Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2150179	01/25/2022
Name of Provider or Supplier	**Street Address, City, State**	
Cypress Dermatology	14930 Mueschke Rd, Cypress, TX	

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
D0000	The laboratory was found out of compliance with the following CONDITION LEVEL DEFICIENCIES: D5200 - 42 C.F.R. 493.1230 Condition: General Laboratory Systems Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory's personnel competency assessment documents, review of quality assessments for 2020 and 2021 and staff interview it was revealed the laboratory failed to meet general systems requirements. Findings included: 1. The laboratory failed to ensure competency assessments for technical consultant, technical supervisor and general supervisor were documented (refer to D5209). 2. The laboratory failed to ensure twice annual accuracy assessments for Mohs testing were

	documented (refer to D5217). 3. The laboratory failed to ensure it's quality assessment identified and corrected issues with general laboratory systems (refer to D5291).
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form 209, review of laboratory's policies, review of personnel records for 2020 and 2021 and staff interview it was determined the laboratory failed to document competency assessment for one of one technical supervisor, one of one general supervisor and three of three technical consultants. Note: This is a repeat deficiency from the survey conducted on 01/21 /2020. Findings included: 1. Review of the laboratory's submitted Form 209 (signed and dated 01/25/2022) revealed the laboratory identified one technical supervisor /general supervisor and three technical consultants. 2. Review of the laboratory's policy Laboratory Manual (last reviewed 01/06/2021) under Quality Assurance for Laboratory Personnel (page 4) revealed: "The Laboratory Director will oversee a competency assessment for the General Supervisor, and either the Laboratory Director or General Supervisor will oversee competency assessments for all other laboratory personnel (technical supervisors and laboratory technicians)." 3. Review of personnel records for 2020 and 2021 revealed no competency assessments documented for either the general supervisor, technical supervisor or technical consultants. 4. In an interview on 01/25/2022 at 1100 hours in the break room the medical assistant confirmed that there was no documentation of competency assessments specific to the roles of general supervisor, technical supervisor or technical consultant available for review.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of laboratory's policies, review of quality assessment records for 2020 and 2021 and staff interview it was determined the laboratory failed to have documentation of performing twice annual accuracy assessment for Mohs, one of two tests performed in the laboratory. Note: This is a repeat deficiency from the survey conducted on 01/21/2020. Findings included: 1. Review of laboratory's policy Mohs Lab Proficiency Testing Procedure (last reviewed/signed on 01/06/2021) revealed: "Frequency Biannually, each calendar year" And, "Procedure Four Mohs cases are randomly selected twice a year to be pulled and reviewed by an outside board certified Dermatopathologist." 2. Review of laboratory's quality assurance records for 2020 and 2021 revealed: a. There was no documentation of twice annual Mohs accuracy assessment for 2020 b. There was only one Mohs accuracy assessment documented in

	June of 2021. There was no second accuracy assessment documented in 2021. 3. In an interview on 01/25/2022 at 1200 hours in the break room the medical assistant confirmed the findings.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, quality assessment records, personnel records and staff interview it was determined the laboratory's quality assessment failed to identify and correct issues with general laboratory systems (refer to D5209 and D5217). Note: This is a repeat deficiency from the survey conducted on 01/21 /2020.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of laboratory's Cryostat maintenance logs for 2020 and 2021 and staff interview it was determined the laboratory failed to follow its own protocols for documentation of performance of monthly preventive maintenance and grounding checks for 24 of 24 months reviewed. Findings included: 1. Review of the laboratory's policy Laboratory Manual (last reviewed/signed 01/06/2021) under Equipment Quality Control for Cryostats (page 5) revealed: "9. Preventive maintenance and grounding check are done once a month." 2. Review of the laboratory's Cryostat Maintenance and Quality Control Logs for 2020 and 2021 revealed no documentation of monthly performance of preventive maintenance or grounding checks for the 24 months reviewed. 3. In an interview on 01 /25/2022 at 1030 hours in the break room the medical assistant confirmed the findings.
D5609	HISTOPATHOLOGY CFR(s): 493.1273(e)(f) (e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of the laboratory's Reagent Log

	for 2020 and 2021, review of the laboratory's H&E stain quality control (QC) records for 2021 and staff interview it was determined the laboratory failed to ensure all quality control records are documented for one of two stains performed by the laboratory. Findings included: 1. Review of the laboratory's policy Laboratory Manual (last reviewed/signed on 01/06/2021), section Test Methods, Equipment, Reagents, Materials and Supplies (page 3) revealed: a. "Reagents, solutions, culture media, controls, and other supplies are not used when they have exceeded their expiration dates, have deteriorated, or are of substandard quality. Bi-annually, the Laboratory Technician will inspect all reagents and supplies in laboratory area to ensure all supplies and materials available meet expectations and will be documented in the Reagent Log." b. There was no mention in the policy of required documentation of lot numbers, dates prepared/opened, expiration dates, expected reactions and/or observations to demonstrate controls were tested when shipments of stains were opened/tested. 2. Review of the laboratory's Reagent Log for 2020 and 2021 revealed: a. H&E Stain solutions have been received in the laboratory as follows: 08/11/2020 - Gill 3 Hematoxylin; Lot 103485; Expiration 2022-02-28 08/11/2020 - Select Eosin; Lot 102442; Expiration 2022-07-31 03/17/2021 - Gill 3 Hematoxylin; Lot 113888; Expiration 2022-08-31 07/20/2021 - Select Eosin; Lot 124309; Expiration 2023-07-31 07/20/2021 - Gill 3 Hematoxylin; Lot 124992; Expiration 2023-01-31 12/15/2-21 - Gill 3 Hematoxylin; Lot 136569; Expiration 2023-05-31 b. There were no quality control records demonstrating each of the H&E stain solutions was tested when shipments of stains were opened. 3. Review of the laboratory's H&E stain QC records for 2021 revealed there was no documentation of lot number/expiration date of the H&E stain reagents each day of use. 4. In an interview on 01/25/2022 at 0945 hours in the break room the medical assistant confirmed the findings. Legend: H&E = Hematoxylin and Eosin
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assessment records, review of personnel records and staff interview it was determined the Laboratory Director failed to ensure the laboratory was in compliance with all applicable regulations (refer to D5200).
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 laboratory's quality assessment records, review of laboratory's personnel records and staff interview it was determined the Laboratory Director failed to ensure quality assessment (QA) for general laboratory systems was maintained (refer to D5291).