Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2150179	01/21/2020
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	Noted deficiencies and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. 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 the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
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 CMS 209, review of the laboratory's personnel records, lack of laboratory policy and staff interview, it was revealed the laboratory failed to have documentation of performing competency assessments on 3 of 3 technical consultants 1 of 1 technical supervisor and 1 of 1 general supervisor. The findings were: 1. A review of the laboratory's submitted Form CMS 209 (signed and dated by the laboratory director on 01/20/2020) revealed the laboratory identified three technical consultants and one technical/general supervisor. 2. A review of the personnel records from 2018 - 2019 for the technical consultants and general supervisor revealed the records did not contain documentation of a

	competency assessment. 3. A review of the the laboratory SOPs revealed there was policy or no documentation for a competency assessment for technical consultants and general supervisor. 4. An interview with the histology tech on 01/21/2020 at 1035 hours in the conference room revealed no competency assessment was performed for 2018 and 2019 for the above personnel. Key: CMS - Center for Medicare and Medicaid Services SOP- Standard operating practice
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 the laboratory's quality assurance records from 2018 and 2019 and staff interview, it was revealed the laboratory failed to have documentation of performing twice annual accuracy assessment for 2 of 2 tests performed in the laboratory. a) MOHS b) KOH Findings included: a) MOHS 1. A review of the laboratory's quality assurance records (approved by the laboratory director 01/20 /2020), under "Mohs Lab Proficiency Testing Procedure" states "Biannually, each calendar year. Four Mohs cases ware randomly selected twice a year to be pulled and reviewed by an outside board certified Dermapathologist" 2. Review of the laboratory quality assurance records revealed the laboratory performed no accuracy assessments for 2018. One accuracy assessment for MOHS testing was performed on October 15, 2019. The records did not contain documentation of a second assessment in 2019. b) KOH 3. A review of the laboratory's quality assurance records from 2018- 2019 revealed the laboratory had no documentation to verify accuracy of KOH twice annually for the year 2018 and 2019. 4. Review of the CMS116 form revealed the laboratory performed 480 KOH testing and 486 MOHS testing annually. 5. An interview with histology tech on 01/21/2020 at 1145 hours in the conference room revealed the facility performed the accuracy assessment for Mohs only once in 2019 and none in 2018. She admitted the facility for 2018 through 2019 was neither enrolled in a proficiency testing program nor did the laboratory have a method in place to verify the accuracy of the test at least twice a year of KOH preparations Key: KOH: potassium hydroxide preparation .
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 policies, laboratory records, and confirmed in interview, the laboratory quality assessment failed to identify that the laboratory did not perform and/or assess the twice annual accuracy assessment for all tests performed in the laboratory. Refer to D5217
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

	CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on direct observation and confirmed in interview, the laboratory failed to ensure mineral oil for skin scrappings is stored in a secondary container and labeled with proper identification, and poured dates. Findings: 1. During a tour of the laboratory area on 01/21/2020 at 10:30 hours, the surveyor observed: The laboratory failed to label the secondary container with the mineral oil lot number and poured dates. Without proper labeling, the reagent could not be linked to an original container. 2. During an interview on 01/21/2020 at 10:30 hours, the histology tech confirmed the mineral oil came from a stock bottle.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor observation of reagents currently in use by the laboratory, review of random patient reports from November 5, 2018 to December 17, 2019, laboratory policy and staff interview, it was revealed the laboratory failed to ensure expired reagents were not used for patient testing. The findings were: 1. A review of the laboratory policy "Job Descriptions for laboratories" under "Laboratory Technician it states, (In charge of ordering reagents and supplies. Ensure all reagents are not expired.) 2. Surveyor observation of reagents currently in use by the laboratory on 01 /21/2020 at 0930 hours revealed in a white basket one bottle of Healthlink KOH 10% (# 632613 and expiration 11/21/2017). One bottle of unexpired KOH 10% was stored in the cabinet (not in use). 3. A review of the laboratory's random patient reports from November 5, 2018 to December 17, 2019 revealed the laboratory reported KOH testing on 10 patients using the expired KOH: Patient ID Test date 6141 11/01/2018 2486 11/05/2018 5618 11/05/2018 5689 11/12/2018 6193 12/10/2018 6656 01/17 /2019 3963 02/26/2019 5159 02/21/2019 7273 03/05/2019 8181 04/10/2019 8194 04 /13/2019 9942 08/13/2019 10400 08/27/2019 10674 09/23/2019 04890 10/11/2019 10955 10/11/2019 10956 10/02/2019 11417 11/01/2019 11980 12/17/2019 4 . An interview with the histology tech on 01/21/2020 at 11:45 hours in the laboratory area revealed that the KOH solution in the white basked area is the only one being used for testing. She acknowledged that the expired bottle should have been discarded. This confirmed the findings. Key KOH - Potassium hydroxide
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 laboratory policy, patient reports, and confirmed in interview, the laboratory failed to document the H&E quality control acceptability for 5 of 5 dates from 2018 through 2019. The findings included: 1. Review of the laboratory policy for quality control did not include documentation for acceptability of the H&E quality control stain acceptibility. 2. Random review of the 2018 - 2019 patient records revealed no documentation of the H&E quality control stain acceptability for 5 of 5 days reviewed. Review of patient records revealed the laboratory performed patient testing on the following dates with no documentation of the H&E stain acceptability. Patient ID# test date 5368 02/22/2019 2950 06/13/2019 7275 05/10/2019 8959 08/02 /2019 8651 09/11/2019 3. During an interview with the histology tech on 01/21/2020 at 11:45 hours, its was confirmed that there were verbal confirmation for acceptability but the quality control stain was not documented on any log for 2018 to 2019. Key H&E - Hematoxylin and eosin stain
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and confirmed in interview, the laboratory's quality assurance activities failed to identify that the laboratory had not verified the acceptability of staining characteristics for 2018 or ensured that expired reagent solutions were not available for patient testing. The findings included: 1. Review of the laboratory's policy titled "CLIA Quality Control Program" (signed by the laboratory director on 08/01/2019), states: "It is the policy of the laboratory director to maintain a Quality Control Program to insure accuracy of results reported. All employees of this laboratory must be familiar with and adhere to all the policies herein stated regarding quality control. The Quality Control Program involves monitoring the facilities; testing methods and equipment, reagents, materials and supplies; procedure manual; method verification; equipment maintenance; control procedures; remedial actions; and maintenance of quality control records." 2. The laboratory failed to ensure that expired KOH solutions were not available for patient testing. Refer to D5417. 3. The laboratory failed to ensure proper labeling of secondary containers for reagents. Refer to D5415 3. The laboratory had not reviewed H&E stain performance quality controls logs for 9 of 9 months in 2019. Refer to D5609 6. In an interview on 01/21/2020 at 1145 hours in the conference room, the facility staff revealed they failed to monitor QA for H&E stain acceptiblity for each day of use or that expired KOH solutions were not available for patient testing. Key KOH - Potassium hydroxide HE - Hematoxylin and eosin stain