

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2097373	<b>(X3) Date Survey Completed</b>  07/23/2021
<b>Name of Provider or Supplier</b>  DermSouth Pa	<b>Street Address, City, State</b>  10970 Shadow Creek Parkway Suite 340, Pearland, 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>	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.
<b>D5473</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on a random review of patient test records, a review of the laboratory's quality control records, and staff interview, it was revealed the laboratory failed to document the negative and positive reactivity of quality control slides for Toluidine Blue O (T Blue) staining on each day of patient testing between March 2020 and June 2021. Findings include: 1. A random review of patient test records between March 2020 and June 2021 revealed the following patient's specimens were tested using T Blue stain on the dates listed below: a) July 20, 2020 Patient #089 Patient #090 Patient #091 Patient #092 b) May 10, 2021 Patient #103 Patient #104 Patient #105 Patient #106 Patient #107 Patient #108 Patient #109 2. A review of the laboratory's quality control records revealed there was no documentation of the negative and positive reactivity of</p>

quality control slides for the T Blue stain on the dates listed above. 3. An interview with the histology technician on 7/23/21 at 1:30 p.m. in the nurse's station, after review of the records, confirmed the above findings.