Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0999920	01/30/2018
Name of Provider or Supplier	**Street Address, City, State**	
Genesis Medical Laboratory	6504 Nw 77 Ct, Miami, FL	

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
D2066	SYPHILIS SEROLOGY CFR(s): 493.835(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on review of American Proficiency Testing (API) testing results and interview with the office manager, the laboratory failed to have satisfactory results in Syphilis Serology in 1 out of 3 events. The findings include: API results for year 2016 showed a score of 40 % for Syphilis serology and 20 % for Syphilis (titer, serum) in 2016 3rd event. During an interview with the office manager at 2:00 pm on January 30th 2018 she confirmed that laboratory failed PT for syphilis serology and syphilis (titers serum) in 2016 third event. 39027
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(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: 39027 Based on review of American Proficiency Testing (API) testing results and interview with the office manager, the laboratory failed to have satisfactory results in sodium in 1 out of 3 events. The findings include: API results for year 2016 showed a score of 60 % for sodium test for 2016 first event. During an interview with the office manager at 2:00 pm on January 30th 2018 she confirmed that the laboratory failed PT sodium analyte test result for first event 2016.

D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: 39027 Based on review of American Proficiency Testing (API) testing results and interview with the office manager, the laboratory failed to have satisfactory results in lymphocytes and neutrophils analytes in the Hematology specialty in 2 out of 2 consecutive events. The findings include: API results for years 2016 showed a score of 40 and 60 % for the lymphocyte and 60 % and 60 % for neutrophils in the specialty of hematology in the white blood cell differential lymphocyte respectively for the second and third event of 2016. During an interview with the office manager at 2:00 pm on January 30th 2018, she confirmed that the laboratory failed PT second and third event for lymphocyte and neutrophils analyte test for year 2016.
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation, record review and interview with the laboratory staff, laboratory failed to provide the safety and sanitary conditions to the patients and personnel by; 1) The blood-draw chair was in the entrance passage to the laboratory. 2) There were big boxes on the floor along with big biohazard bin, leaving not adequate room for testing personnel to move around and to have smooth work flow. 3) There were reagent bottles and reagent boxes on workbench, along with daily work log binders for the tests performed and test specimens, leaving no workspace on workbench for testing personnel. 4) The employee bathroom did not have paper towel and bathroom toilet did not flush. 5) Allow the processing personnel to use the laboratory computer with gloves, and not having specific sign or written procedure posted on computer or in procedure manual, for the use of computer and any sterility measures or means for disinfection. Findings include: During the tour of the laboratory on January 30, 2018, the surveyor observed; A) Blood-draw chair was in the entrance passage to the laboratory not leaving any room for smooth blood drawing, or leaving privacy for the patient. The passage had 3 doors: laboratory door, patient waiting area door and a door to a very small office opened up in the laboratory entrance passage, where the blood-draw chair was. B) There were big boxes on the floor along with big biohazard bin in testing area. C) There were reagent bottles and reagent boxes on workbench, along with daily work log binders for the tests performed and urine and blood test specimens leaving no room for workspace. D) The employee bathroom did not flush and there was no paper towels to use after hand wash. E) Testing personnel using computer with gloves on in the laboratory. there was no written procedure posted on the computer, nearby bulletin board or in procedure manual for any safety procedure, sterility measures or means of disinfection for the computer. F) There was no posted sign on computer or nearby bulletin board, for use of computer with gloves. Procedure manual did not include the procedure for

	decontamination of computer. (i) On 1/30/18 at 5PM, laboratory assistant and laboratory manager confirmed that the blood- drawing chair was in the laboratory entrance passage. The passage had three doors opening from the laboratory, a very small office and a patient waiting area, leaving no room for smooth blood collection or leaving privacy of the patient. (ii) On 1/30/18 at 12PM, the supervisor and the laboratory assistant confirmed about the big boxes on the floor along with big biohazard bin in testing area. (iii) On 1/30/18 at 12PM, the supervisor and the laboratory assistant confirmed that reagent bottles and reagent boxes were on workbench, along with daily work log binders for the tests performed and urine and blood test specimens leaving no room for work. (iv) On 1/30/18 at 11:30AM, the laboratory manager confirmed that employee bathroom that did not flush after it was used and there was no paper towels to use after hand wash. (v) On 2/6/18 at 8:45 AM, the laboratory supervisor confirmed on the phone that the laboratory personnel used gloves while using computer and there was no posted sign or written procedure for decontamination of the computer.
D5201	CONFIDENTIALITY OF PATIENT INFORMATION CFR(s): 493.1231 The laboratory must ensure confidentiality of patient information throughout all phases of the total testing process that are under the laboratory's control. This STANDARD is not met as evidenced by: Based on observation and interview with the laboratory staff, the laboratory failed to ensure the patient's privacy by having the blood-drawing chair in the entrance passage to the laboratory. The findings include: On January 30, 2018 at 9:30 am, the surveyor observed the blood-draw chair was in the entrance passage to the laboratory, which did not allow any privacy for patient or enough room for smooth blood drawing. Blood-draw chair was in the passage where laboratory door, patient waiting area door and a door to a very small office opened up. On 1/30/18 at 5PM, the laboratory assistant, the laboratory manager and the laboratory supervisor confirmed that the blood-draw chair was in the laboratory entrance passage and had three doors opening from laboratory, a very small office and a patient waiting area, leaving no room for smooth blood collection or leaving privacy of the patient.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on record review and interview with the supervisor, the facility failed to; 1-write a correct year for serology quality control log for month of October 2017. 2-review and document the quality assurance (QA) activity for patients test requisitions and final report from 8/2016 to 2018. The findings include: A-Review of serology quality control logs from 3/20/16 to 1/20/18 showed that the serology quality control monthly log for October 2017 had month and year as October 2018. B- Review of QA

	for test requisitions and final test reports from January 2016 to 2018 showed that after July 2016, there was no records for QA activity for patients test requisitions and final reports from 8/2016 to 1/2018 and there was no corrective action for that QA review period. On 1/30/18 at 2PM, the laboratory supervisor confirmed that; a)- the serology quality control monthly log for October 2017 had month and year as October 2018 instead of October 2017. b)- there was no records for QA activity for patients test requisitions and final reports from 8/2016 to 1/2018 and there was no corrective action for that QA review period. There was no documentation of corrective action to indicate wether or not any error has being made. There was no pre-analytic, analytic or post analytic systems assessment review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of quality assessment reviews with appropriate staff.
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 observation, record review and interview with the laboratory supervisor, laboratory failed to use updated and approved procedure for manual differential and erythrocyte morphology evaluation. The findings include: Review of policies and procedures of the test reagents for manual differential and erythrocyte morphology evaluation showed; A- Immersion oil B- Wright stain C- Slides, as reagents. Observation during a tour of laboratory on 1/30/18 at 3:50PM showed the stain kit used for the test was Camco stain pak, having three solutions; 1-fixative solution 2-Solution I Xanthine dye 3- Solution II Thiazine dye. On 1/30/18 at 4 PM, the supervisor confirmed that laboratory used Camco stain pak, not Wright stain as written in the procedure manual. And that the director did not update or approve the policies and procedure for manual differential and erythrocyte morphology evaluation.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on surveyor record review and interview with the supervisor, the laboratory failed to; 1- Conduct or document the instrument maintenance for ARCHITECT i1SR55324 for the days of validation and patient testing from 2017 to 2018. 2-Conduct or document the monthly maintenance for Coulter LH750 hematology analyzer for the months of April, July, August, September, November and December of 2017. The findings include: A) Review of 2017 and 2018 instrument validation,

	maintenance and patients test report records for ARCHITECT i1SR55324 for the days of validation and patient testing showed that laboratory did not perform or document: Daily maintenance for November 1 to 14, 16 to 26. December 1, 8, 15 to 25. January 9, 18, 22, 25 of 2018. Weekly maintenance for November 2 to 14, 22 to 26. December 19 to 26. B)Review of 2017 Coulter LH750 Daily maintenance records for hematology showed that the laboratory did not perform or document the monthly maintenance for Coulter LH750 hematology analyzer for the months of April, July, August, September, November and December of 2017. On 1/30/18 at 2:30 PM, the laboratory supervisor stated that; a) The laboratory did not perform daily or weekly maintenance for part of November, December 2017 and January 2018 for ARCHITECT i1SR55324. b) The laboratory did not perform or record the monthly maintenance for Coulter LH750 hematology analyzer for the months of April, July, August, September, November and December of 2017.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on surveyor review of instrument calibration records for hematology and interview with the laboratory supervisor, the laboratory failed to conduct and document the calibration for Coulter LH750 hematology analyzer during the year 2017. The findings include: Review of 2016 to 2018 calibration records for hematology showed that the laboratory did not perform or document the calibration for Coulter LH750 hematology analyzer after 11/10/16 till 1/5/18.There were no calibration records for year of 2017. On 1/30/18 at 3:30 PM, the laboratory supervisor stated that the laboratory did not perform the calibration for Coulter LH750 hematology analyzer after 11/10/16 to 1/5/18, instrument was not calibrated for year 2017 and and there were no records.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)

	Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor record review and interview with the laboratory staff, the laboratory failed to; 1- conduct and document the quality controls for Folic acid following the calibration and during March 2017. 2- conduct and document the quality controls for Triiodothyronine (T3) during March 2017. The findings include: Review of quality control Levey-Jennings charts (Levey-Jennings chart is a graph that quality control data is plotted on to give a visual indication whether a laboratory test is working well) and patients test records for March, 2017 for Folic acid and T3 showed that the laboratory did not perform and document the quality controls for: (I) Folic acid after calibration on March 7, 2017 and from March 1 to 14, 18 to 20, 25 to 27, 29 and 31 of 2017. (II) T3 from March 4 to 22 and from March 25 to 27, 2017. (III) Instrument records for 3/7/17 and 3/8/17 showed; (a) six specimens tested and reported on 3/8/17 for folic acid. (b) 21 specimens tested and reported on 3/8/17 for T3. On 1/30/18 at 6:11 PM, the laboratory assistant confirmed that the laboratory did not perform quality controls for; (i) T3 from March 4 to 22 and from March 25 to 27, of 2017. (ii) Folic acid after calibration on March 7, 2017 and from March 1 to 14, 18 to 20, 25 to 27, 29 and 31,2017 AND; (a) six specimens tested and reported for folic acid on 3/8/17. (b) 21 specimens tested and reported for T3 on 3/8/17.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) 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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation, record review and interview with the laboratory supervisor, the laboratory failed to monitor, access, and correct the problems identified in analytic systems for chemistry and hematology tests using ARCHITECT i1SR55324 chemistry analyzer and Coulter LH750 hematology analyzer. The findings include: Review of 2017 and 2018 instrument validation, calibration,maintenance and patients test report records showed that laboratory did not conduct and document; (A) daily maintenance for ARCHITECT i1SR55324 for the days of validation and patient testing for November 1 to 14, 16 to 26. December 1, 8, 15 to 25. January 9, 18, 22, 25 of 2018. Weekly maintenance for the days of validation and patient testing for November 2 to 14, 22 to 26. December 19 to 26. The following is the list of test analytes on ARCHITECT i1SR55324 chemistry analyzer; Vitamin B12 Folic acid B-hcg, serum (quantitative) T3 (triiodothyronine) total Thyroid uptake (T3UP) Total (thyroxine) T4 T4,free T3free FSH(Follicle-stimulating hormone) LH (Luteinizing hormone) Estradiol Testosterone CEA(Carcinoembryonic Antigen) Cortisol PSA(Prostate-Specific Antigen) free Insulin level ultrasensitive Progesterone Prolactin SHBG PSA TSH(thyroid stimulating hormone) Vitamin D, 25-Hydroxy HIV(human immunodeficiency virus) Ag/ab(antigen/antibody) HBsAgQu(surface antigen of the

	hepatitis B virus, (qualitative) HBsAb (hepatitis B surface antibody) HAVAB-M (hepatitis A virus antibody M) Hepatitis B Core Anti-HCV(hepatitis C virus) (B) the calibration for Coulter LH750 hematology analyzer after 11/10/16 till 1/5/18.There were no calibration records for year of 2017. The following is the list of test analytes on Coulter LH750 hematology analyzer; WBC (White Blood Cell) RBC(Red Blood Cell) Hemoglobin Hematocrit MCV(Mean corpuscular volume) MCHC(Mean corpuscular hemoglobin concentration) RDW(red blood cell distribution width) Platelet count MPV(mean Platelet Volume) % Eosinophils Absolute Lymphocytes Absolute monocytes Absolute Neutrophils Absolute Eosinophils % Lymphocytes % Monocytes % Neutrophils % Basophils Absolute Basophils (C) the monthly maintenance for Coulter LH750 hematology analyzer for the months of April, July, August, September, November and December of 2017. (D) the laboratory Instrument records for Access 2 Immunoassay system did not have the testing person signature for the date of 3/8/17. There was no corrective action documentation, for if there was any errors for (A), (B), (C) and (D). There was no analytic systems assessment review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytical systems quality assessment reviews with appropriate staff. On 1/30/18 at 6:15 PM, the laboratory assistant confirmed that Access 2 Immunoassay system did not have the testing person signature for the date of 3/8/17.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on observation, record review and the interview with the laboratory staff, the laboratory director failed to be responsible for overall operation and administration of the laboratory, including the facility administration, general laboratory systems, pre-analytic systems, analytic systems, and post analytic systems and to establish and maintain the quality assessment program. The findings include: 1 Blood-drawing chair, in the entrance passage to the laboratory. Laboratory door, patient waiting area door and a door to a very small office opened up in the laboratory entrance passage, not to leave any privacy for patient or enough room for smooth blood drawing where the blood-drawing chair was. Refer to D5201. 2 A- The Blood-draw chair was in a very small entrance passage to the laboratory, where three doors opened up, leaving no workspace for smooth blood draw. B- There were big boxes on the floor along with big biohazard bin, in test area. C- There were reagent bottles and reagent boxes on workbench, daily quality control logs-binders, blood and urine specimens on work bench with no room for workspace. D- There was no paper towel in employee bathroom, and bathroom toilet did not flush. E- Allow the processing personnel to use the laboratory computer with gloves, and not having specific sign or written procedure

	posted on computer or in procedure manual, for the use of computer and any sterility measures or means for decontamination. Refer to D3011 3 F- Review of serology quality control logs from 3/20/16 to 1/20/18 s howed that the serology quality control monthly log for October 2017 had month and year as October 2018. G- No records for quality control (QA) activity for patients test requisitions and final reports from 8 /2016 to 1/2018 and there was no corrective action for that QA review period. Refer to D5293. 4 Laboratory failed to use updated and approved procedure for manual differential and erythrocyte morphology evaluation. Refer to D5407. 5 H- Laboratory did not conduct or document; (a) the instrument maintenance for ARCHITECT i1SR55324 for the days of validation and patient testing from 2017 to 2018. (b) the monthly maintenance for Coulter LH750 hematology analyzer for the months of April, July, August, September, November and December of 2017. Refer to D5433. 6 The laboratory did not perform or document the calibration for Coulter LH750 hematology analyzer after 11/10/16 till 1/5/18. Refer to D5439. 7 The laboratory failed to monitor, access, and correct the problems identified in analytic systems for chemistry and hematology test system. Refer to D5791. 8 (i) The laboratory failed proficiency testing for Lymphocytes and Neutrophils in hematology specialty for two consecutive Events in year 2016 with the scores of; Lymphocytes : 40% and 60%, Neutrophils : 60% and 60%. Refer to D2130. (ii) The laboratory failed proficiency testing for Syphilis Serology, One out of three test events for year 2016. Syphilis (titer, serum): 20% Syphilis Serology: 40% results for 3rd event PT 2016. Refer to D2066. The laboratory failed proficiency testing for Sodium for one out of three test events for year 2016. Sodium(Na): 60% for 1st event 2016. Refer to D2087. (9) The laboratory did not perform and document the quality controls for: (I) Folic acid after calibration on March 7, 2017 and during March 2017. (II) Triiodothyronine (T3) during March 2017. (III) Instrument records for 3/7/17 and 3/8/17 showed; (a) six specimens tested and reported on 3/8/17 for folic acid. (b) 21 specimens tested and reported on 3/8/17 for T3. Refer to D5447. On 1/30/18 at 5PM, the supervisor and the laboratory assistant confirmed that: (A) the findings 1 to 7. (B) There was no corrective action. (C) There were no quality assessment records for the findings 1 to 7 to determine whether corrective actions taken to resolve problems were effective. (D) There was no documentation to indicate that policies and procedures were revised to prevent recurrence of problems. On 1/30/18 at 2PM, the office manager confirmed finding (8), proficiency testing scores. On 1/30/18 at 6:11 PM, the laboratory assistant confirmed finding (9) and that the patient test results were reported.
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 observation, record review and interview with the laboratory staff, the technical supervisor failed to ensure that patient test results were not reported until all corrective actions had been taken and that test system was functioning properly. The findings include: (1) Serology quality control monthly log error. (2) No records for quality control (QA) activity for patients test requisitions and final reports. Refer to D5293 (3) No updated and approved procedure for manual and Differential erythrocyte morphology evaluation. Refer to D5407. (4) No instrument maintenance for ARCHITECT i1SR55324 for the days of validation and patient testing. (5) No

	monthly maintenance for Coulter LH750 hematology analyzer. (6) No calibration or documented records for the calibration for Coulter LH750 hematology analyzer. (7) the laboratory Instrument records for Access 2 Immunoassay system did not have the testing person signature. (8) No quality control records for Folic acid and T3 for March 2017. Refer to D5433, D5439, D5441, and D5791. On 1/30/18 at 5PM, the supervisor confirmed the findings (1) through (6), and that the laboratory reported the patient test results. On 1/30/18 at 6:15PM, the laboratory assistant confirmed that finding (7) and (8), and that the laboratory reported patient test results.
D6144	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463 The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results. This STANDARD is not met as evidenced by: Based on observation, record review and interview with the laboratory staff, the general supervisor failed to be responsible for day-to-day supervision of laboratory operation and personnel performing testing and reporting test results. The findings include: (1) Serology quality control monthly log error. (2) No records for quality control (QA) activity for patients test requisitions and final reports. Refer to D5293 (3) No updated and approved procedure for manual and Differential erythrocyte morphology evaluation. Refer to D5407. (4) There was no instrument maintenance for ARCHITECT i1SR55324 for the days of validation and patient testing. (5) There was no monthly maintenance for Coulter LH750 hematology analyzer. (6) There was no calibration or documented records for the calibration for Coulter LH750 hematology analyzer. (7) the laboratory Instrument records for Access 2 Immunoassay system did not have the testing person signature. (8) No quality control records for Folic acid and T3 for March 2017. Refer to D5433, D5439, D5441, and D5791. On 1/30/18 at 5PM, the supervisor confirmed the findings (1) through (6). On 1/30/18 at 6:15PM, the laboratory assistant confirmed finding (7) and (8).