Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2185370	07/29/2020
Name of Provider or Supplier	**Street Address, City, State**	
Southern Diagnostics Laboratory	340 East Parker, Suite 340, Baton Rouge, LA	

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	A Complaint Survey was performed at Medlogic, LLC- CLIA ID 19D2185370 on July 27, 2020 through July 29, 2020. Medlogic, LLC was found not in compliance with the following CONDITION LEVEL DEFICIENCIES which constitute an IMMEDIATE JEOPARDY to the patients serviced by the laboratory: 42 CFR 493.1240 CONDITION: Preanalytic Systems 42 CFR 493.1441 CONDITION: Laboratories performing high complexity testing, Laboratory Director A Complaint Survey was performed at Medlogic, LLC- CLIA ID 19D2185370 on July 27, 2020 through July 29, 2020. Medlogic, LLC was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.801 CONDITION: Enrollment and testing of samples 42 CFR 493.1250 CONDITION: Analytic Systems 42 CFR 493.1459 CONDITION: Laboratories performing high complexity testing; General Supervisor 42 CFR 493.1487 CONDITION: Laboratories performing high complexity testing; Testing Personnel
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to ensure testing and reporting of proficiency samples of another CLIA laboratory did not occur. Findings: 1.The laboratory failed to ensure no inter-

	laboratory communications occurred for proficiency testing samples prior to the cut-off date for submission of test results for four (4) of four (4) testing events reviewed. Refer to D2011. 2. The laboratory failed to report to Centers for Medicaid and Medicare Services (CMS) the receipt of proficiency testing samples from another laboratory. Refer to D2013.
D2011	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample (s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program. This STANDARD is not met as evidenced by: Based on observation, proficiency testing record review, and interview with personnel, the laboratory failed to ensure no inter-laboratory communications occured for proficiency testing samples prior to the cut-off date for submission of test results for four (4) of four (4) testing events reviewed. Findings: 1. Observation by surveyors during the laboratory tour on July 27, 2020 at 10:21 am revealed the laboratory utilizes two (2) Quant Studio 12K Flex instruments for the following high complexity testing: Respiratory Panel (includes Bordetella pertussis, Bordetella pan., Chlamydophila pneumoniae. Haemophilus influenza, Legionella pneumophila, Moraxella catarrhalis, Mycoplasma pnuemoniae, Streptococcus pneumoniae, Streptococcus pyogenes (Group A), Klebsiella pneumylococcus aureus, Adenovirus (Type 1 & 2), Bocavirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, Human Metapneumovirus (HMPV) A, HMPV B, Enterovirus (Pan, D68), Rhinovirus (Type 1 &2), Influenza A (Pan, H1, H3), Influenza B (Pan), Parainfluenza virus (PIV) 1, Parainfluenza virus 2, Parainfluenza virus 3, Parainfluenza virus 4, RSV A, and RSV B) and SARS COV-2. 2. Review of the laboratory's 2019 and 2020 College of American Pathologists (CAP) proficiency testing records for 2019 and 2020 revealed the laboratory recieved, tested, and reported results for proficiency testing (PT) samples that were issued to their sister laboratory (19D2066157). Refer to D2013. 3. In interview on July 29, 2020 at 3:44 pm, the Manager of the sister laboratory (19D2066157) stated he had contacted CAP about the CLIA ID number within the last 3 weeks. He further stated he thought the CLIA ID number on the 2020 second event was correct and was unsure of why it had not been changed.
D2013	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(4) The laboratory must not send proficiency testing samples or portions of proficiency testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least one year. If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested

testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason.

This STANDARD is not met as evidenced by:
Based on observation, record review, and interview with personnel, the laboratory failed to report to Centers for Medicaid and Medicare Services (CMS) the receipt of proficiency testing samples from another laboratory. Findings: 1. Observation by surveyors during the laboratory tour on July 27, 2020 at 10:21 am revealed the laboratory utilizes two (2) Quant Studio 12K Flex instruments for the following high complexity testing: Respiratory Panel (includes Bordetella pertussis, Bordetella pan., Chlamydophila pneumoniae. Haemophilus influenza, Legionella pneumophila, Moraxella catarrhalis, Mycoplasma pnuemoniae, Streptococcus pneumoniae, Streptococcus pyogenes (Group A), Klebsiella pneumylococcus aureus, Adenovirus (Type 1 & 2), Bocavirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, Human Metapneumovirus (HMPV) A, HMPV B, Enterovirus (Pan, D68), Rhinovirus (Type 1 &2), Influenza A (Pan, H1, H3), Influenza B (Pan), Parainfluenza virus (PIV) 1, Parainfluenza virus 2, Parainfluenza virus 3, Parainfluenza virus 4, RSV A, and RSV B) and SARS COV-2. 2. In interview on July 27, 2020 at 10:16 am, Technical Supervisor 1 stated prior to June 3, 2020 the Respiratory Panel and COVID testing were performed under their sister laboratory's CLIA Identification number (19D2066157). 3. In interview on July 27, 2020 at 11:27 am, Testing Personnel 1 stated the laboratory (19D2185370) tested PT samples in December 2019 and had an event that was recently received that had not been tested yet. 4. Surveyors observed on July 27, 2020 at 11:27 am, the laboratory had the 2020 second event "IDR-B 2020 Infectious Disease, Respiratory Panel" College of American Pathologists (CAP) proficiency testing (PT) paperwork on the desk in the molecular laboratory. 5. Review of the 2020 second event records for Respiratory Panel revealed the CLIA ID number indicated on the paper work was that of the sister laboratory (19D2066157), not the molecular laboratory (19D2185370). 6. Review of the laboratory's PT records revealed the following: a) No documentation of participation in the 2020 first PT event for Respiratory Panel b) Documentation of 2019 second and third PT events (IDR-B and IDR-C) for Respiratory Panel performed by the laboratory c) No signed attestation for COV2-A 2020 d) No documentation of communication with CMS regarding the receipt of PT samples from another laboratory 7. Further Review of CAP records for COV2-A 2020 revealed the PT event was issued to the sister laboratory 19D2066157. Raw data reviewed confirmed the samples were tested instrument #285881360 on June 10, 2020 by Testing Personnel 1. The event was signed by the laboratory director on July 29, 2020. The testing performed by the laboratory was evaluated by CAP and copied to CMS under 19D2066157 on July 2, 2020. 8. Further review of the laboratory's 2019-2020 PT records for Respiratory Panel revealed the CLIA ID number of the sister laboratory (19D2066157) was listed. Technical Supervisor 1 signed the evaluations on "5-26-2020." 9. In interview on July 29, 2020 at 3:44 pm, the Manager of the sister laboratory (19D2066157) stated he had contacted CAP about the CLIA ID number within the last 3 weeks. He further stated he thought the CLIA ID number on the 2020

	second event was correct and was unsure of why it had not been changed.
D3029	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(2) Test procedures. Retain a copy of each test procedure for at least 2 years after a procedure has been discontinued. Each test procedure must include the dates of initial use and discontinuance. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to retain a copy of discontinued test procedure for antibiotic resistance testing. Findings: 1. Review on July 29, 2020 of random selection of patient final reports from July 2020 revealed the laboratory performed antibiotic resistance marker testing. 2. Review of the laboratory's policy and procedure manual and test menu revealed the laboratory did not include antibiotic resistance testing records. The initial date of testing and discontinuance were not documented. 3. In interview on July 28, 2020, Testing Personnel 1 stated the laboratory previously performed antibiotic resistance testing. Testing Personnel 1 stated the validation studies were performed on the laboratory's previous analyzer Quant Studio 3, not the current instruments Quant Studio 12 K Flex (installed in March 2020). 4. In interview on July 29, 2020 at 10:32 am, Technical Supervisor 1 stated the laboratory discontinued antibiotic resistance testing on July 8, 2020.
D5205	COMPLAINT INVESTIGATIONS CFR(s): 493.1233 The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to have a system for handling complaints and problems reported to the laboratory. Findings: 1. Review of the laboratory's policy and procedure manual on July 27, 2020 revealed the laboratory did not have a written policy and procedure for addressing internal complaints and problems reported to the laboratory. 2. In interview on July 27, 2020 at 1:53 pm, the Quality Assurance Manager stated the laboratory did not have a policy /procedure for complaints.
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: I. Based on record review and interview with personnel, the laboratory failed to establish written policies and procedures to assess competency for testing personnel.

	Findings: 1. Review of the laboratory's policy and procedure manual on July 27, 2020 revealed the laboratory did not include the following six (6) procedures as a minimal requirement for assessing the competency of all personnel performing laboratory testing, as well as frequency of performance: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting or test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills. 2. In interview on July 27, 2020 at 12:47 pm, the Quality Assurance Manager stated the laboratory did not have a policy for competency assessment. II. Based on record review and interview with personnel, the laboratory failed to establish written policies and procedures to address competency for two (2) of two (2) Technical Supervisors and General Supervisors reviewed were complete. Findings: 1. Review of the laboratory's CMS 209 form on July 27, 2020 (Laboratory Personnel Report revealed the following two (2) personnel serve and/or previously served as Technical Supervisor and General Supervisor: Technical Supervisor and General Supervisor 1 (current position) Technical Supervisor and General Supervisor 2 (previously employed) 2. In interview on July 27, 2020, the Quality Assurance (QA) Manager stated Technical Supervisor/General Supervisor 2 is no longer employed at the laboratory. The QA personnel further stated she left the position approximately two weeks prior. 3. Review of the laboratory's policy and procedure manual revealed the laboratory did not include competency assessment criteria or frequency of performance for personal serving as Technical Supervisor and General Supervisor. 4. Review of personnel records on July 27, 2020 revealed the laboratory did not have documentation of competency assessments for Technical Supervisor/General Supervisor 1 and Technical Supervisor/General Supervisor 2. 5. In interview on July 27, 2020 at 12:47 pm, the Quality Assurance Manager stated the Laboratory Director did not perform a competency assessment for the duties of Technical Supervisor /General Supervisor 1. QA Personnel further stated the Laboratory Director did not perform an assessment for technical and general supervisory duties for Technical Supervisor/General Supervisor 2.
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 observation, record review, and interview with personnel, the laboratory failed to ensure the accuracy of non regulated Bacteriology and Virology analytes at least twice annually. Findings: 1. Observation by surveyors during the laboratory tour on July 27, 2020 at 10:21 am revealed the laboratory utilizes two (2) Quant Studio 12K Flex instruments for the following high complexity testing: Respiratory Panel (includes Bordetella pertussis, Bordetella pan., Chlamydophila pneumoniae. Haemophilus influenza, Legionella pneumophila, Moraxella catarrhalis, Mycoplasma pneumoniae, Streptococcus pneumoniae, Streptococcus pyogenes (Group A), Klebsiella pneumylococcus aureus, Adenovirus (Type 1 & 2), Bocavirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, Human

	Metapneumovirus (HMPV) A, HMPV B, Enterovirus (Pan, D68), Rhinovirus (Type 1 &2), Influenza A (Pan, H1, H3), Influenza B (Pan), Parainfluenza virus (PIV) 1, Parainfluenza virus 2, Parainfluenza virus 3, Parainfluenza virus 4, RSV A, and RSV B) and SARS COV-2. 2. Review of the laboratory's policy and procedure manual revealed the laboratory did not include a written policy for twice a year verification of all non regulated analytes to ensure the accuracy of testing. 3. In interview on July 27, 2020 at 2:03 pm, the Quality Assurance Manager stated the laboratory did not have a policy for twice a year verification to ensure accuracy of Bacteriology and Virology testing. 4. In interview on July 27, 2020 at 3:31 pm, Technical Supervisor 1 stated the laboratory is enrolled in College of American Pathologists (CAP) proficiency testing (PT) to ensure the accuracy of testing. 5. In interview on July 29, 2020 at 2:38 pm, the Quality Assurance Manager stated CAP does not cover all the analytes the laboratory tests for. 6. Review of the untitled list, with column "Covered by CAP," provided to surveyor on July 29, 2020 revealed the following bacteria and viruses are not included in the CAP survey: a) "Haemophilus influenza b) Moraxella Catarrhalis c) Strep pneumoniae d) Strep pyogenes (Group A) e) Klebsiella pneumoniae f) Staph aureus g) Coronavirus 229 E; note included "X* CAP does not distinguish subtype" h) Coronavirus HKU1; note included "X* CAP does not distinguish subtype" i) Coronavirus NL63; note included "X* CAP does not distinguish subtype" j) Coronavirus OC43; note included "X* CAP does not distinguish subtype" k) HMPV A; note included "X* CAP does not distinguish subtype" l) HMPV B; note included "X* CAP does not distinguish subtype" m) PIV 1; note included "X* CAP does not distinguish subtype" n) PIV 2; note included "X* CAP does not distinguish subtype" o) PIV 3; note included "X* CAP does not distinguish subtype"
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 observation, record review and interview with personnel, the laboratory's system failed to meet the requirements of the preanalytical system. Findings: 1. The laboratory failed to establish specimen handling, stability, and acceptability/rejection requirements for Bacteriology and Virology testing. Refer to D5311 I. 2. The laboratory failed to ensure ten (10) of ten (10) random Respiratory and COVID samples from June 2020 to July 2020 were extracted per laboratory policy. Refer to D5311 II. 3. The laboratory failed to establish detailed written instructions for providers to maintain integrity of samples. Refer to D5317. 4 The laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the preanalytic system. Refer to D5391.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3)

Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:
I. Based on observation, record review and interview with personnel, the laboratory failed to establish specimen handling, stability, and acceptability/rejection requirements for Bacteriology and Virology testing. Findings: 1. Observation by surveyors during laboratory tour on July 27, 2020 at 10:21 am revealed the laboratory utilizes two (2) Quant Studio 12K Flex instruments for the following lab developed high complexity testing: Respiratory Panel (includes Bordetella pertussis, Bordetella pan., Chlamydophila pneumoniae. Haemophilus influenza, Legionella pneumophila, Moraxella catarrhalis, Mycoplasma pnuemoniae, Streptococcus pneumoniae, Streptococcus pyogenes (Group A), Klebsiella pneumylococcus aureus, Adenovirus (Type 1 & 2), Bocavirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, Human Metapneumovirus (HMPV) A, HMPV B, Enterovirus (Pan, D68), Rhinovirus (Type 1 &2), Influenza A (Pan, H1, H3), Influenza B (Pan), Parainfluenza virus 1, Parainfluenza virus 2, Parainfluenza virus 3, Parainfluenza virus 4, RSV A, and RSV B) and SARS COV-2. 2. In interview on July 27, 2020 at 10:05 am the Quality Assurance personnel stated the laboratory began COVID testing on May 15, 2020. 3. In interview on July 27, 2020 at 10:09 am,Technical Supervisor 1 stated the laboratory began respiratory testing on April 26 or 28, 2020. 4.In interview on July 27, 2020 at 11:05 am, Testing Personnel 1 stated the laboratory began respiratory testing in March 2020. 5. Oberservation of laboratory's specimen receipt process on July 28, 2020 at 7:00am revealed the laboratory receives large shipments of patient samples in extra large styrofoam containers containing non-frozen ice packs at the bottom with patient samples filling on top. Further observation of this process revealed laboratory personnel did not detect or record specimen temperatures. Direct observation of surveyor at 7:35am on July 28, 2020 confirmed patient samples were not cool to touch. 6. In interview on July 28, 2020 at 7:30am, the manager of accessioning confirmed the temperature of samples is not checked by accessioning. 7. Observation by surveyor on July 28, 2020 at 8:56 am revealed accessioners separating samples based on test ordered. Surveyor observed the laboratory receiving samples in the following transport media tubes: a) Copan E-swab purple, white and green top tubes b) RMBIO 8. In interview on July 28, 2020 at 8:56 am, the manager of accessioning stated the different colored cap tubes depends on the manufacturer. 9. In interview on July 28, 2020 at 9:08 am the manager of accessioning stated she thought COVID samples are stable for a week and was unsure of the stability of respiratory panel samples. The manager of accessioning further stated the stability of the samples would be rejected on the laboratory side. The manager of accessioning further stated the accessioning area receives everything and rejects samples for missing demographic information, missing label or requisition; stability would be determined by the laboratory. 10. Review of the laboratory's records and policy and procedures revealed "Sample Collection, Handling and Shipping Condition" policy that revealed the following: a) Copan E swab transport media included b) Specimen handling stated "Place Oropharyngeal, Nasopharyngeal swabs or Nasopharyngeal wash/aspirate immediately into a sterile vial containing 1.0 ml of Liquid Amies transporting medium". c) Specimen storage conditions stated "after collection specimen samples can be either stored on ice packs or 4 degrees C until samples are received by Medlogic Laboratory." 11. Review of the e Swab package insert revealed "To maintain optimum organism viability, transport specimens collected using Eswab

	directly to the laboratory, preferably within 2 hours of collection. If immediate delivery or processing is delayed, then specimens shoudl be refrigerated at 4-8 C or stored and room temperature (20-25 C) and processed within 48 hours except for Neisseria gonorrhoeae cultures, which should be processed within 24 hours." 12. Further review of the laboratory's "Sample Collection, Handling and Shipping Condition" revealed the following information was not included: a) the different types of transport media the laboratory utilizes/accepts, including RMBIO b) specimen collection instructions, including training documentation for staff employed by the laboratory b) specimen handling to include the acceptable sample type c) specific sample storage and transport requirements d) stability study including raw data e) specimen acceptability/ rejection requirements including but not limited to what demographic information is required 13. In interview on July 27, 2020 at 10:21 am, Technical Supervisor 1 stated the laboratory only accepts nasopharyngeal samples. 14. In interview on July 29, 2020 at 3:40 pm, the Quality Assurance Manager confirmed the laboratory did not perform sample stability studies. The Quality Assurance Manager further confirmed the laboratory did not establish specimen handling requirements. 15. In interview on July 29, 2020 at 12:20 pm, Technical Supervisor 1 stated since May 14, 2020 119,010 Respiratory Panel and 16,156 COVID tests have been analyzed. II. Based on observation, record review, and interview with personnel, the laboratory failed to ensure ten (10) of ten (10) random Respiratory and COVID samples from June 2020 to July 2020 were extracted per laboratory policy. Findings: 1. Oberservation of laboratory's specimen receipt process on July 28, 2020 at 7:00am revealed the laboratory receives large shipments of patient samples in extra large styrofoam containers. 2. Review of the laboratory's policy and procedure manual revealed "Specimen Receiving, Accessioning, and Rejection SOP" policy that stated "Note: If the specimen will be processed (nucleic acid (DNA/RNA) extraction) for analysis immediately keep it at room temperature (20 degrees Celsius-25 degrees Celsius) and if within 24 hours after collection, refrigerate at 4-8 degrees Celsius." 3. Review of the laboratory's records revealed the laboratory did not establish specimen stability. 4. In interview on July 27, 2020 at 10:21 am, Testing Personnel 1 stated molecular samples are extracted the same day they are received. 5. Review of random selection of respiratory and COVID patient final test reports from June 2020 to July 2020 revealed the following ten (10) patients were received/extracted after 24 hours of collection without documentation of refrigeration: Patient 2006150502: collected June 13, 2020; accessioned June 15, 2020 Patient 2006170530: collected June 13, 2020; accessioned June 17, 2020 Patient 2006200706: collected June 19, 2020; accessioned June 22, 2020 Patient 2006260646: collected June 24, 2020; accessioned June 26, 2020 Patient 2007011252: collected June 29, 2020; accessioned July 2, 2020 Patient 2007070578: collected July 2, 2020; accessioned July 7. 2020 Patient 2007100977: collected July 9, 2020 7:41; accessioned July 13, 2020 16:04 Patient 2007110975: collected July 10, 2020 8:30; accessioned July 14, 2020 10:15 Patient 2007160728: collected July 15, 2020 16:23; accessioned: July 17, 2020 15:08 Patient 2007280538: collected July 26, 2020; accessioned July 28, 2020 6. In interview on July 29, 2020 at 12:20 pm, Technical Supervisor 1 stated since May 14, 2020 119,010 Respiratory Panel and 16,156 COVID tests have been analyzed.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section.

	This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to establish detailed written instructions for providers to maintain integrity of samples. Findings: 1. In interview on July 27, 2020 at 10:21 am, Technical Supervisor 1 stated the laboratory receives Respiratory Panel and COVID samples from all over the Gulf South. 2. Review of the laboratory's client list revealed the laboratory receives samples from Arizona, Alabama, Louisiana, Mississippi, Florida, Utah, Nevada, Tennessee, Georgia, Pennsylvania, and Texas. 3. Review of the laboratory's policy records revealed the laboratory did not establish a detailed written instructions for outside providers that includes the following: (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. 4. In interview on July 27, 2020 at 2: 34 pm, the Quality Assurance Manager stated the laboratory did not have a written client service manual for providers. 5. In interview on July 29, 2020 at 12:20 pm, Technical Supervisor 1 stated since May 14, 2020 119, 010 Respiratory Panel and 16,156 COVID tests have been analyzed.
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 observation, record review, and interview with personnel, the laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the preanalytic system. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory failed to have a Quality Assurance Policy to identify any of the deficiencies identified with the preanalytic system. 2. The laboratory failed to establish specimen handling, stability, and acceptability/rejection requirements for Bacteriology and Virology testing. Refer to D5311 I. 3. The laboratory failed to ensure ten (10) of ten (10) random Respiratory and COVID samples from June 2020 to July 2020 were extracted per laboratory policy. Refer to D5311 II. 4. The laboratory failed to establish detailed written instructions for providers to maintain integrity of samples. Refer to D5317. 5. In interview on July 27, 2020 at 2:09 pm, the Quality Assurance Manager confirmed the laboratory did not have written quality assurance policies and procedures.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

	This CONDITION is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to ensure the quality of testing within the analytic systems. Findings: 1. The laboratory failed to follow their established record retention policy. Refer to D5401 I. 2. The laboratory failed to establish a complete policy and procedure manual. Refer to D5401 II. 3. The laboratory failed to ensure the policy and procedure manual contained complete policies and procedures. Refer to D5403. 4. The laboratory failed to have current policies and procedures approved and signed by the current Laboratory Director. Refer to D5407. 5. The laboratory failed to establish performance specifications for Bacteriology and Virology testing on one (1) of two (2) Quant Studio 12 K Flex analyzers. Refer to D5423. 6. The laboratory failed to take corrective action when quality control (QC) was unacceptable for one (1) of ten (10) Respiratory panel patients reviewed per laboratory policy. Refer to D5783. 7. The laboratory failed to document corrective actions performed when the room temperature was not maintained within acceptable range for twenty (20) of eighty eight (88) days reviewed per laboratory policy. Refer to D5785 I. 8. The laboratory failed to document corrective actions performed when the room humidity was not maintained within acceptable range for fourteen (14) of eighty eight (88) days reviewed per laboratory policy. Refer to D5785 II. 9. The laboratory failed to document corrective actions performed when the freezer temperature was not maintained within acceptable range for two (2) of eighty eight (88) days reviewed per laboratory policy. Refer to D5785 III. 10. The laboratory failed to have a system in place to identify the specific instrument Respiratory samples are tested on. Refer to D5787. 11. The laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the analytic system. Refer to D5791.
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: I. Based on policy review, record review, and interview with personnel, the laboratory failed to follow their established record retention policy. Findings: 1. Review of the laboratory's "Document Control, Storage, and Retention" policy under "Record Retention" section revealed "All records must be maintained for a minimum of two years. Patient laboratory orders, specimen requisition, patient test records, quality control records, calibration records, instrument maintenance records, corrective action logs, proficiency testing records, quality assessment records, patient test reports, laboratory logs, personnel records." 2. In interview on July 27, 2020 at 11:00 am, Testing Personnel 1 stated he did not keep instrument printouts that he manually writes patient results on prior to June 2020 for Respiratory Panel testing. 3. Review of proficiency test records for Respiratory and COVID testing revealed the laboratory did not include the following: a) 2019 IDR-B Infectious Disease, Respiratory: signed attestation statement and raw instrument data b) 2019 IDR-C Infectious Disease, Respiratory: signed attestation statement and raw instrument data c) 2020 COVID: signed attestation statement II. Based on policy and procedure manual review and interview with personnel, the laboratory failed to establish a complete policy and

	procedure manual. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not include the following policies: a) Proficiency Testing including requirements for handling, testing, reporting, and actions for failures b) Twice a year verification procedure for the accuracy of Respiratory Panel testing including acceptability criteria and corrective action plan c) Complaint Investigations to include how to address, document and handle complaints or problems reported to the laboratory d) Personnel competency e) Twice a year instrument comparison of test results for the Quant Studio 12K instruments f) Corrected reports e) Turnaround time for results 2. In interview on July 27, 2020 at 2: 03 pm, the Quality Assurance Manager confirmed the laboratory did not have the identified policies.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure the policy and procedure manual contained complete policies and procedures. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory's written policies and procedures did not include: a) Detailed policies and procedures for patient preparation; to include specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection b) Written instructions of how the laboratory performs preparation and sterility check for RMBIO viral transport media packs 2. In interview on July 28, 2020 at 10:19 am the Technical Supervisor 1 stated staff prepares the RMBIO tubes using a portion of the Centers for Disease Control and Prevention "Preparation of Viral Transport Medium." In further interview at 12:00 pm, the Technical Supervisor 1 stated the laboratory does not perform the sterility check that is listed in the Center for Disease Control and Prevention "Preparation of Viral Transport Medium." Technical Supervisor 1 stated the laboratory tests the new lot of RMBIO Viral Transport Media solution by running as a blank on the plate prior to use. Technical Supervisor 1 confirmed the laboratory did not include written instructions of the laboratory's procedure.

D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on policy and procedure manual review and interview with personnel, the laboratory failed to have current policies and procedures approved and signed by the current Laboratory Director. Findings: 1. Review of the laboratory's policy and procedure manual on July 27, 2020 revealed the following procedures were not approved and signed by the current Laboratory Director: a) "Packing and Shipping of SARS COV-2 Patient Specimens, Cultures, or Isolates b) Document Control, Storage, and Retention c) Bloodborne Pathogen Exposure Control Plan d) Instrument Calibration/Recertification and Preventative Maintenance e) Temperature and Humidity Monitoring f) Validation Plan: Respiratory Panels Using Taqman Open Array Technology g) COVID 19 SOP" 2. In interview on July 27, 2020 at 1:43 pm, the Quality Assurance Manager confirmed the current Laboratory Director had not approved/signed the indicated policies.
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: Based on observation, record review, and interview with personnel, the laboratory failed to establish performance specifications for Bacteriology and Virology testing on one (1) of two (2) Quant Studio 12 K Flex analyzers. Findings: 1. Observation by surveyors during the laboratory tour on July 27, 2020 at 10:21 am revealed the laboratory utilizes two (2) Quant Studio 12 K Flex instruments for the following high complexity testing: Respiratory Panel (includes Bordetella pertussis, Bordetella pan., Chlamydophila pneumoniae. Haemophilus influenza, Legionella pneumophila, Moraxella catarrhalis, Mycoplasma pneumoniae, Streptococcus pneumoniae, Streptococcus pyogenes (Group A), Klebsiella pneumylococcus aureus, Adenovirus (Type 1 & 2), Bocavirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, Human Metapneumovirus (HMPV) A, HMPV B, Enterovirus (Pan, D68), Rhinovirus (Type 1 &2), Influenza A (Pan, H1, H3), Influenza B (Pan), Parainfluenza virus (PIV) 1, Parainfluenza virus 2, Parainfluenza virus 3, Parainfluenza virus 4, RSV A, and RSV B) and SARS COV-2. 2. Review of the laboratory's validation records on July 28, 2020 revealed the Laboratory Director did not approve/sign the validation studies for Quant Studio 12 K Instrument "1" (SN:

	285881360). 3. Review of the laboratory's validation records on July 28, 2020 revealed the laboratory did not have validation studies that included precision, analytical sensitivity and specificity studies, acceptability criteria and approval from Laboratory Director for Quant Studio 12 K Instrument "2" (SN: 285881027). 4. In interview on July 28, 2020 at 2:40 pm, the Quality Assurance Manager confirmed the Laboratory Director did not sign the validation studies for Quant Studio 12 K Instrument "1." 5. Further review of the laboratory's validation records on July 28, 2020 revealed the laboratory performed an instrument comparison between Quant Studio 12 K Instrument "1" and Instrument "2." 6. In interview on July 27, 2020 at 11: 23 am, Testing Personnel 1 sated he performed validation studies for Quant Studio 12 K Flex Instrument "1" and did a comparison for Quant Studio 12 K Flex Instrument "2." 7. In interview on July 29, 2020 at 12:20 pm, Technical Supervisor 1 stated since May 14, 2020, 119,010 Respiratory Panel and 16,156 COVID tests have been analyzed..
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to take corrective action when quality control (QC) was unacceptable for one (1) of ten (10) Respiratory panel patients reviewed per laboratory policy. Findings: 1. Observation by surveyors during laboratory tour on July 27, 2020 at 10:35 am revealed the laboratory utilizes two (2) Quant Studio 12 K Flex instruments for Respiratory Panel and COVID testing. 2. Review of the laboratory's "MedLogic Respiratory Panels: Open Array Assay SOP" under the "Quality Control" section revealed the following: "9.3 Each run must contain a valid BA control. This sample should show amplification in the Bacillus atrophaeus target only. This serves as the DNA extraction control for the run. Runs with out of range BA control values must be reviewed by the Technical Supervisor who will determine further actions." 3. In interview on July 28, 3030 at 12:52 pm, Testing Personnel 1 stated B. atrophaues and Xeno are run as extraction controls at the beginning of each run. 4. Review of quality control, patient run logs, and instrument data of random selection of patients from May 2020 through July 2020 revealed one (1) of ten (10) patients/runs reviewed did not include a B. atrophaeus control for the following: Quant Studio 12 K Flex Instrument Number 2, Patient 200619514. 5. In interview on July 28, 2020 at 12:52 pm, Testing Personnel 1 stated it did not appear as if the B. atrophaeus control was added to the run. Testing Personnel 1 stated the plate was acceptable since the RNP, which is a back up extraction control, was acceptable. 6. Further review of the patient run log that revealed the following ten (10) patients were included on the identified run: Total of twenty (20) patients: Patient 200619501 Patient 200619502 Patient 200619503 Patient 200619504 Patient 200619505 Patient 200619506 Patient 200619507 Patient 200619508 Patient 200619509 Patient 200619510

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: I. Based on record review of temperature logs, policies, and interview with personnel, the laboratory failed to document corrective actions performed when the room temperature was not maintained within acceptable range for twenty (20) of eighty eight (88) days reviewed per laboratory policy. Findings: 1. Review of the laboratory's "Temperature and Humidity Monitoring" policy revealed "Record the temperature onto the log sheet and ensure the temperature is within its respective temperature requirements listed on the temperature/humidity log sheet. If the temperature is not within the specified range, immediately inform lab management and QA personnel so an investigation and assessment can be conducted." 2. Review of the laboratory's temperature logs revealed the following acceptable room temperature range: "20 degrees Celsius to 25 degrees Celsius." 3. In interview on July 27, 2020 at 11:30 am, Testing Personnel 1 stated if room temperature or humidity is out of range the laboratory would not test. 4. Review of the laboratory and accession area's 2020 temperature logs revealed the room temperature was documented as outside of the acceptable limits without documented corrective actions for the following twenty (20) dates: "PCR Lab: Extraction/Accession Room:" May 29, 2020 documented room temperature 26.1 degrees Celsius June 6, 2020 documented room temperature 25.5 degrees Celsius June 7, 2020 documented room temperature 25.6 degrees Celsius June 11, 2020 documented room temperature 25.1 degrees Celsius June 20, 2020 documented room temperature 26.6 degrees Celsius, with note "will monitor to see if temperature will down", no further documentation of investigation or action performed "PCR Lab-PreAmp/Post Amp Room:" May 29, 2020 documented room temperature 25.1 degrees Celsius June 6, 2020 documented room temperature 25.5 degrees Celsius June 7, 2020 documented room temperature 25.1 degrees Celsius June 9, 2020 documented room temperature 25.5 degrees Celsius June 20, 2020 documented room temperature 26.6 degrees Celsius, with note "will monitor to see if temperature will down", no further documentation of investigation or action performed June 22, 2020 documented room temperature 25.1 degrees Celsius "Room Temperature and Humidity Log : Toxicology Lab" July 1, 2020 documented room temperature 25.2 degrees Celsius July 2, 2020 documented room temperature 25.7 degrees Celsius July 3, 2020 documented room temperature 18.7 degrees Celsius July 6, 2020 documented room temperature 16.5 degrees Celsius July 7, 2020 documented room temperature 19.2 degrees Celsius July 8, 2020 documented room temperature 19.3 degrees Celsius July 13, 2020 documented room temperature 19.2 degrees Celsius July 14, 2020 documented room temperature 19.9 degrees Celsius July 16, 2020 documented room temperature 18.9 degrees Celsius July 22, 2020 documented room temperature 19.8 degrees Celsius July 23, 2020 documented room temperature 19.7 degrees Celsius July 24, 2020 documented room temperature 19.9 degrees Celsius July 26, 2020 documented room temperature 19.1 degrees Celsius July 27, 2020 documented room temperature 19.5 degrees Celsius 5. In interview on July 27, 2020 at 11:45 am, the Technical Supervisor stated if temperatures/humidity were outside of the acceptable range corrective actions would be noted on the log sheet. Technical Supervisor 1 confirmed the laboratory did not have documentation of corrective actions for the identified dates with documented room temperatures outside

of acceptable limits. 6. In interview on July 28, 2020 at 9:21 am, the Quality Assurance Manager stated the temperature log labeled "Room Temperature and Humidity Log: Toxicology Lab" is for the specimen receiving area where samples are accessioned. The Quality Assurance Manager confirmed the identified dates for the specimen receiving/accessioning area did not have documented corrective action. II. Based on review of policies, temperature/humidity logs, and interview with personnel, the laboratory failed to document corrective actions performed when the room humidity was not maintained within acceptable range for fourteen (14) of eighty eight (88) days reviewed per laboratory policy. Findings: 1. Review of the laboratory's "Temperature and Humidity Monitoring" policy revealed "Record the humidity onto the temperature/humidity log sheet and ensure that the humidity is within the listed humidity range specification. If the humidity recorded is not within the specified range, immediately inform lab management and QA personnel so an investigation and assessment can be conducted." 2. Review of the laboratory's temperature logs revealed the following acceptable room humidity range: "40 % to 80 %." 3. In interview on July 27, 2020 at 11:30 am, Testing Personnel 1 stated if room temperature or humidity is out of range the laboratory would not test. 4. Review of the laboratory and accession area 2020 temperature/humidity logs revealed the humidity was documented as outside of the acceptable limits without documented corrective actions for the following fourteen (14) dates: "PCR Lab: Extraction/Accession Room:" June 30, 2020 documented humidity 39 % July 2, 2020 documented humidity 37 %, with note "Humidity is out of range. Will monitor;" no further documentation of investigation or action performed July 3, 2020 documented humidity 36 % July 10, 2020 documented humidity 39 % July 11, 2020 documented humidity 36 % July 15, 2020 documented humidity 36 % July 16, 2020 documented humidity 39 % July 17, 2020 documented humidity 37 % July 22, 2020 documented humidity 39 % "PCR Lab-PreAmp/Post Amp Room:" June 22, 2020 documented humidity 36 %, with note "Will monitor to see if humidity stabilize;" no further documentation of investigation or action performed June 23, 2020 documented humidity 38 % "Room Temperature and Humidity Log : Toxicology Lab" July 1, 2020 documented humidity 35 % July 2, 2020 documented humidity 32 % July 6, 2020 documented humidity 31 % July 12, 2020 documented humidity 31 % 5. In interview on July 27, 2020 at 11:45 am, the Technical Supervisor stated if temperatures/humidity were outside of the acceptable range corrective actions would be noted on the log sheet. Technical Supervisor 1 confirmed the laboratory did not have documentation of corrective actions for the identified dates with documented room humidity outside of acceptable limits. 6. In interview on July 28, 2020 at 9:21 am, the Quality Assurance Manager stated the temperature log labeled "Room Temperature and Humidity Log: Toxicology Lab" is for the specimen receiving area where samples are accessioned. The Quality Assurance Manager confirmed the identified dates for the specimen receiving /accessioning area did not have documented corrective action. III. Based on review of temperaure logs and interview with personnel, the laboratory failed to document corrective actions performed when the freezer temperature was not maintained within acceptable range for two (2) of eighty eight (88) days reviewed per laboratory policy. Findings: 1. Review of the laboratory's "Refrigerator of Freezer Temperature Log" revealed for the "Extraction/Accession Room" the following acceptable freezer temperature range "-20 degrees Celsius to -30 degrees Celsius." 2. Review of the freezer temperature logs revealed the following two (2) dates the freezer temperature was documented as outside of the acceptable limits without documented corrective actions: "Extraction/Accession Room Freezer S/N 0145654101140501:" July 8, 2020 documented freezer temperature -19.4 degrees Celsius July 9, 2020 document freezer temperature -19.4 degrees Celsius 3. In interview on July 27, 2020 at 11:45 am, the Technical Supervisor stated if temperatures/humidity were outside of the acceptable

	range corrective actions would be noted on the log sheet. Technical Supervisor 1 confirmed the laboratory did not have documentation of corrective actions for the identified dates with documented freezer temperatures outside of acceptable limits.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to have a system in place to identify the specific instrument Respiratory samples are tested on. Findings: 1. Observation by surveyors during laboratory tour on July 27, 2020 at 10:21 am revealed the laboratory utilizes two (2) Quant Studio 12K Flex instruments for the following high complexity testing: Respiratory Panel (includes Bordetella pertussis, Bordetella pan., Chlamydophila pneumoniae. Haemophilus influenza, Legionella pneumophila, Moraxella catarrhalis, Mycoplasma pneumoniae, Streptococcus pneumoniae, Streptococcus pyogenes (Group A), Klebsiella pneumylococcus aureus, Adenovirus (Type 1 & 2), Bocavirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, Human Metapneumovirus (HMPV) A, HMPV B, Enterovirus (Pan, D68), Rhinovirus (Type 1 &2), Influenza A (Pan, H1, H3), Influenza B (Pan), Parainfluenza virus 1, Parainfluenza virus 2, Parainfluenza virus 3, Parainfluenza virus 4, RSV A, and RSV B) and SARS COV-2. 2. Review of random selection of respiratory panel patient runs revealed the laboratory can not identify the specific instrument the patient sample is tested on. 3. In interview on July 28, 2020 at 12:30 pm, Testing Personnel 1 stated he is unsure which analyzer ran which patient. Testing Personnel 1 stated he has been trying to come up with a way to track it.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the analytic system. Findings: 1. The laboratory failed to follow their established record retention policy. Refer to D5401 I. 2. The laboratory failed to establish a complete policy and procedure manual. Refer to D5401 II. 3. The laboratory failed to ensure the policy and procedure manual contained complete policies and procedures. Refer to D5403. 4. The laboratory failed to have current policies and procedures approved and signed by the current Laboratory Director. Refer to D5407. 5. The

	laboratory failed to establish performance specifications for Bacteriology and Virology testing on one (1) of two (2) Quant Studio 12 K Flex analyzers. Refer to D5423. 6. The laboratory failed to take corrective action when quality control (QC) was unacceptable for one (1) of ten (10) Respiratory panel patients reviewed per laboratory policy. Refer to D5783. 7. The laboratory failed to document corrective actions performed when the room temperature was not maintained within acceptable range for twenty (20) of eighty eight (88) days reviewed per laboratory policy. Refer to D5785 I. 8. The laboratory failed to document corrective actions performed when the room humidity was not maintained within acceptable range for fourteen (14) of eighty eight (88) days reviewed per laboratory policy. Refer to D5785 II. 9. The laboratory failed to document corrective actions performed when the freezer temperature was not maintained within acceptable range for two (2) of eighty eight (88) days reviewed per laboratory policy. Refer to D5785 III. 10. The laboratory failed to have a system in place to identify the specific instrument Respiratory samples are tested on. Refer to D5787. 11. In interview on July 27, 2020 at 2:09 pm, the Quality Assurance Manager confirmed the laboratory did not have written quality assurance policies and procedures.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: I. Based on record review and interview with personnel, the laboratory failed to include the correct CLIA Identification number on the patient final reports. Findings: 1. Review of random selection of patient final reports from May 2020 through July 2020 revealed the laboratory included the following comment on patient final reports: "This test was developed and its performance characteristics determined by Medlogic Laboratory. It has not been cleared of approved by the FDA. However, such approval /clearance is not required, as the laboratory is regulated and qualified under CLIA to perform high-complexity testing (CLIA # 19D2066157). This test is used for clinical purposes, and should not be regarded as investigational or for research." 2. Review of the laboratory's CLIA 116 application revealed June 1, 2020 as the effective certificate date for Microbiology specialty with subspecialities of Bacteriology and Virology. 3. Review of the sister laboratory's (19D2066157) CLIA 116 Application revealed the laboratory is enrolled in Chemistry and Hematology specialties, not in Bacteriology and Virology. 4. Interview with the Technical Supervisor 1 on July 29, 2020 at 9:30am revealed the sister laboratory (19D2066157) ceased testing in February 2020. 5. In interview on July 29, 2020, Technical Supervisor 1 stated he was unaware the laboratory included the CLIA ID number of their sister laboratory (19D2066157) on patient final reports. 6. In interview on July 29, 2020 at 12:20 pm, Technical Supervisor 1 stated since May 14, 2020 119, 010 Respiratory Panel and 16,156 COVID tests have been analyzed. II. Based on record review and interview with personnel, the laboratory failed to include a complete Food and Drug

	Administration (FDA) Emergency Use Authorization statement on patient final reports. Findings: 1. Review of random selection of patient final reports from May 2020 through July 2020 revealed the laboratory included the following statement: "Medlogic Laboratories validation of the SARS-CoV-2 assay is pending FDA review and approval." 2. Further review of the laboratory's specified comment revealed the laboratory did not include the FDA review for SARS-COVID assay is for Emergency Use Authorization, not FDA approval. 3. In interview on July 29, 2020, Technical Supervisor 1 confirmed the laboratory did not include a statement that the SARS-COVID assay is for Emergency Use Authorization.
D5815	TEST REPORT CFR(s): 493.1291(h) When the laboratory cannot report patient test results within its established time frames, the laboratory must determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual(s) of the delayed testing. This STANDARD is not met as evidenced by: Based on review of laboratory's policies, patient final reports, and interview with personnel, the laboratory failed to notify clients of delay in testing for sixteen (16) of thirty eight (38) Respiratory Panel and COVID patient samples from May 2020 through July 2020. Findings: 1. Review of the laboratory's policy and procedure manual on July 27, 2020 revealed the laboratory did not include a written turnaround timeframe for the test process. 2. In interview on July 29, 2020 at 10:08 am, the Quality Assurance Manger stated the turnaround times for the entire process for COVID testing is 1-2 days and for Respiratory 2-4 days. The Quality Assurance Manager later stated the times indicated were from receiving to reporting. 3. Review of random selection of patient final reports from May 2020 through July 2020 revealed the following sixteen (16) patients exceeded the time frame indicated: Respiratory and COVID testing: a) Patient 2005050510: received May 5, 2020; reported May 17, 2020 b) Patient 2006190514: Received June 19, 2020; reported June 25, 2020 c) Patient 2006230524: received June 23, 2020; reported June 30, 2020 d) Patient 2007110975: received July 14, 2020; reported July 20, 2020 e) Patient 2007140656: received July 14, 2020; reported July 20, 2020 f) Patient 2007151830: received July 15, 2020; reported July 26, 2020 g) Patient 2007170542: received July 17, 2020; preliminary report given to surveyor July 28, 2020, final results not reported as of July 28, 2020 h) Patient 2007160728: received July 17, 2020; reported July 27, 2020 COVID testing: a) Patient 2006150504: received June 15, 2020: reported June 23, 2020 b) Patient 2006160782: received June 16, 2020: reported June 25, 2020 c) Patient 2007110960: received July 14, 2020; reported July 19, 2020 d) Patient 2007110988: received July 14, 2020; reported July 20. 2020 e) Patient 2007151831: received July 15, 2020; reported July 26, 2020 f) Patient 2007140913: received July 15, 2020; reported July 19, 2020 g) Patient 2007160225: received July 16, 2020; reported July 20, 2020 h) Patient 2007160233: received July 17, 2020; reported July 20, 2020 4. Review of laboratory records revealed the laboratory did not have documentation of notifiying clients of the delay in test results for the sixteen (16) identified patients.
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the

	following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to indicate on seven (7) corrected COVID patient test reports that the report/ result is a corrected one. Findings: 1. In interview on July 27, 2020 at 2:22 pm, Technical Supervisor 1 stated the laboratory reports samples needing a retest as "Inconclusive." Technical Supervisor 1 further stated after the sample is retested the result is changed to "positive" or "negative" and a new report is issued to providers. 2. Review of the laboratory's policy and procedure manual revealed the laboratory did not have a written procedure for corrected reports. 3. Review on July 29, 2020 of the following COVID patient final test reports revealed the changed report did not have documentation indicating the report findings were corrected: Patient 2007030782 Patient 2007140991 Patient 2007090845 Patient 2007060604 Patient 2007060563 Patient 2007030793 Patient 2007140745 4. In further interview on July 27, 2020 at 2: 22 pm, Technical Supervisor 1 stated he was unaware that the change of the result from "inconclusive" was considered a corrected report.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to establish quality assurance monitors to identify and correct problems in the Post Analytic system. Findings: 1. The laboratory failed to include the correct CLIA Identification number on the patient final reports. Refer to D5805 I. 2. The laboratory failed to include a complete Food and Drug Administration (FDA) Emergency Use Authorization statement on patient final reports. Refer to D5805 II. 3. The laboratory failed to notify clients of delay in testing for sixteen (16) of thirty eight (38) Respiratory Panel and COVID patient samples from May 2020 through July 2020. Refer to D5815. 4. The laboratory failed to indicate on seven (7) corrected COVID patient test reports that the report/ result is a corrected one. Refer to D5821. 5. In interview on July 27, 2020 at 2:09 pm, the Quality Assurance Manager confirmed the laboratory did not have written quality assurance policies and procedures.
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 observation, record review, and interview with personnel, the Laboratory Director failed to provide overall management and direction. Findings: 1. The Laboratory Director failed to delegate, in writing, the responsibilities of Technical Supervisor and General Supervisor. Refer to D6082. 2. The Laboratory Director failed to establish complete performance specifications for Bacteriology and Virology testing. Refer to D6086. 3. The Laboratory Director failed to ensure the laboratory personnel were performing test methods as required. Refer to D6087. 4. The Laboratory Director failed to ensure proficiency samples are tested as required. Refer to D6089. 5. The Laboratory Director failed to ensure that a quality assessment (QA) program was established to assure the quality of laboratory services provided. Refer to D6094. 6. The Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D6096. 7. The Laboratory Director failed to ensure final reports for Bacteriology and Virology tests included pertinent information. Refer to D6098. 8. The Laboratory Director failed to ensure three (3) of five (5) Testing Personnel reviewed had current licenses issued by the State of Louisiana Board of Medical Examiners (LSBME). Refer to D6101 I. 9. The Laboratory Director failed to ensure one (1) of three (3) General Supervisors met the state of Louisiana licensure requirement. Refer to D6101 II. 10. The Laboratory Director failed to ensure a sufficient number of testing personnel are employed for the laboratory's test volume. Refer to D6101 III. 11. The Laboratory Director failed to ensure two (2) of five (5) Testing Personnel reviewed had documentation of training prior to patient testing. Refer to D6102. 12. The Laboratory Director failed to ensure complete policies and procedures were established for assessing personnel competency. Refer to D6103. 13. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D6106. 14. The Laboratory Director failed to include written duties and responsibilities for personnel involved in all phases of testing. Refer to D6107.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to delegate, in writing, the responsibilities of Technical Supervisor and General Supervisor. Findings: 1. Review of the laboratory's CMS 209 form (Laboratory Personnel Report) revealed the Technical Supervisor 1 served as the Technical Supervisor and General Supervisor. 2. Review of personnel records revealed the laboratory did not have documentation of the Laboratory Director delegating the tasks and responsibilities of Technical and General Supervisor to him. 3. In interview on July 27, 2020 at 9:05 am, the Quality Assurance Manager confirmed the laboratory did not have the indicated written delegations.
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 observation, record review, and interview with personnel, the Laboratory Director failed to establish complete performance specifications for Bacteriology and Virology testing. Refer to D5423.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel were performing test methods as required. Findings: 2. The laboratory failed to establish specimen handling, stability, and acceptability/rejection requirements for Bacteriology and Virology testing. Refer to D5311 I. 3. The laboratory failed to ensure ten (10) of ten (10) random Respiratory and COVID samples from June 2020 to July 2020 were extracted per laboratory policy. Refer to D5311 II. 4. The laboratory failed to establish detailed written instructions for providers to maintain integrity of samples. Refer to D5317. 5. The laboratory failed to have a system in place to identify the specific instrument Respiratory samples are tested on. Refer to D5787.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure proficiency samples are tested as required. Findings: 1. The laboratory failed to ensure no inter-laboratory communications occured for proficiency testing samples prior to the cut-off date for submission of test results for four (4) of four (4) testing events reviewed. Refer to D2011. 2. The laboratory failed to report to Centers for Medicaid and Medicare Services (CMS) the receipt of proficiency testing samples from another laboratory. Refer to D2013. 3. The laboratory failed to ensure the accuracy of non regulated Bacteriology and Virology analytes at least twice annually. Refer to D5217.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment 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 observation, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was established to assure the quality of laboratory services provided. Findings: 1. The laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the preanalytic system. Refer to D5391. 2. The laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the analytic system. Refer to D5791. 3. The laboratory failed to establish quality assurance monitors to identify and correct problems in the Post Analytic system. Refer to D5891.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Findings: 1. The laboratory failed to take corrective action when quality control (QC) was unacceptable for one (1) of ten (10) Respiratory panel patients reviewed per laboratory policy. Refer to D5783. 2. The laboratory failed to document corrective actions performed when the room temperature was not maintained within acceptable range for twenty (20) of eighty eight (88) days reviewed per laboratory policy. Refer to D5785 I. 3. The laboratory failed to document corrective actions performed when the room humidity was not maintained within acceptable range for fourteen (14) of eighty eight (88) days reviewed per laboratory policy. Refer to D5785 II. 4. The laboratory failed to document corrective actions performed when the freezer temperature was not maintained within acceptable range for two (2) of eighty eight (88) days reviewed per laboratory policy. Refer to D5785 III.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) The laboratory director must ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure final reports for Bacteriology and Virology tests included pertinent information. Findings: 1. The laboratory failed to include the correct CLIA Identification number on the patient final reports. Refer to D5805 I. 2. The laboratory failed to include a complete Food and Drug Administration (FDA) Emergency Use Authorization statement on patient final reports. Refer to D5805 II. 3. The laboratory failed to notify clients of delay in testing for sixteen (16) of thirty eight (38) Respiratory Panel and COVID patient samples from May 2020 through July 2020. Refer to D5815. 4. The laboratory failed to indicate on seven (7) corrected COVID patient test reports that the report/ result is a corrected one. Refer to D5821.

D6101	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(11) The laboratory director must employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart. This STANDARD is not met as evidenced by: I. Based on personnel record review and interview with personnel, the Laboratory Director failed to ensure three (3) of five (5) Testing Personnel reviewed had current licenses issued by the State of Louisiana Board of Medical Examiners (LSBME). Refer to D6170. II. Based on personnel record review and interview with personnel, the Laboratory Director failed to ensure one (1) of three (3) General Supervisors met the state of Louisiana licensure requirement. Refer to D6143. III. Based on observation, record review, and interview with personnel the Laboratory Director failed to ensure a sufficient number of testing personnel are employed for the laboratory's test volume. Findings: 1. Observation by surveyors during the laboratory tour on July 27, 2020 at 10:21 am revealed the laboratory utilizes two (2) Quant Studio 12K Flex instruments for the following high complexity testing: Respiratory Panel (includes Bordetella pertussis, Bordetella pan., Chlamydophila pneumoniae. Haemophilus influenza, Legionella pneumophila, Moraxella catarrhalis, Mycoplasma pneumoniae, Streptococcus pneumoniae, Streptococcus pyogenes (Group A), Klebsiella pneumylococcus aureus, Adenovirus (Type 1 & 2), Bocavirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, Human Metapneumovirus (HMPV) A, HMPV B, Enterovirus (Pan, D68), Rhinovirus (Type 1 &2), Influenza A (Pan, H1, H3), Influenza B (Pan), Parainfluenza virus (PIV) 1, Parainfluenza virus 2, Parainfluenza virus 3, Parainfluenza virus 4, RSV A, and RSV B) and SARS COV-2. 2. In interview on July 27, 2020 at 10:25 am, Testing Personnel 1 stated the laboratory receives approximately 400-600 samples a day. 3. In interview on July 29, 2020 at 12:20 pm, Technical Supervisor 1 stated since May 14, 2020, 119,010 Respiratory Panel and 16,156 COVID tests have been analyzed. 4. Review of personnel records revealed three (3) of four (4) current Testing Personnel do not have state of Louisiana Board of Medical Examiners (LSBME) licenses for testing. Refer to D6170. 5. In further interview on July 27, 2020 at 11:00 am, Testing Personnel 1 stated Testing Personnel 2 only performs extraction of samples. Testing Personnel 1 performs processing of samples after extraction and interpretation of results for COVID and Respiratory testing. 5. In interview on July 27, 2020 at 12:47 pm, the Quality Assurance Manager stated Testing Personnel 3 works second shift and performs extractions. 6. Review on July 27, 2020 of personnel records for Testing Personnel 3 revealed her hire date as July 20, 2020, with no documentation of training. 7. In interview on July 29, 2020 at 9:05 am, Quality Assurance stated Testing Personnel 3 completed training and the Laboratory Director signed the training documents on "7/28/2020." 8. Review of training documents provided to surveyor on July 29, 2020 revealed Testing Personnel 3 completed training for extraction and COVID test, not respiratory. 9. Observation by surveyors on July 29, 2020 at 10:32 am, revealed Testing Personnel 2 and Testing Personnel 3 extracting patient samples. Testing Personnel 1 was scheduled off for the day. 10. In interview on July 29, 2020 at 10:32 am, Testing Personnel 3 stated Respiratory samples would be extracted and held until Testing Personnel 1 returned to work. 11. In interview on July 29, 2020 at 9: 33 am, Technical Supervisor 1 stated he has been trained to interpret COVID results, not respiratory.

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 personnel record review and interview with personnel, the Laboratory Director failed to ensure two (2) of five (5) Testing Personnel reviewed had documentation of training prior to patient testing. Findings: 1. Review of personnel records for Testing Personnel 1 revealed no documentation of an initial training or approval by Laboratory Director for Respiratory Panel and COVID testing. 2. In interview on July 27, 2020 at 12:34 pm, the Quality Assurance Manger stated he was unsure if Testing Personnel 1 was grandfathered in or who assessed his competency. The Quality Assurance Manager stated he suspected the training for Testing Personnel 1 was not documented. 3. Review of personnel records for previously employed Technical Supervisor 2, who also served as testing personnel, revealed the laboratory did not have documentation of training for Respiratory Panel and COVID testing. 4. In interview on July 27, 2020 at 12:47 pm , the Quality Assurance Manger confirmed the laboratory did not have training documentation of testing competency for Technical Supervisor 2.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure complete policies and procedures were established for assessing personnel competency. Findings: 1. The laboratory failed to establish written policies and procedures to assess competency for testing personnel. Refer to D5209 I. 2. The laboratory failed to establish written policies and procedures to address competency for two (2) of two (2) Technical Supervisors and General Supervisors reviewed were complete. Refer to D5209 II.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.

	This STANDARD is not met as evidenced by: Based on policy and procedure manual review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Findings: 1. The laboratory failed to retain a copy of discontinued test procedure for antibiotic resistance testing. Refer to D3029. 2. The laboratory failed to have a system for handling complaints and problems reported to the laboratory. Refer to D5205. 3. The laboratory failed to follow their established record retention policy. Refer to D5401 I. 4. The laboratory failed to establish a complete policy and procedure manual. Refer to D5401 II. 5. The laboratory failed to ensure the policy and procedure manual contained complete policies and procedures. Refer to D5403. 6. The laboratory failed to have current policies and procedures approved and signed by the current Laboratory Director. Refer to D5407.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to include written duties and responsibilities for personnel involved in all phases of testing. Findings: 1. Review of the laboratory's policy and procedure manual and personnel records, revealed job duties for the following personnel were not included: a) Laboratory Director b) Clinical Consultant: no written job description and no written statement of who serves in this role c) General Supervisor 2. Further review of the laboratory's policy and procedure manual revealed the laboratory included a job description for "Technologist" and "Technical Supervisor;" however, no written statement specifying which personnel were assigned to these roles were included. 3. In interview on July 27, 2020 at 9:05 am, the Quality Assurance Manager confirmed the laboratory did not have the indicated written duties.
D6112	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451 The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section. This STANDARD is not met as evidenced by: Based on observation and interview with personnel, the Technical Supervisor failed to provide technical and scientific oversight for the laboratory. Findings: 1. The laboratory failed to establish specimen handling, stability, and acceptability/rejection requirements for Bacteriology and Virology testing. Refer to D5311 I. 2. The laboratory failed to ensure ten (10) of ten (10) random Respiratory and COVID

	samples from June 2020 to July 2020 were extracted per laboratory policy. Refer to D5311 II. 3. The laboratory failed to establish detailed written instructions for providers to maintain integrity of samples. Refer to D5317. 4. The laboratory failed to have a system in place to identify the specific instrument Respiratory samples are tested on. Refer to D5787.
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 observation, record review, and interview with personnel, the Technical Supervisor failed to ensure the laboratory established complete performance specification for Bacteriology and Virology testing. Refer to D5423.
D6116	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(3) The technical supervisor is responsible for enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Technical Supervisor failed to ensure laboratory personnel performed proficiency samples as required. Findings: 1. The laboratory failed to ensure no inter-laboratory communications occurred for proficiency testing samples prior to the cut-off date for submission of test results for four (4) of four (4) testing events reviewed. Refer D2011. 2. The laboratory failed to report to Centers for Medicaid and Medicare Services (CMS) the receipt of proficiency testing samples from another laboratory. Refer to D2013. 3. The laboratory failed to ensure the accuracy of non regulated Bacteriology and Virology analytes at least twice annually. Refer to D5217.
D6118	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(5) The technical supervisor is responsible for resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Technical Supervisor failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Findings: 1. The laboratory failed to take corrective action when quality control (QC) was unacceptable for one (1) of ten (10) Respiratory panel patients reviewed per laboratory policy. Refer to D5783. 2. The laboratory failed to document corrective actions performed when the room temperature was not maintained within acceptable range for twenty (20) of eighty

	eight (88) days reviewed per laboratory policy. Refer to D5785 I. 3. The laboratory failed to document corrective actions performed when the room humidity was not maintained within acceptable range for fourteen (14) of eighty eight (88) days reviewed per laboratory policy. Refer to D5785 II. 4. The laboratory failed to document corrective actions performed when the freezer temperature was not maintained within acceptable range for two (2) of eighty eight (88) days reviewed per laboratory policy. Refer to D5785 III.
D6121	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Supervisor failed to ensure the criteria for assessing testing personnel competency for 2020 were complete. Findings: 1. Review of the laboratory's policy and procedure manual on July 27, 2020 revealed the laboratory utilizes the following competency assessment forms: a) "Competency Assessment Form: Nucleic Acid Extraction" b) "Competency Assessment Form: Data Integration and Reporting to LIMS" 2. In interview on July 27, 2020 at 12:34 pm, the Quality Assurance Manager stated the indicated "Competency Assessment Forms" are used for initial, 6 month and annual assessments. 3. Further review of the "Competency Assessment Forms" revealed the laboratory did not include the following: a) Six (6) procedures, minimum requirement for testing personnel assessment: a1) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. a2) Monitoring the recording and reporting or test results. a3) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. a4) Direct observation of performance of instrument maintenance and function checks. a5) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. a6) Assessment of problem solving skills. b) Test specific 4. In further interview on July 27, 2020 at 12:34 pm, the Quality Assurance Manager confirmed the laboratory's forms did not include the information indicated above.
D6141	GENERAL SUPERVISOR CFR(s): 493.1459 The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure one (1) of three (3) General Supervisors reviewed met the qualifications of General Supervisor. Refer to D6143.
D6143	GENERAL SUPERVISOR QUALIFICATIONS

CFR(s): 493.1461

(a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a-- (b)(1) Laboratory director under 493.1443; or (b)(2) Technical supervisor under 493.1449. (c) If the requirements of paragraph (b)(1) or paragraph (b)(2) of this section are not met, the individual functioning as the general supervisor must-- (c)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; and (c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or (c)(2)(i) Qualify as testing personnel under 493.1489(b)(2); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3)(i) Except as specified in paragraph (3)(ii) of this section, have previously qualified as a general supervisor under 493.1462 on or before February 28, 1992. (c)(3)(ii) Exception. An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a general supervisor if he or she meets the requirements of 493. 1462 on or before January 1, 1994. (c)(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995-- (c) (4)(i) Meet one of the following requirements: (c)(4)(i)(A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS. (c)(4)(i)(B) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician). (c)(4)(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or (c) (5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and-- (c)(5)(i) Be a high school graduate or equivalent; and (c)(5) (ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992. (d) For blood gas analysis, the individual providing general supervision must-- (d)(1) Be qualified under 493.1461(b)(1) or (2), or 493.1461(c); or (d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (d)(3) (i) Have earned an associate degree related to pulmonary function from an accredited institution; and (d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis. (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (e)(1) In histopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l) or (2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(1)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(m).

	This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to ensure one (1) of three (3) General Supervisors reviewed met the state of Louisiana licensure requirement. Findings: 1. Review of the laboratory's CMS 209 (Laboratory Personnel Report) revealed the laboratory listed Technical Supervisor 1 as the laboratory's current General Supervisor; however, Testing Personnel 1 assessed competency of testing personnel. 2. Review of personnel records revealed Testing Personnel 1 trained all testing personnel, including Techncial Supervisor 1 who also serves as Testing Personnel. 3. Review of personnel records for Testing Personnel 1 revealed no documentation of the following: a) No documentation of current state of Louisiana State Board of Medical Examiners License (LSBME) b) No documentation of training records showing initial competency on instrument/test peformance 4. In interview on July 27, 2020 at 12:34 pm, the Quality Assurance Manager stated Testing Personnel 1 was awaiting a test date. The Quality Assurance Manager confirmed the indicated Testing Personnel did not have a LSBME license for testing.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to ensure three (3) of five (5) testing personnel reviewed met state of Louisiana licensure requirements for performing high complexity testing. Refer to D6170.
D6170	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(a) Each individual performing high complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to ensure three (3) of five (5) testing personnel reviewed met the state of Louisiana licensure requirement to perform high complexity Respiratory Panel testing. Findings: 1. Observation by surveyors during the laboratory tour on July 27, 2020 at 10:21 am revealed the laboratory utilizes two (2) Quant Studio 12K Flex instruments for the following high complexity testing: Respiratory Panel (includes Bordetella pertussis, Bordetella pan., Chlamydophila pneumoniae. Haemophilus influenza, Legionella pneumophila, Moraxella catarrhalis, Mycoplasma pneumoniae, Streptococcus pneumoniae, Streptococcus pyogenes (Group A), Klebsiella pneumylococcus aureus, Adenovirus (Type 1 & 2), Bocavirus, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, Human Metapneumovirus (HMPV) A, HMPV B, Enterovirus (Pan, D68), Rhinovirus (Type 1 &2), Influenza A (Pan, H1, H3), Influenza B (Pan), Parainfluenza virus 1, Parainfluenza virus 2, Parainfluenza virus 3, Parainfluenza virus 4, RSV A, and RSV B) and SARS COV-2. 2. Review of the laboratory's personnel records revealed no documentation of Louisiana State Board of Medical Examiners (LSBME) licenses for

	the following testing personnel: a) Testing Personnel 1 b) Testing Personnel 2 c) Testing Personnel 3 3. In interview on July 27, 2020 at 12:34 pm, the Quality Assurance Manager stated Testing Personnel 1 was awaiting a test date. The Quality Assurance Manager further stated at 12:47 that Testing Personnel 2 and Testing Personnel 3 were in the process of applying for a state license. The Quality Assurance Manager confirmed the indicated Testing Personnel did not have LSBME licenses for testing.