Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0063277	04/28/2022
Name of Provider or Supplier	**Street Address, City, State**	
County Of Santa Cruz, Hsa,	1080 Emeline Ave, Bldg D, Santa Cruz, 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
D2020	BACTERIOLOGY CFR(s): 493.823(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on review of the College of American Pathologist (CAP) laboratory proficiency testing (PT) results, Casper Report 155, Five (5)) randomly selected patient records ranging from 10/13/2021 to 3/30/2022 , and interview with the laboratory's technical supervisor (TS); it was determined that the laboratory failed to attain an overall testing event score of at least 80 percent in Bacteriology which is unsatisfactory performance. The findings included: 1. The laboratory attained a score of 67% for Bacteriology on the analyte "Bacterial Identification" obtaining Unacceptable Grades for samples D-04 and D-05 for the first PT event of 2022 (Q1-2022) 2. Based on the laboratory's annual testing declaration submitted 04/28/2022 at the time of the survey, the laboratory performed and reported approximately 31 bacteriology identifications on patients samples. 3. The laboratory TS affirmed on 04/28/2022 at approximately 11:15 a.m. that the laboratory received the above unsatisfactory proficiency testing scores.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

	This STANDARD is not met as evidenced by: Based on observation of the laboratory's reagent materials used for identification of bacterial organisms and interview with the laboratory's technical supervisor (TS); it was determined that the laboratory failed to label the Bacteriology and Mycology reagents to indicate the opening, preparation, and expiration dates when such reagents are used in the bacteriology laboratory. The findings included: 1. Based on the surveyor's observation during the laboratory tour on April 28, 2022, at approximately 2:00 pm., no opening, preparation, or expiration date labels were used or documented for reagents used for the examination and identification of bacterial and fungal organisms (3% KOH, Blue mount media, Beta Lactamase, Indole, Bile Spot Reagent, etc.). 2. The laboratory's TS affirmed in an interview conducted April 28, 2022at approximately 2:00 p.m. that the reagents mentioned in statement 1 were not labeled with opening, preparation, and expiration dates or documented. 3. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory analyzed approximately 50 Bacteriology and Mycology samples.
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 characteristics for the high complexity testing SARS-CoV-2 (RNA detection by BD Max Biofire panel with SARS), interviews with the laboratory's technical supervisor (TS) and three (3) randomly selected patient test records for COVID-19 reviewed from 10/13/2021 to 12/22/2021; 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 raw data by Biofire 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 04/28/2022 at approximately 12:00 p. m. that no documents could be retrieved to show that the SARS-CoV-2 RNA detection by the Biofire instrument 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 04/28/2022; the laboratory performed and reported approximately 5,628 SARS-CoV-2 Biofire panel PCR tests. 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 review of the laboratory's proficiency testing records, lack of labelling of reagents, and interview with the technical supervisor on April 28, 2022; it was determined that the laboratory director failed to ensure that several aspects of the preanalytic and analytic phases of laboratory testing were monitored. See D2020 and D 5415.
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 on April 28, 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 Biofire instrument procedure adequately. The findings include: See D5421
D6101	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(11) The laboratory director must employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart. This STANDARD is not met as evidenced by: Based on review of laboratory personnel records and completed Form CMS-209, Laboratory Personnel Report, and interview with the technical supervisor (TS); the laboratory director failed to employ enough laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise, accurately perform tests, and report test results in accordance with the personnel responsibilities. The findings include: 1. The individual the laboratory identified as "technical supervisor" (TS) was performing in addition of duties of technical supervisor, the duties of general supervisor, testing personnel, and was responsible of delegated responsibilities from the laboratory director. 2. On April 28, 2022, at approximately 11:15 a.m. the TS confirmed by interview that the laboratory did not have sufficient full-time personnel to perform the duties described above. 3. The laboratory reported processing and reporting approximately 5,765 tests annually.