

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0871188	(X3) Date Survey Completed 10/10/2019
Name of Provider or Supplier Chana E Gelbfish Md	Street Address, City, State 2502 Avenue I, Brooklyn, 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
D2121	<p>HEMATOLOGY CFR(s): 493.851(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's review of the College of American Pathologists (CAP) Proficiency testing (PT) 2018 and 2019 records and an interview with the laboratory testing person, the laboratory failed to participate and perform successfully in a PT program, approved by CMS, for the test analytes White Blood Cell Count (WBC) , Red Blood Cell Count (RBC), Hematocrit (HCT) and Hemoglobin (Hgb). The following scores were assigned: 2019 second event = 60% for each analyte This is considered a unsatisfactory PT performance.</p>
D2122	<p>HEMATOLOGY CFR(s): 493.851(b)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's review of the CAP PT 2018 and 2019 records and an interview with the laboratory testing person, the laboratory failed to participate and perform successfully in a PT program, approved by CMS, for the test speciality Hematology. The following scores were assigned: 2019 second event = 70% This is considered a unsatisfactory PT performance.</p>
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES

	<p>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 a review of the laboratory's competency assessment policies, competency evaluation records and an interview with the laboratory testing person, the laboratory failed to follow their establish written policies and procedures to assess the competency of the laboratory testing personnel that perform both Bacteriology/throat cultures and Hematology/CBC testing. FINDINGS: The laboratory testing person confirmed on October 10, 2019 at approximately 2:00 PM, that the laboratory did not follow the established competency evaluation policy. The laboratory did not perform annual 2018 competency evaluation for five of five laboratory testing personnel who perform moderate complexity testing.</p>
<p>D5211</p>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of CAP PT reports and an interview with the laboratory testing person, the laboratory failed to review and evaluate for the CAP PT for both the sub-specialty bacteriology throat cultures and Hematology for all 3 events in 2018 and the 1st & second events of 2019. FINDINGS: The laboratory testing person confirmed on October 10, 2019 at approximately 2:00 PM, that the laboratory director failed to review and evaluate the CAP PT results for all 3 events in 2018 and the 1st and 2nd events of 2019 for both the sub-specialty bacteriology/throat cultures and Hematology.</p>
<p>D5291</p>	<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> <p>This STANDARD is not met as evidenced by: Based on a surveyor's review of the laboratory's Quality Assurance (QA) policy and confirmed in an interview with the laboratory manager and testing person, the laboratory failed to follow their established written QA policy and perform an annual QA review, as required by the laboratory's QA policy, for the calendar year 2018.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p>

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on surveyor's findings and an interview with the laboratory testing person, the laboratory director failed to provide overall management of the laboratory. The laboratory director failed to ensure that the laboratory: 1. Evaluated the CAP PT summary reports and perform corrective action, Refer to D6019; 2. Maintained the laboratory's established QA program for all phases of laboratory testing, Refer to D6021;. 3. Maintained the competency evaluation procedure, Refer to D6054.

D6019

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(iv)

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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on a review of the CAP PT records and confirmed in an interview with the laboratory testing person, the laboratory director failed to ensure that corrective action was taken for the speciality Hematology and test analytes that were unsatisfactory. Refer to D2121 and D2122.

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 the surveyor's review of the laboratory's QA policy and confirmed during the interview with the laboratory testing person, the laboratory director failed to ensure that the laboratory's QA policy/procedure was followed and perform an annual QA review in 2018 as required. Refer to: D5211 and D5291

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:
Based on a surveyor's review of the personnel files and confirmed in an interview with the laboratory manager/testing person, the laboratory director, acting as the technical consultant, failed to perform annual competency evaluation for five out of five testing persons in calendar year 2018. Refer to D5209.