

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D0686795	<b>(X3) Date Survey Completed</b> 01/28/2020
<b>Name of Provider or Supplier</b> Dermatology Consultants	<b>Street Address, City, State</b> 9 Medical Parkway Plaza 4 Suite # 105, Dallas, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The Histotech was at the entrance conference conducted 01/28/2020. The survey process was discussed. An opportunity for questions and comments was given. Exit conference was held with the Histotech on 01/28/2020. The laboratory was found to be in substantial compliance for the specialties/subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained.
<b>D5391</b>	<p><b>PREANALYTIC SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1249(a)</p> <p>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 preanalytic systems specified at 493.1241 through 493.1242.</p> <p>This STANDARD is not met as evidenced by: Based on review of the potassium hydroxide (KOH) patient log, patient charts, laboratory's annual test volume, and in interview with staff, the laboratory failed to ensure their policies and procedures were effective for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems for KOH tests. Findings included: 1. Review of the KOH patient log from 10 /2017 through 01/2020 included dates of service, patient names, physician last name initial, patient chart number, specimen source, KOH type, and results. 2. Random sampling of 4 patient charts that included KOH results were selected for review. In the sampling, 1 of 4 patient chart numbers was inaccurately documented in the KOH log, as follows: The log had documented, "11/01/2019; [Patient Name]; [Physician Initial]; 230001 (patient chart number); L (left) hand; M (mycology); - (negative)." Review of the patient chart with this patient's name included a chart number of 922690, not 230001. The chart did not include a description of a left hand, it included a description of a right hand with KOH negative results. The chart included a visit date of 11/01/2019 and time of 10:10 am. 3. The laboratory was asked to provide the</p>

patient's chart with the chart number 230001 and it included a visit date/time of 11/01/2019 at 10:30 am. The chart included assessment of the left buttock and did not include a KOH result. The laboratory did not ensure accurate documentation of patient chart numbers when performing a KOH test. The laboratory's policies and procedures were not effective for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems for KOH tests. 4. Review of the laboratory's annual volume included 89 KOH tests. 5. During an interview on 01/28/2020 at 10:25 am, the Histotech reviewed and confirmed the above findings.

**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 direct observation, laboratory annual test volume, and in interview with staff, the laboratory failed to ensure reagents used for histopathology procedures had not exceeded their expiration dates. Findings included: 1. During a tour of the laboratory on 01/28/2020 at 9:51 am, the following reagents were observed to be stored on the counter and in-use: Submount (1 pint), Lot #7214, expiration date 07/14/2019 Red Margin Marker (Tissue Marking Dye), Lot #26738, expiration date 09/2015 Blue Margin Marker (Tissue Marking Dye), Lot #26953, expiration date 10/2015 Black Tissue Marking Dye, Lot #057300, expiration date 08/2019 The laboratory did not ensure the above items had not exceeded their expiration date. 2. Review of the laboratory's annual volume included 170 histopathology tests. 3. During an interview on 01/28/2020 at 10:25 am, the Histotech confirmed the above findings.