Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2113281	07/09/2018
Name of Provider or Supplier	**Street Address, City, State**	
Beta Biosciences, Llc	1420 Nw Vivion, Suite 113, Kansas City, MO	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An entrance conference was held 07/09/2018 with Testing Person #2. The survey process was discussed. An opportunity for questions and comments was given. Based upon the onsite survey conducted 07/09/2018, this facility was found NOT to be compliance with CLIA regulations found at 42 CFR for the specialties/subspecialties in which it was surveyed. 493.1250 Analytic Condition 493.1403 Laboratory Director; Moderate Complexity An exit conference was held on 07/09/2018 with the VP of laboratory operations, Director of laboratory operations, Laboratory Director and Compliance. The exit conference attendees were advised the laboratory was out of compliance and advised of conditions and deficiencies found during the survey. An opportunity for questions and comments was provided.
D5309	TEST REQUEST CFR(s): 493.1241(e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, the laboratory's Specimen Transport Temperature Log and patient's final test report, the laboratory failed to ensure time of receipt was transcribed accurately from the transport log to the final test report for 19 of 19 respiratory pathogen profile patient specimens when received from a different laboratory in 2018 (06/2018 & 07/2018). Findings include: 1. Review of the Nanosphere Verigene Respiratory Pathogens Flex Nucleic Acid Test (RP Flex) instructions stated, "Specimens may be stored at 2-8C for a total of 48 hours from the time of collection before testing." The laboratory's practice included receiving specimens from another laboratory via courier, documenting temperature of conditions in which specimens were transported and documenting time of receipt in their Specimens Transport Temperature Log. 2. Review of the laboratory Specimen

	Transport Temperature Log and final patient test reports from 06/01/2018 through 07 /07/2018 revealed individual date/time received. The times of receipt into the laboratory recorded on the Specimen Transport Temperature Logs and the final patient test report were not consistent with one another, as follows: Specimen ID Specimen Final Test Transport Log Report 1806010002 Date Received 06/01/2018 06 /01/2018 Time 10:20 11:29AM 1806070001 Date Received 06/07/2018 06/07/2018 Time 11:14 12:24PM 1806070002 Date Received 06/07/2018 06/07/2018 Time 11:14 12:33PM 1806080001 Date Received 06/08/2018 06/08/2018 Time 09:30 11:45AM 1806080002 Date Received 06/08/2018 06/08/2018 Time 09:30 01:44PM 1806120001 Date Received 06/12/2018 06/12/2018 Time 13:43 02:53PM 1806130001 Date Received 06/13/2018 06/13/2018 Time 09:27 10:39AM 1806150001 Date Received 06/14/2018 06/15/2018 Time 10:15 10:19AM 1806190001 Date Received 06/19/2018 06/19/2018 Time 09:40 10:19AM 1806190002 Date Received 06/19/2018 06/19/2018 Time 09:40 10:26AM 1806210001 Date Received 06/21/2018 06/21/2018 Time 09:27 11:34AM 1806210002 Date Received 06/20/2018 06/21/2018 Time 08:54 12:04PM 1806220001 Date Received 06/22/2018 06/22/2018 Time 08:34 09:03AM 1807030002 Date Received 07/03/2018 07/03/2018 Time 08:35 09:31AM 1807030003 Date Received 07/03/2018 07/03/2018 Time 08:35 09:36AM 1807050001 Date Received 07/05/2018 07/05/2018 Time 08:28 09:50AM 1807050002 Date Received 07/05/2018 07/05/2018 Time 08:27 10:02AM 1807060001 Date Received 07/06/2018 07/06/2018 Time 09:46 10:00AM 1807070001 Date Received 07/07/2018 07/07/2018 Time 12:30 02:06PM The laboratory did not ensure time of receipts were transcribed accurately for final test reports to reflect the actual received time, as documented in the Specimen Transport Specimen Log. The laboratory did not accurately transcribe received times, as the manufacturer has a defined stability for specimens when testing the Respiratory Pathogen Panel (48 hours at 2-8C).
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of laboratory policy manual, manufacturer's instructions, laboratory specimen transport logs, and Verigene test records, the laboratory failed to follow its own written policy and manufacturer's instructions for specimen storage during transport for 1 of 42 Verigene Respiratory Panel specimens from 04/30/2018 through 07/09/2018. Findings included: 1. Review of laboratory policy titled "MOL4003 RPP-RESPIRATORY PATHOGEN PROFILE ON THE VERIGENE SYSTEM" stated, "Specimens may be stored at 2-8C for a total of 48 hours from the time of collection before testing." 2. Review of the Nanosphere Verigene Respiratory Pathogens Flex Nucleic Acid Test (RP Flex) instructions stated, "Specimens may be stored at 2-8C for a total of 48 hours from the time of collection before testing." 3. Review of the laboratory's Specimen Transport Temperature log revealed the specimen for Patient 180628001 (Received 06/27/2018 at 0943) was received at a temperature of 9.0C. The

	laboratory failed to follow its own written policy for specimen temperature storage requirements (2-8C). 4. Review of Verigene test records revealed the specimen for Patient 180628001 was tested 06/28/2018 13:55 hours with the following results: Adenovirus Not Detected B. holmesii Not Detected B. parapertussis/broncise Not Detected B. pertussis Not Detected hMPV Not Detected Influenza A Not Detected Influenza A /H1 Not Detected Influenza A/ H3 Not Detected Parainfluenza 1 Not Detected Parainfluenza 2 Not Detected Parainfluenza 3 Not Detected Parainfluenza 4 Not Detected Rhinovirus Not Detected RSVA Not Detected RSVB Not Detected
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 records, manufacturer's instructions and patient test records, the laboratory failed to meet the requirements of the analytic systems as evidenced by: 1. The laboratory failed to follow their own written policy and manufacturer's instructions for running external quality control on the Verigene processors from 05/10/2018 through 07/07/2018. (Refer to D5401) 2. The laboratory failed to have documentation of performing complete studies. (Refer D5421) 3. The laboratory failed to run positive and negative controls for each processor used for patient testing for 17 of 17 days from 05/10/2018 through 07/07/2018. (Refer to D5449)
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of laboratory policy manual, manufacturer's instructions, Verigene test records, and confirmed in interview with laboratory staff, the laboratory failed to follow their own written policy for running external positive and negative quality control on the Verigene processors prior to Respiratory Pathogen Profile (RPP) patient testing from 05/10/2018 through 07/07/2018. 1. Review of laboratory policy titled "MOL4003 RPP-RESPIRATORY PATHOGEN PROFILE ON THE VERIGENE SYSTEM" stated, "Good laboratory practice recommends running external positive and negative controls regularly. For example, viral transport medium may be used as the external Negative Control, and previously characterized positive samples or negative sample spiked with well characterized target organisms may be used as external Positive Controls. Regardless, of the choice of quality control materials, external controls should be used in accordance with local, state, federal

accrediting organizations, as applicable." 2. Review of the Verigene Repiratory Pathogens Flex Nucleic Acid Test manufacturer's instructions, (027-00050-01, Rev. D; December 2105), stated "Good laboratory practice recommends running external positive and negative controls regularly. For example, viral transport medium may be used as the external Negative Control, and previously characterized positive samples or negative sample spiked with well characterized target organisms may be used as external Positive Controls. Regardless, of the choice of quality control materials, external controls should be used in accordance with local, state, federal accrediting organizations, as applicable." (Refer to CFR 493.1256 (d)(3)(ii)) 3. Review of Verigene Respiratory Pathogen Panel (RPP) records revealed that the RPP tested for the following pathogens: Influenza A Influenza A/H1 Influenza B/H3 Influenza B RSV A RSV B Adenovirus hMPV (Human Metapneumovirus) Parainfluenza 1 Parainfluenza 2 Parainfluenza 3 Parainfluenza 4 Rhinovirus B. para/bronch (Bordetella parapertussis/bronchiseptica) B. pertussis (Bordetella pertussis) B. holmesii (Bordetella holmesii) Review of the ZeptoMetrix NATtrol RP Control package insert (Rev.No./Replaces: 9/4/2017) revealed the results for each pathogen in Control Level 1 and Control Level 2: Control 1 Expected Result Influenza A Not Detected Influenza A/H1 Not Detected Influenza A/H3 Not Detected Influenza B Detected RSV A Detected RSV B Detected Adenovirus Detected hMPV Detected Parainfluenza 1 Detected Parainfluenza 2 Detected Parainfluenza 3 Not Detected Parainfluenza 4 Not Detected Rhinovirus Not Detected B. para/bronch Detected B. pertussis Not Detected B. holmesii Not Detected Control 2 Expected Results Influenza A Detected Influenza A/H1 Detected Influenza A/H3 Detected Influenza B Not Detected RSV A Not Detected RSV B Not Detected Adenovirus Not Detected hMPV Not Detected Parainfluenza 1 Not Detected Parainfluenza 2 Not Detected Parainfluenza 3 Detected Parainfluenza 4 Detected Rhinovirus Detected B. para /bronch Not Detected B. pertussis Detected B. holmesii Detected Negative control ("Neg" or "negative" = negative control). Viral Transport Medium utilized as the negative control reagent. Acceptable result for all parameters= Not Detected. 4. Review of the Verigene test records revealed positive and negative controls were NOT performed on each individual processor for 17 of 17 days from 05/10/2018 through 07/07/2018 before Respiratory Pathogen Panel patient testing. 05/10/2018 A: 1 Patient 051018-1 A:2 Patient 051018-2 A:3 "CRTL 1" A:4 "CRTL 2" B:1 "NEG" Positive and Negative controls not performed on A:1 and A:2. 05/11/2018 A:1 Patient 051118-1 A:2 Patient 051118-2 A:3 "CTRL 1" A:4 "CTRL 2" (Adenovirus result=Detected. This is not within acceptable parameters. No documentation was provided that control was repeated.) B:1 "NEG" Positive and Negative controls not performed on A:1 and A:2. 5/16/18 A:1 "CTRL 1" A:2 "CTRL 2" A:3 "NEG" A:4 Patient 051618-1 B:1 Patient 1805160001 Positive and Negative controls not performed on A:4 and B:1. 05/31/2018 A:1 "NEG" A:2 Patient 1805310001 A:4 "CTRL 1" B:1 "CTRL 2" Positive and Negative controls not performed on A:2. 06/01 /2018 A:1 "CTRL 2" A:2 "NEG" A:3 Patient 1806010002 B:1 "CTRL 1" Positive and Negative controls not performed on A:3. 06/07/2018 A:1 Patient 1806070001 /Result = No Call -INT CTL A:2 "ctrl 1"/Result = No Call-VARIATION (No Call-VARIATION result unacceptable. No documentation that control was repeated.) A:2 Patient 1806070001 (Second Run) A:3 "ctrl 2" A:4 "negative" B:1 Patient 1806070002 Positive and Negative controls not performed on A:1, A:2, and B:1. NOTE: The manufacturer's instructions for Verigene Respiratory Pathogens Flex Nucleic Acid test stated, "No Call-VARIATION. Reader unable to obtain result because of high variability in the target-specific signals. Repeat RP Flex." The instructions also stated "No Call-INT CTL. INT CLT1 and INT CTL 2 not detected, indicating lysis, extraction, amplification, or target hybridization issue. Repeat RP Flex." 06/08/2018 A:1 "negative" A:2 Patient 1806080001 A:3 Patient 1806080002 A:

	4 "ctrl 1" B:1 "ctrl 2" Positive and Negative controls not performed on A:2 and A:3. 06 /13/2018 A:1 "ctrl 2" A:2 "neg ctrl" A:3 "ctrl 1 new lot" (Test Completed at 2:53PM) A:3 Patient 1806120001 (Test Completed at 12:33PM) Positive and Negative controls not performed on A:3 before patient testing. 06/15/2018 A:1 "neg ctrl" A:2 "ctrl 1" A: 3 "ctrl 2" A:4 Patient 1806150001 Positive and Negative controls not performed on A: 4. 06/19/2018 A:1 Patient 1806190001 A:2 Patient 1806190002 A:3 "neg qc" (Adenovirus Result=Detected. This is not within acceptable parameters.) A:4 "QC 1" A:4 "NEG QC "(Second run. Adenovirus Result=Detected. This is not within acceptable parameters.) B:1 "QC 2" B:1 "NEG QC RR#3" (Third run. Results Acceptable) Positive and Negative controls not performed on A:1 and A:2. 06/21 /2018 A:1 Patient 1806210002 A:2 "NEG" A:3 "QC 1" (Result= No Call-VARIATION (No Call-VARIATION result unacceptable.) A:3 "QC 1" (Second run) A:4 "QC 2" B:1 Patient 1806210001 Positive and Negative controls not performed on A:1 and B:1. 06/22/2018 A:1 "QC 2" A:2 Patient 1806220001 A:4 "NEG" B:1 "QC 1" Positive and Negative controls not performed on A:2. 06/28/2018 A:1 "NEG QC" A:2 "QC 2" A:3 "QC 1" A:4 Patient 1806280001 Positive and Negative controls not performed on A:4. 07/03/2018 A:1 "NEG QC" (Adenovirus Result=Detected. This is not within acceptable parameters.) A:2 Patient 1807030002 (Test completed at 11: 53AM) A:2 "QC 2" (Second run. Results acceptable. Test completed at 2:38PM) A:3 "QC 1" A:3 Patient 1807030001 A:4 Patient 1807030003 B:4 "QC 2" (Adenovirus Result=Detected. This is not within acceptable parameters.) B:4 "NEG QC" (Second run. Results acceptable.) Control 1 and Control 2 not performed on A:2 prior to patient testing. Control 2 not performed on A:3. Positive and Negative controls not performed on A:4. 07/05/2018 A:1 Patient 1807050002 A:2 "NEG QC" A:3 "QC 2" A:4 "QC 1" B:4 Patient 1807050001 Positive and Negative controls not performed on A:1 and B:4. 07/06/2018 A:1 "QC 1" A:2 "QC 2" A:3 "NEG QC" (Second run) A:4 Patient 1807050113 B:4 "NEG QC" Result =Test Cartridge has not been analyzed (This is an unacceptable result) Positive and Negative controls not performed on A:4. 07/07/2018 A:1 Patient 180707001 A:3 "NEG" A:4 "CTRL 1" B:4 "NEG 2" Positive and Negative controls not performed on A:1. 5. The above findings were confirmed by laboratory staff during the exit interview 07/19/2108 at 3:30pm. Word Key: CTRL=control QC=Quality Control Neg=Negative
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's verification studies, review of manufacturer's instructions, and staff interview, revealed the laboratory failed to have documentation of performing complete studies. The findings were: 1. A review of the Verigene's System User's manual (Version A) under the section titled "1.1 Features of the Reader" revealed: "The Verigene Reader is the central control unit of the Verigene System. Through its simple touchscreen interface and barcode scanner, users identify and track their reports." 2. Further review of the Verigene's System User's manual

	under the section titled "1.2 Features of the Processor SP" revealed: "The Verigene Processor SP is a 'hands off' instrument which integrates sample preparation, target amplification (included with Processor SPamp models) and target hybridization within a single device. Once the sample is inserted into the appropriate consumable and the procedure is selected, the device performs all necessary steps, including automatically transferring reagents." Because the processors performed the sample manipulation and testing, the Verigene Processor SPs were required to have the necessary verification studies performed. 3. A review of the laboratory's verification studies performed on the Luminex Verigene Respiratory Pathogens Flex Nucleic Acid Test (approved by the laboratory director on 04/30/2018) revealed the laboratory performed verification utilizing the following instrumentation: Verigene Processor SP A1 (serial number 17296005) Verigene Processor SP A2 (serial number 17296009) Verigene Processor SP A3 (serial number 17296008) Verigene Processor SP A4 (serial number 17242007) Verigene Processor SP B1 (serial number 17333001) Verigene Reader (serial number 17284009) 4. Further review of the verification studies revealed the laboratory failed to have documentation of performing the following required studies: a) Processor SP A1 accuracy for: Influenza A H1N1 Influenza A H3N2 Parainfluenza 3 Parainfluenza 4 Rhinovirus 1A B. pertussis B. holmesii precision for: Influenza B RSV A RSV B Parainfluenza 1 Parainfluenza 2 hMPV-8 Adenovirus 3 B. parapertussis Influenza A H1N1 Influenza A H3N2 Parainfluenza 3 Parainfluenza 4 Rhinovirus 1A B. pertussis B. holmesii b) Processor SP A2 accuracy for: Influenza B RSV A RSV B Parainfluenza 1 Parainfluenza 2 hMPV-8 Adenovirus 3 B. parapertussis precision for: Influenza A H1N1 Influenza A H3N2 Parainfluenza 3 Parainfluenza 4 Rhinovirus 1A B. pertussis B. holmesii c) Processor SP A3 accuracy: no positive samples tested precision: no positive samples tested d) Processor SP A4 accuracy for: Influenza A H1N1 Influenza A H3N2 Parainfluenza 3 Parainfluenza 4 Rhinovirus 1A B. pertussis B. holmesii precision for: Influenza B RSV A RSV B Parainfluenza 1 Parainfluenza 2 hMPV-8 Adenovirus 3 B. parapertussis e) Processor SP B1 accuracy for: Influenza B RSV A RSV B Parainfluenza 1 Parainfluenza 2 hMPV-8 Adenovirus 3 B. parapertussis precision for: Influenza A H1N1 Influenza A H3N2 Parainfluenza 3 Parainfluenza 4 Rhinovirus 1A B. pertussis B. holmesii 5. A review of the laboratory's patient records from April 30, 2018 to July 9, 2018 revealed the laboratory performed testing on 44 patient samples (refer to patient alias list). 6. An interview with the laboratory director on 07/09/2018 at 1115 hours in the break room revealed the laboratory was informed by the manufacturer that Verigene reader was required to be verified, not each Verigene processor. He stated that he thought each processor needed to be verified, but followed the manufacturer's instructions and only verified the reader. This confirmed the 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 direct observation, review of laboratory policy, manfacturer's instructions and Verigene test records, and confirmed in interview with laboratory staff, the

laboratory failed to run positive and negative controls for each processor used for Respiratory Pathogen Panel patient testing for 17 of 17 days from 05/10/2018 through 07/07/2018. Findings included: 1. A tour of the laboratory on 07/09/2018 at 11: 00AM, revealed 5 Verigene Processors in use and 1 Verigene Reader. Verigene Processor A1; Serial Number 17296005 Verigene Processor A2; Serial Number 17296009 Verigene Processor A3; Serial Number 17296008 Verigene Processor A4; Serial Number 17242007 Verigene Processor B1; Serial Number 17333001 Verigene Reader; Serial Number 17284009 2. Review of laboratory policy titled "MOL4003 RPP-RESPIRATORY PATHOGEN PROFILE ON THE VERIGENE SYSTEM" stated, "Good laboratory practice recommends running external positive and negative controls regularly. For example, viral transport medium may be used as the external Negative Control, and previously characterized positive samples or negative sample spiked with well characterized target organisms may be used as external Positive Controls. Regardless, of the choice of quality control materials, external controls should be used in accordance with local, state, federal accrediting organizations, as applicable." 3. Review of the Verigene Repiratory Pathogens Flex Nucleic Acid Test manufacturer's instructions, (027-00050-01, Rev. D; December 2105), stated "Good laboratory practice recommends running external positive and negative controls regularly. For example, viral transport medium may be used as the external Negative Control, and previously characterized positive samples or negative sample spiked with well characterized target organisms may be used as external Positive Controls. Regardless, of the choice of quality control materials, external controls should be used in accordance with local, state, federal accrediting organizations, as applicable." (Refer to CFR 493.1256 (d)(3)(ii)) 4. Review of Verigene Respiratory Pathogen Panel (RPP) records revealed that the RPP tested for the following pathogens: Influenza A Influenza A/H1 Influenza B/H3 Influenza B RSV A RSV B Adenovirus hMPV (Human Metapneumovirus) Parainfluenza 1 Parainfluenza 2 Parainfluenza 3 Parainfluenza 4 Rhinovirus B. para/bronch (Bordetella parapertussis/bronchiseptica) B. pertussis (Bordetella pertussis) B. holmesii (Bordetella holmesii) Review of the ZeptoMetrix NATtrol RP Control package insert (Rev.No./Replaces: 9/4/2017) revealed the results for each pathogen in Control Level 1 and Control Level 2: Control 1 Expected Result Influenza A Not Detected Influenza A/H1 Not Detected Influenza A /H3 Not Detected Influenza B Detected RSV A Detected RSV B Detected Adenovirus Detected hMPV Detected Parainfluenza 1 Detected Parainfluenza 2 Detected Parainfluenza 3 Not Detected Parainfluenza 4 Not Detected Rhinovirus Not Detected B. para/bronch Detected B. pertussis Not Detected B. holmesii Not Detected Control 2 Expected Results Influenza A Detected Influenza A/H1 Detected Influenza A/H3 Detected Influenza B Not Detected RSV A Not Detected RSV B Not Detected Adenovirus Not Detected hMPV Not Detected Parainfluenza 1 Not Detected Parainfluenza 2 Not Detected Parainfluenza 3 Detected Parainfluenza 4 Detected Rhinovirus Detected B. para/bronch Not Detected B. pertussis Detected B. holmesii Detected Negative control ("Neg" or "negative" = negative control). Viral Transport Medium utilized as the negative control reagent. Acceptable result for all parameters= Not Detected. 5. Review of the Verigene test records revealed positive and negative controls were not performed on each individual processor for 17 of 17 days from 05/10 /2018 through 07/07/2018 before patient testing on the following dates: 05/10/2018 A: 1 Patient 051018-1 A:2 Patient 051018-2 A:3 "CRTL 1" A:4 "CRTL 2" B:1 "NEG" Positive and Negative controls not performed on A:1 and A:2. 05/11/2018 A:1 Patient 051118-1 A:2 Patient 051118-2 A:3 "CTRL 1" A:4 "CTRL 2" (Adenovirus result=Detected. This is not within acceptable parameters. No documentation was provided that control was repeated.) B:1 "NEG" Positive and Negative controls not performed on A:1 and A:2. 5/16/18 A:1 "CTRL 1" A:2 "CTRL 2" A:3 "NEG" A:4 Patient 051618-1 B:1 Patient 1805160001 Positive and Negative controls not

	performed on A:4 and B:1 05/31/2018 A:1 "NEG" A:2 Patient 1805310001 A:4 "CTRL 1" B:1 "CTRL 2" Positive and Negative controls not performed on A:2. 06/01 /2018 A:1 "CTRL 2" A:2 "NEG" A:3 Patient 1806010002 B:1 "CTRL 1" Positive and Negative controls not performed on A:3. 06/07/2018 A:1 Patient 1806070001 /Result = No Call -INT CTL A:2 "ctrl 1"/Result = No Call-VARIATION (No Call-VARIATION result unacceptable. No documentation that control was repeated.) A:2 Patient 1806070001 (Second Run) A:3 "ctrl 2" A:4 "negative" B:1 Patient 1806070002 Positive and Negative controls not performed on A:1, A:2, and B:1. NOTE: The manufacturer's instructions for Verigene Respiratory Pathogens Flex Nucleic Acid test stated, "No Call-VARIATION. Reader unable to obtain result because of high variability in the target-specific signals. Repeat RP Flex." The instructions also stated "No Call-INT CTL. INT CLT1 and INT CTL 2 not detected, indicating lysis, extraction, amplification, or target hybridization issue. Repeat RP Flex." 06/08/2018 A:1 "negative" A:2 Patient 1806080001 A:3 Patient 1806080002 A: 4 "ctrl 1" B:1 "ctrl 2" Positive and Negative controls not performed on A:2 and A:3. 06 /13/2018 A:1 "ctrl 2" A:2 "neg ctrl" A:3 "ctrl 1 new lot" (Test Completed at 2:53PM) A:3 Patient 1806120001 (Test Completed at 12:33PM) Positive and Negative controls not performed on A:3 before patient testing. 06/15/2018 A:1 "neg ctrl" A:2 "ctrl 1" A: 3 "ctrl 2" A:4 Patient 1806150001 Positive and Negative controls not performed on A: 4. 06/19/2018 A:1 Patient 1806190001 A:2 Patient 1806190002 A:3 "neg qc" (Adenovirus Result=Detected. This is not within acceptable parameters.) A:4 "QC 1" A:4 "NEG QC "(Second run. Adenovirus Result=Detected. This is not within acceptable parameters.) B:1 "QC 2" B:1 "NEG QC RR#3" (Third run. Results Acceptable) Positive and Negative controls not performed on A:1 and A:2. 06/21 /2018 A:1 Patient 1806210002 A:2 "NEG" A:3 "QC 1" (Result= No Call-VARIATION (No Call-VARIATION result unacceptable.) A:3 "QC 1" (Second run) A:4 "QC 2" B:1 Patient 1806210001 Positive and Negative controls not performed on A:1 and B:1. 06/22/2018 A:1 "QC 2" A:2 Patient 1806220001 A:4 "NEG" B:1 "QC 1" Positive and Negative controls not performed on A:2. 06/28/2018 A:1 "NEG QC" A:2 "QC 2" A:3 "QC 1" A:4 Patient 1806280001 Positive and Negative controls not performed on A:4. 07/03/2018 A:1 "NEG QC" (Adenovirus Result=Detected. This is not within acceptable parameters.) A:2 Patient 1807030002 (Test completed at 11: 53AM) A:2 "QC 2" (Second run. Results acceptable. Test completed at 2:38PM) A:3 "QC 1" A:3 Patient 1807030001 A:4 Patient 1807030003 B:4 "QC 2" (Adenovirus Result=Detected. This is not within acceptable parameters.) B:4 "NEG QC" (Second run. Results acceptable.) Control 1 and Control 2 not performed on A:2 prior to patient testing. Control 2 not performed on A:3. Positive and Negative controls not performed on A:4. 07/05/2018 A:1 Patient 1807050002 A:2 "NEG QC" A:3 "QC 2" A:4 "QC 1" B:4 Patient 1807050001 Positive and Negative controls not performed on A:1 and B:4. 07/06/2018 A:1 "QC 1" A:2 "QC 2" A:3 "NEG QC" (Second run) A:4 Patient 1807050113 B:4 "NEG QC" Result =Test Cartridge has not been analyzed (This is an unacceptable result) Positive and Negative controls not performed on A:4. 07/07/2018 A:1 Patient 180707001 A:3 "NEG" A:4 "CTRL 1" B:4 "NEG 2" Positive and Negative controls not performed on A:1. The laboratory failed to run a positive and a negative control on each Verigene processor used for 17 of 17 days when patient samples were tested from 05/10/2018 through 07/07/2018. 6. The above findings were confirmed by laboratory staff during the exit interview 07/19/2108 at 3: 30pm.
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 verification studies, review of manufacturer's instructions, the laboratory director failed to provide overall management and direction, as evidenced by: 1. The laboratory director failed to ensure verification procedures used were adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. Refer to D6013. 2. The laboratory director failed to ensure the quality control program was established and maintained to assure quality of laboratory services. Refer to 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 review of the laboratory's verification studies, review of manufacturer's instructions, the laboratory director failed to ensure verification procedures used were adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. The laboratory failed to have documentation of performing complete studies. Refer 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 laboratory policy manual, manufacturer's instructions, Verigene test records, the laboratory director failed to ensure the quality control program was established and maintained to assure quality of laboratory services, as evidenced by: 1. The laboratory failed to follow their own written policy for running external positive and negative quality control on the Verigene processors prior to Respiratory Pathogen Profile (RPP) patient testing from 05/10/2018 through 07/07/2018. Refer to D5401. 2. The laboratory failed to run positive and negative controls for each processor used for Respiratory Pathogen Panel patient testing for 17 of 17 days from 05/10/2018 through 07/07/2018. Refer to D5449.