

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D0699525	<b>(X3) Date Survey Completed</b>  08/12/2022
<b>Name of Provider or Supplier</b>  Danner Laboratory	<b>Street Address, City, State</b>  5230 Carroll Canyon Rd, Ste 114, San Diego, 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>D2020</b>	<p><b>BACTERIOLOGY</b> 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 laboratory's proficiency testing (PT) result reports, and interview with the laboratory personnel, it was determined that the laboratory failed to attain an overall testing event score of at least 80 percent is unsatisfactory performance. The findings included as follows: a. The laboratory performed beta B Strep group and enrolled its proficiency testing (PT) programs with CAP (College of American Pathologists), DS - Group B Strep Detection. b. The laboratory failed to attain an overall testing event score of at least 80 percent was unsatisfactory performance. c. The laboratory attained scores of 0% for beta B Strep identification for Q2 2020 and Q1 2022 CAP DS PT events which were unsatisfactory performance. d. The laboratory performed beta B Strep identification in approximately 9 patient specimens monthly. e. The laboratory personnel affirmed (8/12/2022 @ 12:45PM) that the laboratory attained scores of 0% for beta (B) Strep identification for Q2 2020 and Q1 2022 CAP DS PT events which were unsatisfactory performance.</p>
<b>D5805</b>	<p><b>TEST REPORT</b> CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the</p>

condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on review of the laboratory records and patient test result reports, and interview with the laboratory personnel, it was determined that the laboratory failed to indicate the test report date to ensure the test result reports were released timely. The findings included as follows: a. The laboratory failed to indicate a "Reported Date" on its patient test result reports. b. Laboratory use a computer system to print out its cytology patient test result reports. b. Base on review of 8 patient test result for both Gyn cytology and Non-gyn Cytology reports, two Gyn patient reports provided no "DATE OF REPORT:" and other two showed 8/12/2022, which was a date the report was printed, NOT the real "DATE OF REPORT:" for the test result reports. c. The laboratory provided two in consist of printing formats in "DATE OF REPORT:" as follow: ID # Date Received Date of Report 0027865 10/19/21 blank 0011979 5/14/21 blank 0003008 2/7/2022 8/12/2022 0010015 4/18/2022 8/12/2022 d. The laboratory personnel confirmed (8/12/2022 @ 12:25 PM) that was the computer system problems for the inconsistency.

**D6089**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(4)(i)

The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's proficiency testing (PT) result reports, and interview with the laboratory personnel, it was determined that the laboratory director failed to ensure the proficiency testing samples were tested as required under subpart H of 42 CFR part 493. The findings included as follows: a. The laboratory performs beta B Strep group and enrolled with CAP (College of American Pathologists) proficiency testing (PT) programs, DS - Group B Strep Detection, b. The laboratory director failed to ensure the laboratory to attain an overall testing event score of at least 80 percent was unsatisfactory performance, see D-2020.

**D6094**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on review of the laboratory records, and interview with the laboratory personnel, it was determined that the laboratory director failed to ensure the quality assessment programs were established and maintained to provide accuracy, reliability, and timely of the patient test result reports, and to assure the quality of laboratory services provided and to identify failures in quality as they occur. The findings included as follows: a. The laboratory director failed to ensure the quality assessment programs were established and maintained to assure the accurate, reliable, and timely

of the patient test result report and to provides mandatory formats include the "DATE OF REPORT" to assure the turnaround time of the patient result report, see D-5805