Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2237355	06/16/2022
Name of Provider or Supplier	**Street Address, City, State**	
Resolve Molecular Diagnostics Llc	2920 Kingman Street, Suite 120, Metairie, 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 Special focus survey was performed at Resolve Molecular Diagnostics, LLC-CLIA ID 19D2237355 on June 15, 2022 through June 16, 2022. Resolve Molecular Diagnostics was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1100 CONDITION: Facility Administration
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on observation by surveyor, review of test logs, and interview with personnel, the laboratory failed to report one (1) positive SARS COV-2 result to the state as required. Findings: 1. Observation by surveyor during the laboratory on June 15, 2022 at 9:42 am revealed the laboratory utilizes Accula for SARS COV-2 testing. 2. In interview on June 15, 2022 at 9:44 am, the General Supervisor stated the laboratory began testing patients utilizing the Accula test kits in April 2022. 3. In interview on June 16, 2022 at 10:07 am the laboratory's three (3) Testing Personnel and greeter stated the laboratory did not report positive results to the state for the Accula test. 4. Review of the laboratory's Accula test log revealed the laboratory had one (1) patient in May 2022 with a positive result that was not reported to the state. The laboratory tested seventeen patients in May 2022.

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: Review of the laboratory's CMS-209 form, policies, personnel records, and interview with personnel revealed the laboratory failed to ensure the Laboratory Director performed a competency assessment for two (2) personnel serving as Technical Supervisor and General Supervisor. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed one (1) personnel serving as Technical Supervisor and General Supervisor. 2. Review of the laboratory's "Competency Assessments" policy revealed the laboratory did not include performance of competency for the Technical Supervisor and General Supervisor, to include, but not limited to the frequency. 3. Review of the personnel records for the Technical Supervisor/ General Supervisor revealed the laboratory did not have a competency assessment for her duties as Technical Supervisor and General Supervisor. 4. Further review of personnel records revealed Technical Supervisor 2 previously served as Technical Supervisor from January 3, 2022 through April 10, 2022. The laboratory did not have documentation of a competency assessment for her duties as Technical Supervisor. 5. In interview on June 15, 2022 at 11:26 am, the General Supervisor confirmed a competency assessment was not performed for her duties as Technical Supervisor and General Supervisor. The General Supervisor confirmed the laboratory's policies did not include performance of competency assessments for Technical Supervisor and General Supervisor.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual 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: a) Proficiency Testing to include,but not limited to, corrective actions for unacceptable results b) Reporting SARS COV-2 results, to include, but not limited to procedure, who is responsible, and frequency of reporting. c) Written procedure for distribution of SARS-COV-2 fact sheets to patients 2. In interview on June 15, 2022 at 9:37 am, the General Supervisor stated a third party agency distributes the fact sheets to the patients. 3. Review of the laboratory's policies revealed the laboratory did not have a written policy that stated how the fact sheets are distributed since not distributed by the testing laboratory. 4. In interview on June 15, 2022 at 2:42 pm, the General Supervisor confirmed the laboratory did not include the identified written 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 review of laboratory's policies and interview with personnel, the laboratory failed to establish complete policies and procedures. Findings: 1. Review of the laboratory's policies and procedures revealed the laboratory did not have written procedures to include the following: a) SARS COV-2 procedure to include, but not limited to duplicate testing, controls, result review, and corrective actions 2. In interview on June 15, 2022 at 2:42 pm, the General Supervisor stated if less than twenty four (24) samples are tested the samples are tested in duplicate to shorten the turnaround time for clients. The General Supervisor further stated testing in duplicate was not written in the laboratory's policy; she was verbally told to do so in her training. The General Supervisor confirmed the laboratory's SARS COV-2 procedure did not include duplicate testing or the identified items related to testing.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: I. Based on observation by surveyor, review of manufacturers' requirments, and interview with personnel, the laboratory failed to ensure reagents were stored per manufacturers' requirements. Findings: 1. Observation by surveyor during the laboratory tour on June 15, 2022 at 9:42 am revealed the laboratory stored the following items in the refrigerator: a) Invitrogen Ambio Nuclease Free Water, Lot

	2108466, Quantity: six (6) bottles b) Gen Clone Phosphate Buffered Saline, Lot 21C40026, Quantity: three (3) bottles 2. Review of the manufacturers' requirements revealed the following storage temperatures: a) Invitrogen Ambio Nuclease Free Water: 15-30 degrees Celsius b) Gen Clone Phosphate Buffered Saline: 15-30 degrees Celsius 3. In interveiw on June 15, 2022 at 10:17 am, the Technical Director stated the identified items are stored in the refrigerator for stability. The Technical Director confirmed the laboratory did not store the identified items per manufacturer requirements. II. Based on observation by surveyor, review of manufacturers requirements, and interview with personnel, the laboratory failed to monitor the temperature and humidity of rooms where supplies are stored. Findings: 1. Observation by surveyor during the laboratory tour on June 15, 2022 at 9:42 am revealed the following items are stored in the extraction room without temperature monitoring.: a) Applied Biosystems MagMax Viral/Pathogen Wash Solution, Quantity: two (2) bottles b) Applied Biosystems MagMax Viral/Pathogen Binding Beads, Quantity: one (1) bottle c) Applied Biosystems MagMax Viral/Pathogen Proteinase K, Quantity: one (1) bottle d) Elution buffer, Quantity: one (1) bottle e) MagMax instrument 2. Further observation by surveyor during the laboratory tour on June 15, 2022 at 9:42 am revealed the following items stored in a storage closet without temperature monitioring: Daksy VSMO 1 Disposable Sampling Tube 3. Review of the manufacturers' requirments revealed the following temperature requirememts: a) Applied Biosystems MagMax Viral/Pathogen Wash Solution 15-25 dgrees Celsius b) Applied Biosystems MagMax Viral/Pathogen Binding Beads 15-25 degrees Celsius c) Applied Biosystems MagMax Viral/Pathogen Proteinase K 15-25 degrees Celsius d) Elution buffer 15-25degrees Celsius e) MagMax: operating conditions 10-40 degrees Celsius, maximum relative humidity 80% for temperatures up to 31 degrees Celsius decreasin linearly to 50 % relative humidity at 40C f) Daksy VSMO 1 Disposable Sampling Tube storage condition 5-30 degrees Celsius 4. In interview on June 15, 2022 at 9:44 am, the General Supervisor confirmed the laboratory did not monitor the temperature of the extraction room where supplies and the MagMax instrument were stored. 5. In further interview on June 15, 2022 at 11:43 am, the General Supervisor confirmed the laboratory did not monitor the temperature of the storage closet where the Dasky sampling tubes were stored.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of policies, and interview with personnel, the laboratory failed to ensure supplies did not exceed expiration dates. Findings: 1. Observation by surveyor during laboratory tour on June 15, 2022 at 9:42 am revealed the following expired items: a) Quant Studio 12 K Flex Open Array Accessories Kit Starter, Lot 2108321, Expiration date: 2022-02-17, Quantity: two (2) boxes b) MicroAmp Optical Adhesive Film, Lot 338DJR, Expiration date: 2022-03-17 , Quantity: one (1) box c) MicroAmp Optical Adhesive Film, Lot 338MNN, Expiration date: 2022-04-07 , Quantity: one (1) box d) QuantStudio 12 K Flex Open Array Practice Kit -20C, Lot 2108126, Expiration date: 2022-04-30, Quantity: one (1) box e) Taq Path COVID -19 Control, Lot 237139, Expiration date: 2022-02-08, Quantity: eight (8) tubes 2. Review of the laboratory's "Reagents" policy revealed "will

	correctly label, store, and dispose of reagents used in the laboratory based on manufacturers' recommendations. 3. In interview on June 15, 2022 at 9:52 am, the General Supervisor stated the laboratory does not use the Quant Studio 12 K Flex Open Array kits. The General Supervisor further stated at 9:58 am the Quant Studio 12 K Flex Open Array Practice kit was used for training. The General Supervisor confirmed the practice kit was not labeled for training use. 4. In further interview on June 15, 2022 at 10:05 am, the General Supervisor confirmed the identified TaqPath controls and supplies were expired.
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: I. Based on observation by surveyor, review of validation studies, test menu, and interview with personnel, the laboratory failed to establish complete performance specifications for SARS COV-2 nasal testing. Findings: 1. Observation by surveyor during the laboratory tour on June 15, 2022 at 9:42 am revealed the laboratory utilizes the TaqPath COVID-19 Combo kit with the Quant Studio 12 instrument. 2. Review of the laboratory's validation records revealed the laboratory did not include the following: a) Precision: to include run-to run, day to day, within-run, operator variance studies and supporting raw data b) Laboratory personnel participation c) Acceptability criteria 3. In interview on June 15, 2022 at 2:39 pm, the Technical Director stated she performed the validation studies for the laboratory. The Technical Director confirmed the laboratory did not include the identified information in their validation studies. 4. Review of the laboratory's test menu revealed the laboratory performs 10,000 SARS COV-2 tests annually. II. Based on observation by surveyor, review of validation studies, patient logs, and interview with personnel, the laboratory failed to establish complete performance specifications for SARS COV-2 saliva testing. Findings: 1. Observation by surveyor during the laboratory tour on June 15, 2022 at 9:42 am revealed the laboratory utilizes the TaqPath COVID-19 Combo kit with the Quant Studio 12 instrument. 2. In interview on June 15, 2022 at 9:26 am, the General Supervisor stated the laboratory does not currently have any clients that submit saliva samples. The General Supervisor stated samples were received and tested February 15, 2022 through April 26, 2022. 2. Review of the laboratory's validation records revealed the laboratory did not include the following: a) Accuracy: to include raw data b) Precision: Supporting raw data to demonstrate run-to run, day to day, within-run, operator variance studies and supporting raw data c) Laboratory personnel participation d) Acceptability criteria e) Laboratory Director's approval prior to patient testing (Laboratory Director approved April 6, 2022) 3. In interview on June 15, 2022 at 2:39 pm, the Technical Director stated she performed the majority of the validation studies. The Technical Director stated Testing Personnel 4

	(previously employed) assisted with the cross contamination runs. The Technical Director confirmed the laboratory did not include the identified information in their validation studies. 4. Review of the laboratory's patient logs revealed the laboratory performed 1,105 SARS COV-2 saliva tests from February 15, 2022 through April 26, 2022.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of quality control records, laboratory policies, test menu, and interview with personnel, the laboratory failed to document the results of quality control (QC) tested in duplicate for nasal SARS COV-2 testing. Findings: 1. Observation by surveyor during the laboratory tour on June 15, 2022 at 9: 42 am revealed the laboratory utilizes the TaqPath COVID-19 Combo kit with the Quant Studio 12 instrument. 2. . Review of the laboratory's policies and procedures revealed the laboratory did not have written procedures to include performing QC testing in duplicate. 3. In interview on June 15, 2022 at 2:42 pm, the General Supervisor stated if less than twenty four (24) samples are tested the samples are tested in duplicate to shorten the turnaround time for clients. The General Supervisor further stated testing in duplicate was not written in the laboratory's policy; she was verbally told to do so in her training. The General Supervisor confirmed the laboratory's SARS COV-2 procedure did not include duplicate testing. 4. Review of random selection of patient runs in February 2022, March 2022, April 2022, and May 2022 revealed the laboratory documented one set of controls on their batch sheets if tested in duplicate. 5. In interview on June 15, 2022 at 2:42 pm, the General Supervisor stated if tested in duplicate,only one set of controls is documented/used to determine acceptability. 6. Review of the laboratory's test menu revealed the laboratory performs 10,000 SARS COV-2 tests annually.
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 review of laboratory policies, quality control (QC) records, patient test logs, and interview with personnel, the laboratory failed to take corrective action when QC values were unacceptable for SARS COV-2 saliva testing for random selection of two (2) of two (2) runs reviewed. Findings: 1. In interview on June 15, 2022 at 9:26 am, the General Supervisor stated the laboratory does not currently have any clients that

	submit saliva samples. The General Supervisor stated samples were received and tested February 15, 2022 through April 26, 2022. 2. Review of random selection of SARS COV-2 saliva runs revealed the laboratory did not perform corrective actions for the following two (2) runs: a) April 18, 2022: Positive Control Targets: N gene Ct value 31.4 reported; Expected Ct +/- 2 cycles: 34 RNase P Ct value 25.5 reported; Expected Ct +/- 2 cycles: 29 Negative Control: RNase P: N/A reported; Expected Ct +/-2 cycles 23 "Comments: Neg was saliva ready" The Laboratory Director reviewed /signed run on April 17, 2022 b) April 26, 2022: Positive Control Targets: ORF1a Ct value 26.9 reported; Expected Ct +/- 2 cycles: 33 ORF1b Ct value 22.3 reported; Expected Ct +/- 2 cycles: 33 N gene Ct value 27.2 reported; Expected Ct +/- 2 cycles: 34 RNase P Ct value 20.7 reported; Expected Ct +/- 2 cycles: 29 Negative Control: RNase P Ct value 28.1 reported; Expected Ct +/- cycles: 23 "Comments: 1) Pos Ctrl Run Prior to being diluted. 2) Neg Control degraded due to improper storage. Run passed, all patients Neg and Ran properly with ctrl range for RNase P. The Laboratory Director reviewed/signed run on May 27, 2022 3. Review of the laboratory's "COVID-19 Saliva ThermoFisher" policy revealed the following positive control cutoffs that did not match the values on the QC sheets for each run: "Positive Control cutoffs: RNase P control is Negative Cutoff Ct Range (+/-) 2 cycles 23 ORF1a Cutoff Ct range (+/-) 2 cycles 33 ORF1b Cutoff Ct range (+/-) 2 cycles 33 N gene Cutoff Ct range (+/-) 2 cycles 24 (listed as 34 on QC sheets for each run) RNase P in Positive Control (+/-) 2 cycles 29 4. Review of patient logs revealed the following twenty seven (27) patients were reported without corrective action: April 18, 2022: twenty (20) patients tested April 26, 2022: seven (7) patients tested in duplicate 5. In interview on June 15, 2022 at 5:18 pm, Testing Personnel 1 confirmed the laboratory did not perform corrective action for the identified twenty seven (27) that were reported with unacceptable QC.
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 review of the laboratory's temperature logs and interview with personnel, the laboratory failed to document complete corrective actions performed for room temperatures that exceeded the acceptable range for one (1) of thirty one (31) days in March 2022. Findings: 1. Review of the laboratory's March 2022 "Room Temperature and Humidity Log" revealed the laboratory documented one (1) temperature that exceeded the acceptable range (15-25 degrees Celsius) without documentation of complete corrective actions: March 6, 2022: 26.1 degrees Celsius documented 2. Further review of the laboratory's March 2022 "Room Temperature and Humidity Log" revealed the following comment: "adjusted temp." The laboratory did not have documentation of the room temperature after the temperature was adjusted. 3. In interview on June 15, 2022 at 3:32 pm, the General Supervisor confirmed the laboratory did not document complete corrective actions performed. II. Based on review of the laboratory's temperature logs and interview with personnel, the laboratory failed to document complete corrective actions performed for freezer temperatures that exceeded the acceptable range for seventeen (17) of thirty one (31) days in March 2022. Findings: 1. Review of the laboratory's March 2022 "Freezer Temperature Log" revealed the laboratory documented seventeen (17) temperatures

	that exceeded the acceptable range (-15 to -25 degrees Celsius) without documentation of complete corrective actions: March 2, 2022: Max temperature recorded -10 degrees Celsius March 3, 2022: Max temperature recorded -6 degrees Celsius March 4, 2022: Max temperature recorded -6 degrees Celsius March 6, 2022: Max temperature recorded -4 degrees Celsius March 7, 2022: Max temperature recorded -5 degrees Celsius March 8, 2022: Max temperature recorded 2 degrees Celsius March 9, 2022: Max temperature recorded 2 degrees Celsius March 10, 2022: Max temperature recorded 3 degrees Celsius March 11, 2022: Max temperature recorded 3 degrees Celsius March 14, 2022: Max temperature recorded 0 degrees Celsius March 15, 20222: Max temperature recorded 0 degrees Celsius March 16, 2022: Max temperature recorded 0 degrees Celsius March 17, 2022: Max temperature recorded -6 degrees Celsius March 18, 2022: Max temperature recorded -7 degrees Celsius March 23, 2022: Max temperature recorded -13 degrees Celsius March 24, 2022: Max temperature recorded -11 degrees Celsius March 30, 2022: Max temperature recorded -14 degrees Celsius 2. Further review of the laboratory's March 2022 "Freezer Temperature Log" revealed the following comments for March 2, 2022 through March 17, 2022: "1. Temperature corrected within one hour, no corrective action needed." New freezer was put into use March 20, 2022. The laboratory did not have documentation of the corrected temperature. 3. In interview on June 15, 2022 at 3:32 pm, the General Supervisor confirmed the laboratory did not document complete corrective actions performed.
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: Based on observation by surveyor, review of manufacturer's instructions, patient final test reports, test menu, and interview with personnel, the laboratory failed to include the the Food and Drug Administration (FDA) Emergency Use Authorization statement on the Accula test SARS COV-2 patient final reports. Findings: 1. Observation by surveyor during the laboratory on June 15, 2022 at 9:42 am revealed the laboratory utilizes Accula for SARS COV-2 testing. 2. In interview on June 15, 2022 at 9:44 am, the General Supervisor stated the laboratory began testing patients utilizing the Accula test kits in April 2022. 3. Review of the manufacturer's instructions revealed "This product has not been FDA cleared or approved; but has been authorized by FDA under an Emergency Use Authorization (EUA) for use by authorized laboratories." 4. Review of the following random patient final test report for SARS COV-2 revealed the laboratory did not include the identified Emergency Use Authorization statement on the patient final report: Patient ID P10120217 5. In interview on Juen 16, 2022 at 9:57 am, Testing Personnel 1 confirmed the laboratory's patient final reports for the Accula test SARS COV-2 did not include the identified statement. 6. Review of the laboratory's test menu revealed the laboratory performs eighty (80) Accula SARS COV-2 tests annually.

D5809	TEST REPORT CFR(s): 493.1291(e) The laboratory must, upon request, make available to clients a list of test methods employed by the laboratory and, as applicable, the performance specifications established or verified as specified in 493.1253. In addition, information that may affect the interpretation of test results, for example test interferences, must be provided upon request. Pertinent updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, test menu, and interview with personnel, the laboratory failed to include "Fact Sheets" to patients for Emergency Use Authorization (EUA) SARS COV-2 testing. Findings: 1. Review of the laboratory's test menu revealed the laboratory utilizes Accula test kits for SARS COV-2 testing. 2. Review of the manufacturer's instructions revealed "Authorized laboratories * using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media." 3.. In interview on June 16, 2022 at 9:57 am the Testing Personnel 1 stated the laboratory does not provide "fact sheets" to patients for the Accula SARS COV-2 tests. 4. Review of the laboratory's test menu revealed the laboratory performs eighty (80) SARS COV-2 tests annually.
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 by surveyor, record review, and interview with personnel, the Laboratory Director failed to provide overall management and direction. Findings: 1. The Laboratory Director failed to establish complete performance specifications for SARS COV-2 testing. Refer to D6086. 2. The Laboratory Director failed to ensure laboratory personnel performed test methods as required. Refer to D6087. 3. The Laboratory Director failed to ensure that a quality control program was maintained to assure the quality of laboratory testing. Refer to D6093. 4. The Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D6096. 5. The laboratory failed to ensure patient final reports included required information. Refer to D6098. 6. The Laboratory Director failed to ensure all personnel met state licensure requirement for performing high complexity testing. Refer to D6102. 7. The Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D6103. 8. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D6106. 9. The Laboratory Director failed to delegate responsibilities of Technical Supervisor and General Supervisor to one (1) of one (1) supervisor reviewed. Refer to D6107.

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 by surveyor, record review, and interview with personnel, the Laboratory Director failed to establish complete performance specifications for SARS COV-2 testing. Refer to D5423 I and D5423 II.
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 by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to ensure reagents were stored per manufacturers' requirements. Refer to D5413 I. 2. The laboratory failed to monitor the temperature and humidity of rooms where supplies are stored. Refer to D5413 II. 3. The laboratory failed to ensure supplies did not exceed expiration dates. Refer to D5417.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that a quality control program was maintained to assure the quality of laboratory testing. Refer to D5481.
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 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 document the results of quality control (QC) tested in duplicate for nasal SARS COV-2 testing. Refer to D5783. 2. The laboratory failed to document complete corrective actions performed for room temperatures that exceeded the acceptable range for one (1) of thirty one (31) days in March 2022. Refer to D5785 I. 3. The laboratory failed to document complete corrective actions performed for freeezer temperatures that exceeded the acceptable range for seventeen (17) of thirty one (31) days in March 2022. Refer to D5785 II.
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 review of patient final reports, test menu, and interview with personnel, the laboratory failed to ensure patient final reports included required information. Findings: 1. The laboratory failed to include the the Food and Drug Administration (FDA) Emergency Use Authorization statement on the Accula test SARS COV-2 patient final reports. Refer to D5805. 2. The laboratory failed to include "Fact Sheets" to patients for Emergency Use Authorization (EUA) SARS COV-2 testing. Refer to D5809.
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 record review and interview with personnel, the Laboratory Director failed to ensure all personnel met state licensure requirement for performing high complexity testing. Refer to D6111.
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 policies and procedures for assessing personnel competency were maintained. Refer to D5209.
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 record 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 establish a complete policy and procedure manual. Refer to D5401. 2. The laboratory failed to establish complete policies and procedures. Refer to D5403.
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 review of the laboratory's CMS-209 form, personnel records, and interview with personnel, the Laboratory Director failed to delegate responsibilities of Technical Supervisor and General Supervisor to one (1) of one (1) supervisor reviewed. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed one (1) Technical Supervisor who also serves as General Supervisor. 2. Review of personnel records for the personnel serving as Technical Supervisor and General Supervisor revealed the laboratory did not have documentation of the Laboratory Director delegating the tasks to her. 3. In interview on June 15, 2022 at 11: 26 am, the General Supervisor confirmed the laboratory did not have documentation of the Laboratory Director delegating the Technical Supervisor and General Supervisor responsibilities to him.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Technical Supervisor failed to provide technical oversight for high complexity testing.

	Findings: 1. One (1) of two (2) personnel functioning as the Technical Supervisor failed to meet the state of Louisiana licensure requirement. Refer to D6111. 2. The Technical Supervisor failed to provide technical and scientific oversight for the laboratory. Refer to D6112. 3. The Technical Supervisor failed to ensure the laboratory established complete performance specification for COVID testing. Refer to D6115. 4. The Technical Supervisor failed to ensure that a quality control program was established to assure the quality of testing for COVID testing. Refer to D6117. 5. The Technical Supervisor failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D6118.
D6111	TECHNICAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1449 (a) The technical supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory may perform anatomic and clinical laboratory procedures and tests in all specialties and subspecialties of services except histocompatibility and clinical cytogenetics services provided the individual functioning as the technical supervisor-- (b)(1) Is a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(2) Is certified in both anatomic and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or Possesses qualifications that are equivalent to those required for such certification. (c) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of bacteriology, the individual functioning as the technical supervisor must-- (c)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (c)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (c)(2)(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; and (c)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (c)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (c)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; and (c)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology. (d) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycobacteriology, the individual functioning as the technical supervisor must-- (d)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which

the laboratory is located; and (d)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (d)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor or podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (d)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (d)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (d)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (d)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology. (e) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycology, the individual functioning as the technical supervisor must-- (e)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (e)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (e)(2)(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; and (e)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (e)(3)(ii) Have at least 1 year of laboratory training or experience, or both in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (e)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (e)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology. (f) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of parasitology, the individual functioning as the technical supervisor must-- (f)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or

osteopathy in the State in which the laboratory is located; and (f)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (f)(2)(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; and (f)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; (f)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (f)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or (f)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (f)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or (f)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (f)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology. (g) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of virology, the individual functioning as the technical supervisor must-- (g)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (g)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (g)(2)(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; and (g)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (g)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (g)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (g)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology. (h) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of diagnostic immunology, the individual functioning as the technical supervisor must- (h)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or

osteopathy in the State in which the laboratory is located; and (h)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (h)(2)(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; and (h)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or (h)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (h)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of diagnostic immunology; or (h)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (h)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or (h)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (h)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology. (i) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of chemistry, the individual functioning as the technical supervisor must-- (i)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (i)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (i)(2)(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; and (i)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or (i)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (i)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of chemistry; or (i)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (i)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or (i)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (i)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry. (j) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of hematology, the individual functioning as the technical supervisor must-- (j)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (j)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (j)(2)(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; and (j)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of hematology (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (j)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (j)(3)(ii) Have at least 1 year of

laboratory training or experience, or both, in high complexity testing within the specialty of hematology; or (j)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (j)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology; or (j)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (j)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology. (k)(1) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of cytology, the individual functioning as the technical supervisor must-- (k)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (k)(1)(ii) Meet one of the following requirements-- (k)(1)(ii)(A) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (k)(1)(ii)(B) Be certified by the American Society of Cytology to practice cytopathology or possess qualifications that are equivalent to those required for such certification; (l) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of histopathology, the individual functioning as the technical supervisor must-- (l)(1) Meet one of the following requirements: (l)(1)(i)(A) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (l)(1)(i)(B) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; (l)(1)(ii) An individual qualified under 493.1449(b) or paragraph (l)(1) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (l)(1)(i)(B) of this section, the responsibility for examination and interpretation of histopathology specimens. (l)(2) For tests in dermatopathology, meet one of the following requirements: (l)(2)(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (l)(2)(i)(B) Meet one of the following requirements: (l)(2)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(i)(B)(2) Be certified in dermatopathology by the American Board of Dermatology and the American Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(i)(B)(3) Be certified in dermatology by the American Board of Dermatology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(ii) An individual qualified under 493.1449(b) or paragraph (l)(2)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (l)(2)(i)(B) of this section, the responsibility for examination and interpretation of dermatopathology specimens. (l)(3) For tests in ophthalmic pathology, meet one of the following requirements: (l)(3)(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (l)(3)(i)(B) Must meet one of the following requirements: (l)(3)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(3)(i)(B)(2) Be certified by the American Board of Ophthalmology or possess qualifications that are equivalent to those required for such certification and have successfully completed at least 1 year of formal post-residency fellowship training in

ophthalmic pathology; or (l)(3)(ii) An individual qualified under 493.1449(b) or paragraph (1)(3)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (1)(3)(i)(B) of this section, the responsibility for examination and interpretation of ophthalmic specimens; or (m) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of oral pathology, the individual functioning as the technical supervisor must meet one of the following requirements: (m)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (m)(1)(ii) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (m)(2) Be certified in oral pathology by the American Board of Oral Pathology or possess qualifications for such certification; or (m)(3) An individual qualified under 493.1449(b) or paragraph (m)(1) or (2) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (m)(1) or (2) of this section, the responsibility for examination and interpretation of oral pathology specimens. (n) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of radiobioassay, the individual functioning as the technical supervisor must-- (n)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (n)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (n)(2)(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; and (n)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or (n)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (n)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of radiobioassay; or (n)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (n)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or (n)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (n)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay. (o) If the laboratory performs tests in the specialty of histocompatibility, the individual functioning as the technical supervisor must either-- (o)(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; and (o)(1)(ii) Have training or experience that meets one of the following requirements: (o)(1)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (o)(1)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (o)(1)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility; or (o)(2)(i) Have an earned doctoral degree in a biological or clinical laboratory science from an accredited institution; and (o)(2)(ii) Have training or experience that meets one of the following requirements: (o)(2)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (o)(2)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (o)(2)(ii)(B)(2)

Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility. (p) If the laboratory performs tests in the specialty of clinical cytogenetics, the individual functioning as the technical supervisor must-- (p)(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; and (p)(1)(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics; or (p)(2)(i) Hold an earned doctoral degree in a biological science, including biochemistry, or clinical laboratory science from an accredited institution; and (p)(2)(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics. (q) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of immunohematology, the individual functioning as the technical supervisor must-- (q)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (q)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (q)(2)(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; and (q)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of immunohematology. Note: The technical supervisor requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service. For example, an individual, who has a doctoral degree in chemistry and additionally has documentation of 1 year of laboratory experience working concurrently in high complexity testing in the specialties of microbiology and chemistry and 6 months of that work experience included high complexity testing in bacteriology, mycology, and mycobacteriology, would qualify as the technical supervisor for the specialty of chemistry and the subspecialties of bacteriology, mycology, and mycobacteriology.

This STANDARD is not met as evidenced by:
Based on review of personnel records, records, and interview with personnel, one (1) of two (2) personnel functioning as the Technical Supervisor failed to meet the state of Louisiana licensure requirement. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed the laboratory did not list the Technical Director as the Technical Supervisor. 2. Review of the laboratory's records revealed the Technical Director performed review of the following: a) The laboratory's" Monthly Quality Improvement Review (April 18, 2022)" b) The laboratory's COVID-19 nasal and saliva validation reports. The Technical Director signed the validation reports as the Technical Director for the nasal studies and the Technical Supervisor for saliva studies. c) The laboratory's March logs: "Laboratory Cleaning Log, Report Correction Log, Safety Check Log, SimpliAmp Thermocycler Maintenance Log, Temperature Logs, and Specimen Rejection." The Technical Director reviewed/signed the identified logs on May 23, 2022 3. In interview on June 16, 2022 at 2:39 pm the Technical Director stated she performed the laboratory's COVID-19 nasal validation studies and reviews the patient runs performed by the Testing Personnel before they are released. The Technical Director further stated she reviews the Testing Personnel's runs as they are all in their 90 day probationary period. 4. Review of personnel records revealed the Technical Director did not hold a state license from the Louisiana Board of Medical Examiners. 5. In interview on June 16, 2022 at 2:39 pm, the Technical Director stated she did not have a state license from the Louisiana Board of

	Medical Examiners.
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 by surveyor, record review, and interview with personnel, the Technical Supervisor failed to provide technical and scientific oversight for the laboratory. Findings: 1. The laboratory failed to establish a complete policy and procedure manual. Refer to D5401. 2. The laboratory failed to establish complete policies and procedures. Refer to D5403. 3. The laboratory failed to ensure reagents were stored per manufacturers' requirements. Refer to D5413 I. 4. The laboratory failed to monitor the temperature and humidity of rooms where supplies are stored. Refer to D5413 II. 5. The laboratory failed to ensure supplies did not exceed expiration dates. Refer to D5417. 6. The laboratory failed to include the the Food and Drug Administration (FDA) Emergency Use Authorization statement on the Accula test SARS COV-2 patient final reports. Refer to D5805. 7. The laboratory failed to include "Fact Sheets" to patients for Emergency Use Authorization (EUA) SARS COV-2 testing. Refer to D5809.
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 by surveyor, record review, and interview with personnel, the Technical Supervisor failed to ensure the laboratory established complete performance specification for COVID testing. Refer to D5423 I and D5423 II.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Supervisor failed to ensure that a quality control program was established to assure the quality of testing for COVID testing. Refer to D5481.

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 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 QC values were unacceptable for SARS COV-2 saliva testing for random selection of two (2) of two (2) runs reviewed. Refer to D5783. 2. The laboratory failed to document complete corrective actions performed for room temperatures that exceeded the acceptable range for one (1) of thirty one (31) days in March 2022. Refer to D5785 I. 3. The laboratory failed to document complete corrective actions performed for freezer temperatures that exceeded the acceptable range for seventeen (17) of thirty one (31) days in March 2022. Refer to D5785 II.