Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0699525	09/24/2024
Name of Provider or Supplier	**Street Address, City, State**	
Danner Laboratory	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's verification of performance specifications documentation for the Hologic instrument and interviews with the laboratory director (LD) and compliance officer (CO) it was determined that the laboratory failed to verify performance specifications and update protocol in place with the effective date and signature of approval by the laboratory director. The findings included: 1. On the day of the survey September 24, 2024, at approximately 1:45 p.m. the documentation of verification of performance specifications for the Hologic instrument in place had not been reviewed, approved, signed, and dated by the laboratory director. 2. The LD and CO affirmed on September 24, 2024, that the laboratory failed to update protocols for the current verification of performance specification performed in the laboratory for the Hologic instrument and that the effective date and the laboratory director's signature were missing. 4. The laboratory's testing declaration form stated that the laboratory processes approximately 33,000 patients' cytology test 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 lack of a complete laboratory verification of performance specifications for the Hologic instrument and interviews with the laboratory director (LD), compliance officer (CO) and testing personnel (TP) on September 24, 2024, the laboratory failed to provide an established verification of performance specifications documentation comparable to those established by the manufacturer. The findings included: 1. Based on review of the laboratory's documentation for verification procedure for the Hologic Thin Prep 5000 serial number 93162123DO instrument at the time of survey, it was found that the documentation was incomplete. Performance specifications for accuracy, precision, reportable range, and reference range method of validation were incomplete. 2. The LD, CO, and TP affirmed at the time of the survey on September 24, 2024, at approximately 1:40 p. m. that the testing and documentation for verification provided at the time of the survey were incomplete as indicated in 1. 3. Based on the testing declaration submitted at the time of survey, the laboratory performed and reported approximately 33,000 cytology tests for which the Hologic instrument was used with incomplete verification of performance specifications.
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 surveyor's review of the laboratory's policies and procedures, proficiency testing records, validation of new tests established in the laboratory, five (5) randomly selected patients test records, and interviews with the laboratory director, compliance officer, and testing personnel on September 24, 2024; it was determined that the laboratory director is cited herein due to failure to ensure that several aspects of the preanalytic and analytical phases of the laboratory testing were monitored. See D5407, D5421, and D6107.
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, five (5) randomly selected patient testing records, and interview with the laboratory 's compliance officer (CO) 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/general supervisor. In addition, the responsibilities of the technical supervisor/general supervisor, and testing personnel (TP) were not specified in writing. 2. On September 24, 2024, at approximately 1:00 p.m. the CO 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 09/24/2024 stated that the laboratory performs 33,000 cytology tests annually.