Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2175144	09/21/2021
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	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. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and staff interview, it was revealed that

	the laboratory failed to have a written procedure for the laboratory personnel to follow for performing KOH (potassium hydroxide) preps. Findings include: 1. A review of the laboratory's policies revealed no documentation of a written procedure for KOH preps including the following: a) Requirements for patient preparation b) Microscopic examination c) Step-by-step performance of the procedure d) Preparation of slides e) Corrective action 2. An interview with the histotech on 9/21/20 at 1:05 p.m. in the laboratory revealed that the laboratory did not have a policy for KOH preps. This confirmed the above findings.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on a review of the laboratory's submitted CMS 209 form, the laboratory's personnel records, and staff interview, it was revealed that the laboratory director failed to ensure one of two testing personnel had documentation of on-site training to perform high complexity testing- Mohs. Findings include: 1. A review of the CMS 209 form (signed by the laboratory director on 9/15/21) revealed the laboratory identified two testing personnel performing high complexity testing- Mohs. 2. A review of the laboratory's personnel records revealed the following testing person failed to have documentation of on-site training for performing Mohs: Testing person #2 3. An interview with the histotech on 9/21/21 at 1:33 p.m. in the laboratory, after review of the records, confirmed the above findings.