

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2116798	(X3) Date Survey Completed 09/08/2022
Name of Provider or Supplier Dermisurgery Associates-The Woodlands	Street Address, City, State 17183 I-45 Suite 510, Conroe, 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 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 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	<p>HISTOPATHOLOGY CFR(s): 493.1273(e)(f)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control (QC) records for January to September of 2022 and staff interview it was determined the laboratory failed to document acceptability of stain reaction for toluidine blue (TB) for 63 of 63 days the stain was performed on patient samples. Findings included: 1. Review of the laboratory's QC records for January to September of 2022 revealed the laboratory did not have documentation of acceptability of stain reaction for TB stain for 63 of 63 days the stain was performed on patient samples. 2. The laboratory was asked to provide documentation of TB stain acceptability and no such documentation was available for review prior to survey exit. 3. In an interview on 05/03/2022 T 0950</p>

hours in the laboratory the facility's Histotech, after review of the data, confirmed the findings.

D6128

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's submitted Form 116, review of laboratory's policies and procedures, review of the personnel competency assessment documents for 2021 and 2022 and staff interview, it was determined the laboratory's Technical Supervisor failed to document competency assessment for Specimen Grossing as per laboratory's policy for one of two testing personnel employed by the facility. Findings included: 1. Review of the laboratory's submitted Form 116 (signed by the Laboratory Director on 09/07/2022) revealed the laboratory employed 2 testing personnel. 2. Review of laboratory's policies and procedures for histopathology (last reviewed 05/13/2022) revealed: "C. Competency Assessment ... Competencies will be documented to include evaluation of grossing for testing personnel. Policy: Director of lab will assess laboratory personnel annually by completing the competency forms located in the form section of this manual." 3. Review of the personnel competency assessment documents for 2021 and 2022 revealed no documentation of competency assessment for specimen grossing for Testing Person number 2 (as described on submitted Form 116), one of two testing personnel employed by the facility. 4. In an interview on 09/08/2022 at 0930 hours in the laboratory, the facility's Director of Operations, after review of the data, confirmed the findings.