Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D2080766	02/14/2019
Name of Provider or Supplier	**Street Address, City, State**	
Genesis Medical Group	22001 Northpark Dr Suite 220, Kingwood, 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	The laboratory was found out of compliance with the CLIA regulations. 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; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director; 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.
D3005	FACILITIES CFR(s): 493.1101(a)(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation. This STANDARD is not met as evidenced by: Based on observation, review of the manufacturer's instructions, and confirmed in interview, the laboratory failed to establish procedures to monitor for cross-contamination of patient specimens per the manufacturer's instructions for Respiratory Pathogen Panel on the GenMark ePlex analyzer. 1. Observation of specimen processing on 2/14/19 at 1230 hours in the laboratory revealed the testing person (TP) # 2 processing sample IFD00006766, IFD00006777, and IFD6778. Direct observation revealed TP #2 cleaned the work area with Clorox non-bleach wipes. Observations also revealed TP#2 handled 3 of 3 specimens using 1 set of gloves. 2. In an interview of the TP#2 on 2/14/19 at 1010 hours in the laboratory, he stated "that he cleans the metal table with non bleach wipes because the bleach rusts the table." 3. Review of the package insert for the GenMark ePlex Respiratory Pathogen Panel (P1060-D) revealed under Procedural Notes "decontaminate laboratory areas and affected equipment with 10% bleach followed by 70% ethanol or isopropyl alcohol (or equivalent). Samples and cartridges should be handled and/or tested one at a time. To

	mitigate the risk of sample to sample contamination, change gloves after dispensing sample into the cartridge." 4. An interview with the general supervisor on 2/14/19 at 1035 hours in the office confirmed the above 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 records, observation, and interview of laboratory personnel, it was revealed that the laboratory did not meet the applicable preanalytic system(s) requirements. Refer to D5311
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 observations, review of the manufacturer's instructions, laboratory records, and confirmed in interview, the laboratory failed to follow the manufacturer's instructions for specimen transport for patient testing for Ethyl Alcohol on the Beckman Coulter AU480 chemistry analyzer. Findings were: 1. Surveyor observations on 2/13/19 at 1110 hours in the laboratory revealed the laboratory received urine specimens at ambient temperature via FedEx. Patient ID TOX000015716 TOX000015726 TOX000015729 TOX000015730 TOX000015717 TOX000015718 TOX000015720 TOX000015731 TOX000015733 TOX000015727 TOX000015714 TOX000015715 TOX000015719 TOX000015721 TOX000015722 TOX000015723 TOX000015725 TOX000015728 TOX000015732 2. An interview with the specimen processor on 2/13/19 at 1115 hours revealed the laboratory received all urine specimens at ambient temperature. She further indicated that the laboratory did not document the temperature before, after, or during transport of the specimens the laboratory received. 3. Review of the Beckman Coulter Emit II Plus Ethyl Alcohol Assay package insert (9K052.3D-D) revealed under specimen collection and preparation "if not analyzed immediately, specimens may be stored refrigerated at 2 - 8 C for up to 3 days following collection. After 3 days, specimen should be stored frozen. Repeated freeze-thaw cycles should be avoided. For transporting, maintain the specimen temperature at 2-8 C." 4. Review of the laboratory policy Specimen Integrity and Rejection Policy effective date 4/28/15 revealed "all specimens received by the laboratory will be evaluated for acceptability

	as follows...urine 80 hours of ambient storage for delivery 80 hrs and 15 days at 2 -8 C." 5. Review of the laboratory records revealed the laboratory performed Ethyl Alcohol testing on the above specimens that were not stored at 2-8 C during transport per the manufacturer's instructions prior to testing. 6. An interview with the general supervisor on 2/14/19 at 1140 hours in the office confirmed the above findings. He was unaware the specimens were required to be transported at 2-8 C. B. Based on review of the manufacturer's instructions, laboratory records, and confirmed in interview, the laboratory failed to follow the manufacturer's instructions for testing within specimen stability for Ethyl Alcohol on the the Beckman Coulter AU480 chemistry analyzer. Findings were: 1. Review of the Beckman Coulter Emit II Plus Ethyl Alcohol Assay package insert (9K052.3D-D) revealed under specimen collection and preparation "if not analyzed immediately, specimens may be stored refrigerated at 2 - 8 C for up to 3 days following collection. After 3 days, specimen should be stored frozen. Repeated freeze-thaw cycles should be avoided. For transporting, maintain the specimen temperature at 2-8 C." 2. Random review of patient final reports and their corresponding specimen requisition from November 2018 to January 2019 revealed 5 of 5 patient specimens that were analyzed after 3 days stored at 2 - 8 C. Patient ID TOX000012884: Collection Date/time 11/01/18, 1445 hours; Report date 01/03/19; elapsed time 28 days Patient ID TOX000013692: Collection Date/time 11/21/18, 1030 hours; Report date 11/27/18; elapsed time 6 days Patient ID TOX000013925: Collection Date/time 11/30/18; Report date 12/04/18; elapsed time 4 days Patient ID TOX000015357: Collection Date/time 01/30/19, 0855 hours; Report date 02/04/19; elapsed time 5 days Patient ID TOX000015108: Collection Date/time 01/18/19, 0919 hours; Report date 01/23/19; elapsed time 5 days 3. An interview with the general supervisor on 2/14/19 at 1105 hours in the office confirmed the above findings. He was unaware there was a 3 day stability for Ethanol. C. Based on review of the manufacturer's instructions, laboratory records, and confirmed in interview, the laboratory failed to follow the manufacturer's instructions for testing within specimen stability at room temperature for Urine Creatinine on the the Beckman Coulter AU480 chemistry analyzer. Findings were: 1. Review of the Instructions for Use for the Beckman Coulter Creatinine (BAOSR6X78 10, December 2016) revealed under specimen storage and stability "Creatinine in urine is stable for 2 days at room temperature (20-25 C) and for 6 days at 4 - 8 C." 2. Surveyor observations on 2/13/19 at 1110 hours in the laboratory revealed the laboratory received urine specimens at ambient temperature via FedEx. Patient ID TOX000015716 TOX000015726 TOX000015729 TOX000015730 TOX000015717 TOX000015718 TOX000015720 TOX000015731 TOX000015733 TOX000015727 TOX000015714 TOX000015715 TOX000015719 TOX000015721 TOX000015722 TOX000015723 TOX000015725 TOX000015728 TOX000015732 3. An interview with the specimen processor on 2/13/19 at 1115 hours revealed the laboratory received all urine specimens at ambient temperature. She further indicated that the laboratory did not document the temperature before, after, or during transport of the specimens the laboratory received. 4. Random review of patient final reports and their corresponding specimen requisition from November 2018 to January 2019 revealed 3 of 5 patient specimens that were received for analysis for Creatinine after 2 days. Patient ID TOX000013692: Collection Date/time 11/21/18, 1030 hours; received 11-26-2018; elapsed time 6 days Patient ID TOX000013925: Collection Date/time 11/30 /18; received 12-03-2018; elapsed time 3 days Patient ID TOX000015108: Collection Date/time 01/18/19, 0919 hours; received 01-21-2019; elapsed time 3 days 5. An interview with the general supervisor on 2/14/19 at 1140 hours in the office 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, and staff interview, it was revealed the laboratory's quality assessment plan failed to identify and correct issues in pre-analytic systems. Refer to D5311-A, B, C
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 review of the laboratory's records, and staff interview, it was revealed the laboratory failed to monitor and evaluate overall quality and correct identified problems in analytic systems as evidenced by: 1. The laboratory failed to verify the manufacturer's specifications for accuracy by identifying the presence and absence of the analytes Barbiturate, Cocaine, Methadone, Phecyclidine on the Beckman AU chemistry analyzer. Refer to D5421 2. The laboratory failed to document complete establishment studies for the modified FDA approved Ethyl Alcohol testing on the Beckman Coulter AU480 chemistry analyzer. Refer to D5423-A 3. The laboratory failed to document complete establishment studies for the modified FDA approved Urine Creatinine testing on the Beckman Coulter AU480 chemistry analyzer. Refer to D5423-B 4. The laboratory failed to document complete establishment studies for the Axiom Diagnostics Test True pH Assay. Refer to D5423-C 5. The laboratory failed to document an INDIVIDUALIZED QUALITY CONTROL PLAN (IQCP) that included all five components and all phases of testing in their risk assessment for the Respiratory Pathogen Panel on the GenMarch ePlex analyzer. Refer to D5445-A 6. The laboratory IQCP failed to have documentation of a complete quality control study to include quality control material for each target organism for each day of the quality control plan prior to modifying the frequency of quality control testing for the Respiratory Pathogen Panel on the GenMarch ePlex analyzer. Refer to D5445-B 7. The laboratory failed to document a positive and negative control for each target organism on the Respiratory Pathogen Panel on the GenMarch ePlex analyzer every day of patient testing. Refer to D5449
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the

	manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory verification records and confirmed in interview the laboratory failed to verify the manufacturer's specifications for accuracy by identifying the presence and absence of the analytes Barbiturate, Cocaine, Methadone, Phecyclidine on the Beckman AU480 chemistry analyzer. Findings were: 1. Review of the accuracy assessment for the Beckman Coulter AU480 chemistry analyzer revealed no documentation of any positive specimens for 4 of 9 toxicology analytes. No known positive were documented to have been tested or analyzed. Barbiturate Cocaine Methadone Phecyclidine 2. An interview with the general supervisor on 2/13 /19 at 1245 hours in the office confirmed the above 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 manufacturer's instructions, laboratory verification records, patient final reports, and confirmed in interview, the laboratory failed to document complete establishment studies for the modified FDA approved Ethyl Alcohol testing on the Beckman Coulter AU480 chemistry analyzer. Findings were: 1. Review of the Beckman Coulter Emit II Plus Ethyl Alcohol Assay package insert (9K052.3D-D) revealed "for use in the quantitative analysis of ethyl alcohol (ethanol) in human urine, serum, or plasma...quantifies alcohol concentration in human urine, serum, or plasma containing 10-600 mg/dL (0.01-0.60%, 0.1-6.0 g/L) alcohol." 2. Random review of laboratory patient final reports from October 2018 to February 2019 revealed the laboratory reported Ethyl Alcohol as Negative and Positive with a cut-off value of 100 mg/mL. The laboratory modified the intended use; thus making the Ethyl Alcohol testing high complexity. TOX000013563 - Negative TOX000011662 - Negative TOX000012018 - Negative TOX000012448 - Negative TOX000012792 - Negative TOX000013225 - Negative TOX000014241 - Negative TOX000014535 - Negative TOX000014671 - Negative TOX000014908 - Negative TOX000015461 - Negative TOX000015625 - Negative TOX000010868 - Negative TOX000011206 - Negative TOX000011478 - Negative TOX000015616 - Negative 3. Review of the laboratory policy Equipment Validation with an effective date of 4/28/15 revealed "for tests that are not FDA-cleared or approved or for FDA cleared/approved tests modified by the laboratory, the laboratory must establish: Accuracy, Precision,

	Analytic Sensitivity, Interferences, Linearity, Reportable Range (as applicable)." 4. Review of the laboratory verification records revealed documentation of the precision, accuracy, and linearity studies. No documentation was available for review of the laboratory performing sensitivity, specificity, carryover, interfering substances, and any other pertinent studies. 5. An interview with the general supervisor on 2/14/19 at 1020 hours in the office confirmed the above findings. B. Based on review of the manufacturer's instructions, laboratory verification records, patient final reports, and confirmed in interview, the laboratory failed to document complete establishment studies for the modified FDA approved Urine Creatinine testing on the Beckman Coulter AU480 chemistry analyzer. Findings were: 1. Review of the Instructions for Use for the Beckman Coulter Creatinine (BAOSR6X78 10, December 2016) revealed under intended use "system reagent for the quantitative determination of Creatinine in human serum or urine on Beckman Coulter AU analyzers." 2. Random review of laboratory patient final reports from October 2018 to February 2019 revealed the laboratory reported Urine Creatinine to determine adulteration with a cutoff value of 20 mg/dL; stating that "a sample reported with a Creatinine value less than 20 mg/dL is suggestive of adulteration. Furthermore, a Creatinine value less than 5 mg/dL is not consistent with human urine." The laboratory modified the intended use; thus making the Urine Creatinine testing high complexity. TOX000013563 - Crea 103 mg/dL TOX000011662 - Crea 111.9 mg/dL TOX000012018 - Crea 267.6 mg/dL TOX000012448 - Crea 68.7 mg/dL TOX000012792 - Crea 142.7 mg/dL TOX000013225 - Crea 186.7 mg/dL TOX000014241 - Crea 120.6 mg/dL TOX000014535 - Crea 205.3 mg/dL TOX000014671 - Crea 93.5 mg/dL TOX000014908 - Crea 116.6 mg/dL TOX000015461 - Crea 13.9 mg/dL (possible adulteration) TOX000015625 - Crea 29.9 mg/dL TOX000010868 - Crea 76.4 mg/dL TOX000011206 - Crea 263.5 mg/dL TOX000011478 - Crea 117.6 mg/dL TOX000015616 - Crea 45 mg/dL 3. Review of the laboratory policy Equipment Validation with an effective date of 4/28/15 revealed "for tests that are not FDA-cleared or approved or for FDA cleared/approved tests modified by the laboratory, the laboratory must establish: Accuracy, Precision, Analytic Sensitivity, Interferences, Linearity, Reportable Range (as applicable)." 4. Review of the laboratory verification records revealed documentation of the precision, accuracy, and linearity studies. No documentation was available for review of the laboratory performing sensitivity, specificity, carryover, interfering substances, and any other pertinent studies. 5. An interview with the general supervisor on 2/14/19 at 1020 hours in the office confirmed the above findings. C. Based on review of the FDA website, review of laboratory establishment studies, patient final reports, and confirmed in interview, the laboratory failed to document complete establishment studies for the Axiom Diagnostics Test True pH Assay. Findings were: 1. Review of the FDA website revealed the Axiom Diagnostics Test True pH Assay was not FDA approved for testing on the Beckman Coulter AU480 chemistry analyzer. 2. Review of the laboratory policy Equipment Validation with an effective date of 4/28/15 revealed "for tests that are not FDA-cleared or approved or for FDA cleared/approved tests modified by the laboratory, the laboratory must establish: Accuracy, Precision, Analytic Sensitivity, Interferences, Linearity, Reportable Range (as applicable)." 3. Review of the laboratory establishment records available revealed the laboratory performed accuracy, precision, and linearity studies. No documentation was available for review of the laboratory performing sensitivity, specificity, carryover, interfering substances, and any other pertinent studies. 4. An interview with the general supervisor on 2/14/19 at 1020 hours in the office confirmed the above findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)

	Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of laboratory chemistry analyzer records and interview of facility personnel, the laboratory failed to document every 6 month calibration verifications on all required analytes on the Beckman Coulter AU480 chemistry analyzer. (Creatinine, Ethyl Alcohol, Amphetamine, Barbiturate, Benzodiazepine, Cocaine, Opiate, Methadone, oxycodone, Phencyclidine, Cannabinoid) Findings were: 1. Review of the laboratory records from 2017 and 2018 revealed the following assays utilized two or few calibrators and and less than three controls on the Beckman Coulter AU480 chemistry analyzer; thus requiring 6 month calibration verification. Creatinine, Ethyl Alcohol, Amphetamine, Barbiturate, Benzodiazepine, Cocaine, Opiate, Methadone, oxycodone, Phencyclidine, Cannabinoid 2. Review of the laboratory records for the Beckman AU480 in 2017 and 2018 revealed no documentation of the 6 month calibration verification for 11 of 11 analytes on the Beckman AU480: Creatinine, Ethyl Alcohol, Amphetamine, Barbiturate, Benzodiazepine, Cocaine, Opiate, Methadone, oxycodone, Phencyclidine, Cannabinoid. 3. Interview with the technical supervisor on 02/14/19 at 1100 hours in the office confirmed the above findings. He was unaware that testing on the AU480 required 6 month calibration verification.
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:
A. Based on review of the laboratory test records, quality control records, manufacturer's instructions, and confirmed in interview, the laboratory failed to document an INDIVIDUALIZED QUALITY CONTROL PLAN (IQCP) that included all five components and all phases of testing in their risk assessment and quality assessment plan for the Respiratory Pathogen Panel on the GenMarch ePlex analyzer. Findings were: 1. Review of the laboratory risk assessment for the IQCP for the Respiratory Pathogen Panel on the GenMarch ePlex analyzer revealed no documentation of the risk assessment evaluation for specimen, reagent, environment, and/or testing personnel in the pre-analytic, analytic, and post-analytic processes. 2. Review of the laboratory risk assessment for the IQCP for the Respiratory Pathogen Panel on the GenMarch ePlex analyzer revealed no documentation of the quality assessment plan for specimen, reagent, environment, and/or testing personnel in the pre-analytic, analytic, and post-analytic processes. 3. An interview with the general supervisor on 2/13/19 at 1350 hours in the office confirmed the above findings. B. Based on review of the laboratory test records, manufacturer's instructions, laboratory policy, laboratory quality control records, and confirmed in interview, the laboratory IQCP failed to have documentation of a complete quality control study to include quality control material for each target organism for each day of the quality control plan prior to modifying the frequency of quality control testing for the Respiratory Pathogen Panel on the GenMarch ePlex analyzer. Findings were: 1. Review of the laboratory records available revealed the laboratory performed Respiratory Pathogen Panel on the GenMarch ePlex analyzer screened for the following 17 target organisms: Adenovirus, Coronavirus, Influenza A, Influenza A H3, Parainfluenza Virus 4, Respiratory Synctial Virus A, Chlamydia Phneumoniae, Human Metapneumovirus, Influenza A H1-2009, Parainfluenza Virus 2, Respiratory Synctial Virus B, Influenza A H1, Parainfluenza Virus 1, Parainfluenza Virus 3, Human Rhinovirus/Enterovirus, Influenza B, Mycoplasma pneumoniae 2. Review of the Maine Molecular Quality Controls ePlex RP Control M306 (M306 17May2018.02) revealed under composition "ePlex RP control M306 is comprised of 10 tubes, 2 tubes of each positive control A, B, C, and D, and 2 tubes of negative control, 200 ul of each." Positive A: Adenovirus, Coronavirus, Influenza A, Influenza A H3, Parainfluenza Virus 4, Respiratory Synctial Virus A, Chlamydia Phneumoniae Positive B: Adenovirus, Coronavirus, Human Metapneumovirus, Influenza A, Influenza A H1-2009, Parainfluenza Virus 2, Respiratory Synctial Virus B Positive C: Coronavirus, Influenza A, Influenza A H1, Parainfluenza Virus 1, Parainfluenza Virus 3 Positive D: Coronavirus, Human Rhinovirus/Enterovirus, Influenza B, Mycoplasma pneumoniae 3. Review of the INDIVIDUALIZED QUALITY CONTROL PLAN (IQCP) available revealed no documentation of the quality control study that included 1 positive and 1 negative for each day for 17 of 17 target organisms. Review of the quality control study revealed a 22 day study that included 1 or 2 positive pool and 1 negative control performed for each day. 12/27/17: Positive A, Positive B, Negative 12 /28/17: Postive C, Negative 12/29/17: Postive D, Negative 01/02/18: Positive A, Negative 01/03/18: Positive B, Negative 01/04/18: Positive C, Negative 01/05/18: Positive D, Negative 01/08/18: Positive A, Negative 01/09/18: Positive B, Negative 01 /10/18: Positive C, Negative 01/11/18: Positive D, Negative 01/12/18: Positive A, Negative 01/15/18: Positive B, Negative 01/16/18: Positive C, Negative 01/17/18: Positive D, Negative 01/18/18: Positive A, Negative 01/19/18: Positive B, Negative 01 /22/18: Positive C, Negative 01/23/18: Positive D, Negative 01/24/18: Positive A, Negative 01/25/18: Positive B, Negative 01/30/18: Positive B, Negative 4. An interview with the general supervisor on 2/13/19 at 1350 hours in the office confirmed the above findings.

D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory test records, quality control records, manufacturer's instructions, and confirmed in interview, the laboratory failed to document a positive and negative control for each target organism on the Respiratory Pathogen Panel on the GenMarch ePlex analyzer every day of patient testing. Findings were: 1. Review of the laboratory records available revealed the laboratory performed Respiratory Pathogen Panel on the GenMarch ePlex analyzer screened for the following 17 target organisms: Adenovirus, Coronavirus, Influenza A, Influenza A H3, Parainfluenza Virus 4, Respiratory Synctial Virus A, Chlamydia Phneumoniae, Human Metapneumovirus, Influenza A H1-2009, Parainfluenza Virus 2, Respiratory Synctial Virus B, Influenza A H1, Parainfluenza Virus 1, Parainfluenza Virus 3, Human Rhinovirus/Enterovirus, Influenza B, Mycoplasma pneumoniae 2. Review of the Maine Molecular Quality Controls ePlex RP Control M306 (M306 17May2018.02) revealed under composition "ePlex RP control M306 is comprised of 10 tubes, 2 tubes of each positive control A, B, C, and D, and 2 tubes of negative control, 200 ul of each." Positive A: Adenovirus, Coronavirus, Influenza A, Influenza A H3, Parainfluenza Virus 4, Respiratory Synctial Virus A, Chlamydia Phneumoniae Positive B: Adenovirus, Coronavirus, Human Metapneumovirus, Influenza A, Influenza A H1-2009, Parainfluenza Virus 2, Respiratory Synctial Virus B Positive C: Coronavirus, Influenza A, Influenza A H1, Parainfluenza Virus 1, Parainfluenza Virus 3 Positive D: Coronavirus, Human Rhinovirus/Enterovirus, Influenza B, Mycoplasma pneumoniae 3. Review of the laboratory quality control data from July 2018 to February 2019 revealed the laboratory performed 1 of 4 positive pool and 1 negative monthly. 07/03/18: Positive C, Negative 08/01/18: Positive D, Negative 09/04/18: Positive A, Negative 09/28/18: Positive B, Negative 11/02/18: Positive C, Negative 12 /13/18: Positive D, Negative 12/20/18: Positive A, Negative 01/03/19: Positive A, Negative 02/04/19: Positive A, Negative 4. Random review of the patient final reports from September 2018 to February 2019 revealed 18 of 18 patients the laboratory screened and resulted for 17 of 17 target organisms, without documentation of a positive and negative control for each target organism for each day of patient testing. 2 /13/19 Patient ID IFD000006775 Patient ID IFD000006774 2/11/19 Patient ID IFD000006738 2/4/19 Patient ID IFD000006696 1/17/19 Patient ID IFD000006560 1 /3/18 Patient ID IFD000006448 12/12/18 Patient ID IFD000006294 Patient ID IFD000006304 11/20/18 Patient ID IFD000006079 11/2/18 Patient ID IFD000005925 11/1/18 Patient ID IFD000005897 10/31/18 Patient ID IFD000005894 10/26/18 Patient ID IFD000005851 10/16/18 Patient ID IFD000005741 10/4/18 Patient ID IFD000005615 09/27/18 Patient ID IFD000005548 09/17/18 Patient ID IFD000005417 09/06/18 Patient ID IFD000005336 5. An interview with the general supervisor on 2/13/19 at 1330 hours in the office confirmed the above findings. He was unaware the laboratory was required to perform a positive and negative control for each organism.
D5469	CONTROL PROCEDURES

	CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, quality control records, patient test records, and confirmed in interview, the laboratory failed to follow the manufacturer's instructions to establish its own acceptable ranges for Creatinine, Ethanol (ETOH), and pH for the Beckman AU480 chemistry analyzer. Findings were: 1. Review of laboratory records revealed the laboratory used BioRad Liquichek urine Chemistry Control for quality control for Creatinine. 2. Review of laboratory records revealed the laboratory used BioRad Liquid Assayed Multiqual for quality control for Ethanol. 3. Review of laboratory records revealed the laboratory used Axiom Diagnostics Test True Truetrol T-Level Adulteration controls for pH. 4. Review of the package insert for the BioRad Liquichek urine Chemistry Control (1599-00, 02/2016) revealed "it is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides." 5. Review of the package insert for the BioRad Liquid Assayed Multiqual (5351-00, 05/2017) revealed it is recommended that each laboratory establish its own acceptable ranges and use those provided only as guides." 6. Review of the package insert for the Axiom Diagnostics Test True Truetrol T-Level Adulteration controls revealed "every laboratory should establish its own test requirements using Test True Truetrol T-Level Adulteration controls (five level) to meet your program needs." 7. Review of the laboratory policy Quality Control Program effective 4/28/15 revealed under QC Acceptable Range Verification "for quantitative tests, a valid acceptable range must be established or verified for each lot of QC material." 8. Review of the laboratory QC parameters on the Beckman coulter AU480 chemistry analyzer revealed the following acceptable ranges for the following analytes. The laboratory had no documentation for establishing the acceptable ranges. CREA Level 1 (52.6 - 78.8); Level 2 (126 - 190) ETOH Level 1 (15.1 - 33.1) Level 2 (166 - 258) pH 2.7 (2.4 - 3.0) pH 3.6 (3.2 - 4.0) pH 6.0 (5.4 - 6.6) pH 10.4 (9.9 - 10.9) pH 11.6 (9.86 - 13.34) 9. An interview with the general supervisor on 2/14/19 at 1005 hours in the office confirmed the above findings. He was unaware the laboratory needed to establish its own ranges.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

	This CONDITION is not met as evidenced by: Based on review of the laboratory's policies and procedures, quality control records, quality assessment records and staff interview, the laboratory director failed to provide overall management and direction of the laboratory. (Refer to D6013, D6020)
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) 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 a review of the laboratory's test system records and interview of facility personnel it was revealed that the laboratory director failed to ensure verification studies were complete for the analytes Barbiturate, Cocaine, Methadone, Phecyclidine on the Beckman AU chemistry analyzer before reporting patient test results. (Refer to D5421)
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory quality control (QC) records, and confirmed in interview, the laboratory failed to ensure the laboratory established and maintained a quality control program as evidenced by: 1. The laboratory failed to document an INDIVIDUALIZED QUALITY CONTROL PLAN (IQCP) that included all five components and all phases of testing in their risk assessment for the Respiratory Pathogen Panel on the GenMarch ePlex analyzer. Refer to D5445-A 2. The laboratory director failed to ensure the laboratory established their own control means and acceptable ranges as instructed by the manufacturer's instruction for the Biorad QC for the Beckman Coulter AU480 chemistry analyzer. (Refer to D5469)
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) 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 a review of quality control records and staff interview, it was revealed that the technical consultant failed to ensure an appropriate quality control program was maintained throughout the testing process. refer to D5445-A, D5469
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 verification studies for the FDA-approved modified toxicology tests using the Beckman AU480 chemistry analyzer, and confirmed in interview, the laboratory director failed to ensure the studies were complete prior to performing patient testing (refer to D5423-A, B, C).