

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0688774	(X3) Date Survey Completed 09/05/2018
Name of Provider or Supplier Garden City Dermatology Pc	Street Address, City, State 901 Stewart Avenue Suite 201, Garden City, NY	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's review of laboratory records and an interview with the laboratory director, the laboratory failed to establish a comprehensive written policy and procedure that includes the six required components that assess testing personnel's competency, twice annually during the first year of testing and annually thereafter. The six required components are: 1. direct observation of routine patient test performance, including preparation, specimen handling and testing; 2. monitoring the recording and reporting of test results; 3. review of intermediate results of worksheets, quality control records, proficiency testing results, and preventive maintenance records; 4. direct observation of performance of instrument maintenance and function checks; 5. assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and, 6. assessment of problem solving skills.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p>

This STANDARD is not met as evidenced by:
Based on a lack of Quality Assessment policy and procedure and confirmed in an interview with the laboratory director at the time of this survey, the laboratory failed to establish and follow a written Quality Assessment (QA) policy and procedure for an ongoing mechanism to monitor, assess, and when indicated correct problems that may occur in the laboratory testing.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on a lack of the quality assessment (QA) program and confirmed in an interview with the laborator director at the time of the survey, the laboratory director failed to ensure that the laboratory's QA program was maintained as part of the laboratory's overall quality systems program. Refer to D5209, D5291