

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D0699865	<b>(X3) Date Survey Completed</b>  10/19/2022
<b>Name of Provider or Supplier</b>  Spectra Clinical Laboratory	<b>Street Address, City, State</b>  5160 Campus Dr, Newport Beach, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3005</b>	<p>FACILITIES CFR(s): 493.1101(a)(3)</p> <p>Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation of the facilities layout, observation of the of the laboratory's SARS-CoV-2 RNA (COVID-19) Polymerase Chain Reaction (PCR) testing, and interviews with the laboratory's technical supervisor (TS) and testing personnel (TP) on October 19, 2022 on its molecular amplification procedure; it was determined that the laboratory failed to ensure that the PCR procedures which are not contained in closed systems have a unidirectional flow with separate areas for specimen preparation, master mix and reagents preparation, amplification, and product detection. The findings included: 1. The laboratory performed PCR testing for the presumptive detection of SARS-CoV-2 using Thermofisher procedure and equipment. 2. During the laboratory tour on October 19, 2022, at approximately 11:30 a.m. the surveyor observed that processing of the specimens, preparation of reagents, and sample template addition were all performed in the same open area without unidirectional flow. 3. The TS and TP confirmed by interview on 10/19/2022 that the laboratory's molecular PCR testing for the presumptive detection of SARS-CoV-2 RNA was not set up in a unidirectional flow area. 4. Based on laboratory records, the laboratory performed and reported approximately 4,500 SARS-CoV-2 Real Time PCR molecular diagnostic tests annually.</p>
<b>D3007</b>	<p>FACILITIES CFR(s): 493.1101(b)</p> <p>The laboratory must have appropriate and sufficient equipment, instruments, reagents,</p>

materials, and supplies for the type and volume of testing it performs.

This STANDARD is not met as evidenced by:

Based on the surveyor's observation during the laboratory's tour, review of laboratory policies and procedures, and interviews with the technical supervisor (TS) and testing personnel (TP); it was determined that the laboratory failed to have a Biosafety Cabinet (BSC) when preparing reagents and control to use in the polymerase reaction (PCR) to detect SARS-CoV-2. Findings include: 1. The surveyor observed during the laboratory's tour testing personnel using an open bench table to prepare reagents such as master mix and controls used for the PCR detection of SARS-CoV-2. 2. The TS and TP affirmed by interview that the laboratory lacked a designated BSC for the preparation of PCR reagents and controls. 3. Based on the testing volume declaration the laboratory processed and reported approximately 4,5000 SARS-CoV-2 annually.

**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:

Based on the incomplete laboratory's verification of performance documentation for the high complexity testing SARS-CoV-2 (COVID-19) RNA detection by the Polymerase Chain Reaction (PCR), interviews with the laboratory's technical supervisor (TS) and the testing personnel (TP), and four (4) randomly selected patient test records for COVID-19 reviewed from 3/17/2021 and 7/27/2022; the laboratory failed to demonstrate that it established performance specifications comparable to those established by the manufacturer. The findings included: 1. The laboratory did not have any documentation to show for determination of PCR performance specifications for SARS-CoV-2 (COVID-19) RNA detection prior to reporting patient test results. The laboratory must be able to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (A) Accuracy (B) Precision (C) Reportable range of test results for the test system (D) Analytical sensitivity and (E) analytic specificity to include interfering substances. 2. The laboratory was unable to provide for review additional documents using patient samples to establish the performance specifications in 1. 3. The TS affirmed at the time of the survey on 10/19/2021 at approximately 11:15 a. m. that no documents could be retrieved to show that the SARS-CoV-2 RNA detection by PCR performance specifications were performed prior to reporting patient test results when the laboratory went live testing and reporting COVID-19 diagnostic tests. 4. Based on the estimated annual tests volumes reported on 10/19/2021; the laboratory performed and reported approximately 4,5000 SARS-CoV-2 PCR test. The precision and reliability of the reported results could not be assured.

**D6082**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(1)

The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.

This STANDARD is not met as evidenced by:

Based on the lack of the laboratory's verification of performance specification of the manufacturer for the detection of SARS-CoV-2, lack of unidirectional workflow when performing molecular amplification procedures that are not contained in a closed system, lack of a designated Biosafety Cabinet to minimize contamination when preparing reagents and controls used in the polymerase reaction, lack of delegation of responsibilities, and interviews with the laboratory's technical supervisor and testing personnel on October 19, 2022; it was determined that the laboratory director failed to ensure that several aspects of the preanalytic, analytic, and postanalytic phases of laboratory testing were monitored. See D3005, D3007, D5421, and D6107.

**D6086**

**LABORATORY DIRECTOR RESPONSIBILITIES**

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

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

This STANDARD is not met as evidenced by:

Based on the surveyor's review of the laboratory's policies & procedures, performance specifications validation and verification records, and interview with the laboratory's technical supervisor and testing personnel on October 19, 2022, at approximately 12:15 p.m.; the laboratory failed to perform verification/validation of performance characteristics for the detection of SARS-CoV-2 by the Thermofisher procedure. The findings include See D5421.

**D6107**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as 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 result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's records of personnel training, competency evaluation, laboratory policies and procedures, random patient testing records, and interview with the laboratory's technical supervisor (TS) and testing personnel (TP); the laboratory failed to provide records showing that the laboratory director (LD) has authorized, delegated, and approved lab personnel of any responsibilities and duties in

writing. The findings include: 1. The laboratory did not have any records of written delegation and authorization of responsibilities and duties by the LD for the laboratory's technical supervisor and testing personnel. 2. On October 19, 2022, at approximately 11:30 a.m. the TS and TP affirmed that the LD did not assign, delegated, and authorized in writing duties and responsibilities to the laboratory personnel including the TS and TP. 3. The laboratory testing declaration form, signed by the LD on October 29, 2022, stated that the laboratory performs 101,615 tests annually.