

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2123558	(X3) Date Survey Completed 04/16/2019
Name of Provider or Supplier Clark Dermatology, Llc	Street Address, City, State 175 Cedar Lane, Teaneck, 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
D5301	<p>TEST REQUEST CFR(s): 493.1241(a)</p> <p>The laboratory must have a written or electronic request for patient testing from an authorized person.</p> <p>This STANDARD is not met as evidenced by: Based on lack of requested Test Requisition (TR) and interview with the Account Representative (AR), the laboratory failed to locate six of six written or electronic test request from an authorized person for Biopsy tests from June to July 2018 and January to February 2019 . The AR stated on 4/16/19 at 11:45 am that TR were not filled properly so cannot locate.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: a) Based on surveyor review of the Procedure Manual (PM), observation of microscope and interview with the Account Representative (AR), the laboratory failed to follow Microscope Maintenance Procedure (MMP) in the calendar year 2018. The finding includes: 1. The PM stated to perform preventive maintenance of microscope annually but there was no evidence of maintenance performed. 2. The AR confirmed on 4/16/19 at 10:30 am that the laboratory did not follow MMP. b) Based on surveyor review of the PM and interview with the AR, the laboratory failed to have a retention</p>

of records and slide procedure from 11/29/17 to the date of survey. The AR confirmed on 4/16/19 at 10:35 am that the laboratory do not have a retention procedure. c) Based on surveyor review of the PM and interview with the AR, the laboratory failed to follow "QC stain by Pathologist" procedure from 11/29/17 to the date of survey. The finding includes: 1. The PM stated request of special stain and immunohistochemistry stain will be logged on the log sheet but there was no evidence of the procedure followed. 2. The AR confirmed on 4/16/19 at 10:30 am that the laboratory did not follow PM. d) Based on surveyor review of the PM and interview with the AR, the laboratory failed to have an accurate facility address on the PM, annual review of PM form, Stats, Turn Around Time log, Random pathology review QA form, Monthly microscope maintenance chart from 11/29/17 to the date of survey. The AR confirmed on 4/16/19 at 11:00 am that the address was not correct on all records. e) Based on surveyor review of the PM and interview with the AR, the laboratory failed to follow "Quality Assurance" procedure from 11/29/17 to the date of survey. The findings include: 1. The PM stated '10 random cases are pulled twice a year and sent for review' but the laboratory sent first case of each month for review. 2. The AR confirmed on 4/16/19 at 11:45 am that the laboratory did not follow PM.

D5805

TEST REPORT
CFR(s): 493.1291(c)

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.

This STANDARD is not met as evidenced by:
Based on surveyor review of the Final Reports (FR) and interview with the Account Representative (AR), the laboratory failed to ensure that the name and address of the Technical Component (TC) laboratory was on the FR from 11/29/17 to the date of survey. The AR confirmed on 4/16/19 at 11:55 am that the FR did not include the name and address of TC laboratory.