| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 05D0696576 | 11/10/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Ucsb Student Health Services Laboratory | Bldg 588, Santa Barbara, CA | |

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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| **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 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 technical supervisor (TS) and testing personnel (TP) on November 10, 2021 on its molecular amplification procedure; it was determined that the laboratory failed to ensure that the molecular amplification procedures which are not contained in closed systems have a unidirectional flow with separate areas for specimen preparation, RNA extraction, amplification, and product detection. The findings included: 1. The laboratory performed PCR testing for the presumptive detection of SARS-CoV-2 using the COVID-19 PCR Atilla thermo-amplification kit and amplification method on the BioRad instrument. 2. During the laboratory tour on 11/10/2021 at approximately 1:30 p.m. the surveyor observed that RNA extraction, 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 November 10, 2021 that the laboratory's molecular PCR testing for the presumptive detection of SARS-CoV-2 RNA was not set up in an unidirectional flow area. 4. Based on laboratory records, the laboratory performed and reported approximately 2,468 SARS-CoV-2 Real Time PCR molecular diagnostic tests annually. |
| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1)<br><br>Each laboratory that introduces an unmodified, FDA-cleared or approved test system |

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| | 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.<br><br>This STANDARD is not met as evidenced by:<br>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 two (2) randomly selected patient test records for COVID-19 reviewed from 11/08/2021 and 11/19/2021; the laboratory failed to demonstrate that it established performance specifications comparable to those established by the manufacturer. The findings included: 1. The laboratory had only documentation to show for determination of accuracy with no raw data by PCR performance specifications 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) Sensitivity and (E) Specificity. 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 10/11/2021 at approximately 12:00 p. 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 11/10/2021; the laboratory performed and reported approximately 2,468 SARS-CoV-2 PCR test. The precision and reliability of the reported results could not be assured. |
| **D6083** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(2)<br><br>The laboratory director must 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 the surveyor's direct observations of the laboratory's SARS-CoV-2 PCR testing processes and interview with the laboratory's technical supervisor and testing personnel on November 10, 2021; the laboratory director failed to ensure that the physical plant and environmental conditions of the laboratory were appropriate for the testing performed. Findings include: See D3005. |
| **D6086** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(3)(ii)<br><br>The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. |

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| | This STANDARD is not met as evidenced by:<br>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 on November 10, 2021 at approximately 1;00 pm; the laboratory failed to perform verification/validation procedures adequately. The findings include:<br>See D5421 |