Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0576616	07/22/2025
Name of Provider or Supplier	**Street Address, City, State**	
Providence Brea Dermatology	955 W Imperial Hwy, Ste 200, Brea, 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
D2046	MYCOLOGY CFR(s): 493.827(e) (e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing report, it was determined that the laboratory failed to achieve satisfactory performance for the same analyte or test in two out of three consecutive PT events for the specialty, Mycology, resulting in unsatisfactory performance for the analyte KOH Preparation (glass slide). The findings include: 1. The laboratory failed to maintain satisfactory performance with the PT program by failing to obtain a score of 80% of acceptable responses in two out of three consecutive PT events for the specialty of Mycology, as follows: Q1-2023 = 0% Q2-2023 = 50% and Q3-2024 = 50% Q1-2025 = 50% Q1 = First Testing Event Q2 = Second Testing Event Q3 = Third Event 2. Failure to achieve satisfactory performance for the same analyte or test in two out of three consecutive PT resulted in unsatisfactory performance for the specialty, Mycology.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (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 policies and procedures manual and interviews with the laboratory director (LD), clinical program manager (CPM), and testing

	personnel (TP); the laboratory failed to update protocols in place when changes in the practice occurred in the laboratory and the effective date and signature of approval by the laboratory director of such changes. The findings included: 1. On the day of the survey July 22, 20255, at approximately 5:00 p.m. the policies and procedure manual in place had not been reviewed by the current LD to reflect current practice and testing, neither had it been approved, signed, and dated by the laboratory director. 2. The LD affirmed on July 22, 2025, that the laboratory failed to update protocols for the current test performed in the laboratory and that the effective date and the laboratory director's signature were missing. 3. The laboratory's testing declaration form stated that the laboratory processes approximately 900 patients test annually.
D5821	TEST REPORT CFR(s): 493.1291(k) (k)When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on the surveyor's review of nine (9) randomly selected patient records, and interviews with the laboratory director (LD) and testing personnel (TP), the laboratory failed to correctly document patient information upon its occurrence. The findings include: 1. The surveyors reviewed five dermatopathology-Mohs patient records dated from 07/13/2023 to 06/10/2025 and four (4) Patients records for Mycology and Parasitology dated from 2/12/2024 to 5/21/2025. One out of four (4) Mycology and Parasitology records reviewed contained the following discrepancy: a. The patient reviewed from 05/22/2024 MR ending in 808019 had documented in the test log a KOH preparation documented as negative test result. b. The patient chart from patient in a. above was documented as the final report: "scabies negative" for the same date and source logged under KOH in the test log. c. There was no scabies test request or result documented in the test log for patient in a. 2. The laboratory's protocol involved daily checks of patient information recorded across all documentation. However, one patient from 05/22/2024 erroneous test result request/result were missed to be corrected upon its occurrence. No documentation for corrective action was available at the time of the survey. 3. The LD and TP affirmed by interview on July 22, 2025, at approximately 4:00 p.m., that the discrepancy was missed, therefore; no corrective action took place. 4. According to the laboratory's testing declaration form submitted at the time of the survey July 22, 2025, and signed by the LD stated thar the laboratory performed and reported approximately 400 mycology and parasitology patient test samples annually including for the year 2023 when the discrepancy occurred. The accuracy and reliability of the patient tests reported cannot be assured.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) (e) The laboratory director must-- (e)(1) 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 surveyor's review of the proficiency testing results, laboratory's policies and procedures, nine (9) randomly selected patient test results, lack of corrective action documentation, and interviews with the laboratory's director, the clinical program manager, and testing personnel on July 22, 2025; the laboratory director failed to provide effective preanalytic, analytic, and postanalytic phases of testing direction of the laboratory. See 2016, D2046, D5407, and D5821.