Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0999920	03/26/2020
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
D0000	An announced CLIA recertification survey was conducted at Genesis Medical Laboratory on 03/16/2020 thru 03/26/2020. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. Based on the survey findings, an Immediate Jeopardy situation was identified and the laboratory was notified at 5:00 PM on 03/20/2020. Based on record review and staff interviews the laboratory failed to ensure blood tubes were not used past their expiration since 12/09/19 and failed to ensure 1 of 2 centrifuges produced platelet poor specimens for Coagulation testing for 2 (2018-2020) out of 2 years reviewed (See D5311), failed to document the date and time of 1786 QuantiFERON (QFT) specimen after blood collection, and failed to have an effective quality assurance (QA) plan that identified issues during the pre-analytic phase of testing for 2 (2018-2020) out of 2 years reviewed (See D5300). Based on observation, record review and staff interview, the laboratory failed to follow the QuantiFERON (QFT) manufacturer's instructions (MI) for documenting QFT specimen incubation times for 16 to 24 hour and failed to follow MI for bacteriology cultures for 2 (2018-2020) out of 2 years reviewed, failed to provide water and 70% ethanol spray bottles that were not expired in Molecular Genetics room, failed to perform the initial instrument validation for the Qiagen QIA stat-Dx Analyzer per the Manufacturer's Instructions (MI) when validating the instrument on 09/09/19 for a Respiratory Panel, failed to document controls for QuantiFERON TB Gold Plus testing and Pharmacogenomics (PGX) testing for the years of January 2018 through January 2020, failed to create a policy for quality control and use positive controls for each mutation, negative control and a non-template control for the Pharmacogenomics (PGX) assay CYP2C19, CYP4502D6-BC and CYP4502C9 from June 2018 to January 2020, failed to perform and document the comparison of the two methodologies used to perform the microscopic evaluation of Hematology White Blood Cell (WBC) differential at least twice annually from 01/17/19 to 03/23/20, failed to follow Pharmacogenomics manufactures instructions for acceptable specimens and provide patient testing results without expired samples on the instrument from January 2018 thru January 2020 and failed to document each step from media inoculation to organism isolation and identification and who ran each part of the test in Bacteriology for 2 (2018-2020) out of 2 years reviewed, and failed to

	perform all required maintenance on the BD Phoenix Microbiology analyzer since 07 /10/18 (See D5400). The following Conditions were cited: D5300 Preanalytic Systems 493.1240 D5400 Analytic Systems 493.1250 D6076 Laboratory Director 493.1441
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed do an initial and 6-month personnel competency assessment for 1 (TP#C) out of 9 testing personnel (TP) . Findings Included: A review of CMS 209 Laboratory Personnel record revealed Employee C was a TP#C Review of "Competency Assessment" policy (last reviewed by the Laboratory Director on 05/08/2018) revealed that "The Laboratory will assess competency of all technical personnel subsequent to initial training, after six months, yearly and as needed there after (due to additions in testing equipment-protocols or any other reason that may warrant it) in accordance with CLIA regulations." A review of Personnel Competency Assessment record showed that TP#C was missing an initial and 6-month personnel competency assessment. During an interview on 03/20 /2020 at 12:30 pm, General manager confirmed that Initial and 6-month personnel competency assessment were not preformed.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the College of American Pathologist (CAP) proficiency testing (PT) and interview, the laboratory failed to provide documentation to verify the accuracy of the testing methods for 21 out of 98 analytes tested in urine toxicology from 01/01/19 to 12/31/19, at least twice annually. Findings Included: Review of the College of American Pathologist (CAP) proficiency testing (PT) showed that 21 analytes were not included in CAP's test menu. The following 21 analytes were not included in CAP's test menu: 7-Hydroxyquetiapine, Alpha-hydroxytriazolam, Alpha-PVP (Alpha Pyrrolidinopentiophenone), Amobarbital Pentobarbital, Butalbital, JWH-018 4-Hydroxypenty, JWH-073 3-Hydroxybutyl, JWH 250-N-4 Hydroxypentyl, Maprotiline, MDEA (3,4-Methylenedioxy-N-ethylamphetamine), Mephedrone, Methylone, Mitragynine, Naloxone, Naltrexone, Oxcarbazepine, Ritalinic Acid, Secobarbital, Sufentanil, Yangonin, and Zaleplon. The raw date for the split testing performed on 4/20/19 with an outside laboratory was not available for review. During an interview on 03/20/19 at 5:30 PM, the Technical Supervisor stated that they were unable to locate the raw data for the split testing.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240

	Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review and staff interviews the laboratory failed to ensure blood tubes were not used past their expiration since 12/09/19 and failed to ensure 1 of 2 centrifuges produced platelet poor specimens for Coagulation testing for 2 (2018-2020) out of 2 years reviewed (See D5311), failed to document the date and time of 1786 QuantiFERON (QFT) specimen after blood collection (See D5313), and failed to have an effective quality assurance (QA) plan that identified issues during the pre-analytic phase of testing for 2 (2018-2020) out of 2 years reviewed (See D5391).
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: Based on record review and interview with the General Manager the laboratory failed to ensure blood tubes were not used past their expiration since 12/09/19 and failed to ensure 1 of 2 centrifuges produced platelet poor specimens for Coagulation testing for 2 (2018-2020) out of 2 years reviewed. Findings Included: 1. During a tour of the laboratory's in-house blood drawing station on 03/16/2020 at 2:00 PM revealed 12 expired blue top (Coagulation tubes with 3.2% Sodium Citrate) used for Pro-time testing that expired 03/08/2020. Observations in the patient specimen refrigerator on 03/16/2020 at 2:00 PM revealed 8 Patients that had expired tubes. Patient #1 was drawn on 03/14/20 at 13:46 and the tube expired 03/08/20, Patient #2 was drawn on 03 /13/20 at 10:03 and the tube expired 03/08/20, Patient #3 was drawn on 03/13/20 at 16: 34 and the tube expired 12/09/19, Patient #4 was drawn on 03/13/20 at 18:58 and the tube expired 12/09/19, Patient #5 was drawn on 03/14/20 at 16:12 and the tube expired 01/04/20, Patient #6 was drawn on 03/13/20 at 19:48 and the tube expired 03 /08/20, Patient #7 was drawn on 03/13/20 at 16:29 and the tube expired 12/09/19, and Patient #8 was drawn on 03/14/20 at 13:35 and the tube expired on 03/08/20. Patients' #1, #2, #6, and #8 had testing performed and each result was high. Patient #5 had testing ordered but the sample quantity was not sufficient for analysis. Review of the manufacturer's instruction for the blue top tubes revealed under "Vacuette Precautions /Cautions" to "Do not use the tubes after the expiration date." Review of the Coagulation policy and procedures (last reviewed by the Laboratory Director on 03/16 /20) under "Rejection Criteria" does not list expired tube as a criteria for rejection. 2. Review of the manufacturer's instructions for the blue top tubes revealed routine tests need a platelet poor specimen or spun at 1500-2000 g-force for 10 minutes. Review of

	"Plasma Poor Study" procedure (last reviewed by the Laboratory Director on 03/16 /20) revealed that "Platelet poor plasma (5 samples) is randomly tested twice a year to ensure quality of platelet poor plasma specimens received from different institutions and all in-house centrifuges are used to prepare PPP". Tour of the laboratory on 03/16 /20 at 2:00 PM revealed 2 centrifuges (an Eppendorf Centrifuge 5702 and a LW Scientific Combo Centrifuge) with a sticker on each that said "CENTRIFUGUE BLUE TUBES 10 MIN". Review of the poor plasma study revealed one performed on 07/08/19, 01/29/19, 07/23/18, and 05/04/18. Interview on 03/20/20 at 3:30 PM the Technical Supervisor confirmed that a platelet poor specimen study was only performed on the Eppendorf Centrifuge 5702 and that blue top Coagulation tubes were spun down in both centrifuges.
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: Based on record review, observation and Staff interview, the laboratory failed to document the time of QuantiFERON (QFT) specimen after blood collection through March 2019 through January 2020. Findings Included: A review of TB QuantiFERON Gold Plus procedure record revealed lithium heparin tubes can be stored up to 12 hours after blood collection. QFT blood specimen tubes must be placed into an incubator within 2 hours. A review of QuantiFERON Gold Plus specimen record revealed QFT samples had no time collection recorded for March 2019 through January 2020. During an interview on 03/20/2020 at 12:30 PM, the general manager confirmed that QFT samples had no time collection documented for March 2019 through January 2020.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on record review and interview with the General Manager the laboratory failed to have an effective quality assurance (QA) plan that identified issues during the pre-analytic phase of testing for 2 (2018-2020) out of 2 years reviewed. Findings Included: Review of the "Quality Assurance Program" policy (last signed as reviewed by the Laboratory Director on 03/16/20) revealed that it should monitor "Pre-Analytic (patient test management)", to "Identify and correct problems", and "Parameters to be monitored (proficiency testing, competency review, unacceptable specimen, turnaround time, wrong patient report, unlabeled specimen, etc.) are established." Review of the "Monthly Laboratory Quality Assessment" revealed no issues identified in "Evaluated specimen submissions and test ordered, handling and rejections." Interview on 03/16/20 at 5:00 PM the General Manager confirmed that the QA did not identify the pre-analytic issues found in D5311 and D5313.
D5400	ANALYTIC SYSTEMS

	CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation, record review and staff interview, the laboratory failed to follow the QuantiFERON (QFT) manufacturer's instructions (MI) for documenting QFT specimen incubation times for 16 to 24 hour and failed to follow MI for bacteriology cultures for 2 (2018-2020) out of 2 years reviewed (See D5411), failed to provide water and 70% ethanol spray bottles that were not expired in Molecular Genetics room (See D5417), failed to perform the initial instrument validation for the Qiagen QIA stat-Dx Analyzer per the Manufacturer's Instructions (MI) when validating the instrument on 09/09/19 for a Respiratory Panel (See D5421), failed to document controls for QuantiFERON TB Gold Plus testing and Pharmacogenomics (PGX) testing for the years of January 2018 through January 2020 (See D5441), failed to create a policy for quality control and use positive controls for each mutation, negative control and a non-template control for the Pharmacogenomics (PGX) assay CYP2C19, CYP4502D6-BC and CYP4502C9 from June 2018 to January 2020 (See D5445), failed to perform and document the comparison of the two methodologies used to perform the microscopic evaluation of Hematology White Blood Cell (WBC) differential at least twice annually from 01/17/19 to 03/23/20 (See D5775), failed to follow Pharmacogenomics manufactures instructions for acceptable specimens and provide patient testing results without expired samples on the instrument from January 2018 thru January 2020 and failed to document each step from media inoculation to organism isolation and identification and who ran each part of the test in Bacteriology for 2 (2018-2020) out of 2 years reviewed (See D5787), and failed to perform all required maintenance on the BD Phoenix Microbiology analyzer since 07/10/18 (See D5429).
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on observation, record review and staff interview, the laboratory failed to follow the QuantiFERON (QFT) manufacturer's instructions (MI) for documenting QFT specimen incubation times for 16 to 24 hr and failed to follow MI for bacteriology cultures for 2 (2018-2020) out of 2 years reviewed. Findings Included: 1. An observation of the hallway showed an incubator on the floor . A review of QuantiFERON TB Gold Plus EIA-700 procedure record revealed that QFT- Plus Blood Collection Tubes are incubated upright at 37 C for 16 to 24 hours . Unreliable or indeterminate results may occur do to exceeding specimen draw to incubation .

	During an interview on 03/20/2020 at 12:30 PM , the office manager confirmed 16-24 incubation times were not documented for QFT specimen . 2. Interview on 03/19/20 at 9:30 AM the Bacteriology Testing Personnel revealed that all culture plates were preliminarily read at 24 hours and final read and reported at 48 hours. She confirmed that no one works Sundays and that the culture plates that were at 48 hours on Sunday would be read at 72 hours on Monday. Review of MI reveal that Blood, Macconkey, Xylose-Lysine-Desoxycholate, Phenylethyl alcohol, Thioglycollate Medium, and Mueller Hinton agar plates are to be read at 18-24 hours, Chocolate agar plates are to be read at 24-48 hours, and Thayer Martin and Anaerobic Blood agar plates are examined 24-48 hours however negative plates need to be incubated 72-96 hours before reporting as negative. Interview on 03/19/20 at 9:30 AM the Bacteriology Testing Personnel confirmed that Bacteriology culture plates were not being read and reported out per MI.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation and staff interview, the laboratory failed to provide water and 70% ethanol spray bottles that were not expired in Molecular Genetics room . Findings Included: An observation of Molecular Genetics room revealed a water and 70% ethanol spray bottle that had an expiration date of 12/21/19 on a work counter. During an interview on 03/20/2020 at 12:30 PM, the General Supervisor confirmed that water and 70% ethanol spray were expired.
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 record review and interview with the General Manager the laboratory failed to perform the initial instrument validation for the Qiagen QIA stat-Dx Analyzer per the Manufacturer's Instructions (MI) when validating the instrument on 09/09/19 for a Respiratory Panel. Findings Included: Review of the MI for the Qiagen QIA Stat-Dx Analyzer revealed that to validate the analyzer "For each assay run the method provides either 5 or 6 positive results and, correspondingly, 15 or 14 negative results for the 20 pathogens, in total, which are detected and differentiated by the QIA stat-Dx Respiratory Panel." Review of the validation conducted on 09/09/19 and approved

	by the Laboratory Director on 09/10/19 the laboratory ran 1 negative sample and 16 positive samples. Interview on 03/20/20 at 5:00 PM the General Manager confirmed that the samples tested for validation did not meet the MI instructions.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on record review and interview with the Technical Supervisor and General Supervisor the laboratory failed to perform all required maintenance on the BD Phoenix Microbiology analyzer since 07/10/18. Findings Included: Review of the BD Phoenix maintenance log revealed that every 3 months the Nephelometer needs calibrated. No documentation of the Nephelometer calibration was provided. Logs were reviewed since the instrument began testing on 07/10/18. Interview on 03/20/20 at 1:00 PM the Technical Supervisor confirmed that the calibration of the Nephelometer was not done. Review of the BD Phoenix maintenance log revealed that the printer paper needed to be checked on the instrument daily and documented on the log. The log had no documentation of the paper being checked since 02/05/19. Interview on 03/19/20 at 11:00 AM the General Supervisor confirmed that the BD Phoenix maintenance logs were not complete.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document controls for QuantiFERON TB Gold Plus testing and Pharmacogenomics(PGX) testing for the years of 2018 through January 2020. Findings Included: A review of QuantiFERON TB Gold Plus assay record revealed the Nil (gray top tube) served as the negative control and Mitogen (purple cap tube) serves as the positive control. A review of QuantiFERON Assay Results record revealed that Nil and Mitogen controls were documented for March 2019 through January 2020 . A review CYP2C19 , CYP4502D6-BC and CYP4502C9 Assay package insert record showed in quality control section "positive samples for each mutation (heterozygous and homozygous) , A negative control (wild-type) and a non template control (molecular grade water) should also be included in each run." A review of the PGX Results July 2018 -January

	2020 record revealed that controls were not documented . The Molecular Testing person stated that controls would be in the first 3 rows on the sample preparation sheet . Sample preparation sheet contained no controls in the first three rows . A review Molecular Pharmacogenetics procedure manual was missing a procedure on quality control for CYP2C19 ,CYP4502D6-BC and CYP4502C9. During an interview on 3/20 /2020 at 10 am , the office manager confirmed that testing personnel were not documenting controls for QuantiFERON and Pharmacogenetics for 2018 through January 2020.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation, record review, and staff interview the laboratory failed to create a policy for quality control, use positive controls for each mutation , a negative control, and a non-template control for the Pharmacogenomics (PGX) assay CYP2C19 ,CYP4502D6-BC and CYP4502C9 from June 2018 to January 2020. Findings Included: An observation of Molecular Genetics room revealed 2 Eppendorf mastercycler , 2 Eppendorf Vapoprotect , Microarray and Mircoarray analyzer . A review of PGX Procedure record revealed no policy on quality control . A review CYP2C19 ,CYP4502D6-BC and CYP4502C9 Assay package insert record showed in quality control section "positive samples for each mutation (heterozygous and homozygous) , A negative control (wild-type) and a non template control (molecular grade water) should also be included in each test run." A review of the PGX Results July 2018 - January 2020 record revealed that controls were not done and documented . The Molecular Testing person stated that control would be in the first 3 rows on the sample preparation sheet . Sample preparation sheet contained no controls in the first three rows . During an interview on 03/20/2020 at 12:30 PM , the General Supervisor confirmed the lab failed to create a policy for quality control and use positive controls for each mutation , negative control and a non-template control for the Molecular genetics assay CYP2C19 ,CYP4502D6-BC and CYP4502C9.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by:

	Based on record review and interview, the laboratory failed to perform and document the comparison of the two methodologies used to perform the microscopic evaluation of Hematology White Blood Cell (WBC) differential at least twice annually from 01 /17/19 to 03/23/20. Findings Included: Review of the quality control documentation showed that there was no documentation comparing the automated WBC differential performed on the Beckman Coulter DxH 900 Hematology analyzer to the manual microscopic WBC differential. Initial calibration records for the Beckman Coulter DxH 900 Hematology analyzer were dated 01/17/19. During an interview on 03/20/19 at 2:55 PM, the Laboratory Consultant confirmed that method to method comparison for microscopic examinations of WBC differentials had not been done.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to follow Pharmacogenomics manufacturer's instructions for acceptable specimens and provide patient testing results without expired samples on the instrument from January 2018 thru January 2020 and failed to document each step from media inoculation to organism isolation and identification and who ran each part of the test in Bacteriology for 2 (2018-2020) out of 2 years reviewed. Findings Included: 1. A review CYP2C19 , CYP4502D6-BC and CYP4502C9 Assay package insert record revealed that extracted Specimen should be kept refrigerated (2 to 8 Celsius) and extracted within nine days from the day the specimen was collected . Extracted DNA samples should be kept refrigerated (2 to 8 Celsius) and assayed within two days from the day the specimen was extracted. Buccal swab specimen should be assayed up to 7 days from collection day . A review of the PGX Results July 2018 -January 2020 record showed specimens were tested 7 days past collection date and the specimens were run in two monthly batches and patient results were reported. During an interview on 03/20/20 at 12:30 pm , the General Supervisor and previous Testing Personnel confirmed that specimens were tested past expiration and patient test results were reported for January 2018 thru January 2020. 2. Review of Bacteriology worksheets revealed no date, time, or Testing Personnel of who made the identification of result of culture. Interview on 03/19/20 at 9:30 AM the Bacteriology Testing Personnel confirmed that each step was not documented for time, date, and person who performed the test.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by:

	Based on record review and staff interview the Laboratory Director failed to have oversight of the laboratory for 2 (2018-2020) out of 2 years reviewed (See D6079).
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 record review and staff interview the Laboratory Director failed to have oversight of the laboratory for 2 (2018-2020) out of 2 years reviewed. Findings Included: See D5300: Based on record review and staff interviews the laboratory failed to ensure blood tubes were not used past their expiration since 12/09/19 and failed to ensure 1 of 2 centrifuges produced platelet poor specimens for Coagulation testing for 2 (2018-2020) out of 2 years reviewed (See D5311), failed to document the date and time of 1786 QuantiFERON (QFT) specimen after blood collection (See D5313), and failed to have an effective quality assurance (QA) plan that identified issues during the pre-analytic phase of testing for 2 (2018-2020) out of 2 years reviewed (See D5391). See D5400: Based on observation, record review and staff interview, the laboratory failed to follow the QuantiFERON (QFT) manufacturer's instructions (MI) for documenting QFT specimen incubation times for 16 to 24 hour and failed to follow MI for bacteriology cultures for 2 (2018-2020) out of 2 years reviewed (See D5411), failed to provide water and 70% ethanol spray bottles that were not expired in Molecular Genetics room (See D5417), failed to perform the initial instrument validation for the Qiagen QIA stat-Dx Analyzer per the Manufacturer's Instructions (MI) when validating the instrument on 09/09/19 for a Respiratory Panel (See D5421), failed to document controls for QuantiFERON TB Gold Plus testing and Pharmacogenomics (PGX) testing for the years of January 2018 through January 2020 (See D5441), failed to create a policy for quality control and use positive controls for each mutation, negative control and a non-template control for the Pharmacogenomics (PGX) assay CYP2C19, CYP4502D6-BC and CYP4502C9 from June 2018 to January 2020 (See D5445), failed to perform and document the comparison of the two methodologies used to perform the microscopic evaluation of Hematology White Blood Cell (WBC) differential at least twice annually from 01/17/19 to 03/23/20 (See D5775), failed to follow Pharmacogenomics manufactures instructions for acceptable specimens and provide patient testing results without expired samples on the instrument from January 2018 thru January 2020 and failed to document each step from media inoculation to organism isolation and identification and who ran each part of the test in Bacteriology for 2 (2018-2020) out of 2 years reviewed (See D5787), and failed to perform all required maintenance on the BD Phoenix Microbiology analyzer since 07/10/18 (See D5429).