

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D1089622	<b>(X3) Date Survey Completed</b>  11/16/2021
<b>Name of Provider or Supplier</b>  Genex Laboratories	<b>Street Address, City, State</b>  1301 N San Fernando Blvd, Burbank, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2075</b>	<p>GENERAL IMMUNOLOGY CFR(s): 493.837(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 review of the laboratory's American Association of Bioanalysts (AAB) testing records, six (6) random patients sampling, and interview with the testing personnel; it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for anti-HCV on the third event of 2020 (Q3-2020). The findings included: 1. The API proficiency program gave an unsatisfactory score of 40% for anti-HCV on the third event of 2020 (Q3-2020). . 2. Based on the laboratory's annual testing declaration submitted on the day of the survey November 16, 2021, the laboratory analyzed and reported approximately 1,116 anti-HCV, during the time the laboratory had unsatisfactory proficiency testing results. 3. The technical supervisors confirmed on 11/16/2021 at approximately 12:00 p.m. that the laboratory received the above proficiency score of 40% for anti-HCV on the third event of 2020 described in 1.</p>
<b>D2088</b>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(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 review of the American Association of Bioanalysts (AAB) proficiency testing records and interview with the testing personnel (TP); it was determined that</p>

the laboratory failed to attain a score of at least 80 percent of acceptable responses for Folate analyte for the third event of 2020 (Q3-2020). The finding included: 1. Based on review of PT records for Q3-2020, AAB reported an unsatisfactory score of 50% for Folate: Folate (ng/ml) Sample # Reported Intended range 11 6.4 3.3 - 6.2 12 2 1.1 - 2.9 2. Based on the laboratory testing declaration submitted at the time of the survey on 11/16/2021 the laboratory analyzed and reported approximately 80,436 routine chemistry tests including Folate during the time the laboratory had unsatisfactory proficiency testing results. 3. The TP affirmed 11/16/2021 at approximately 1:15 p.m. that the laboratory received the above unsatisfactory proficiency testing score.

**D2121**

**HEMATOLOGY**

CFR(s): 493.851(a)

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.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's American Association of Bioanalysts (AAB) testing records, six (6) random patients sampling, and interview with the testing personnel; it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for Neutrophil cell counts on the second event of 2020 (Q2-2020). The findings included: 1. The API proficiency program gave an unsatisfactory score of 60% for Neutrophil cell count for Q2-2020. 2. Based on the laboratory's annual testing declaration submitted on the day of the survey November 16, 2021, the laboratory analyzed and reported approximately 20,689 complete blood cell counts which included Neutrophil cell counts, during the time the laboratory had unsatisfactory proficiency testing results. 3. The technical supervisors confirmed on 11/16/2021 at approximately 11:45 a.m. that the laboratory received the above proficiency score of 60% for Neutrophil cell counts described in 1.

**D5401**

**PROCEDURE MANUAL**

CFR(s): 493.1251(a)

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.

This STANDARD is not met as evidenced by:  
Based on the lack of laboratory current written policies and procedures and interview with the laboratory personnel, it was determined that the laboratory failed to have available and follow written procedures for SARS-CoV-2 Antibody detection test procedure performed in the laboratory. The findings included: 1. On the day of the survey on November 16, 2021 at approximately 12:30 p.m. the laboratory failed to provide written policies and procedures for SARS-CoV-2 Antibody detection test procedures currently performed in the laboratory. 2. For two (2) out of six (6) random patient test results reviewed covering period from 9/22/2020 to 08/18/2021 the patients had SARS-CoV-2 Antibody detection test ordered, analyzed, and reported for which the laboratory had no written policies and procedures available for the current

practice. 3. The laboratory staff confirmed on November 16, 2021 at approximately 12:45 p.m. that the laboratory did not have written policies and procedures available for the current SARS-CoV-2 Antibody detection test performed in the laboratory.

**D6082**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(1)

The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's records for policies and procedures, proficiency testing results, lack of delegation of responsibilities, and interview with the technical supervisor and laboratory testing personnel on November 16, 2021; it was determined that the laboratory director failed to ensure that several aspects of the preanalytic, analytic, and postanalytic phases of laboratory testing were monitored. See D2075, D2088, D2121, D5401, and D6107.

**D6107**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's records of personnel training, competency evaluation, laboratory policies and procedures, random patient testing records, and interview with the laboratory's testing personnel (TP); the laboratory failed to provide records showing that the laboratory director (LD) has authorized, delegated, and approved lab personnel of any responsibilities and duties in writing. The findings include: 1. The laboratory did not have any records of written delegation and authorization of responsibilities and duties by the LD for laboratory testing personnel. 2. On November 16, 2021 at approximately 2:00 p.m., the TP affirmed that the LD did not assign, delegate, and authorize in writing duties and responsibilities to the laboratory personnel including the technical supervisor and the general supervisor. 3. The laboratory testing declaration form, signed by the LD on November 11, 2021 stated that the laboratory performs 528,743 tests annually.