Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2037411	09/24/2019
Name of Provider or Supplier	**Street Address, City, State**	
Genesys Biolabs	15810 Gaither Dr Suite 235, Gaithersburg, MD	

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
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of patient requisitions and interview with the general supervisor, the laboratory failed to maintain the integrity of patient samples collected for immunology testing (Refer to D5203)
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on review of patient requisitions and interview with the general supervisor (GS), the laboratory did not maintain the integrity of all patient samples collected for immunology testing. Findings: 1. The laboratory received a patient sample on February 9, 2018. The sample was given the sample ID G21256. 2. Sample G21256 was rejected. The laboratory manager was unable to locate the original rejection form.

	3. The laboratory used the sample ID G21256 on a different specimen collected on April 6, 2018. The sample was ran and results were released to the requesting provider. 4. The GS was unable to identify the name of the patient collected on February 9, 2018 and was unsure if it was the same patient collected on April 6, 2018. 5. The GS was unaware that the sample ID G21256 was used multiple times.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: I. Based on review of patient logs and interview with the general supervisor (GS), the laboratory did not establish and follow written procedures for identifying and labeling patient specimens when performing immunology testing. Findings: 1. The laboratory performs the "One Test" on the Cobas e411 analyzer. The "One Test" is a tumor marker panel which consists of 8 markers in patient serum that include AFP (Alpha Fetal Protein), CEA (Carcinoembryonic antigen), CA 125 (Cancer antigen), CA 19-9, CA 15-3, Cyfra 21-1(Cytokeratins), and PSA (Prostate-specific antigen) . 2. The laboratory did not establish written procedures for identifying and labeling patient specimens. 3. Specimen collection kits were sent to facilities that collected samples for the "One Test" 3. The laboratory labeling and unique identification process consisted of hand written letters and sample identification numbers that depended on the location the sample was collected. 4. The laboratory used various formats when assigning identification numbers that included a "TC or OT followed by a group of numbers that was hand written on the requisition form and labels included in the kit. 5. The labels were added to the specimen and the final report. 6. The GS stated that a written procedure was not available. II. Based on review of patient requisitions and interview with the general supervisor (GS), the laboratory did not maintain the integrity of all patient samples collected for immunology testing. Findings: 1. The laboratory received a patient sample on February 9, 2018. The sample was given the sample ID G21256. 2. Sample G21256 was rejected. The GS was unable to locate the original rejection form. 3. The laboratory used the sample ID G21256 on a different specimen collected on April 6, 2018. The sample was ran and results were released to the requesting provider. 4. The GS was unable to identify the name of the patient collected on February 9, 2018 and was unsure if it was the same patient collected on April 6, 2018. 5. The laboratory manager was unaware that the sample ID G21256 was used multiple times and rejection information was not maintained.
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 review of the written procedure manual and interview with the general supervisor (GS), the laboratory did have written procedures for all areas of the laboratory when performing patient immunology testing. Findings: 1. The laboratory performs the "One Test" on the Cobas e411 analyzer. The "One Test" is a tumor marker panel which consists of 8 markers in patient serum that include AFP (Alpha Fetal Protein), CEA (Carcinoembryonic antigen), CA 125 (Cancer antigen), CA 19-9, CA 15-3, Cyfra 21-1(Cytokeratins), and PSA (Prostate-specific antigen). 2. The laboratory did not have written procedures for performing patient testing beyond 30 days nor the storage requirements. 3. In January 2019 a sample was discovered that did not have physician information on the requisition. The laboratory froze the sample for three months. 4. The sample was tested in April 2019 when the physician called requesting results. 5. The written procedure states that patient samples can be frozen and tested up to 30 days. 6. The GS stated that serum samples can be held for over a year frozen but did not provide validation data to support the claim.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the written procedure manual and interview with the general supervisor (GS), the laboratory director (LD) did not review and sign the proficiency testing (PT) procedure for performing in house developed PT. Findings: 1. The laboratory performs in house developed PT for Cyfra 21-1(Cytokeratins) 2. The LD did not review and sign the written procedure prior to performing PT. 3. The GS stated that the LD has the procedure but just had not returned it to the laboratory.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory validation and interview with the general supervisor (GS), the laboratory did not maintain the original raw data that was accumulated during the validation process on the Cobas e411 analyzer. Findings: 1. The laboratory performed a validation on the new Cobas e411 analyzer for performing immunology during the year 2018. 2. The laboratory did not maintain the data the was collected during the validation procedure. 3. The laboratory did not perform a method comparison of the Cobas analyzer validation results to ensure the that the manufacturers expected results correlate to the expected results of in house testing. 3.

	The GS stated that she did have the original data from the validation of the immunology analyzer and stated that a analyzer method comparison was not performed.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: I. Based on review of the laboratory validation and interview with the general supervisor (GS), the laboratory did not maintain the original raw data that was accumulated during the validation process of the "One Test" immunoassay. Findings: 1. The laboratory performs the "One Test" on the Cobas e411 analyzer. The "One Test" is a tumor marker panel which consists of 8 markers in patient serum that include AFP (Alpha Fetal Protein), CEA (Carcinoembryonic antigen), CA 125 (Cancer antigen), CA 19-9, CA 15-3, Cyfra 21-1(Cytokeratins), and PSA (Prostate-specific antigen). 2. The laboratory did not maintain the raw data that was accumulated during the validation process for each individual analyte that is included in the "One Test". 3. The laboratory did not perform a comparison of results obtained during the validation with an established method to ensure the "One Test" was producing accurate results. 4. The laboratory did not have validation data for the "One Test" that determined the analytical specificity, analytical sensitivity, storage of samples, and interfering substances. 5. The GS stated that patient specimens can be stored over a year prior to testing. 6. The laboratory did not identify during the validation method the testing which included the presence or absence of each individual analyte included in the "One Test" 7. The GS stated that raw data from the validation was not available. II. Based on review of the laboratory validation and interview with the general supervisor (GS), the laboratory did not maintain the original raw data that was accumulated during the development of the "One Test algorithm". Findings: 1. The laboratory utilizes a "One Test algorithm" that was developed to predict an individual's risk of cancer when tested for tumor markers in patient serum. 2. The laboratory performs the "One Test" on the Cobas e411 analyzer. The "One Test" is a tumor marker panel which consists of 8 markers in patient serum that include AFP (Alpha Fetal Protein), CEA (Carcinoembryonic antigen), CA 125 (Cancer antigen), CA 19-9, CA 15-3, Cyfra 21-1(Cytokeratins), and PSA (Prostate-specific antigen). 3. Each individual marker result is put in the "One Test algorithm" and a score is given. 4. The score gives the overall predicted probability of the patient developing cancer. 5. The laboratory did not maintain the raw data that was obtained during the development of the algorithm. 6. The laboratory did not present data that ensured the "One Test algorithm" predicted score was acceptable for the purpose of performing the test. 7. The laboratory did not split samples to compare the "One Test" method and another method results that was given a score by the "One Test

	algorithm". 8. The GS stated that split samples were not performed and that a validation of the "One Test algorithm" was not performed.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of quality control and calibration records and interview with the general supervisor (GS), the laboratory did not document calibrator failures and problems when performing Immunology testing. Findings: 1. The laboratory failed calibration testing on the Cobas e411. 2. The laboratory failed CEA and CA 19-9 on 7 /1/19 it was repeated on 7/8/19 and passed. 3. The laboratory failed Cyfra 211 on 7/25 /19 it was repeated and passed on 7/26/19. 4. The laboratory did not document corrective action procedures as to why the calibrators failed nor any patient information that may have been involved. 5. The GS stated that patients were not ran on the days of calibration failures.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) 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. This STANDARD is not met as evidenced by: Based on review of patient records and interview with the laboratory manager, the laboratory director failed (LD) to maintain quality procedures for the overall acceptability of laboratory testing. Findings: Refer to D5203, D5311, D5401, and D5783 The LD failed to maintain and document quality assessment procedures during the preanalytic, analytic, and post analytic phases of immunology testing.
D6119	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(6) The technical supervisor is responsible for ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly. This STANDARD is not met as evidenced by: Based on review of quality control and calibration records and interview with the

	general supervisor, the technical supervisor (TS) failed to document corrective action procedures when performing Immunology testing. Findings: Refer to D5783 The TS failed to document corrective action procedures when calibrators failed.