

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0683431	(X3) Date Survey Completed 11/05/2019
Name of Provider or Supplier Santa Barbara County Public Health Lab	Street Address, City, State 315 Camino Del Remedio, Rm 262, 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
D2020	<p>BACTERIOLOGY CFR(s): 493.823(a)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of the College of American Pathologist (CAP) laboratory proficiency testing results, Casper Report 155, interview with the Laboratory Director (LD), and laboratory testing personnel (TP); 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: a. The laboratory attained scores of 66 % for the subspecialty of Bacteriology on the analyte "Bacterial Identification" for the second PT event on 2018 (Q2/2018) and 58% for the second PT event on 2019 (Q2/2019) respectively. b. Based on the laboratory's annual testing declaration submitted for 2018-2019, the laboratory performed and reported approximately 315 patient samples in the Bacteriology section which accuracy of the identification cannot be assured. c. The Laboratory Director and Testing Personnel confirmed (11/05 /2019 at 17:00) that the laboratory received the above unsatisfactory proficiency testing scores.</p>
D5441	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1)</p>

Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the quality control (QC) logs, and interview with the laboratory's Technical supervisor and testing personnel; it was determined that the laboratory failed to update the number, type, and frequency of testing control materials for the current media and reagents used in Bacteriology. The findings included: a. On the day of the survey (11/5/2019), the laboratory had no documentation presented to the surveyor for all the current media and reagents currently being used in Bacteriology for example Campylobacter media and Oxidase reagent. b. For two (2) out of nine (9) random patient test results reviewed covering period from 1/15/2018 to 6/10/2019, two patients for Bacteriology culture identification, the laboratory failed to document QC for Campylobacter media and Oxidase reagent. c. The Technical supervisor and testing personnel confirmed (11/5/2019, 1600) that the laboratory failed to document QC for Bacteriology culture media.

D5477

CONTROL PROCEDURES

CFR(s): 493.1256(e)(4)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on lack of quality control documentation, observation of all culture media (Hardy), interview with the Technical supervisor, and testing personnel; it was determined that the laboratory failed to perform quality control (QC) testing on all culture media. The findings included: a. The laboratory did not check and document sterility, ability to support growth, physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer of all the media used for cultures. b. Based on the laboratory's annual declaration submitted for 2018-2019, the laboratory analyzed and reported approximately 315 cultures which results cannot be assured. c. The Technical supervisor and testing personnel confirmed (11/05/2019 at 1600) that the laboratory failed to perform and document; check of sterility, ability to support growth, physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer of all the media used for cultures.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

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.

This STANDARD is not met as evidenced by:

Based on review of the quality control (QC) logs, random patient sampling test results and interview with the testing personnel, it was determined that; the laboratory director failed to ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. See D 5441, D5445, and D5477.