Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2092474	02/27/2018
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Genomics Llc Dba Geneus Diagnostics	10750 Hammerly Blvd Ste 120, Houston, TX	

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	Intakes: TX00278069 Complaint TX00278069 was not substantiated. The laboratory was found out of compliance with the CLIA regulations. Immediate jeopardy findings were identified. The conditions not met were: D5300 - 42 C.F.R. 493.1240 Condition: Preanalytic systems; D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director; D6108 - 42 C.F.R. 493.1447 Condition: Laboratories performing high complexity testing; technical supervisor; The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The laboratory voluntarily ceased the practice of receiving respiratory samples at ambient temperature as documented in a letter signed by the chief executive officer on February 2, 2018. Actual exit date was 2/27/2018 when final documentation was received via email at 3:04 PM (Central Time)
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 a review of personnel records and interview of facility personnel it was revealed that the laboratory failed to assess clinical consultant competency and failed to have an established procedure to assess technical consultant competency. Findings were: 1. A review of personnel files found that one of one clinical consultant did not have documentation of competency assessment. 2. There was no procedure available for review for assessing the competency of clinical consultant. 3. Interview of the

	general supervisor on 2/1/2018 at 1640 hours in the office confirmed there were no competency assessment records or procedure for assessing the competence of the clinical consultant.
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 laboratory's College of American Pathologists' proficiency testing records from 2017, review of the laboratory's alternate assessment records from 2017, and staff interview, it was revealed the laboratory failed to have documentation of two annual accuracy assessments for the analytes of Influenza A H1, Influenza A H3, Respiratory Syncytial Virus A, Respiratory Syncytial Virus B, Coronavirus 229E, Coronavirus OC43, Coronavirus NL63, Coronavirus HKU1, Parainfluenza virus 4, Human Bocavirus, Chlamydophila pneumoniae and Mycoplasma pneumoniae. The findings were: 1. A review of the laboratory's College of American Pathologists' proficiency testing records from 2017 revealed the laboratory had enrolled in the Infectious Disease Respiratory Panel for Molecular Multiplex Testing IDR. The program did not include the analytes Influenza A H1, Influenza A H3, Respiratory Syncytial Virus A, Respiratory Syncytial Virus B, Coronavirus 229E, Coronavirus OC43, Coronavirus NL63, Coronavirus HKU1, Parainfluenza virus 4, Human Bocavirus, Chlamydophila pneumoniae and Mycoplasma pneumoniae. 2. A review of the laboratory's alternate assessment records from 2017 revealed the laboratory performed one of two accuracy assessments for Influenza A H1, Influenza A H3, Respiratory Syncytial Virus A, Coronavirus 229E, Coronavirus OC43, Coronavirus NL63, Coronavirus HKU1, Parainfluenza virus 4, Human Bocavirus, Chlamydophila pneumoniae and Mycoplasma pneumoniae. 3. A review of the laboratory's alternate assessment records from 2017 revealed no positive sample for Respiratory Syncytial Virus B was included in the accuracy assessment. 3. The laboratory was asked to provide documentation of the missing accuracy assessments. No documentation was provided. 4. An interview with general supervisor on 1/29/2018 at 1430 hours in the office - after her review of the records- confirmed the findings.
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 a review of laboratory temperature records, quality assurance records, and interview of laboratory personnel, it was revealed that the laboratory did not meet the applicable preanalytic system(s) requirements and failed to monitor and evaluate the

	quality of all preanalytic systems. Findings were: 1. Failure of the laboratory to properly store and preserve all patient specimens (refer to D5311) resulted in the laboratory not being able to ensure the accuracy and reliability of all patient test results. 2. Failure of the laboratory to document the received time for patient samples for Rapid Respiratory Panel testing that were received from outside clinics (D5313) resulted in the laboratory not being able to ensure samples were not tested beyond manufacturer stated stability. 2. Failure of the laboratory to monitor the quality of the preanalytic phase of all testing processes (refer to D5391) caused the laboratory to be unable to identify and correct all preanalytic problems.
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: A. Based on review of the laboratory's policies, review of manufacturer's instructions, review of the laboratory's establishment studies, and staff interview, it was revealed the laboratory failed to have documentation of performing complete preanalytic studies to support the laboratories defined criteria for sample collection and preservation, sample transport, and sample storage for the FDA modified rapid respiratory panel testing using the NxTag Respiratory Pathogen Panel prior to patient testing on 12/19/2016. The findings were: 1. A review of the laboratory Client Services Manual for collection RRP Sample Collection revealed samples would be rejected if "Samples not received within 48 hours." 2. A review of the procedure Intra-Facility Specimen Transport (Procedure 3402 effective 10/02/2017) states: "Specimen Delivery by Transport Specimens received and handled at a location other than the processing laboratory will be transported to the laboratory as follows:" ... "Nasopharyngeal swabs are NOT to be opened or accessioned outside of the laboratory and should be kept in original biohazard bag. Separate specimens based on the following collection/shipping conditions:" "Original Shipment Condition Specimen Collection Time REPACKAGE Specimen Transport Conditions Room Temperature Less than 48hrs Room Temperature Room Temperature Greater than 48hrs 4C Cold Less than 48hrs 4C Cold Greater than 48hrs 4C Frozen Less than 48hrs FROZEN (on ice) Frozen Greater than 48hrs FROZEN (on ice)" 3. A review of the laboratory procedure RRP Specimen Collection (procedure 3501, effective date 12/28 /2016) under the section titled "Policy" revealed the laboratory accepted samples for RRP testing within 48 hours if kept at room temperature or 7 days if refrigerated from the date of collection. "Samples should arrive to Advanced Genomics for testing within 48 hours if kept at room temperature or 7 days if kept in refrigerator storage FROM date of collection." 4. A review of the laboratory procedure NxTag RRP Assay (Procedure 7021, effective date 10/16/17) under the section titled 'SPECIMEN REQUIREMENTS" revealed: "The temperature requirement during transportation is ambient if shipped within 24 hours of collection or on ice if shipped after 24 hours from collection. Specimen is stable at room temperature within 24 hours from collection and refrigerated for up to 7 days after collection in Universal Transport Media." 5. A review of the package insert for the universal transport media utilized by

the laboratory (Puritan UniTranz-RT Transport System HWP UTZ-RT R1 04/16) revealed the laboratory modified the manufacturer-defined storage/shipping temperatures. "Specimens should be placed in the transport medium immediately following collection and promptly transferred to the laboratory for processing. For optimum recovery, specimens should be refrigerated during transport. For long term storage, specimens should be frozen at -70C or colder." 6. A review of the NxTAG Respiratory Pathogen Panel package insert (MLD-051-KPI-001 Rev B April 2017) revealed the laboratory modified the manufacturer-defined storage/shipping temperatures and allowable times for testing after collection: Under Specimen Collection "Specimen Collection and Nucleic Acid Extraction "Specimens can be stored between 2C and 8C for up to 7 days after collection in Universal Transport Media (UTM (Trademark)) or equivalent. If the specimen is not going to be tested within 7 days of collection, then it may be stored at -70C or below for up to 12 months." 7. Furher review of the NxTAG Respiratory Pathogen Panel package insert (MLD-051-KPI-001 Rev B April 2017) revealed the following organism types and subtypes detected by the test and type of genome (RNA or DNA): Under "Intended Use" "NxTAG Respiratory Pathogen Panel is a qualitative test intended for use on the Luminex MAGPIX instrument for the simultaneous detection and identification of nucleic acids from multiple respiratory viruses and bacteria extracted from nasopharyngeal swabs collected from individuals with clinical signs and symptoms of a respiratory tract infection. The organism types and subtypes detected by the test are Influenza A [RNA], Influenza A H1 [RNA], Influenza A H3 [RNA], Influenza B [RNA], Respiratory Syncytial Virus A [RNA], Respiratory Syncytial Virus B [RNA], Coronavirus 229E [RNA], Coronavirus OC43 [RNA], Coronavirus NL63 [RNA], Coronavirus HKU1 [RNA], Human Metapneumovirus [RNA], Rhinovirus /Enterovirus [RNA], Adenovirus [DNA], Parainfluenza virus 1 [RNA], Parainfluenza virus 2 [RNA], Parainfluenza virus 3 [RNA], Parainfluenza virus 4 [RNA], Human Bocavirus [DNA], Chlamydophila pneumoniae [DNA], and Mycoplasma pneumoniae [DNA]." And Under Specimen Collection "Specimen Collection and Nucleic Acid Extraction "NOTE: Standard precautions should be taken with regard to sample collection, handling, and storage prior to extraction (refer to the latest edition of the CLSI MM13 Guideline; and Farkas et al. (1996)). 6. A review of the document CLSI MM13A available to the surveyor revealed the following for transport and storage: During transport and storage, the specimen must not be exposed to conditions that might result in degradation of target nucleic acids. The storage conditions vary depending on specimen type, analyte (RNA or DNA), and/or microorganism being tested. Proper transport and storage conditions must be determined by the assay manufacturer or in the case of "home-brewed" test, by the laboratory. RNA is highly susceptible to degradation and can be more difficult to recover than DNA." 7. A review of the package insert for the universal transport media utilized by the laboratory (Puritan UniTranz-RT Transport System HWP UTZ-RT R1 04/16) revealed the manufacturer did not evaluate the transport media for survival and recovery for 11 of the 20 pathogens in the NxTAG Respiratory Pathogen Panel. The manufacturer did not evaluate the transport media for Influenza B [RNA], Coronavirus 229E [RNA], Coronavirus OC43 [RNA], Coronavirus NL63 [RNA], Coronavirus HKU1 [RNA], Human Metapneumovirus [RNA], Rhinovirus /Enterovirus [RNA], Parainfluenza virus 1 [RNA], Parainfluenza virus 2 [RNA], Parainfluenza virus 4 [RNA], Human Bocavirus [DNA]. Under "PERFORMANCE CHARACTERISTICS" "Test viruses used for evaluation of the transport medium were adenovirus, cytomegalovirus, echovirus type 30, herpes simplex virus type 1, herpes simplex virus type 2, influenza A, parainfluenza 3, respiratory syncytial virus, and varicella-zoster virus. Among bacteria, Chlamydia pneumoniae, Chlamydia trachomatis, Mycoplasma pneumoniae, Mycoplasma hominis, and Ureaplasma

urealyticum were used for testing." And "Caution: Viability of microorganisms in the Puritan UniTranz-RT transport system other than the ones tested here is not known and should be validated by the user." 7. Surveyor observation of samples received by the facility on 1/30/2018 at 1010 hours in the pre-amplification room revealed the facility received nasopharyngeal swabs in Puritan UniTranz-RT Transport media shipped overnight by Fed-Ex at ambient temperature. Patients samples RRP18-00803, RRP18-00804, RRP18-00811, RRP18-00812, RRP18-00813, RRP18-00814, RRP18-00815. 8. A review of the laboratory "RRP Stability Study 04/06/2017" approved by the laboratory director on 4/7/2017 revealed the laboratory's purpose of the study was "extend the time frame from 24-48 hours to possible 72 or 96 hours after collection". The laboratory concluded: "..not all organisms can be detected if the specimen is left at room temperature for longer than 48 hours post collection. Based on this data, Advanced Respiratory cannot extend the expiration of a sample beyond 48 hours post-collection. The criteria for accepting RRP specimens still remains as follows: Specimens are stable at room temperature within 24 hours from collection and at 4C for up to 7 days after collection. Specimens shipped within 24 hours, should be shipped at ambient temperatures. Any specimens shipped after 24 hours of collection, should be shipped refrigerated or on ice." "Stability beyond 48 hours could not be established for Influenza A H1, Respiratory Syncytial Virus A, Parainfluenza virus 1, Parainfluenza virus 2, Parainfluenza virus 4, Coronavirus HKU1, Chlamydophila pneumoniae since none of the patient samples were positive for those organisms during the study." The study did not document: a) Initial (time zero) results. b) Time of collection of specimens and time of receipt of specimens c) The temperature ranges samples were exposed to during shipment - which samples were shipped at "ambient" temperatures - which samples were shipped at "with ice" or refrigerated temperatures d) Definitions of ambient temperature, room temperature, "with ice" temperature and refrigerated temperature acceptable range. e) The acceptability criteria used to evaluate the study results f) Stability studies for 7 of analytes in the panel 9. Further review of the stability study revealed the examples of results which indicated a potential loss in pathogen recovery at laboratory room temperature. a) Influenza A (sample RRP17-00119) showed positive at 24 hours, skipped at 48 hours and negative at 72 hours. b) Coronavirus 229E (sample RRP17-00097) showed positive at 24 hours, invalid at 48 hours. c) Coronavirus OC43 (sample RRP17-00044) showed "NA" at 24 hours, "fail" at 48 hours. d) Human Bocavirus (sample HHRRP17-00021) showed positive at 24 hours, negative at 48 hours. 9. Review of the "Analytical Validation Plan for Rapid Respiratory Panel (RRP) using the NXTAG Respiratory Pathogen Panel Assay (Luminex) and MagPIX Instrumentation" approved by the laboratory director on 2/17/2017 and by the technical supervisor on 5/11/2017 revealed the that in addition to Puritan UniTranz-RT Transport media the laboratory accepted specimens in 5 other types of transport Media: "We accept the following equivalent medias and their associated nasopharyngeal swabs; Becton Dickeinson BD universal Viral Transport System (UVT), Copan UTM Viral Transport Media, Quest VCM, Healthlink Inc UTM, Hary Diagnostics VTM." 9. The laboratory was asked to provide documentation of successful studies which supported the laboratory's specimen storage/preservation, transport, and storage claims to modify the FDA-approved NxTag Respiratory Pathogen Panel for storage of specimens between 2C and 8C for up to 7 days after collection in Puritan UniTranz-RT Transport media as well as studies to evaluate samples sent to the laboratory in different types transport media. No documentation was provided. 10. In an interview of the general supervisor at 1437 hours on 1/31/2018 in the office, she confirmed the above findings. According to the Annual Test Volume & Proficiency Testing Programs Worksheet, the laboratory performs an estimated 54,000 tests annually. Please refer to the RRP Test results statistics 2017 and 2018 alias list for patients tested from 3/1/2017 to 1/29

/2018. B. Based on observation, review of the facility Specimen Rejection Policy RRP (rapid respiratory panel) (number 3602 effective 12/27/2016), Client Services Manual, and interview of facility personnel it was revealed that the laboratory failed to establish a specimen rejection policy based on specimen storage and preservation, conditions for specimen transport, and specimen stability for rapid respiratory panel specimens to be tested at the facility. Findings were: 1. Observation of rapid respiratory panel specimen processing on 1/30/2018 at 10:10 hours in the pre-amplification room revealed the testing personnel date stamping specimens received from outside clients. Observation revealed the testing persons were checking specimen type, container and verbally verifying patient identifiers. 2. In an interview of testing person 2 (as listed on the Laboratory Personnel Report) on 1/30/2018 at 1015 hours she stated that samples were good for 24 hours at room temperature. In an interview on 1/30/2018 at 1015 hours testing person 5 stated that samples were good for 48 hours at room temperature. 3. On 1/30/2018 at 1015 hours surveyor requested the facility specimen rejection policy for RRP. Testing person 2 stated the policy was not posted, but was available to all staff electronically. She accessed policy number 3602 "Specimen Rejection Policy RRP" on the computer in the preamplification room. 4. A review of the facility "Specimen Rejection Policy RRP" (number 3602 effective 12/27/2016) revealed no documentation at the time of the survey of a policy for rejecting samples based on specimen storage and preservation, conditions for specimen transport, and specimen stability. The Specimen Rejection Policy for RRP stated: "All specimens received by this Laboratory will be evaluated for acceptability, as follows: a. Adulterated b. Improperly labeled specimen c. Inappropriate specimen container d. Specimen has arrived out of its container e. Wrong specimen submitted f. Broken specimen container (contamination) g. Insufficient patient information or incomplete or incorrect test request form h. Test order without a specimen i. Specimen without a test order" 5. A review of the Client Services Manual for collection RRP Sample Collection revealed samples would be rejected if "Samples not received within 48 hours." 6. An interview of the general supervisor on 1/30/2018 at 1410 hours in the common area confirmed the above findings. B. Based on direct observations, review of establishment studies, and confirmed in interview, it was revealed the laboratory failed to provide documentation of performing complete preanalytic studies for sample storage, transportation and preservation prior to patient testing on May 5, 2015 for pharmacogenetic (PGX) testing and prior to patient testing in January 2017 for Nutrigenomic testing. The findings included: 1. Direct observation of swabs provided to clients for collection of buccal DNA (deoxyribonucleic acid) for PGX testing revealed the laboratory provides Puritan Sterile Polyester Tipped applicators, reference number 25-806-2PD. 2. Direct observation of swabs provided to clients for collection of buccal DNA (deoxyribonucleic acid) for Nutrigenomic testing revealed the laboratory received Copan 4N6FL00QSwabs, reference 4504C. 3. In an interview of the general supervisor on 1/29/2018 at 1515 hours in the common area she stated that they used the Copan swab for Nutrigenomics. For PGX 99% of the samples are received on the Puritan swabs and 1% are Copan swabs. In addition all swabs were shipped to the laboratory by FedEX at ambient temperatures. 4. A review of the facility procedure "DNA Isolation from Buccal Swabs" (Procedure 7001, effective date 6/15/ 2016) revealed the procedure did not identify the type of acceptable Buccal swab: "SPECIMEN REQUIREMENTS All specimens will come from buccal swabs. Swabs will be collected by client and placed inside a clearly marked envelope, and shipped in a clinical package envelope. All specimens are shipped the lab overnight by FedEx. The courier picks the specimen up and delivers them to the lab each day, Monday through Friday. The temperature requirement during transportation is ambient. Specimen is stable at room temperature for 49 days, refrigerated for 49 days or frozen

for 70 days." 5. A review of the Analytical Validation Plan for DME and SNP OpenArray Genotyping and Copy Number Assays on the QuantStudio 12K Flex Platform for instrument 1 approved by the laboratory director on 12/27/2016, the Analytical Validation Plan for DME and SNP OpenArray Genotyping and Copy Number Assays on the QuantStudio 12K Flex Platform for instrument 2 approved by the laboratory director on 05/04/2015, the March 2015 "Analytical Validation Bridging Study Plan Summary for DME and SNP Open Array Genotyping and Copy Number Variation on the QuantStudio 12K Flex Platform" for instrument 1, approved by the laboratory director on 5/4/2015 and the Analytical Validation Plan for Nutrigenomics 2 (55) Panel SNP Genotyping (OpenArray) on QuantStudion12K Instrument #1" approved by the laboratory director on 5/11/2017 revealed no documentation of swab and/or swab part number used in the validation. 6. A review of the facility validation plans revealed the facility used the MagMax extraction equipment and the protocol MagMax Express-96 DNA Multi-Sample Ultra Kit User Guide. The plans did not identify the extraction kit used. a. A review if the "Analytical Validation Plan for DME and SNP OpenArray Genotyping and Copy Number Assays on the QuantStudio 12K Flex Platform" for instrument 1 approved by the laboratory director on 05/04/2015 listed the MagMax Express-96 DNA Multi-Sample Ultra Kit User Guide under protocols. b. The Analytical Validation Plan for DME and SNP OpenArray Genotyping and Copy Number Assays on the QuantStudio 12K Flex Platform for instrument 2, approved by the laboratory director on 12/27 /2016 listed the MagMax Express-96 DNA Multi-Sample Ultra Kit User Guide under protocols. (A notation on the signature page "The individual supervisor initially responsible for this validation ...departed with this document unsigned. The omission was noted by subsequent personnel after thorough review.") c. The March 2015 "Analytical Validation Bridging Study Plan Summary for DME and SNP Open Array Genotyping and Copy Number Variation on the QuantStudio 12K Flex Platform" for instrument 1 approved by the laboratory director on 5/4/2015 listed the MagMax Express-96 DNA Multi-Sample Ultra Kit User Guide under protocols. 7. In an interview with the general supervisor on 02/01/2018 at 0930 hours she confirmed they had changed the isolation kit from MagMax to Omega Bio-Tek Mag-Bind Blood & Tissue DNA HDQ 96 Kit in March of 2016. She stated the initial validation was done with the MagMax kit. 8. A review of the Thermo Fisher "Pharmacogenomics Experiments APPLICATION GUIDE" (For Research Use Only. Not for use in diagnostic procedures. Publication Number MAN0009612) under "Isolate DNA using the MagMAX (Trademark) DNA Multi-Sample Ultra Kit ", "Required materials not supplied": "One of the following types of buccal swabs, or equivalent buccal swabs with foam tips:" "Puritan (Trademark) PurFlock (Trademark) Ultra Flocked Swabs"; "Fisher Scientific 22-025-192" "Puritan (Trademark) HydraFlock (Trademark) Swabs, standard tip"; "Puritan 25-3306-H" "Sterile Foam Tipped Swabs"; "Puritan 25-1506 1PF" "4N6FLOQSwabs (Trademark), regular tip"; "4473979" 9. A review of the manufacturer's directions "MagMax DNA Multi-Sample Utra Kit (November 28, 2016) revealed Under Sample collection and storage: "Use one of the following polyester swabs with foam tips. Use of cotton or generic polyester swabs may result in lower DNA yields or DNA that contains PCR inhibitors." "Puritan 'Purflock' Ultra Flocked Swabs (Fisher Scientific, Cat. no 22-025-192)" "Puritan 'HydraFlock' Swabs, standard tip (Puritan, Cat. no. 25-3306-H)" "Sterile Foam Tipped Swabs (Puritan, Cat. no. 25-1506 1PF)" "4N6FLOQSwabs, regular tip (Cat. no. 4473979)" A review of the manufacturer's directions "MagMax DNA Multi-Sample Utra Kit (November 28, 2016) revealed Under Sample collection and storage for shipping: "Sample shipping: Shipped dried buccal swabs after sample collection at 25 C or below." 10. A review of the "Pharmacogenomics Copy Number Experiments Best Practices & Troubleshooting Guide" (Revision August 14 2015) revealed: "High DNA yields from

buccal swabs are not needed specifically for copy number testing, but are needed for the PGx workflow overall. For this reason, it is important to take steps to maximize DNA yield, including use of the recommended buccal swab types and swabbing protocol. The CNV analysis portion of the workflow requires using 5 ng/uL of high quality DNA sample stocks. The presence of PCR inhibitors, from food or other contaminants in the sample preparation, can negatively impact copy number call accuracy." "The following buccal swab types are recommended: 4N6FLOQSwabs (Trademark) (p/n 4473979, Life Technologies) PurFlock Ultra Flocked Swab (p/n 22-025-192, Fisher Scientific) HydraFlock Flocked Swab (p/n 25-3306-H, Puritan Medical Products) Sterile Foam Tipped Swabs (Puritan, Cat. no. 25-1506 1PF) The following swab types are not supported: Generic Cotton Generic Polyester" Further review of the "Pharmacogenomics Copy Number Experiments Best Practices & Troubleshooting Guide" page 8, revealed a bar graph showing the mean concentration versus swab and the statement: "Cotton and polyester swab yields drop below 50 ng /uL minimum. Note: Each error bar is constructed using 1 standard error from the mean. N=7" 11. A review of the "Analytical Validation Plan for DME and SNP OpenArray Genotyping and Copy Number Assays on the QuantStudio 12K Flex Platform" for instrument 1 and 2, the "Analytical Validation Bridging Study Plan Summary for DME and SNP Open Array Genotyping and Copy Number Variation on the QuantStudio 12K Flex Platform" for instrument 1 and the Analytical Validation Plan for Nutrigenomics 2 (55) Panel SNP Genotyping (OpenArray) on QuantStudion12K Instrument #1" revealed specimen stability was not part of the validation plan: "Specimen stability will be studied by Advanced Genomics, LLC as required outside this validation. It is expected that throughput and turnaround time will minimize any potential impact by specimen stability for sample analysis and results reporting are real - time exercises and not historical analysis." 12. A review of the facility "Sample Stability Study" approved by the laboratory director on April 6, 2016 revealed the study did not specify the type of swab used or mimic specimen collection, storage or transportation of samples received from outside clinics. "Longevity Study to Extend DNA Buccal Swab Expiry from 21d Post-collection to 49d" "Our standard kit polyester buccal swabs were used to swab five lab personnel. Samples were allowed to air-dry for 24 hours at room temperature before storage in one of three locations: " "1. Room temperature in the lab in the kit sample storage envelopes (indicated RT)" "2. Refrigerated on the side near the front, 4C temperature, with regular traffic (4)" "3. Frozen, on the side door that swings out, -20 C temperature, with regular traffic (-20)" "Based on this data as of 4/6/2016 Advanced Genomics can extend their dry buccal swab specimen expiration from 21 to 49 days post-collection (50 day expiration)" 13. A review of "SAMPLE STABILITY STUDY #2" approved by the laboratory director on May 11, 2017 for Copan swabs (4N6FLOQSwabs ref 4504C) revealed the study did not mimic specimen collection, storage or transportation of samples received from outside clinics. "Our COPAN 4N6FLOQSwab Regular flocked swab with Active Drying system were used to swab five lab personnel. Swabs contain an Active Drying System. Samples were allowed to sit for 24 hours at room temperature before storage in one of three locations." "1. Room temperature in the lab in the kit sample storage envelopes (indicated RT)" "2. Refrigerated on the side near the front, 4C temperature, with regular traffic (4)" "3. Frozen, on the side door that swings out, -20 C temperature, with regular traffic (-20)" "Based on this data, Advanced Genomics can extend their dry buccal swab specimen expiration from 49 days to 70 days post-collection." 14. A review of the FAQ's and material data safety sheet section of the Copan website revealed the COPAN 4N6FLOQSwabs were not for diagnostic use. "Can COPAN Genetics 4N6FLOQSwabs (Trademark) be used for diagnostics? No. 4N6FLOQSwabs (Trademark) Genetics are not intended for diagnostic use." "Intended use: Collection

of samples for forensic investigation." 15. A review of the Copan 4N6FLOQSwabs (RED 4504C) package revealed an acceptable temperature range of 2-30C 16. A review of client instructions for the Copan swab and "Directions for DNA Sample Collection" included in the collection kit revealed no documentation of requiring swabs to dry at room temperature for 24 hours. "Return swab immediately" "Return the swab immediately into the plastic vile and screw lid tight" 17. A review of the document "Sample Stability Evaluation Summary" (no date) revealed a sample stability study was performed at room temperature, 4 to 8C and at outside temperatures for 21 days. The type of swab used was not identified, the outside temperature range was not documented and the study did not support the stability of swabs at outside temperatures for 14 days: "The sample stability assay was conducted to check the integrity of the samples for analysis. 3 different temperature settings for storage were validated: room temperature, refrigerator temperature, and outside temperatures. A total of 3 volunteers were swapped in samples were placed at room temperature (68F to 73F), and outside temperatures (variable) for 21 days. The genotyping, CNV and DNA concentrations results showed consistency with outside temperatures for up to the 7th day, room temperatures up to the 14th day and 4 to 8C temperatures for up to the 21st day." "Sample swabs stored at outside temperatures showed molded or contaminated after the 7th day of collection." "In summary our data show swabs that are kept at room temperature (68F to 73F) and at 4 8C has reproducible results for the validated time-frame." "Therefore, sample stability has been validated as follows: Outside temperatures - samples swabs stable for 14 days Room temperature - sample swab stable for 14 days Refrigerator temperatures (2 - 4C) - sample swab stable for 21 days." 18. A review of the facility Procedure "Specimen Collection" (Procedure 3500, effective date 6/15/2016) for sample collection and transport directions revealed swabs were allowed to air dry for 3-5 minutes, stored in the refrigerator and were to be transported at room temperature. "Place swab back into pouch and into package AFTER the sample is dry. Collect 2-4 swabs and allow for swabs to dry for 3-5 minutes. " Store swabs immediately in the refrigerator until delivery to FedEx." "Special handling o Specimen will be transported at room temperature." 19. A review of the client services manual under PGX sample collection revealed that after collection the directions stated to allow swabs to dry for 5 minutes and ship in FedEx shipping envelope. 20. A review of the "ALL OPEN PGX/ NTG samples" report for all pending samples revealed 43 open PGX panels and 197 NTG (Nutrigenomic) panels pending as of 2/1/2018. (please refer to patient alias list ALL OPEN PGX/ NTG samples) A random sampling of accession and collection dates PGX18-000001 collected 12/07/2017 PGX18-00015 collected 1/11/2018 PGX18-00029 collected 1/17/2018 GFLPGX18-00008 collected 12/22/2017 NUG5518-00116 collected 12/28/2017 NUG5518-00118 collected 12/11 /2017 NUG5518-00111 collected 01/09/2018 NUG5518-00105 collected 01/06/2018 21. In an interview of the testing person 2 (as listed on the Laboratory Personnel Report) on 1/30/2018 at 1030 hours in the laboratory she stated they received PGX samles in FedEx envelopes at ambient temperature and then hold the samples in the refrigerator until they get enough for a batch - need 95 samples for batch. In addition, she stated they try to do at least once a week, so if need to they do 1/2 plate. 22. In an interview of the specimen processor in the receiving area on 2/2/2018 at approximately 0930 hours she stated they received NTG samles in FedEx envelopes at ambient temperatureand and held samples until they receive notification the patient has paid for the test. Once the patient paid, they send the samples to the lab for processing. 23. An interview of the general supervisor on 2/1/2018 at 1500 hours in the common area confirmed the above findings. She stated that the previous manager had performed the studies and after reviewing them, she realized that they would have to be repeated. According to the CMS-116 signed by the laboratory director on 1/29

	/2018 the facility PGX annual test volume is approximately 347,660 tests. Key: CMS-Centers for Medicare & Medicaid Services PGX- Pharmacogenetic testing
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: A. Based on direct observation, review of patient requisitions, test reports, client services manual and confirmed in interview, the laboratory failed to document the received time for patient samples for Rapid Respiratory Panel testing that were received from outside clinics. (random sample of 7 specimens received 1/30/2018) Findings Include: 1. Observation of rapid respiratory panel specimen processing on 1 /30/2018 at 1010 hours in the pre-amplification room revealed that incoming specimens were stamped with the date of receipt but not the time of receipt into the laboratory. The stamping instruments in use in the pre-amplification accessioning area were not capable of recording the time. Patients samples RRP18-00803, RRP18-00804, RRP18-00811, RRP18-00812, RRP18-00813, RRP18-00814, RRP18-00815. 2. Review of tests reports showed time received in the laboratory was not included on the report of test results. Reports RRP18-00803, RRP18-00804, RRP18-00811, RRP18-00812, RRP18-00813, RRP18-00814, RRP18-00815. 3. A review of the Client Services Manual for collection RRP Sample Collection revealed samples would be rejected if "Samples not received within 48 hours." 4. An interview of the general supervisor on 1/30/2018 at 1410 hours in the common area confirmed the above findings. B. Based on interview, review of patient test reports and client service manual instructions, the laboratory failed to document the received date and time for patient samples for Rapid Respiratory Panel testing that were received from outside clinics delivered by Fed-Ex on Saturdays. 1. During an interview of the general supervisor on 1/30/2018 at 1155 hours she stated that specimens collected on Friday were shipped overnight and delivered to a box outside the building on Saturday because the laboratory was closed. An employee would stop by the laboratory on Saturday and remove the specimens from the outside box and place them in the refrigerator. This employee would not date or time stamp the incoming specimens. On Monday, the testing persons would date stamp the specimens as received on Saturday. In addition, the general supervisor admitted that they did not track who or when the employee came in on Saturday to put the respiratory samples in the refrigerator. 2. Review of test reports from the week of 1/29/2018 revealed 43 test reports documented as collected on Friday 1/26/2018 with a received date of Saturday 1/27 /2018 with no received time. PELRRP18-00040 PELRRP18-00041 PELRRP18-00042 PELRRP18-00043 PELRRP18-00044 PELRRP18-00045 PELRRP18-00046 PELRRP18-00047 PELRRP18-00048 PELRRP18-00049 RRP18-00768 RRP18-00769 RRP18-00770 RRP18-00771 RRP18-00772 RRP18-00773 RRP18-00774 RRP18-00775 RRP18-00776 RRP18-00777 RRP18-00778 RRP18-00779 RRP18-00780 RRP18-00782 RRP18-00783 RRP18-00784 RRP18-00785 RRP18-00786 RRP18-00787 RRP18-00788 RRP18-00789 RRP18-00790 RRP18-00791 RRP18-00792 RRP18-00793 RRP18-00794 RRP18-00795 RRP18-00796 RRP18-00797 RRP18-00798 RRP18-00799 RRP18-00800 RRP18-00801 3. Review of test reports from the week of 1/29/2018 revealed 1 test report documented as colleted on Thursday 1/25/2018 with a received date of Saturday 1/27/2018 with no received time. RRP18-00781 4. A review of the Client Services Manual for collection RRP Sample Collection revealed samples would be rejected if "Samples not received

	within 48 hours." 5. An interview of the general supervisor on 1/30/2018 at 1410 hours in the common area confirmed the above findings.
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 review of the laboratory's quality assessment plan(procedure 5800), and staff interview, it was revealed the laboratory's quality assessment plan failed to identify and correct issues in pre-analytic systems. The findings were: 1. The laboratory's quality assessment ("Quality Assessment", procedure 5800, effective 08 /15/2016) plan failed to identify and correct that the laboratory failed to have documentions of performing pre-analytic studies to support its sample stability claims (refer to D5311). 2. The laboratory's quality assessment ("Quality Assessment", procedure 5800, effective 08/15/2016) plan failed to identify and correct that the laboratory failed to document the time of receipt for Rapid Respiratory Panel testing samples. (refer to 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 record review, direct observation and interview with staff, the laboratory failed to ensure the requirements under analytic systems were met as evidenced by: 1. The laboratory failed to document the room temperature of the preamplification room used for Rapid Respiratory Panel testing and room temperature and humidity of the postamplification room used for Rapid Respiratory Panel testing. (refer to D5413) 2. The laboratory failed to have documentation of ensuring expired reagents were not used for patient testing. (refer to D5417) 3. The laboratory the laboratory failed to have documentation of complete establishment studies for 2 of 2 test systems prior to beginning patient testing. (refer to D5423) 4. The laboratory failed to have documentation of performing a negative external control for the NxTAG RRP Assay each day of patient testing for testing days between December 19, 2016 and January 30, 2018. (refer to D5447) 5. The laboratory failed to perform comparison studies for 2 QuantStudio 12 Flex analyzers used for CNV (Copy number variation) for PGX testing twice per year in 2016 or 2017. (refer to D4775) 6. The laboratory failed to have documentation of performing corrective actions when the temperature and humidity values listed exceeded the laboratory's defined acceptability limits. (refer to D5785)

D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation, review of manufacturer's operating manuals, facility records and interview of laboratory personnel it was revealed that the laboratory failed to document the room temperature of the preamplification room used for Rapid Respiratory Panel testing and room temperature and humidity of the postamplification room used for Rapid Respiratory Panel testing. Findings were: 1. During a tour of the facility, it was observed that there was no environmental charts in the preamplification or postamplification rooms used for Rapid Respiratory Panel testing. 2. A review of the instruments and sampling of supplies in the pre and post amplification rooms revealed the following for storage: Pre-amplification QIAamp MinElute Virus Spin Kit (ref 57704) Store at 15-20C- 11 kits Applied Bioscience PK buffer (ref 448911) Store at 15-25C- 12 bottles Post -amplification Luminix Magpix instrument: Luminix MAGPIX Installation and Hardware User Manual documentation revealed that the manufacturer stated: Operating temperature of 15C to 35C (59F to 95F) Operating relative humidity of 20% to 80%, noncondensing Invitrogen e-gel 48 (ref 6800804); 15-25C- 2 boxes 3. The facility was asked to provide environmental records for the pre and post amplification rooms used for Rapid Respiratory Panel testing. No documentation was provided. 4. A review of the facility test volume documentation revealed the facility performed approximately 54000 tests annually. 5. An interview of the of testing person 2 (as listed on the Laboratory Personnel Report) on 1/30/2018 at 1030 hours in the preamplification room she confirmed the above findings. She stated that they took the temp in the PGX preamplification room because it was on the same thermostat. 6. An interview with the general supervisor on 1/30/2018 at 1410 hours in the common area confirmed the above findings.
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 review of the laboratory's quality control records from October 2017, November 2017, December 2017 and January 2018, review of patient test records, and staff interview, it was revealed the laboratory failed to have documentation of ensuring expired reagents were not used for patient testing. The findings were: 1. A review of the laboratory's quality control records from October 2017, November 2017, December 2017, and January 2018 revealed the laboratory performed testing utilizing the following expired test plates: Date Assay Expiration date 10/20 Psych Openarray

	06/24/2017 11/07 TaqMan Custom 11/04/2017 11/18 TaqMan Custom 11/18/2017 12 /01 TaqMan Custom 11/04/2017 12/13 TaqMan Custom 11/04/2017 12/19 TaqMan Custom 11/04/2017 01/02 TaqMan Custom 11/04/2017 01/12 TaqMan Custom 11/04 /2017 01/19 TaqMan Custom 11/04/2017 01/25 TaqMan Custom 11/04/2017 2. A review of patient test records from October 2017, November 2017, December 2017 and January 2018 revealed the following patients whose samples were testing utilizing the expired test plates: Date Specimen ID 10/20 PHH17-00525 GFLPGX17-00015 GFLPGX17-00016 PHH17-00511 GFLPGX17-00017 GFLPGX17-00018 GFLPGX17-00019 GFLPGX17-00020 6551 6751 11/07 NUG5517-02668 11/18 NUG5517-02757 NUG5517-02774 NUG5517-02798 NUG5517-02812 NUG5517-02822 NUG5517-02824 12/01 NUG5517-02893 NUG5517-02939 NUG5517-02969 12/13 NUG5517-03028 NUG5517-03052 12/19 NUG5517-03103 01/02 NUG5517-03193 NUG5517-03194 NUG5517-03195 01/12 NUG5517-03251 NUG5518-00004 NUG5518-00007 01/19 NUG5518-00024 01/25 NUG5518-00064 NUG5518-00073 3. An interview with the general supervisor on 02/01/2018 at 1545 hours in the common area revealed the laboratory was aware the test plates were expired. She stated quality control samples as well as previously tested samples were tested on the plates with each run to determine if they were functioning properly. She add the laboratory owner and laboratory director instructed testing personnel to use the expired plates for testing because they were too expensive to throw out. This confirmed the findings.
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: A. Based on review of the CLIA complexity database on the FDA website, laboratory's test menu, review of the laboratory's establishment studies performed on its modified FDA-approved rapid respiratory panel testing using the NxTag Respiratory Pathogen Panel, and staff interview, it was revealed the laboratory failed to have documentation of complete studies prior to patient testing on December 19, 2016. The findings were: 1. A review of the CLIA complexity database on the FDA website revealed that the Luminix NxTag Respiratory Pathogen Panel was a high complexity FDA-approved test on the MAGPIX only with bioMrieux NucliSENS easyMag for Nucleic acid extraction. 2. A review of the review of the NxTAG Respiratory Pathogen Panel package insert (MLD-051-KPI-001 Rev B April 2017) revealed the laboratory modified the manufacturer-defined storage/shipping temperatures and allowable times for testing after collection: Under Specimen Collection "Specimen Collection and Nucleic Acid Extraction "Specimens can be stored between 2C and 8C for up to 7 days after collection in Universal Transport Media (UTM (Trademark)) or equivalent. If the specimen is not going to be tested

within 7 days of collection, then it may be stored at -70C or below for up to 12 months."(refer to D5311-A) 3. A review of the "Analytical Validation Summary for the Rapid Respiratory Panel (RRP) using the NxTAG Respiratory Pathogen Panel Assay (Luminex) and MagPIX Instrumentation" revealed the laboratory modified the manufacturer defined extraction method for nasopharyngeal swabs by using the Qiagen QIAmp MinElute Virus Spin Kit for nucleic extraction. 4. A review of the Qiagen QIAmp MinElute Virus Spin Kit package insert (3rd edition, April 2010) revealed it was " For simultaneous purification of viral RNA and DNA from plasma, serum, and cell-free body fluids." 5. A review of the "Analytical Validation Plan for the Rapid Respiratory Panel (RRP) using the NxTAG Respiratory Pathogen Panel Assay (Luminex) and MagPIX Instrumentation" revealed: a) "Reagent stability will not be tested as a part of this validation but given the expected sample throughput, it is highly improbable that reagents will be used near end of life." b) "Sample stability will be studied by Advance Respiratory testing as required outside this validation) c) Performance characteristics of the Modified FDA approved test system were copied from the FDA submission of Luminix NxTag Respiratory Pathogen Panel on the MAGPIX with bioMrieux NucliSENS easyMag for Nucleic acid extraction. d) Limit of Detection (LOD) of the Modified FDA approved test system were copied from the FDA submission of Luminix NxTag Respiratory Pathogen Panel on the MAGPIX with bioMrieux NucliSENS easyMag for Nucleic acid extraction. 6. A review of the "Analytical Summary Plan for the Rapid Respiratory Panel (RRP) using the NxTAG Respiratory Pathogen Panel Assay (Luminex) and MagPIX Instrumentation" revealed: a) "Cutoff determination of both MFI and MDD thresholds were provided for each target by Luminex FDA acceptance documents." b) "Reference range" "See Appendix E page 66" was the location of the FDA submission of Luminix NxTag Respiratory Pathogen Panel on the MAGPIX with bioMrieux NucliSENS easyMag for Nucleic acid extraction. c) "Shipping and Storage Stability" "See Appendix E-page 44" w as the location of the FDA submission of Luminix NxTag Respiratory Pathogen Panel on the MAGPIX with bioMrieux NucliSENS easyMag for Nucleic acid extraction. d) Limit of Detection (LOD) of the Modified FDA approved test system were copied from the FDA submission of Luminix NxTag Respiratory Pathogen Panel on the MAGPIX with bioMrieux NucliSENS easyMag for Nucleic acid extraction. 7. A review of the "Analytical Summary Plan for the Rapid Respiratory Panel (RRP) using the NxTAG Respiratory Pathogen Panel Assay (Luminex) and MagPIX Instrumentation" revealed: a) "Cutoff determination of both MFI and MDD thresholds were provided for each target by Luminex FDA acceptance documents." b) "Reference range" "See Appendix E page 66" was the location of the FDA submission of Luminix NxTag Respiratory Pathogen Panel on the MAGPIX with bioMrieux NucliSENS easyMag for Nucleic acid extraction. c) "Shipping and Storage Stability" "See Appendix E-page 44" was the location of the FDA submission of Luminix NxTag Respiratory Pathogen Panel on the MAGPIX with bioMrieux NucliSENS easyMag for Nucleic acid extraction. d) "Detection Limit" "This laboratory does not quantitative respiratory samples, therefore limit of detection validation is deemed unnecessary for this report. Instead, herein, we reference the FDA submission from Luminex for the limit of detection information, where the only difference from our LDT testing is the isolation method." e) "Analytical Reactivity" "See Appendix E - page 25" was the location of the FDA submission of Luminix NxTag Respiratory Pathogen Panel on the MAGPIX with bioMrieux NucliSENS easyMag for Nucleic acid extraction. f) "Analytical Specificity" "See Appendix E - page 34" was the location of the FDA submission of Luminix NxTag Respiratory Pathogen Panel on the MAGPIX with bioMrieux NucliSENS easyMag for Nucleic acid extraction. g) "Potentially Interfering Substances" "See Appendix E - page 40" was the location of the FDA submission of Luminix NxTag Respiratory Pathogen Panel on the MAGPIX

with bioMrieux NucliSENS easyMag for Nucleic acid extraction. h) "Carryover" "See Appendix E - page 43" was the location of the FDA submission of Luminix NxTag Respiratory Pathogen Panel on the MAGPIX with bioMrieux NucliSENS easyMag for Nucleic acid extraction. 8. The "Analytical Validation Summary for the Rapid Respiratory Panel (RRP) using the NxTAG Respiratory Pathogen Panel Assay (Luminex) and MagPIX Instrumentation" revealed the laboratory failed to have documentation of performing the following required establishment studies: a) Complete preanalytic studies to include (refer to D5311): - sample storage /preservation - sample transport - sample stability b) sensitivity c) specificity d) interfering substances/ inhibition studies e) carryover 9. Further review of the "Analytical Validation Summary for the Rapid Respiratory Panel (RRP) using the NxTAG Respiratory Pathogen Panel Assay (Luminex) and MagPIX Instrumentation" revealed the failed to have documentation of approval and acceptance prior to patient testing on December 19, 2016. a. The validation was approved by the laboratory director on 02/17/2017 b. The validation was approved by the technical supervisor on 05/11/2017 9. The laboratory was asked to provide documentation of performing the complete establishment studies to ensure patient results were accurate for the modified FDA-approved assay. No documentation was provided. 10. Interview with the general supervisor on 1/31/2018 at 0935 hours in the office revealed the laboratory was not aware that by modifying the FDA-approved assay extraction method, they would have to perform full establishment studies. In addition, she stated she was not aware the QIAmp kit was not designed for nasopharyngeal specimens. 11. In an interview of the general supervisor at 1437 hours on 1/31/2018 in the office, she confirmed the preanalytic studies that were performed did not support their stability claims. The facility stated patient testing on 12/19/2016 date. According to the Annual Test Volume & Proficiency Testing Programs Worksheet, the laboratory performs an estimated 54,000 tests annually. Please refer to the RRP Test results statistics 2017 and 2018 alias list for patients tested from 3/1/2017 to 1/29/2018. B. Based on a review of test menu, performance verification documentation and interview, the laboratory failed to perform complete establishment studies prior to patient testing on May 5, 2015 for laboratory developed Pharmacogenetic testing: Qualitative Genotyping and Quantitative Copy Number. Findings were: 1. A review of the "Analytical Validation Bridging Study Plan Summary for DME and SNP Open Array Genotyping and Copy Number Variation on the QuantStudio 12K Flex Platform" and the " Summary of DME and SNP Open Array Genotyping and Copy Number Variation on the QuantStudio 12K Flex Platform" revealed that the facility: a. Failed to specify the type of swabs used in the establishment study. (cross refer to D5311) b. Failed to perform studies to determine specimen storage and preservation conditions prior to patient testing. (cross refer to D5311) c. Failed to perform studies to determine specimen transport conditions prior to patient testing. (cross refer to D5311) d. Failed to perform studies to determine specimen stability prior to patient testing. (cross refer to D5311) e. Failed to perform studies to determine reagent (buffer) stability. f. Failed to perform studies of interfering substances. g. Failed to perform validations studies on the Omega Bio-Tek Mag-Bind Blood & Tissue DNA HDQ 96 Kit put into use in March 2016. 2. A review of the March 2015 "Analytical Validation Bridging Study Plan Summary for DME and SNP Open Array Genotyping and Copy Number Variation on the QuantStudio 12K Flex Platform" approved by the laboratory director on May 4, 2015 revealed reagent stability and specimen stability were not part of the validation plan: "Reagent stability will not be tested as part of this validation but given the expected sample throughput, it is highly improbable that reagents will be used in your end-of-life. Procedures will be in place to ensure expiration dates online or examined before using them for routine testing." "Specimen stability will be studied by Advanced Genomics, LLC as required outside this

	validation. It is expected that throughput and turnaround time will minimize any potential impact by specimen stability for sample analysis and results reporting are real - time exercises and not historical analysis." 3. A review of the "Pharmacogenomics Copy Number Experiments Best Practices & Troubleshooting Guide" (Revision August 14 2015) revealed: "Effect of PCR inhibitors" "PCR inhibitors are present in the food we eat and can be carried over during the sample preparation process. Furthermore, PCR inhibitors from the purification (such as alcohols, phenols, and salts) can make their way into the final DNA sample solution. During the PCR process, these inhibitors can delay amplification and/or distort CT values, as well as reduce the dye fluorescence. Since copy number values are derived from an exponential function of the difference between the FAM Target CT and the VIC Target CT (CT), small deviations in the CT can lead to inaccurate or ambiguous copy number values. The figures below illustrate a drastic example where food carried over from swab sample B10 delayed the VIC target 's CT more than the FAM CT (figure 4c). Compared to uninhibited sample B09, the VIC amplification curve is shallower for sample B10. This is indicative of PCR inhibition and resulted in an incorrect copy number of 7, whereas the sample is known to have 2 copies for this gene." 4. The laboratory was asked to provide documentation of the missing portions of the establishment study. No documentation was provided. 5. In an interview with the general supervisor on 02/01/2018 at 1500 hours she confirmed the swab stability studies had not been completed prior to patient testing on July 19, 2016. She stated the studies had been done in April 2016 and May 2017. (cross- refer to D5311) 6. In an interview with the general supervisor on 02/01/2018 at 0930 hours she confirmed they had changed the isolation kit from MagMax to Omega Bio-Tek Mag-Bind Blood & Tissue DNA HDQ 96 Kit in March of 2016. She stated the initial validation was done with the MagMax kit. According to the CMS-116 signed by the laboratory director on 1/29/2018 the facility PGX annual test volume is approximately 347,660 tests. Key: CMS- Centers for Medicare & Medicaid Services PGX- Pharmacogenetic testing
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: A. Based on review of the laboratory's quality control policies and procedures, manufacturer package inserts, quality control records, patient records, and confirmed in interview, the laboratory failed to have documentation of performing a negative external control for the NxTAG RRP Assay each day of patient testing for testing days between December 19, 2016 and January 30, 2018. The finding were: 1. Review of the RRP Quality Control Guidelines (Policy 5902 Effective date 02/20/2017) states: "Perform controls per SOP #7021 NxTAG RRP Assay Protocol." and "TO ACCEPT A RUN:" "Two of the three controls (NEC, NTC and QC POS) must read within the expected value. Internal control should have at least the following: final MFI cutoff of 100 and final MDD cutoff of 80." 2. A review of the NxTag RRP Assay (Policy 7021 Effective date 10/16/2017) states: "PREPARATION OF STANDARDS For proper confidence in patient results, a run maximum of 93 patients or one full test kit (96 tests) will include a known control, a negative control and a negative extract

control. Types of known controls used are a) Zeptometrix positive controls formulated with purified, intact virus particles and bacterial cells in a purified protein matrix to mimic clinical specimen, b) patient specimens that have been previously tested and verified as positives for specific analytes OR c) previously run proficiency test specimens. The positive control will result in positive for at least one known pathogen. The negative template control (NTC) will consist of water which will result in negative for all pathogens on panel. The negative extract control (NEC) consists of unused Universal Transport Media which has been taken through the extraction/ purification steps. The negative extract control will result in negative for all pathogens on panel except the spike in. Control specimens are tested in the same manner and by the same personnel as patient samples. Purchased controls are utilized per manufacturer's instructions." 3. A review of the NxTAG Respiratory Pathogen Panel package insert (MLD-051-KPI-001 Rev B April 2017) revealed the following: "Internal Control - Bacteriophage MS2 is the internal control for the assay. This internal positive control is added to each specimen prior to extraction. This internal control allows the user to ascertain whether the assay is functioning properly. Failure to detect the MS2 control indicates a failure at either the extraction step, or the reverse-transcription step, or the PCR step, and may be indicative of the presence of amplification inhibitors, which can lead to false negative results. Negative Amplification Control (No Template Control (NTC)) - The negative amplification control is RNase-free water. Negative Extraction Control (NEC) - The negative extraction control is the sample collection media that has undergone the entire assay procedure, starting from extraction. External Controls - Good laboratory practice recommends running external positive and negative controls regularly. External controls should be used in accordance with local, state, federal accrediting organizations, as applicable." and "Please follow your own institutional or CLSI guidelines for run and QC controls." 4. Review of quality control records December 2017 to January 30, 2018 revealed that the laboratory performed quality control using a previously run patient sample as a positive control (cross refer to D5447-B), a NTC control, a NEC control and an internal control. There was no documentation of a negative external control. 5. In an interview of the general supervisor at 1310 hours on 1/30/2018 in the office, she confirmed that they did not include a negative control with each sample run or day of testing. According to the Annual Test Volume & Proficiency Testing Programs Worksheet, the laboratory performs an estimated 54,000 tests annually. Please refer to the RRP Test results statistics 2017 and 2018 alias list for patients tested from 3/1/2017 to 1/29/2018. B. Based on review of the laboratory's quality control policies and procedures, quality control records, NxTAG RRP Assay manufacturer package inserts, patient records, and confirmed in interview, the laboratory failed to have documentation of using a positive external control covering each analyte with established reactivity each day of patient testing for testing days between 1/12/2018 and 1/29/2018 (random sampling). Findings were: 1. A review of the NxTag RRP Assay (Policy 7021 Effective date 10/16/2017) states: "PREPARATION OF STANDARDS For proper confidence in patient results, a run maximum of 93 patients or one full test kit (96 tests) will include a known control, a negative control and a negative extract control. Types of known controls used are a) Zeptometrix positive controls formulated with purified, intact virus particles and bacterial cells in a purified protein matrix to mimic clinical specimen, b) patient specimens that have been previously tested and verified as positives for specific analytes OR c) previously run proficiency test specimens. The positive control will result in positive for at least one known pathogen. The negative template control (NTC) will consist of water which will result in negative for all pathogens on panel. The negative extract control (NEC) consists of unused Universal Transport Media which has been taken through the extraction/ purification steps. The negative extract

control will result in negative for all pathogens on panel except the spike in. Control specimens are tested in the same manner and by the same personnel as patient samples. Purchased controls are utilized per manufacturer's instructions." 2. A review of the NxTAG Respiratory Pathogen Panel package insert (MLD-051-KPI-001 Rev B April 2017) revealed the following: "Intended Use: NxTAG Respiratory Pathogen Panel is a qualitative test intended for use on the Luminex MAGPIX instrument for the simultaneous detection and identification of nucleic acids from multiple respiratory viruses and bacteria extracted from nasopharyngeal swabs collected from individuals with clinical signs and symptoms of a respiratory tract infection. The organism types and subtypes detected by the test are Influenza A, Influenza A H1, Influenza A H3, Influenza B, Respiratory Syncytial Virus A, Respiratory Syncytial Virus B, Coronavirus 229E, Coronavirus OC43, Coronavirus NL63, Coronavirus HKU1, Human Metapneumovirus, Rhinovirus/Enterovirus, Adenovirus, Parainfluenza virus 1, Parainfluenza virus 2, Parainfluenza virus 3, Parainfluenza virus 4, Human Bocavirus, Chlamydophila pneumoniae, and Mycoplasma pneumoniae." 3. A random review of 11 Batch runs from 1/12/2018 to 1/29/2018 revealed the facility was using previously tested patient samples (extracted residual patient samples) that were not independently verified. In addition, the positive patient samples selected for quality control (QC) were positive for 1 or 2 of 20 of the analytes in the panel. 1/12/2018 Batch 232 Positive Patient QC sample positive for RSV-B and negative for the other 19 analytes 1/15/2018 Batch 233 Positive Patient QC (RRP18-00335 reported 1/13/2018) sample positive for RSV-B and negative for the other 19 analytes. 1/17/2018 Batch 234 Positive Patient QC (RRP18-00324 reported 1/13 /2018) sample positive for Coronavirus OC43 and negative for the other 19 analytes. 1 /18/2018 Batch 235 Positive Patient QC (RRP18-00402 reported 1/17/2018) sample positive for Influenza A H3(includes Influenza A) and negative for the other 18 analytes. 1/19/2018 Batch 236 Positive Patient QC (RRP18-00455 reported 1/18 /2018) sample positive for Rhinovirus/Enterovirus and negative for the other 19 analytes. 1/22/2018 Batch 237 Positive Patient QC (RRP18-00495 reported 1/24 /2018, tested 1/19/2018) sample positive for Rhinovirus/Enterovirus and negative for the other 19 analytes. 1/23/2018 Batch 238 Positive Patient QC (RRP18-00566 reported 1/22/2018) sample positive for Metapneumovirus and negative for the other 19 analytes. 1/24/2018 Batch 239 Positive Patient QC (RRP18-00605 reported 1/23 /2018) sample positive for Rhinovirus/Enterovirus and negative for the other 19 analytes. 1/25/2018 Batch 240 Positive Patient QC (RRP18-00640 reported 1/24 /2018) sample positive for Influenza B and negative for the other 19 analytes. 1/26 /2018 Batch 241 Positive Patient QC (RRP18-00696 reported 1/25/2018) sample positive for Influenza B and negative for the other 19 analytes. 1/29/2018 Batch 242 Positive Patient QC (RRP18-00740 reported 1/26/2018) sample positive for Influenza A H3(includes Influenza A) and negative for the other 18 analytes. 4. Further review of Batch run sheets (document #AG5002) revealed no documentation of what positive control was utilized for 6 of 6 batch runs. In addition, for 4 of 6 batch runs there was no documentation of the reaction of the positive control. (note: The second page of the batch run where QC was documented was missing for 5 runs- Batches 232, 233, 234, 235, 241) Batch 236- positive control area blank Batch 237- positive control area filled with a check mark Batch 239- positive control area filled with a check mark Batch 242- positive control area filled with a check mark 5. The laboratory was asked to provide documentation that the patient samples utilized as QC were independently verified for reactivity to the analyte. No documentation was provided. 6. In an interview of testing person 5 (as listed on the Laboratory Personnel Report) on 1/30 /2018 at 1053 hours in the laboratory she stated that the positive control was from a patient from the previous week- it was already extracted. 7. In an interview of the general supervisor on 1/30/2018 at 1410 hours in the office she confirmed the positive

	patient samples used as controls were not independently verified and were previously extracted. 8. In an interview of the technical supervisor on 1/29/2018 at 1455 hours she stated she was not aware the laboratory stopped using the Zeptometrix positive controls. According to the Annual Test Volume & Proficiency Testing Programs Worksheet, the laboratory performs an estimated 54,000 tests annually. Please refer to the RRP Test results statistics 2017 and 2018 alias list for patients tested from 3/1 /2017 to 1/29/2018. Key: RRP: Rapid Respiratory panel RSV-B : Respiratory syncytial virus B
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 review of facility procedures, lack of documentation and confirmed in interview the laboratory failed to perform comparison studies for 2 QuantStudio 12 Flex analyzers used for CNV (Copy number variation) for PGX testing twice per year in 2016 or 2017. Findings were: 1. A review of procedures revealed the facility had a procedure "Correlation Study" (Procedure 6101, effective 7/20/2016). "The performance of correlation testing is a part of good laboratory practice between two or more similar instruments testing the same Single Nucleotide Polymorphisms (SNP's)." 2. The facility was requested to provide documentation of performing twice annual comparison studies for CNV (Copy number variation) for PGX testing in 2016 and 2017. No documentation was provided. 3. An interview of testing person 2 (as listed on the Laboratory Personnel Report) on 2/1/2018 at 1020 hours in the post amplification room she stated they "sometimes swap instruments." 4. An interview of the general supervisor on 02/02/2018 at 1100 hours she confirmed the above findings. Key: PGX- Pharmacogenomics
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of the laboratory's environmental monitoring records from January 2017 to January 2018, and staff interview, it was revealed the laboratory failed to have documentation of performing corrective actions when the values listed exceeded the laboratory's defined acceptability limits. The findings were: 1. A review of the laboratory's environmental monitoring records from January 2017 to January 2018 revealed the laboratory defined the following limits for temperatures and humidity: Lab Humidity 10 - 80% Lab #2 Temperature 59 - 86F Freezer 1 Temperature -15 to -20C Freezer 2 Temperature -15 to -20C 2. Further review of the laboratory's environmental monitoring records revealed the following days where the documented

	temperature or humidity levels were outside the laboratory's defined acceptability limits: Date Monitor Temp/Humidity 01/03/17 Lab 2 Temp 55F 01/04/17 Lab 2 Temp 55F 01/05/17 Lab 2 Temp 55F 01/23/17 Lab 2 Temp 57F 01/27/17 Lab Humidity 81% 01/30/17 Lab 2 Temp 57F 03/06/17 Freezer 2 Temp -20.3C 03/29/17 Freezer 1 Temp -21.4C 07/14/17 Freezer 2 Temp -20.3C 07/27/17 Freezer 2 Temp -20.1C 07/31 /17 Freezer 2 Temp -20.5C 11/08/17 Freezer 2 Temp -20.1C 12/06/17 Freezer 1 Temp -20.3C 12/28/17 Freezer 1 Temp -20.6C 01/30/18 Freezer 1 Temp -14.3C 01/31/18 Freezer 1 Temp -14.3C 3. The laboratory was asked to provide documentation of performing actions to correct the identified environmental records documented outside the laboratory's acceptable limits. No documentation was provided. 4. An interview with the general supervisor on 02/01/2018 at 1505 hours in the common area - after her review of the records- confirmed the findings.
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 review of the laboratory's quality assessment plan (procedure 5800), and staff interview, it was revealed the laboratory's quality assessment plan failed to identify and correct issues in analytic systems. The findings were: 1. The laboratory's quality assessment plan ("Quality Assessment", procedure 5800, effective 08/15 /2016) failed to identify and correct that the laboratory failed to have documentation of ensuring expired reagents were not used for patient testing. (refer to D5417) 2. The laboratory's quality assessment plan ("Quality Assessment", procedure 5800, effective 08/15/2016) failed to identify and correct that the laboratory failed to have documentation of complete establishment studies prior to patient testing on December 19, 2016 on its modified FDA-approved rapid respiratory panel testing using the NxTag Respiratory Pathogen Panel. (refer to D5423-A) 3. The laboratory's quality assessment plan ("Quality Assessment", procedure 5800, effective 08/15/2016) failed to identify and correct that the laboratory failed to have documentation of complete establishment studies prior to patient testing on May 5, 2015 for its laboratory developed pharmacogenetic testing. (refer to D5423-B) 4. The laboratory's quality assessment plan ("Quality Assessment", procedure 5800, effective 08/15/2016) failed to identify and correct that the laboratory failed to have documentation of performing a negative external control for the NxTAG RRP Assay each day of patient testing for testing days between December 19, 2016 and January 30, 2018. (D5447) 5. The laboratory's quality assessment plan ("Quality Assessment", procedure 5800, effective 08/15/2016) failed to identify and correct that the laboratory failed to perform comparison studies for 2 QuantStudio 12 Flex analyzers used for CNV (Copy number variation) for PGX testing twice per year in 2016 or 2017. (refer to D5775) 6. The laboratory's quality assessment plan ("Quality Assessment", procedure 5800, effective 08/15/2016) failed to identify and correct that the laboratory failed to have documentation of performing corrective actions when the temperature and humidity values listed exceeded the laboratory's defined acceptability limits. (refer to D5785)
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 review of the laboratory's records and staff interview, it was revealed the laboratory director failed to provide overall management for the laboratory. (refer to D6086, D6093, D6102)
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on review of the laboratory's establishment studies for the FDA modified rapid respiratory panel testing using the NxTag Respiratory Pathogen Panel, the laboratory developed Pharmocogenetic testing using the QuantStudio 12 Flex analyzers, and staff interview, it was revealed the laboratory director failed to have ensure the studies were complete prior to performing patient testing (refer to D5423).
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 quality control records for the NxTAG RRP Assay and interview, the laboratory director failed to ensure that the quality control programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occurred. Please see D5447- A, B.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on a review of personnel records, policies and procedures and interview of facility personnel the laboratory director failed to ensure that prior to testing patient

	specimens 4 of 5 testing personnel demonstrated they could perform high complexity testing and failed to document authorization to perform testing. Findings were: 1. Review of personnel records found no written authorization by the laboratory director for 4 of 5 testing personnel (Testing persons 2-5 as listed on the Laboratory Personnel Report) to begin patient testing. Testing person 2 Hired 3/17/2015. No documentation that training records and education records were approved by the laboratory director or date he authorized patient testing to begin. Testing person 3 Hired 2/03/2016 No documentation that training records and education records were approved by the laboratory director or date he authorized patient testing to begin. Testing person 4 Hired 09/11/2015 No documentation that training records and education records were approved by the laboratory director or date he authorized patient testing to begin. Retraining performed 10/5/2017. Competency Performed 11/09/2017. No documentation that training records were approved by the laboratory director or date he authorized patient testing to begin. Testing person 5 Hired 07/17/2017. Training documented 09/03/2017. No competency evaluations. No documentation that training records and education records were approved by the laboratory director or date he authorized patient testing to begin. 2. The laboratory was asked to provide documentation that the laboratory director reviewed education and training records and approved testing persons prior to testing patient samples for the PGX and Respiratory Panel testing performed. No documentation was provided. 2. Interview of the general supervisor on 02/01/2018 at 1640 hours in the office confirmed the above findings. She stated those duties had been delegated to the technical supervisor and general supervisor. Key: PGX: Pharmacogenetic
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory records, manufacturer instructions, and confirmed in interview, the technical supervisor failed to provide technical oversight of the laboratory (refer to D6115, D6117, D6120, D6127, D6128).
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu, review of the laboratory's establishment studies, and staff interview, it was revealed the technical supervisor failed to ensure studies were complete in order to provide quality results. The findings were: 1. The technical supervisor failed to ensure establishment studies were complete for the FDA modified rapid respiratory panel testing using the NxTag Respiratory Pathogen Panel.(refer to D5423A). 2. The technical supervisor failed to ensure establishment studies were complete for pharmacogenetic testing. (refer to D5423B).

D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control plan, review of the laboratory's quality control records, and staff interview, it was revealed the technical supervisor failed to establish and ensure a quality control plan was followed for the NxTAG RRP Assay. The findings were: 1. The technical supervisor failed to ensure the laboratory's quality control plan could detect immediate errors (refer to D5447-A). 2. The technical supervisor failed to ensure the laboratory's quality control plan was followed to ensure quality control material was verified prior to being placed into use (refer to D5447-B).
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of the technical supervisor performing competency assessments for testing personnel performing rapid respiratory panels and pharmacogenetic testing. The findings were: 1. A review of the laboratory's personnel records revealed 1 of 1 testing persons with semi-annual competency assessments for rapid respiratory panels and pharmacogenetic testing, the assessments were performed by the general supervisor not by the technical supervisor: Testing personnel 4 2016 semi-annual competency assessment performed by the general supervisor 2. In an interview of the technical supervisor on 1/31/2018 at 0930 hours in the office she stated "We don't do that" when asked if the technical supervisor performed the competency assessments. In addition she stated that she delegated that duty to the general supervisor. 3. An interview with the general supervisor on 02/1/2018 at 1640 hours in the office - after her review of the records- confirmed the findings.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

	This STANDARD is not met as evidenced by: Based on a review of the laboratory's personnel records and interview of facility personnel, the technical supervisor failed to document semiannual competency evaluations during the first year of personnel performing patient testing. Findings were: 1. A review of the facility's personnel files, revealed that one of two files for testing personnel hired in 2016 contained no documentation at the time of the survey, of initial competency evaluation or a second evaluation within the first year, relating to laboratory testing. (testing person 1 as listed on the Laboratory personnel report) 2. An interview of the of the general supervisor on 02/01/2018 at 1640 hours in office and following the facility representative's own review of the records the above findings were confirmed.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on a review of the laboratory's personnel records and interview of facility personnel it was revealed that the technical supervisor failed to document annual competency evaluations of all personnel performing patient testing. Findings were: 1. A review of the facility's personnel files, revealed that one of two files for testing personnel contained no documentation at the time of the survey, of annual competency evaluations for the year 2016 relating to laboratory testing. 2. An interview of the of the general supervisor on 02/01/2018 at 1640 hours in office and following the facility representative's own review of the records the above findings were confirmed.