

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D1067292	(X3) Date Survey Completed 10/04/2019
Name of Provider or Supplier Cosmetic Skin Surgery Center	Street Address, City, State 333 Sylvan Avenue, Englewood Cliffs, NJ	
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
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory records, procedure manual and interview with the Testing Personnel (TP), the laboratory failed to establish a maintenance protocol for the Microscope when protocols were not provided by the manufacturer from 10/27/17 to the date of the survey. The TP confirmed on 10/4/19 at 10:30 am that the laboratory did not establish a maintenance protocol.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p>

This STANDARD is not met as evidenced by:
Based on surveyor review of the Final Report (FR) and interview with the Testing Personnel (TP), the laboratory failed to have the address of the laboratory where the Histopathology tests were performed from 10/27/17 to the date of survey. The TP confirmed on 10/4/19 at 11:30 am the address of the laboratory was not on the FR.

D6103

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:
Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to establish a Competency Assessment (CA) procedure with all the required elements for Testing Personnel from 10/27/17 to the date of survey. The TP confirmed on 10/4/19 at 9:30 am that a CA procedure was not established.