileDetect BIO BCC19 Test Kit for SARS-CoV-2 Detection for 69 of 69 days. Findings included: 1. The MobileDetect BIO BCC19 Instructions for Use-Ver 2.1 for Emergency Use Authorization only, dated June 17, 2020, stated the following: "BCC19 Test Kit Storage Conditions: Store the unopened BCC19 reagents at -20C. Thaw reagents on ice for approximately 30 minutes after taking out of storage conditions. Do not use reagents until they are completely thawed. Keep reagents on ice in between tests. If there is a delay in between tests, store reagents back at -20C ...BCC19 Testing Conditions: Run a BCC19 at room temperature. This test should not be used outdoors and has not been tested at high temperatures or humidity ...Quality Control-Positive and Negative Controls: The BCC19 Positive control must be stored at -20C. The positive control must be thawed on ice for at least 15 minutes before use. Do not use the positive control unless it is completely thawed. Keep the positive control stored at -20C anytime it is not being used ....Step 6 Heat Cycle: For an approved Thermal Cycler: Utilize the operators manual and instructions of the chosen thermal cycler. Set the well plate temperature to 65C and lid temperature to 95C ..." 2. The provided MobileDetect BIO BCC19 Test Kit for SARS-CoV-2 Detection Standard Operating Procedure (no documentation of laboratory director approval) stated the following: "Step 4: Keep reagents on ice in between tests. If there is a delay in between tests, store reagents back at -20C ... Step 6 Heat Cycle: For an approved Thermal Cycler: Utilize the operator's manual and instructions of the chosen thermal cycler. Set the well plate temperature to 65C and lid temperature to 95C ..." NOTE: This standard operating procedure, provided by the facility, indicated the source of the procedure as "Formula Diagnostics". The laboratory did not provide documentation that this procedure was reviewed or approved by the Formula Wellness laboratory director. 3. Observed in the laboratory area on 06/29/2021 at 10:07am was a Roche Hitachi C311 and a Roche Hitachi C411 that were currently not in use. The laboratory area had one stainless steel workbench area. Also, in the laboratory area was a Frigidaire Frost Free household refrigerator/freezer. No temperature monitoring devices for room temperatures or refrigerator/freezer temperatures were observed. 4. Review of laboratory records (a patient testing log) revealed the laboratory has performed the MobileDetect BIO BCC19 for SARS-CoV-2 testing from 02/10/2021 through 04/20 /2021. The laboratory was asked to provide documentation of room temperature monitoring, freezer temperature monitoring, and thermal cycler plate and lid monitoring. No documentation was provided. The laboratory testing volume form 02 /10/2021 through 04/20/2021 was 187 patients. 5. During the exit conference on 06/29 /2021 at 02:20 pm in the laboratory area, the laboratory director confirmed that the laboratory failed to document required temperatures. This confirmed the above

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| | findings. |
| **D5449** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(ii)(g)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the MobileDetect BIO BCC19 Instructions for Use, review of provided MobileDetect BIO BCC19 Test Kit for SARS-CoV-2 Detection Standard Operating Procedure, laboratory patient records (02/10/21 - 04/20/2021), and confirmed by the laboratory director, the laboratory failed to document a negative and positive control each day patient specimens were analyzed for 22 of 22 days of patient testing on the MobileDetect BIO BCC19 Test Kit. Findings included: 1. The MobileDetect BIO BCC19 Instructions for Use-Ver 2.1 for Emergency Use Authorization only, dated June 17, 2020, stated the following: "Quality Control-Positive and Negative Controls: Quality control requirements must be performed in conformance with local, state, and federal regulations or accreditation requirements and the user's laboratory standard quality control procedure ...MD-Bio recommends that a BCP19 Negative control and Positive Control be run: Once for every 8 tube PCR strip or cluster of PCR tubes run in the same heat cycle." 2. Review of the provided MobileDetect BIO BCC19 Test Kit for SARS-CoV-2 Detection Standard Operating Procedure (no documentation of laboratory director approval) revealed the procedure did not document any quality control procedures. 3. Review of laboratory records (a patient testing log) revealed the laboratory has performed the MobileDetect BIO BCC19 for SARS-CoV-2 patient testing on the following 22 days from 02/10 /2021 through 04/20/2021 for a total of 187 patients.: 02/10/2021; 34 patients tested 02 /24/2021; 4 patients tested 02/25/2021; 5 patients tested 02/26/2021; 3 patients tested 02/27/2021; 7 patients tested 03/01/2021; 4 patients tested 03/02/2021; 5 patients tested 03/03/2021; 3 patients tested 03/04/2021; 6 patients tested 03/05/2021; 5 patients tested 03/26/2021; 10 patients tested 03/27/2021; 6 patients tested 03/29 /2021; 5 patients tested 03/30/2021; 3 patients tested 04/01/2021; 9 patients tested 04 /05/2021; 7 patients tested 04/06/2021; 9 patients tested 04/07/2021; 17 patients tested 04/08/2021; 1 patient tested 04/09/2021; 9 patients tested 04/16/2021; 9 patients tested 04/19/2021; 4 patients tested 04/20/2021; 22 patients tested 4. The laboratory was asked to provide documentation of performance of a negative and a positive control each day patient specimens were analyzed and for documentation of a negative and positive control performed once for every 8 tube PCR strip or cluster of PCR tubes run in the same heat cycle (per MobileDetect BIO BCC19 Instructions for Use-Ver 2.1 for Emergency Use Authorization) on those days when over 8 patients were tested. No documentation was provided. The laboratory failed to document a negative and positive control each day patient specimens were analyzed for 22 of 22 days of patient testing on the MobileDetect BIO BCC19 Test Kit. 5. During the exit conference on 06/29/2021 at 02:20 pm in the laboratory area, the laboratory director confirmed the above findings |
| **D6000** | MODERATE COMPLEXITY LABORATORY DIRECTOR<br>CFR(s): 493.1403 |

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| | 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.<br><br>This CONDITION is not met as evidenced by:<br>Based on direct observations, review of laboratory policies, manufacturer's instructions, laboratory records, patient records, CMS 209 form, and confirmed in interview, it was revealed the laboratory director failed to provide overall management and direction in accordance with 493.1403 of this subpart, as evidenced by: 1. The laboratory director failed to ensure laboratory overall operations and test systems were in compliance with regulations. Refer to D6004. 2. The laboratory director failed to ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed. Refer to D6010. 3. The laboratory director failed to ensure that the quality control program was established and maintained to assure the quality of laboratory services provided. Refer to D6020. 4. The laboratory director failed to ensure all personnel had appropriate education. Refer to D6029. 5. The laboratory director failed to ensure written policies and procedures were established to assess, monitor, and maintain competency for 1 of 1 Testing Persons performing moderate complexity testing and for 1 of 1 Technical Consultants. Refer to D6030. 6. The laboratory director failed to specify in writing the responsibilities and duties for 1 of 1 Technical consultant (TC-1) and for 1 of 1 Testing Persons (TP-1) performing moderate complexity testing. Refer to D6032. |
| **D6004** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(a)(b)<br><br>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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on direct observations, review of laboratory procedures, review of laboratory records, and confirmed by the laboratory director, the Laboratory Director failed to ensure laboratory overall operations and test systems were in compliance with regulations as evidenced by: 1. The laboratory failed to provide a procedure for this laboratory (Formula Wellness) that included all required components of a procedure for 1 of 1 moderate complexity laboratory tests (MobileDetect BIO BCC19 Test Kit for SARS-CoV-2 Detection). Refer to D5403. 2. The laboratory failed to ensure that Formula Wellness procedures were approved, signed, or dated by the laboratory director before use. Refer to D5407. 3. The laboratory failed to ensure room temperature, freezer temperatures, and Thermal Cycler plate and lid temperatures were within operating specifications for the MobileDetect BIO BCC19 Test Kit for SARS-CoV-2 Detection for 69 of 69 days. Refer to D5413. |
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| **D6010** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(2)<br><br>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)(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on direct observations, review of laboratory procedures, and laboratory records, the laboratory director failed to ensure that the physical plant and environmental conditions of the laboratory were appropriate for the testing performed, as evidenced by: 1. The laboratory failed to ensure the laboratory met the space and temperature requirements specified for the MobileDetect BIO BCC19 Polymerase Chain Rection (PCR) test system. Refer to D3001. 2. The laboratory failed to have a unidirectional workflow for virology PCR testing using the MobileDetect BIO BCC19 Polymerase Chain Rection (PCR) test system to ensure contamination prevention of patient specimens, equipment, reagents, and supplies. Refer to D3005. |
| **D6020** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory procedures, review of laboratory records, and confirmed by the laboratory director, it was revealed the laboratory director failed to ensure that the quality control program was established and maintained to assure the quality of laboratory services provided, as evidenced by: 1. The laboratory failed to document a negative and positive control each day patient specimens were analyzed for 22 of 22 days of patient testing on the MobileDetect BIO BCC19 Test Kit. Refer to D5449. |
| **D6029** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(11)<br><br>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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. |

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| | This STANDARD is not met as evidenced by:<br>Based on review of personnel records and confirmed by the laboratory director, it was revealed the laboratory director failed to ensure all personnel had appropriate education, as evidenced by: 1. The laboratory failed to ensure the technical consultant had documentation of minimum educational requirements to perform moderate complexity testing. Refer to D6035. |
| **D6030** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(12)<br><br>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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the CMS 209 form, review of laboratory records, and confirmed by the laboratory director, the laboratory director failed to ensure written policies and procedures were established to assess, monitor, and maintain competency for 1 of 1 Technical Consultant, as evidenced by: 1. The laboratory failed to have documentation of a policy to assess competency, based on the position responsibilities, for 1 of 1 Technical Consultant (TC-1). Refer to D5209. |
| **D6032** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(14)<br><br>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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the CMS 209 form and confirmed in interview, the Laboratory Director failed to specify in writing the responsibilities and duties for 1 of 1 Technical consultants (TC-1) and for 1 of 1 Testing Persons (TP-1) performing moderate complexity testing. Findings included: 1. Review of the CMS 209 form listed TC-1 as the technical consultant and TP-1 as the testing person performing the moderate |

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| | complexity MobileDetect BIO BCC19 Test Kit for SARS-CoV-2 detection; 2. During an interview on 06/29/2021 at 11:53 am in the laboratory area, the executive assistant was asked to provide documentation of technical consultant and testing person duties. No documentation was provided. This confirmed the above findings. |
| **D6033** | TECHNICAL CONSULTANT-MODERATE COMPEXITY<br>CFR(s): 493.1409<br><br>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.<br><br>This CONDITION is not met as evidenced by:<br>Based on direct observations, review of laboratory procedures, manufacturer's instructions, laboratory records, patient records, and the CMS 209 form, it was revealed the technical consultant failed to provide technical oversight of the laboratory, as evidenced by: 1. The laboratory failed to provide documentation that individuals met the minimum educational requirements to qualify as a technical consultant. D6035 2. The technical consultant failed to ensure requirements were met for the analytical phase of testing. Refer to 6036. 3. The technical consultant failed to ensure that the quality control program was established and maintained to ensure the quality of laboratory services provided. Refer to D6042. 4. The technical consultant failed to identify the need for training for 1 of 1 testing persons (TP-1). Refer to D6045. |
| **D6035** | TECHNICAL CONSULTANT QUALIFICATIONS<br>CFR(s): 493.1411<br><br>(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for |

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| | "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the CMS-209 form and staff interview, the laboratory failed to provide documentation that individuals met the minimum educational requirements to qualify as a technical consultant. Findings included: 1. Initial review of the submitted Centers for Medicare and Medicaid Services (CMS) 209 form revealed the laboratory did not list a technical consultant. The laboratory was asked to provide the name of the technical consultant. On 06/29/2021 at 12:17 pm, the executive assistant, after conferring with the Chief Executive Officer of Formula Diagnostics, stated that the laboratory did not have a technical consultant. On 06/29/2021 at 1:39 pm, the executive assistant provided an email stating the name of the technical consultant. The executive assistant added this individual's name on the submitted CMS-209 form as the technical consultant (TC-1). At the exit conference on 06/29/2021 at 2:13 pm, surveyors were given a curriculum vitae (CV) for another individual not listed on the submitted CMS-209 form. The executive assistant stated that the person listed as TC-1 performed the MobileDetect validation studies and that the other individual was the laboratory's technical consultant. 2. During an interview on 06/20/2021 at 12:21 pm, the executive assistant was asked to provide educational documentation for the technical consultant that had been added to the CMS-209 form. No documentation was provided. On 06/29/2021 at 2:13 pm, the laboratory was asked to provide educational documentation for the second individual in which a CV was provided. No documentation was provided. The laboratory failed to provide documentation that one or more individuals met the minimum educational requirements to qualify as a technical consultant. |
| **D6036** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413<br><br>The technical consultant is responsible for the technical and scientific oversight of the laboratory.<br><br>This STANDARD is not met as evidenced by:<br>Based on direct observations, review of laboratory procedure, manufacturer's instructions, laboratory records, patient records, CMS 209 form, and confirmed by the laboratory director, it was revealed the technical consultant failed to ensure requirements were met for the analytical phase of testing, as evidenced by: 1. The laboratory failed ensure room temperature, freezer temperatures, and Thermal Cycler plate and lid temperatures were within operating specifications for the MobileDetect BIO BCC19 Test Kit for SARS-CoV-2 Detection for 69 of 69 days. Refer to D5413. |
| **D6042** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(4)<br><br>(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control |

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| | program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory records and patient test records, it was revealed the technical consultant failed to ensure that the quality control program was established and maintained to ensure the quality of laboratory services provided, as evidenced by:<br>1. The laboratory failed to document a negative and positive control each day patient specimens were analyzed for 22 of 22 days of patient testing on the MobileDetect BIO BCC19 Test Kit. Refer to D5449. |
| **D6045** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(7)<br><br>(b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;<br><br>This STANDARD is not met as evidenced by:<br>Based on review of personnel records and confirmed by the laboratory director, it was revealed the technical consultant failed to identify the need for training for 1 of 1 testing persons (TP-1). Refer to D6066. |
| **D6066** | TESTING PERSONNEL QUALIFICATIONS<br>CFR(s): 493.1423(b)(4)(ii)<br><br>Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's submitted Centers for Medicare and Medicaid (CMS -209) form, review of laboratory records, and in staff interview, it was revealed the laboratory failed to have documentation of training for 1 of 1 testing persons (TP-1) to qualify them to perform moderate complexity testing on the MobileDetect BIO BCC19 Test Kit. Findings included: 1. Review of the CMS 209 form (signed by the laboratory director on 06/29/2021) revealed one Testing Person (TP-1) performing moderate complexity testing on the MobileDetect BIO BCC19 Test Kit. 2. Review of laboratory records revealed the laboratory began testing using the MobileDetect BIO BCC19 Test Kit on 02/10/2021. 3. During an interview on 06/29/2021 at 11:53 am in the laboratory area, the executive assistant was asked to provide the date of hire and documentation of training for the MobileDetect BIO BCC19 Test Kit. No documentation was provided. This confirmed the above findings. |