Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D2193000	08/26/2021
Name of Provider or Supplier	**Street Address, City, State**	
Linda Laboratory	320 R Thompson Rd, Lumberton, MS	

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
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 deficiencies cited for preanalytic systems, the laboratory failed to meet the applicable preanalytic systems requirements at 493.1241 and 493.1242 or 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. Refer to D5311 (Failure to establish policies and procedures for specimen collection, labeling, storage, preservation, transportation, processing, acceptability, rejection).
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 review of manufacturer's instructions for the Co-Diagnostics Inc. Logix Smart COVID-19 polymerase chain reaction (PCR) test and the RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit and interview with the testing personnel on 8/26 /21 at 11:15 a.m., the laboratory failed to establish and follow written policies and procedures for specimen collection, specimen storage and preservation, conditions for specimen transportation, specimen processing, and specimen acceptability and rejection for the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test and the RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit. Findings include: A. Review of manufacturer's instructions for the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test revealed the Instructions for Use state, "For nasopharyngeal swab and oropharyngeal swabs, use only synthetic fiber swabs with plastic shafts. Do not use calcium alginate swabs or swabs with wooden shafts, as they may contain substances that inactivate some viruses and inhibit PCR testing. Place swabs immediately into sterile tubes containing 2 -3 milliliters of viral transport media. Refrigerate specimens at 2 - 8 degrees Celsius and ship overnight to the testing laboratory on an ice pack." There were no written procedures for specimen collection, specimen storage and preservation, conditions for specimen transportation, specimen processing, or for specimen acceptability and rejection available for review on 8/26 /21, the day of the survey. In an interview with the testing personnel on 8/26/21 at 11: 15 a.m., the testing personnel stated the specimens for Coronavirus Disease 2019 (COVID-19) testing with the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test were collected at other sites and transported to the laboratory for testing. B. Review of manufacturer's instructions for the RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit revealed the User Manual states, "This product is intended for research only and is not to be used for clinical diagnosis." There were no written policies and procedures establishing acceptable specimens for performing COVID-19 testing with the RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit. II. Based on review of patient test logs, interview with the testing personnel on 8/26/21 at 11:15 a.m., and lack of written policies and procedures, the laboratory failed to establish a written specimen labeling policy, to include patient name or unique patient identifier, and, when appropriate, specimen source, in order to ensure positive identification of seventy-eight patient specimens tested with the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test from 12/6/20 through 2/11/21 and of nine patient specimens tested from 3/12/21 through 3/28/21 with the RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit. Findings include: There was no written policy for specimen labeling to include patient name or unique patient identifier, and, when appropriate, specimen source, available for review on 8/26/21, the day of the survey. In an interview with the testing personnel on 8/26/21 at 11:15 a.m., the testing personnel confirmed there were no written policies and procedures. Review of patient test logs revealed seventy-eight patient specimens were tested with the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test from 12/6/20 through 2/11/21 and nine patient specimens were tested with the RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit from 3/12/21 through 3/28/21.
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 deficiencies cited for analytic systems, the laboratory failed to meet the applicable analytic systems requirements in 493.1251 through 493.1283 or 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. Refer to D5401 (Failure to establish a written procedure manual). Refer to D5411 (Failure to follow manufacturer's instructions for test reagent storage). Refer to D5421 (Failure to verify performance specifications for Co-Diagnostics Logix Smart COVID-19 PCR test). Refer to D5423 (Failure to establish performance specifications for RayBiotech COVID-19 Rapid Isothermal PCR Kit). Refer to D5455 (Failure to perform control testing each day of high-complexity testing). Refer to D5791 (Failure to establish quality assessment plan).
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 patient test logs, interview with the testing personnel on 8/26/21 at 11:15 a.m., and lack of a written procedure manual, the laboratory failed to establish a written procedure manual for performing COVID-19 testing with the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test, in use for patient testing from 12/6/20 through 2/11/21 when a total of seventy-eight patient specimens were tested, and for performing COVID-19 testing with the RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit, in use for patient testing from 3/12/21 through 3/28/21, when a total of nine patient specimens were tested. Findings include: In an interview with the testing personnel on 8/26/21 at 11:15 a.m., the testing personnel stated the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test was used by the laboratory for patient COVID-19 testing from December 2020 through February 2021, and the RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit was used for patient COVID-19 testing in March 2021. Review of patient test logs revealed seventy-eight patient specimens were tested from 12/6/20 through 2/11/21 and nine patient specimens were tested in March 2021. There was no procedure manual available for review on the day of the survey, 8/26/21, for performing patient COVID-19 testing with the the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test and the RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

	This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test and RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit, patient test logs, observation of the laboratory freezer on 8/26/21 at 10:00 a. m., and interview with the testing personnel on 8/26/21 at 11:15 a.m., the laboratory failed to store, according to manufacturers' instructions, the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test, used for patient COVID-19 testing from 12/6/20 though 2 /11/21 for seventy-eight patients, and the RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit, used for patient COVID-19 testing from 3/12/21 through 3/28/21 for nine patients. Findings include: The manufacturer's Instructions For Use for the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test state, "The Logix Smart COVID-19 kit is shipped on dry ice. The components should arrive frozen. All components should be stored immediately at or below minus 20 degrees Celsius to prevent degradation of reagents." The manufacturer's instructions for the RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit state, "Kit ships on dry ice. Upon receipt, all components of the RayBio COVID-19 Rapid Isothermal PCR Kit should be stored at minus 20 degrees Celsius." Observation of the laboratory freezer on 8/26 /21 at 10:00 a.m. revealed no thermometer for monitoring freezer temperature. There were no temperature records available for review on the day of the survey, 8/26/21, documenting the freezer temperatures for 12/6/20 through 2/11/21, the time frame in which patient testing was performed with the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test, or for 3/12/21 through 3/28/21, the time frame in which patient testing was performed with the RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit. In an interview with the testing personnel on 8/26/21 at 11:15 a.m., the testing personnel stated the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test was used by the laboratory for patient COVID-19 testing from December 2020 through February 2021, and the RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit was used for patient COVID-19 testing in March 2021. Review of patient test logs revealed the following patient specimens were tested for COVID-19 on the following dates: 12/6/20--Specimens tested: L1, L2, L3, L4, L5, L8, L9, L10, L11, L12, L13, L14, L15, L16, L17, L18, L20. 12/12/20--Specimens tested: H1, H2, H3, H4, H5, H6, H8, H9, H10, H11, H12, H13, H14, H19, H7, H21, H22, H23, H28, H29. 1/3/21--Specimens tested: H25, H26. 1/6/21--Specimens tested: H15, H16, H17, H18. 1/16/21--Specimens tested: E1, E2, E3, E4. 1/17/21--Specimens tested: P1, P2, P3, P4, P5, P6, P7, G7, G8, G9, G10, G11, G12, G13. 1/29/21--Specimens tested: W1. 1 /31/21--Specimens tested: W2, W3, W4, W5, W6, W7, W8, W9, W10, W11, W12, W13, W14, H24. 2/11/21--Specimens tested: G1, H31. 3/12/21--Specimens tested: G2, G3, G4, G5, G6. 3/14/21--Specimens tested: A1, A2. 3/22/21--Specimens tested: H30. 3/28/21--Specimens tested: A3.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i) (B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by:

	Based on interview with the testing personnel on 8/26/21 at 11:15 a.m. and review of the laboratory's patient test logs, the laboratory failed to perform and document verification of performance specifications, including accuracy and precision, for the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test, in use for patient COVID-19 testing from 12/6/20 through 2/11/21, when a total of seventy-eight patient specimens were tested. Findings include: In an interview with the testing personnel on 8/26/21 at 11:15 a.m., the testing personnel stated the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test was used by the laboratory for patient COVID-19 testing from December 2020 through February 2021. There was no documentation of the verification of performance specifications, including accuracy and precision, performed by the laboratory for the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test. Review of the patient test logs revealed the following patient specimens were tested for COVID-19 on the following dates: 12/6/20--Specimens tested: L1, L2, L3, L4, L5, L8, L9, L10, L11, L12, L13, L14, L15, L16, L17, L18, L20. 12/12/20--Specimens tested: H1, H2, H3, H4, H5, H6, H8, H9, H10, H11, H12, H13, H14, H19, H7, H21, H22, H23, H28, H29. 1/3/21--Specimens tested: H25, H26. 1/6/21--Specimens tested: H15, H16, H17, H18. 1/16/21--Specimens tested: E1, E2, E3, E4. 1/17/21--Specimens tested: P1, P2, P3, P4, P5, P6, P7, G7, G8, G9, G10, G11, G12, G13. 1/29/21--Specimens tested: W1 1/31/21--Specimens tested: W2, W3, W4, W5, W6, W7, W8, W9, W10, W11, W12, W13, W14, H24. 2/11/21--Specimens tested: G1, H31.
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 review of manufacturer's instructions for the RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit, patient test logs, and interview with the testing personnel on 8/26/21 at 11:15 a.m., the laboratory failed to establish performance specifications for the RayBio COVID-19 Rapid Isothermal PCR Kit used to perform COVID-19 testing on nine patient specimens from 3/12/21 through 3/28/21. Findings include: Review of manufacturer's instructions for the RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit revealed the manufacturer states in the User Manual, "This product is intended for research only and is not to be used for clinical diagnosis." In an interview with the testing personnel on 8/26/21 at 11:15 a.m., the testing personnel stated the RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit was used for testing patient COVID-19 specimens in March 2021. There was no documentation of the establishment of performance specifications for the RayBio COVID-19 Rapid Isothermal PCR Kit, including accuracy, precision, analytical sensitivity, and analytical specificity, to include interfering substances. Review of the patient test logs

	revealed the following patient specimens were tested for COVID-19 on the following dates: 3/12/21--Specimens tested: G2, G3, G4, G5, G6. 3/14/21--Specimens tested: A1, A2. 3/22/21--Specimens tested: H30. 3/28/21--Specimens tested: A3.
D5455	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(v)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--At least once a day patient specimens are assayed or examined perform the following for-- Each molecular amplification procedure, include two control materials and, if reaction inhibition is a significant source of false negative results, a control material capable of detecting the inhibition. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: 1. Based on review of manufacturer's instructions for the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test, interview with the testing personnel on 8/26/21 at 11:15 a.m., and review of the laboratory's patient test logs, the laboratory failed to include two control materials at least once each day of patient testing with the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test for nine days when a total of seventy-eight patient specimens were tested for COVID-19. Findings include: In an interview with the testing personnel on 8/26/21 at 11:15 a.m., the testing personnel stated the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test was used by the laboratory for patient Coronavirus Disease-19 testing from December 2020 through February 2021. The manufacturer's instructions for the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test state, "Each positive control should show an amplification curve for the COVID-19 marker in the FAM channel and amplification of the internal positive control for RNaseP in the CF610 channel. A positive amplification curve should have a cycle threshold below 45 cycles. The results of the negative control should show no amplification. If controls pass, interpret the sample results." There was no documentation of the testing of control materials on the following days when the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test was used for patient Coronavirus Disease-19 testing: 12/6/20--Specimens tested: L1, L2, L3, L4, L5, L8, L9, L10, L11, L12, L13, L14, L15, L16, L17, L18, L20. 12/12/20--Specimens tested: H1, H2, H3, H4, H5, H6, H8, H9, H10, H11, H12, H13, H14, H19, H7, H21, H22, H23, H28, H29. 1/3/21--Specimens tested: H25, H26. 1/6/21--Specimens tested: H15, H16, H17, H18. 1/16/21--Specimens tested: E1, E2, E3, E4. 1/17/21--Specimens tested: P1, P2, P3, P4, P5, P6, P7, G7, G8, G9, G10, G11, G12, G13. 1/29/21--Specimens tested: W1 1 /31/21--Specimens tested: W2, W3, W4, W5, W6, W7, W8, W9, W10, W11, W12, W13, W14, H24. 2/11/21--Specimens tested: G1, H31. 2. Based on interview with the testing personnel on 8/26/21 at 11:15 a.m. and review of the laboratory's patient test logs, the laboratory failed to include two control materials at least once each day of patient testing with the RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit for four days, when a total of nine patient specimens were tested for Coronavirus Disease-19. Findings include: In an interview with the testing personnel on 8/26/21 at 11:15 a.m., the testing personnel stated the RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit was used by the laboratory for patient COVID-19 testing in March 2021. There was no documentation of the testing of control materials on the following days when the RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit was used for

	patient COVID-19 testing: 3/12/21--Specimens tested: G2, G3, G4, G5, G6. 3/14/21--Specimens tested: A1, A2. 3/22/21--Specimens tested: H30. 3/28/21--Specimens tested: A3.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of manufacturers' instructions for the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test and RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit, patient test logs, and interview with the testing personnel on 8/26/21 at 11: 15 a.m., the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems. Findings include: There was no written policy for quality assessment of analytic systems available for review on 8/26/21, the day of the survey, to include assessing test procedures; accurate and reliable test systems, equipment, instruments, reagents, materials, and supplies; specimen and reagent storage conditions; equipment/instrument/test/system maintenance and function checks; establishment and verification of method performance specifications; control procedures; comparison of test results; corrective actions; and test records for testing performed with the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test for seventy-eight patients from 12/6/20 though 2/11/21 and for testing performed with the RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit for nine patients from 3/12 /21 through 3/28/21. In an interview with the testing personnel on 8/26/21 at 10:00 a. m., the testing personnel confirmed there were no written procedures.
D5800	POSTANALYTIC SYSTEMS CFR(s): 493.1290 Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 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 postanalytic systems and correct identified problems as specified in 493. 1299 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on deficiencies cited for postanalytic systems, the laboratory failed to meet the applicable postanalytic systems requirements in 493.1291 or monitor and evaluate the overall quality of the postanalytic systems and correct identified problems as specified in 493.1299 for each specialty and subspecialty of testing performed. Refer to D5805 (Failure to establish test reports with patient identifier, name and address of laboratory, report date, test performed, specimen source, and test result).
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 interview with the testing personnel on 8/26/21 at 11:15 a.m., review of patient test logs, and lack of patient test reports, the laboratory failed to ensure patient test reports for COVID-19 testing included either the patient's name and identification number, or unique patient identifier, to ensure positive patient identification; the name and address of the laboratory location where the test was performed; the test report date; the test performed; specimen source; and the test results for seventy-eight patient specimens tested with the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test from 12/6/20 though 2/11/21 and nine patient specimens tested with the RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit from 3/12/21 through 3/28/21. Findings include: In an interview with the testing personnel on 8/26/21 at 11:15 a.m., the testing personnel stated the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test was used by the laboratory for patient COVID-19 testing from December 2020 through February 2021, and the RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit was used for patient COVID-19 testing in March 2021. Review of patient test logs revealed the following patient specimens were tested for COVID-19 on the following dates: 12/6/20--Specimens tested: L1, L2, L3, L4, L5, L8, L9, L10, L11, L12, L13, L14, L15, L16, L17, L18, L20. 12/12/20--Specimens tested: H1, H2, H3, H4, H5, H6, H8, H9, H10, H11, H12, H13, H14, H19, H7, H21, H22, H23, H28, H29. 1/3/21--Specimens tested: H25, H26. 1/6/21--Specimens tested: H15, H16, H17, H18. 1/16/21--Specimens tested: E1, E2, E3, E4. 1/17/21--Specimens tested: P1, P2, P3, P4, P5, P6, P7, G7, G8, G9, G10, G11, G12, G13. 1/29/21--Specimens tested: W1. 1 /31/21--Specimens tested: W2, W3, W4, W5, W6, W7, W8, W9, W10, W11, W12, W13, W14, H24. 2/11/21--Specimens tested: G1, H31. 3/12/21--Specimens tested: G2, G3, G4, G5, G6. 3/14/21--Specimens tested: A1, A2. 3/22/21--Specimens tested: H30. 3/28/21--Specimens tested: A3. There were no patient test reports available for review on the day of the survey, 8/26/21.
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 the number of deficiencies cited for laboratory director responsibilities, preanalytic systems, analytic systems, and postanalytic systems, the laboratory did not have a laboratory director who provided overall management and direction in accordance with 493.1445 of this subpart. The testing personnel confirmed on 8/26/21 at 11:15 a.m. that the laboratory director/technical consultant/general supervisor listed

	on the Centers for Medicare and Medicaid Services (CMS) 116 form was unaware the laboratory was performing high-complexity testing. Refer to D6082 (Failure of laboratory director to ensure test systems provide quality laboratory services in preanalytic, analytic, and postanalytic phases of testing). Refer to D6086 (Failure of laboratory director to ensure verification procedures of test methods are adequate). Refer to D6087 (Failure of laboratory director to ensure laboratory personnel are performing test methods as required). Refer to D6093 (Failure of laboratory director to ensure quality control programs are established). Refer to D6094 (Failure of laboratory director to ensure quality assessment programs are established). Refer to D6098 (Failure of laboratory director to ensure test reports include pertinent information). Refer to D6102 (Failure of laboratory director to ensure testing personnel have appropriate training). Refer to D6106 (Failure of laboratory director to ensure an approved procedure manual is available).
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 review of manufacturers' instructions for the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test and RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit, patient test logs, and interview with the testing personnel on 8/26/21 at 11: 15 a.m., the laboratory director failed to ensure that testing systems developed and used for high-complexity COVID-19 testing provided quality laboratory services for all aspects of test performance, including the preanalytic, analytic, and postanalytic phases of testing for seventy-eight patient specimens tested with the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test from 12/6/20 though 2/11/21 and for nine patient specimens tested with the RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit from 3/12/21 through 3/28/21. Refer to D5300 (Condition: Preanalytic Systems). Refer to D5400 (Condition: Analytic Systems). Refer to D5800 (Condition: Postanalytic Systems).
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on review of manufacturers' instructions for the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test and RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit, patient test logs, and interview with the testing personnel on 8/26/21 at 11: 15 a.m., the laboratory director failed to ensure that verification of performance specifications were performed to determine the accuracy and precision of the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test before testing seventy-eight patient specimens from 12/6/20 through 2/11/21 and that establishment of performance

	specifications were performed to determine the accuracy, precision, analytical sensitivity, analytical specificity, to include interfering substances, of the RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit, intended for research use only, before testing nine patient specimens from 3/12/21 through 3/28/21. Refer to D5421 (Verification of performance specifications). Refer to D5423 (Establishment of performance specifications).
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 review of manufacturers' instructions for the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test and RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit, patient test logs, and interview with the testing personnel on 8/26/21 at 11: 15 a.m., the laboratory director failed to ensure that laboratory personnel were performing the test methods as required for accurate and reliable results when the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test was used for testing seventy-eight patient specimens from 12/6/20 through 2/11/21 and the RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit was used for testing nine patient specimens from 3/12 /21 through 3/28/21. Refer to D5401 (Failure to establish a written procedure manual).
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of manufacturers' instructions for the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test and RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit, patient test logs, and interview with the testing personnel on 8/26/21 at 11: 15 a.m., the laboratory director failed to ensure that quality control programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur for nine days from 12/6/20 through 2/11/21, when a total of seventy-eight patient specimens were tested with the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test, and for four days from 3/12/21 through 3/28 /21, when a total of nine patient specimens were tested with the RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit. Refer to D5455 (Failure to include two controls each day of patient testing).
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 review of manufacturers' instructions for the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test and RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit, patient test logs, and interview with the testing personnel on 8/26/21 at 11: 15 a.m., the laboratory director failed to ensure that quality assessment programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occurred for nine days from 12/6/20 through 2/11 /21, when a total of seventy-eight patient specimens were tested with the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test, and for four days from 3/12/21 through 3/28/21, when a total of nine patient specimens were tested with the RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit. Refer to D5791 (Failure to establish quality assessment program for analytic systems).
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 interview with the testing personnel on 8/26/21 at 11:15 a.m., review of patient test logs, and lack of patient test reports, the laboratory director failed to ensure that reports of test results included pertinent information required for interpretation for seventy-eight patient specimens tested with the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test from 12/6/20 though 2/11/21 and nine patient specimens tested with the RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit from 3/12/21 through 3/28/21. Refer to D5805 (Failure to establish test reports with required information).
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 review of manufacturers' instructions for the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test and RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit, patient test logs, and interview with the testing personnel on 8/26/21 at 11: 15 a.m., the laboratory director failed to ensure that prior to testing patients' specimens, the individual performing testing received appropriate training for the type and complexity of the services offered, and had demonstrated that he could perform all testing operations reliably to provide and report accurate results before performing COVID-19 testing on seventy-eight patient specimens with the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test from 12/6/20 through 2/11/21 and before performing testing on nine patient specimens with the RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit from 3/12/21 through 3/28/21. Findings include: There was

	no documentation of training for the testing personnel, available for review on 8/26 /21, for performing COVID-19 testing with the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test and the RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit. In an interview with the testing personnel on 8/26/21 at 11:15 a.m., the testing personnel stated he used the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test for patient COVID-19 testing from December 2020 through February 2021, and he used the RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit for patient COVID-19 testing in March 2021. He confirmed there was no documentation of training.
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 review of patient test logs, interview with the testing personnel on 8/26/21 at 11:15 a.m., and lack of a written procedure manual, the laboratory director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process with the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test, used for testing seventy-eight patient specimens from 12/6/20 through 2/11/21, and with the RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit, used for testing nine patient specimens from 3/12/21 through 3/28/21. Findings include: In an interview with the testing personnel on 8/26/21 at 11:15 a.m., the testing personnel stated he used the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test for patient COVID-19 testing from December 2020 through February 2021, and he used the RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit for patient COVID-19 testing in March 2021. He confirmed there was no written procedure manual.
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 the deficiencies cited for technical supervisor responsibilities, the laboratory did not have a technical supervisor that provided technical supervision in accordance with 493.1451 of this subpart. Refer to D6115 (Failure of technical supervisor to ensure verification and establishment of performance specifications were performed). Refer to D6117 (Failure of technical supervisor to establish appropriate quality control programs). Refer to D6127 (Failure of technical supervisor to evaluate competency of testing personnel at least semiannually).
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) The technical supervisor is responsible for verification of the test procedures

	performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on review of manufacturers' instructions for the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test and RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit, patient test logs, and interview with the testing personnel on 8/26/21 at 11:15 a.m., a technical supervisor failed to ensure that verification of performance specifications were performed to determine the accuracy and precision of the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test before testing seventy-eight patient specimens from 12/6/20 through 2/11/21 and that establishment of performance specifications were performed to determine the accuracy, precision, analytical sensitivity, analytical specificity, to include interfering substances, of the RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit, intended for research use only, before testing nine patient specimens from 3/12/21 through 3/28/21. Refer to D5421 (Verification of performance specifications). Refer to D5423 (Establishment of performance specifications).
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on review of manufacturers' instructions for the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test and RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit, patient test logs, and interview with the testing personnel on 8/26/21 at 11:15 a.m., a technical supervisor failed to establish a quality control program appropriate for the testing performed with the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test, used for nine days in testing seventy-eight patient specimens, and for the testing performed with the RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit, used for four days in testing nine patient specimens, and failed to establish the parameters for acceptable levels of analytic performance and ensure that these levels were maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. Refer to D5455 (Failure to include two controls each day of patient testing).
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of patient test logs and interview with the testing personnel on 8/26

	/21 at 11:15 a.m., a technical supervisor failed to evaluate and document the performance of the testing personnel responsible for high complexity COVID-19 testing at least semiannually during the first year the individual tested patient specimens. Findings include: In an interview with the testing personnel on 8/26/21 at 11:15 a.m., the testing personnel stated he used the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test for patient COVID-19 testing from December 2020 through February 2021, and he used the RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit for patient COVID-19 testing in March 2021. There was no documentation on the day of the survey, 8/26/21, of a semiannual evaluation performed by a technical supervisor for this individual.
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 the deficiencies cited for general supervisor responsibilities, the laboratory did not have a general supervisor that provided general supervision in accordance with 493.1463 of this subpart. Refer to D6144 (Failure of general supervisor to provide oversight of personnel performing testing). Refer to D6148 (Failure of general supervisor to ensure acceptable levels of analytic performance).
D6144	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463 The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test and RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit, patient test logs, and interview with the testing personnel on 8/26/21 at 11: 15 a.m., a general supervisor failed to provide day-to-day supervision and oversight of the laboratory operation and personnel performing testing and reporting test results. Findings include: In an interview with the testing personnel on 8/26/21 at 11:15 a.m., the testing personnel stated he used the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test for patient COVID-19 testing from December 2020 through February 2021, and he used the RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit for patient COVID-19 testing in March 2021. Review of patient test logs revealed the following patient specimens were tested for COVID-19 on the following dates: 12/6/20--Specimens tested: L1, L2, L3, L4, L5, L8, L9, L10, L11, L12, L13, L14, L15, L16, L17, L18, L20. 12/12/20--Specimens tested: H1, H2, H3, H4, H5, H6, H8, H9, H10, H11, H12, H13, H14, H19, H7, H21, H22, H23, H28, H29. 1/3/21--Specimens tested: H25, H26. 1/6/21--Specimens tested: H15, H16, H17, H18. 1/16/21--Specimens tested: E1, E2, E3, E4. 1/17/21--Specimens tested: P1, P2, P3, P4, P5, P6, P7, G7, G8, G9, G10, G11, G12, G13. 1/29/21--Specimens tested: W1. 1/31/21--Specimens tested: W2, W3, W4, W5, W6, W7, W8, W9, W10, W11, W12, W13, W14, H24. 2/11/21--Specimens tested: G1, H31. 3/12/21--Specimens tested: G2, G3, G4, G5, G6. 3/14/21--

	Specimens tested: A1, A2. 3/22/21--Specimens tested: H30. 3/28/21--Specimens tested: A3. There were no patient test reports available for review on the day of the survey, 8/26/21, that documented the test results for these specimens.
D6148	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(a)(4) The general supervisor is responsible for monitoring test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test and RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit, patient test logs, and interview with the testing personnel on 8/26/21 at 11: 15 a.m., a general supervisor failed to monitor test analyses to ensure that acceptable levels of analytic performance were maintained. Findings include: Review of the patient test logs and interview with the testing personnel on 8/26/21 at 11:15 a.m. revealed the Co-Diagnostics Inc. Logix Smart COVID-19 PCR test was used for patient COVID-19 testing for nine days from 12/6/20 through 2/11/21, when seventy-eight patient specimens were tested, and the RayBiotech RayBio COVID-19 Rapid Isothermal PCR Kit was used for patient COVID-19 testing for four days from 3/12 /21 through 3/28/21, when nine patient specimens were tested. There was no documentation of the testing of at least two levels of control material on these days of patient testing to ensure acceptable levels of analytic performance were maintained. Refer to D5455 (Failure to perform control testing each day of high-complexity testing).