

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0889595	(X3) Date Survey Completed 06/25/2024
Name of Provider or Supplier Prism Holistic Care Ltd	Street Address, City, State 33 W Grand Ave, Chicago, IL	
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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory records, lack of documentation and interview with the technical supervisor (TS), the laboratory failed to enroll in a Centers for Medicare and Medicaid (CMS) approved proficiency testing (PT) program for the subspecialty of virology (SARS-CoV-2, Respiratory Syncytial Virus (RSV), Influenza A, and Influenza B) in 2023 and 2024, affecting more than 12,239 patient tests. Findings include: 1. Review of the "Prism Health Lab List of Laboratory Test Performed" revealed the following tests: a. COVID-19 PCR Test Specimen Type: Anterior Nasal Swab, Saliva b. Influenza A PCR Test Specimen Type: Anterior Nasal Swab, Saliva c. Influenza B PCR Test Specimen Type: Anterior Nasal Swab, Saliva d. Respiratory Syncytial Virus (RSV) PCR Test Specimen Type: Anterior Nasal Swab, Saliva 2. Review of laboratory records revealed the reported number of patient test results in 2023 and 2024 for the following tests: - Swab COVID - 19 tests: 11,428 - Swab COVID - 19, Influenza A, Influenza B tests: 294 - Swab COVID - 19, Influenza A, Influenza B, RSV tests: 398 - Swab RSV - 63 - Saliva COVID - 19, Influenza A, Influenza B, RSV tests: 56 3. Review of the "Prism Health Lab Corrective Action Report, Report Release Date: 6/18/2024, Conducted by: XX" revealed the following information: "Deficiencies Identified ...5. Lack of External Proficiency Testing (PT): -</p>

There was no participation in external proficiency testing programs." 4. On 06/25 /2024, at 11:30 a.m., an interview with the TS revealed, "The lab started testing in February 2023. Not enrolled in PT, performed in-house testing. Ordered off schedule testing."

D3000

FACILITY ADMINISTRATION
CFR(s): 493.1100

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.

This CONDITION is not met as evidenced by:
Based on review of laboratory records, lack of documentation, surveyor's direct observation, manufacturer's Emergency Use Authorization (EUA), and interview with the technical supervisor (TS), the laboratory failed to provide a unidirectional workflow for molecular amplification procedures to minimize contamination of patient specimens, equipment, instruments, reagents, materials, and supplies for SARS-CoV-2, Respiratory Syncytial Virus (RSV), Influenza A, and Influenza B testing (Refer to D3005); the laboratory failed to retain quality control and patient result printouts for SARS-CoV-2, Influenza A, Influenza B, and Respiratory Syncytial Virus (RSV) testing in 2023 and 2024. (Refer D3031).

D3005

FACILITIES
CFR(s): 493.1101(a)(3)

Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation.

This STANDARD is not met as evidenced by:
Based on surveyor's direct observation, manufacturer's Emergency Use Authorization (EUA), and interview with the technical supervisor (TS), the laboratory failed to maintain a uni-directional workflow for molecular amplification procedures to prevent potential cross-contamination in specimen processing, preparation, amplification, and detection for SARS-CoV-2, Respiratory Syncytial Virus (RSV), Influenza A, and Influenza B from February 2023 to the date of survey 06/25/2024, affecting 12,239 patient tests. Findings include: 1. Review of the "Yale School of Public Health, Department of Epidemiology of Microbial Diseases SalivaDirect assay EUA summary" (SalivaDirect) revealed the following instructions: a. "Intended Use - ... SalivaDirect is intended for use by qualified clinical laboratory personnel specifically instructed and trained in the techniques of RT-qPCR and in vitro diagnostic procedures ..." 2. On 06/25/2024 at 3:35 p.m., direct observation of the TS demonstrating the testing procedures for the SalivaDirect assay found the laboratory failed to maintain a uni-directional workflow for molecular amplification procedures:

a) the transfer of patient samples to the patient testing plates and the addition of positive and negative control samples to the patient testing plates all performed on two robots (Integra Assist Plus); b) transfer of the patient testing plate from the pre-amplification room to the amplification room, and returned back to the pre-amplification room; c) the Quant Studio 7 Real-Time PCR system (Serial No. 2778722110004) located directly behind two biosafety cabinets (Mystaire - My Prep Station) utilized for the preparation of the extraction buffer reagent. 3. On 06/25/2024 at 3:45 p.m., the TS confirmed the above findings.

D3031

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

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

This STANDARD is not met as evidenced by:
Based on review of laboratory records, lack of documentation and interview with the technical supervisor (TS); the laboratory failed to retain quality control and patient result printouts for three of six patient test reports reviewed for SARS-CoV-2, Influenza A, Influenza B, and Respiratory Syncytial Virus (RSV) in 2023 and 2024. Findings include: 1. Review of the laboratory's patient test records and lack of documentation revealed the laboratory failed to retain quality control records and instrument run information for three of six patient tests reports reviewed for SARS-CoV-2, Influenza A, Influenza B, and Respiratory Syncytial Virus (RSV) for the following dates in 2023 and 2024: a. DATE: 11/13/2023 PATIENT ID: 349539 TEST PERFORMED: SARS-CoV-2, Influenza A, Influenza B, and RSV b. DATE: 11/13/2023 PATIENT ID: 349541 TEST PERFORMED: SARS-CoV-2 (no quality control records and instrument run information), Influenza A, Influenza B, and RSV c. DATE: 02/21/2024 PATIENT ID: 223246 TEST PERFORMED: SARS-CoV-2, Influenza A, Influenza B, and RSV 2. On 06/25/2024 at 4:27 p.m., an interview with the TS revealed the test results for SARS-CoV-2, Influenza A, Influenza B, and RSV were manually entered into the laboratory information system (LIS).

D5400

ANALYTIC SYSTEMS
CFR(s): 493.1250

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:
Based on review of laboratory records, the Yale School of Public Health, Department of Epidemiology of Microbial Diseases - SalivaDirect assay EUA, lack of documentation and interview with the technical supervisor (TS), the laboratory failed to provide a written procedure manual for testing four of four virology analytes (SARS-CoV-2, Influenza A, Influenza B, and Respiratory Syncytial Virus (RSV) utilizing Nasal Swab samples and for testing three of three analytes (Respiratory

Syncytial Virus (RSV), Influenza A and Influenza B) utilizing Saliva samples on two analyzers (Roche Cobas z480 and QuantStudio 7 Pro Serial No. 2778722110004) in 2023 and 2024, affecting more than 12,239 patient tests (refer to D5401); failed to demonstrate performance specifications for the SalivaDirect SARS-CoV-2 assay on one of one test system (Roche Cobas z480) in 2023 and 2024, affecting at least 56 patient tests. (Refer to D5421-A); the laboratory failed to demonstrate performance specifications for the SalivaDirect SARS-CoV-2 assay on one of one test system (QuantStudio 7 Pro, Instrument Serial No. 2778722110004) in 2023 and 2024, affecting at least 56 patient tests (Refer to D5421-B); failed to establish the performance specifications for a modified Yale School of Public Health, Department of Epidemiology of Microbial Diseases - SalivaDirect assay EUA before reporting patient test results for SARS-CoV-2, Influenza A, Influenza B, and Respiratory Syncytial Virus (RSV) on two of two analyzers (Roche Cobas z480 and QuantStudio 7 Pro Serial No. 2778722110004) in 2023 and 2024, affecting more than 12,239 patient tests (Refer to D5423); the laboratory failed to perform positive and negative control procedures with each instrument run for 2 of 6 SARS-CoV-2, Influenza A, Influenza B, and Respiratory Syncytial Virus (RSV) patient test run dates reviewed in 2023 and 2024. (Refer to D5445).

D5401

PROCEDURE MANUAL
CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:
Based on review of laboratory records, lack of documentation and interview with the technical supervisor (TS), the laboratory failed to provide a written procedure manual for testing four of four virology analytes (SARS-CoV-2, Influenza A, Influenza B, and Respiratory Syncytial Virus (RSV) utilizing Nasal Swab samples and for testing three of three analytes (Respiratory Syncytial Virus (RSV), Influenza A and Influenza B) utilizing Saliva samples on two analyzers (Roche Cobas z480 and QuantStudio 7 Pro Serial No. 2778722110004) in 2023 and 2024, affecting more than 12,239 patient tests. Findings include: 1. Review of the "Prism Health Lab List of Laboratory Test Performed" revealed the following tests: a. COVID-19 PCR Test Specimen Type: Anterior Nasal Swab, Saliva b. Influenza A PCR Test Specimen Type: Anterior Nasal Swab, Saliva c. Influenza B PCR Test Specimen Type: Anterior Nasal Swab, Saliva d. Respiratory Syncytial Virus (RSV) PCR Test Specimen Type: Anterior Nasal Swab, Saliva 2. Review of laboratory records revealed the reported number of patient test results in 2023 and 2024 for the following tests: - Swab COVID - 19 tests: 11,428 - Swab COVID - 19, Influenza A, Influenza B tests: 294 - Swab COVID - 19, Influenza A, Influenza B, RSV tests: 398 - Swab RSV - 63 - Saliva Influenza A, Influenza B, RSV tests: 56 3. Review of the "Prism Health Lab Corrective Action Report, Report Release Date: 6/18/2024, Conducted by: XX" revealed the following information: "Limited SOP Coverage: - Existing SOPs focused primarily on test procedures, with insufficient coverage for equipment and other operational processes." 4. Review of laboratory records and lack of documentation revealed the laboratory failed to provide a written procedure manual for testing four of four virology analytes (SARS-CoV-2, Influenza A, Influenza B, and Respiratory Syncytial Virus (RSV) utilizing Nasal Swab samples and for testing three of three analytes (Respiratory Syncytial Virus

(RSV), Influenza A and Influenza B) utilizing Saliva samples on two analyzers (Roche Cobas z480 and QuantStudio 7 Pro Serial No. 2778722110004) in 2023 and 2024, affecting more than 12,239 patient tests. 5. On 06/25/2024 at 4:27 p.m., the TS confirmed the above findings.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

A. Based on review of laboratory records, the Yale School of Public Health, Department of Epidemiology of Microbial Diseases - SalivaDirect assay EUA, lack of documentation and interview with the technical supervisor (TS), the laboratory failed to demonstrate performance specifications for the SalivaDirect SARS-CoV-2 assay on one of one test system (Roche Cobas z480) in 2023 and 2024, affecting at least 56 patient tests. Findings include: 1. Review of the "Prism Health Lab List of Laboratory Test Performed" revealed the following test: a. COVID-19 PCR Test Specimen Type: Saliva 2. Review of laboratory records revealed the reported number of patient test results in 2023 and 2024 for the following tests: - Saliva COVID - 19 tests: 56 3. Review of the laboratory "Incident Report, Date: June 24, 2024, Prepared by XX" revealed the following information: " ...while preparing for our upcoming CLIA survey, it was discovered that all the validation data for our molecular assays on the Roche Cobas z480 had been wiped from the device. This data loss impacts the validation reports for our four molecular assays ..." 4. On 06/25/2024, at 1:42 p.m., the TS confirmed the above findings. B. Based on review of laboratory records, the Yale School of Public Health, Department of Epidemiology of Microbial Diseases - SalivaDirect assay EUA, lack of documentation and interview with the technical supervisor (TS), the laboratory failed to demonstrate performance specifications for the SalivaDirect SARS-CoV-2 assay on one of one test system (QuantStudio 7 Pro, Instrument Serial No. 2778722110004) in 2023 and 2024, affecting at least 56 patient tests. Findings include: 1. Review of the "Prism Health Lab List of Laboratory Test Performed" revealed the following tests: a. COVID-19 PCR Test Specimen Type: Saliva 2. Review of laboratory records revealed the reported number of patient test results in 2023 and 2024 for the following tests: - Saliva COVID - 19 tests: 56 3. Review of the laboratory "Incident Report, Date: June 24, 2024, Prepared by XX" revealed the following information: " ...3. Rapid Re-Validation: Conduct rapid re-validation process of the four molecular assays on the QuantStudio 7Pro. Document the re-validation process comprehensively, noting any deviations from the original protocol due to time constraints." 4. Review of laboratory records and lack of documentation revealed the laboratory failed to verify the accuracy, precision, reportable range of test results for the test system and reference intervals (normal values) established by the manufacturer for one of one test system (QuantStudio 7 Pro, Instrument Serial No. 2778722110004) utilizing saliva specimens before reporting patient test results (SARS-CoV-2) in 2023 and 2024, affecting more than 56 patient tests. 5. On 06/25/2024, at 1:42 p.m., the TS confirmed the above findings.

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 laboratory records, lack of documentation and interview with the technical supervisor (TS), the laboratory failed to establish the performance specifications for a modified test system (Yale School of Public Health, Department of Epidemiology of Microbial Diseases - SalivaDirect assay EUA) before reporting Anterior Nasal Swabs for SARS-CoV-2 and Saliva patient test results for SARS-CoV-2, Influenza A, Influenza B, and Respiratory Syncytial Virus (RSV) on two of two analyzers (Roche Cobas z480 and QuantStudio 7 Pro Serial No. 2778722110004) in 2023 and 2024, affecting more than 12,183 patient tests. Findings include: 1. Review of laboratory documents revealed the "Yale School of Public Health, Department of Epidemiology of Microbial Diseases SalivaDirect assay EUA summary (SalivaDirect)" in use for SARS-CoV-2 patient testing. 2. Review of the "SalivaDirect - Intended Use" revealed the following information: "SalivaDirect is a real-time reverse transcription polymerase chain reaction (rRT-PCR) test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in saliva ..." "Results are for the detection and identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in saliva specimens during the acute phase of infection." 3. Review of the "Prism Health Lab List of Laboratory Test Performed" revealed the following tests: a. COVID-19 PCR Test Specimen Type: Anterior Nasal Swab, Saliva b. Influenza A PCR Test Specimen Type: Anterior Nasal Swab, Saliva c. Influenza B PCR Test Specimen Type: Anterior Nasal Swab, Saliva d. Respiratory Syncytial Virus (RSV) PCR Test Specimen Type: Anterior Nasal Swab, Saliva 4. Review of laboratory records revealed the reported number of patient test results in 2023 and 2024 for the following tests: - Swab COVID - 19 tests: 11,428 - Swab COVID - 19, Influenza A, Influenza B tests: 294 - Swab COVID - 19, Influenza A, Influenza B, RSV tests: 398 - Swab RSV - 63 - Saliva Influenza A, Influenza B, RSV tests: 56 5. Review of laboratory records revealed the following four documents: A. "Singleplex RT-PCR Assay for the Detection of SARS-CoV-2 N1 Gene in Clinical Anterior Nasal Samples - Assay Verification and Validation Report - Developed for Prism Health Lab by (XX)" B. "Multiplex RT-PCR Assay for the Detection of SARS-CoV-2 N1, Influenza A, Influenza B, and Respiratory Syncytial Virus in Clinical Anterior Nasal or Nasopharyngeal Samples - Assay Verification and Validation Report - Developed for Prism Health Lab by (XX)" C. "Singleplex RT-PCR Assay for the Detection of SARS-CoV-2 N1 Gene in Clinical Saliva Samples - Assay Verification and Validation Report - Developed for Prism Health Lab by (XX)" D. "Multiplex RT-PCR Assay for the Detection of SARS-CoV-2 N1, Influenza A, Influenza B, and Respiratory Syncytial Virus in Clinical Anterior Saliva Samples - Assay Verification and Validation Report - Developed for Prism Health Lab by (XX)" 6. Further review

of the laboratory records listed in Finding 5 revealed a lack of documentation of the resulted performance specifications for the following performance characteristics: Accuracy, Precision, Analytical sensitivity, Analytical specificity to include interfering substances, Reportable range of test results for the test system, Reference intervals (normal values) and any other performance characteristic required for test performance before reporting Anterior Nasal Swabs for SARS-CoV-2 and Saliva patient test results for SARS-CoV-2, Influenza A, Influenza B, and Respiratory Syncytial Virus (RSV) on two of two analyzers (Roche Cobas z480 and QuantStudio 7 Pro Serial No. 2778722110004) in 2023 and 2024, affecting more than 12,183 patient tests. 7. On 06/25/2024, at 1:42 p.m., the TS confirmed the above findings.

D5445

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

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

This STANDARD is not met as evidenced by:
Based on review of laboratory records, lack of documentation and interview with the technical supervisor (TS), the laboratory failed to perform positive and negative control procedures with each instrument run for two of six SARS-CoV-2, Influenza A, Influenza B, and Respiratory Syncytial Virus (RSV) patient test run dates reviewed in 2023 and 2024. Findings include: 1. Review of laboratory documents revealed the "Yale School of Public Health, Department of Epidemiology of Microbial Diseases SalivaDirect assay EUA summary (SalivaDirect)" in use for SARS-CoV-2 patient testing. 2. Review of the "SalivaDirect - Intended Use" revealed the following information: "The following controls are run with the SalivaDirect assay: Controls Run With The COVID-19 RT-PCR: CONTROL - Negative Extraction Control (NEC) ... FREQUENCY - Every batch of up to 93 saliva samples CONTROL - Negative Template Control (NTC) ... FREQUENCY - Every PCR plate with up to 93 saliva samples CONTROL - Positive Control ... FREQUENCY - Every PCR plate with up to 93 saliva samples CONTROL - Internal Process Control ... FREQUENCY - Every sample" 3. Review of laboratory SARS-CoV-2 patient test records and lack of documentation revealed the laboratory failed to perform positive and negative control procedures as instructed in Finding 2 for two of six SARS-CoV-2 patient test run dates in 2023 and 2024. Test Result Date A: 11-14-2023 Test Name: SalivaDirect COVID-19 RT-PCR Quality Control: COVID-19 RT-PCR (No Record on file) Test Result Date B: 02-24-2024 Test Name: SalivaDirect COVID-19 RT-PCR, Influenza A, Influenza B, and Respiratory Syncytial Virus (RSV) Quality Control: COVID-19 RT-PCR, Respiratory Syncytial Virus (RSV), Influenza A and Influenza B (No Record on file) 4. On 06/25/2024, at 4:27 p.m., the TS confirmed the above findings.

D5801

TEST REPORT
CFR(s): 493.1291(a)

The laboratory must have an adequate manual or electronic system(s) in place to

ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:
Based on review of laboratory records and interview with the technical supervisor (TS), the laboratory failed to ensure reliable and accurate transfer of patient test information (SARS-CoV-2) for three of six patient reports reviewed in 2023 and 2024. Findings include: 1. Review of the "Prism Health Lab Laboratory Requisition" forms and the "Prism Health Lab" final reports for three of six patient files reviewed revealed the laboratory failed to accurately report the source of specimen for SARS-CoV-2 patient testing for the following dates: a. Prism Health Lab Laboratory Requisition Collection Date: 11/13/2023 Date of Birth: 05/03/1925 Sample Type: Nasal Swab Prism Health Lab Report Status: Final Collection Date: 11/13/2023 Date of Birth: 05/03/1925 Test Name: SalivaDirect COVID-19 RT-PCR b. Prism Health Lab Laboratory Requisition Collection Date: 11/13/2023 Date of Birth: 03/01/1932 Sample Type: Nasal Swab Prism Health Lab Report Status: Final Collection Date: 11/13/2023 Date of Birth: 03/01/1932 Test Name: SalivaDirect COVID-19 RT-PCR c. Prism Health Lab Laboratory Requisition Collection Date: 02/06/2024 Date of Birth: 12/09/1944 Sample Type: Nasal Swab Prism Health Lab Report Status: Final Collection Date: 02/06/2024 Date of Birth: 12/09/1944 Test Name: Real Time RT-PCR SalivaDirect Assay Detection of SARS- CoV-2 COVID-19 (N1-Gene) 2. 06/25 /2024, at 1:42 p.m., the TS confirmed the above findings.

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:
Based on review of laboratory records, lack of documentation and interview with the technical supervisor (TS), the laboratory director failed to verify the procedures utilized to determine accuracy, precision and other performance characteristics for four of four test systems (SARS-CoV-2, Respiratory Syncytial Virus (RSV), Influenza A, and Influenza B) performed in 2023 and 2024. (Refer to D6086); the laboratory director failed to ensure the training of SARS-CoV-2, Respiratory Syncytial Virus (RSV), Influenza A, and Influenza B assays prior to patient testing for three of three testing personnel (TP 1, TP 2 and TP 3) in 2023 and 2024, affecting more than 12,239 patient tests. (Refer to D6102).

D6086

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(3)(ii)

The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of

	<p>the method.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation and interview with the technical supervisor (TS), the laboratory failed to verify the procedures utilized to determine accuracy, precision and other performance characteristics for four of four test systems (SARS-CoV-2, Respiratory Syncytial Virus (RSV), Influenza A, and Influenza B) performed in 2023 and 2024. Findings include: 1. The laboratory failed to provide technical and scientific oversight of testing for four of four test systems (SARS-CoV-2, Respiratory Syncytial Virus (RSV), Influenza A, and Influenza B) before reporting patient test results in 2023 and 2024, affecting more than 12,239 patient tests. (Refer to D6115).</p>
<p>D6102</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)</p> <p>The laboratory director must 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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records, lack of documentation and interview with the technical supervisor (TS), the laboratory failed to ensure the training for three of three testing personnel (TP 1, TP 2 and TP 3) for SARS-CoV-2, Respiratory Syncytial Virus (RSV), Influenza A, and Influenza B assays prior to patient testing in 2023 and 2024, affecting more than 12,239 patient tests. Findings include: 1. Review of laboratory records and lack of documentation revealed the laboratory failed to retain documentation of training and competency for three of three TP (TP 1, TP 2, and TP 3) in 2023 and 2024, affecting more than 12,239 patient tests. (Refer to D6120).</p>
<p>D6108</p>	<p>LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447</p> <p>The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory records, lack of documentation and interview with the technical supervisor (TS), the TS failed to ensure performance specifications for the SalivaDirect SARS-CoV-2 assay on two of two analyzers (Roche Cobas z480 and QuantStudio 7 Pro Serial No. 2778722110004) in 2023 and 2024 (Refer to D6115); the TS failed to ensure training and evaluation of competency for SARS-CoV-2, Respiratory Syncytial Virus (RSV), Influenza A, and Influenza B testing for three of three testing personnel (TP 1, TP 2 and TP 3) in 2023 and 2024, affecting more than 12,239 patient tests. (Refer to D6120).</p>
<p>D6115</p>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES</p>

CFR(s): 493.1451(b)(2)

The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

This STANDARD is not met as evidenced by:

Based on review of laboratory records, the Yale School of Public Health, Department of Epidemiology of Microbial Diseases - SalivaDirect assay EUA (SalivaDirect), lack of documentation and interview with the technical supervisor (TS), the TS failed to ensure performance specifications for the SalivaDirect SARS-CoV-2, Respiratory Syncytial Virus (RSV), Influenza A, and Influenza B assays on two of two analyzers (Roche Cobas z480 and QuantStudio 7 Pro Serial No. 2778722110004) in 2023 and 2024. Findings include: a) The TS failed to ensure performance specifications for the SalivaDirect SARS-CoV-2 assay for two of two analyzers (Roche Cobas z480 and QuantStudio 7 Pro Serial No. 2778722110004) in 2023 and 2024. (Refer to D5421). b) The TS failed to ensure the performance specifications for a modified test system (Yale School of Public Health, Department of Epidemiology of Microbial Diseases - SalivaDirect assay EUA) before reporting Anterior Nasal Swabs for SARS-CoV-2 and Saliva patient test results for SARS-CoV-2, Influenza A, Influenza B, and Respiratory Syncytial Virus (RSV) on two of two analyzers (Roche Cobas z480 and QuantStudio 7 Pro Serial No. 2778722110004) in 2023 and 2024. (Refer to D5423).

D6120

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for 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; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on review of laboratory records, lack of documentation and interview with the technical supervisor (TS), the TS failed to ensure training and evaluate the competency for three of three testing personnel (TP 1, TP 2 and TP 3) for SARS-CoV-2, Respiratory Syncytial Virus (RSV), Influenza A, and Influenza B testing in 2023 and 2024, affecting more than 12,239 patient tests. Findings include: 1. Review of the "Prism Health Lab Corrective Action Report, Report Release Date: 6/18/2024, Conducted by: XX" revealed the following information: "Staff Training and Qualification Records: ...Findings: Staff were adequately trained, but formal records of training and competency assessments were incomplete." 2. Review of laboratory records and lack of documentation revealed the laboratory failed to retain documentation of training and competency for three of three TP (TP 1, TP 2, and TP 3) in 2023 and 2024, affecting more than 12,239 patient tests. 3. On 06/25/2024, at 11:15 a.m., the TS confirmed the above findings.