Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2175144	07/31/2023
Name of Provider or Supplier	**Street Address, City, State**	
Bayou City Dermatology	20320 Northwest Freeway Suite 700, Houston, 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 applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories). 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. Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found in compliance with applicable CLIA conditions, 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 CMS Southern Operations Branch-Dallas 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.
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 quality control records from January to July 2023, review of form CMS 116 and staff interview, the laboratory failed to document lot numbers and expiration dates of Hematoxylin and Eosin (H&E) Stain reagents for 7 of 7 days the stain reagents were in use during the 7-month interval. Findings included: 1. Review of the laboratory's quality control records from January to July 2023 revealed the laboratory performed H&E Stain on the following days: 01/18/2023 02/20/2023 03/29/2023 05/03/2023 06/20/2023 06/21/2023 07/25/2023 There was no documentation of lot numbers or expiration dates for any H&E Stain reagents used on

	those days. 2. Review of form CMS 116 revealed the laboratory used H&E Stain reagents in staining samples from approximately 400 patient cases annually. 3. An interview with the facility's Practice Administrator, and Histology Tech (as indicated on submitted Entrance Conference document) on 07/31/2023 at 1040 hours at the nursing station confirmed the findings.
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 laboratory's submitted form CMS 209, personnel records and staff interview, the laboratory director failed to ensure delegation of grossing was documented for one of two testing personnel performing grossing, Testing Person number 2 (histology tech). Findings included: 1. Review of laboratory's submitted form CMS 209 revealed the laboratory employed one histology tech designated as testing personnel. 2. An interview with the laboratory's Testing Person number 2 (histology tech) on 07/31/2023 at 1000 hours in the laboratory revealed the histology tech performed grossing. 3. Review of personnel records for the histology tech revealed delegation of duties did not include grossing. 4. An interview with the facility's Practice Administrator (as indicated on submitted Entrance Conference document) on 07/31/2023 at 1020 hours at the nursing station confirmed the findings.