

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0998457	(X3) Date Survey Completed 01/12/2018
Name of Provider or Supplier Dermatologic Surgicenter	Street Address, City, State 1200 Locust Street, Philadelphia, PA	
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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on, a tour of the laboratory, the review of laboratory records and interview with the Laboratory Technician, the laboratory failed to properly store flammable Alcohol in a flammable cabinet, from 2016 to the date of survey. Findings: 1) On the date of survey (01/12/2018 at 10:15 am), during the laboratory tour 5 of 5 bottles of StatLab 100% Reagent Alcohol (lot# 062340 exp: 12/19) were found stored in a non-flammable cabinet. 2) According to the Laboratory's Safety Data Sheet "Section 7. Handling and Storage: The Alcohols inside storage should be in a NFPA approved flammable liquid storage room or cabinet." 3) On 01/12/2018 at 10:15 am an interview with the Laboratory Technician confirmed the findings above.</p>
D6094	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p>

This STANDARD is not met as evidenced by:

Based on, the review of laboratory policy and procedure manual and interview with the Laboratory Technician, the Laboratory Director failed to ensure that the quality assessment program is maintained and documented to assure the quality of laboratory services provided from 2016 to date of survey. Findings: 1) On the day of survey 01/12/2018 at 10:30 am the surveyor reviewed the Quality Assurance Program policy and discovered that the laboratory's quality assessment of the pre-analytic, analytic and post analytic phases were not documented from 06/01/2016 to the date of survey. 2) According to the Quality Assurance Program policy, signed by the Laboratory Director, Section titled: Annual Evaluation of Quality Improvement Program: "The Quality Improvement Committee will annually evaluate the effectiveness of the Quality Improvement plan and revise it accordingly." 3) On 01/12/2018 at 10:30 am and interview with the Laboratory Technician confirmed the findings above.