Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2143481	(X3) Date Survey Completed 05/25/2021
Name of Provider or Supplier Premier Acute Care Services, Llc	**Street Address, City, State** 11073 Colonel Armistead Drive - Suite 105, Ruther Glen, VA	

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

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An unannounced onsite Clinical Laboratory Improvement Amendments (CLIA) complaint investigation (Complaint # VA00051811) was conducted at Premier Acute Care Services, LLC on May 20, 2021 by a Medical Facilities Inspector from the Virginia Department of Health, Office of Licensure and Certification. The investigation also included offsite interviews with the Chief Operations Officer and Lab Director on 5/24/21 and 5/25/21 respectively. Based on a tour, review of documents and interviews, the inspector found the complainant's allegation to be substantiated with the following citations that include the Conditions under 42 CFR part 493 CLIA Regulation: D5200 -42 CFR. 493.1230 Condition General Laboratory Systems D5400 -42 CFR. 493.1250 Condition Analytic Systems D6000 -42 CFR. 493.1403 Condition Moderate Complexity Laboratory Director
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a review of the laboratory's policy and procedure manual, temperature monitoring / quality control (QC) records, interviews, and lack of documentation, the laboratory failed to monitor/evaluate/identify problems or follow their quality assurance (QA) policies for rapid COVID-19 patient testing in three separate testing areas (drive through, main laboratory, and Abbott ID Now exam room laboratory) during the four months reviewed (January 2021 through May 20, 2021). See D5291.

D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policy and procedure manual, temperature monitoring records, quality control (QC) records, patient test logs, interviews, and lack of documentation, the laboratory failed to follow their quality assurance (QA) policies for rapid COVID-19 testing during the four months reviewed while reporting five thousand eight hundred fifty-five (5,855) patient results (timeframe: January 2021 through May 20, 2021). Findings include: 1. Review of the laboratory's policy and procedure manual revealed a written QA policy that stated under categories: Analytic Phase Test Reagents and Supplies: "We will ensure correct environmental conditions for all laboratory methods and supplies to ensure reliable operation and test results. Reagents are monitored for acceptable labeling and storage." Procedure Manual: "We have written collection of instructions for all tests performed by our lab. Included in these instructions are how to perform quality control". Quality Control: "For each test system we have control procedures that monitor the accuracy of the analytical process. We perform quality control in the manner and at the frequency recommended by the manufacturer of each waived and non waived test method." Verification of Performance Specifications: "For modified methods or methods that are not FDA approved, we will establish our own performance specifications that include analytical sensitivity, specificity, and meet expected performance specifications." Post Analytic: "Frequency of QA reviews are at least once every three months". 2. The inspector requested to review room temperature/humidity monitoring, QC, test validation studies, instrument maintenance, and QA logs for the laboratory's three (3) COVID-19 testing areas: Test area #1 (drive through building): no temperature, QC, validation of modified test methods, or QA records were available for review January to May 2021; Test area #2 (main laboratory room): no temperature records available for review February to April 2021, no QC or QA records available for review January to May 2021; Test area #3 (Abbott ID Now exam room): no temperature, instrument maintenance, or QA records available for review January to May 2021. 3. The inspector requested to review the patient result logs for all COVID-19 testing areas for the timeframe of January to May 20, 2021. The office manager provided the following patient result data for the number of tests resulted: CareStart rapid at drive through = four thousand three hundred fifty (4,350); Abbott ID Now = one thousand five hundred (1,500); RightSign = five (5); a total of 5,855 patient results. 4. An interview with the laboratory's office manager on 5/25/21 at 11:00 AM confirmed the above listed findings.
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 interviews, review of manufacturer's package inserts, policies/procedures, Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA), available patient test logs, quality control (QC), temperature monitoring, and lack of documentation, the laboratory failed to: 1. have a written policy on protocols to report patient SARS-CoV-2 (COVID-19) positive and negative results to the state agency during the timeframe of January 2021 to the date of the inspection on May 20, 2021; 2. document director's approval/review of the laboratory's modifications of manufacturer's procedure for rapid Access Bio CareStart COVID-19 antigen testing during the five month review timeframe (January to May 2021); 3. document performance of negative and positive external quality control (QC) for Access Bio CareStart COVID-19 antigen test kits according to manufacturer's instructions while reporting four thousand three hundred fifty (4,350) rapid patient results from 1/7/21 to 5/20/21; 4. document performance of Abbott ID Now analyzer cleaning maintenance according to manufacturer's instructions for seven (7) of 7 analyzers while reporting one thousand five hundred (1,500) rapid patient results from 1/2/21 to 5/20/21; 5. follow the manufacturer's instructions for handling of the AccessBio CareStart COVID-19 test cassette devices during the review timeframe (January-May 2021); 6. document monitoring of temperatures to ensure proper storage of COVID-19 immunology kits/reagents from 1/7/21 to 5/20/21; 7. evaluate and verify the performance specifications of a modified test procedure for Access Bio CareStart COVID-19 antigen test kits prior to reporting 4,350 rapid patient results from 1/7/21 to 5/20/21. See D5401, D5407, D5411 (A-C), D5413, D5423.
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 a tour, interviews, review of the Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA), manufacturer's instructions for use (IFU), policies/procedures, and lack of records, the laboratory failed to have a written policy on protocols to report patient SARS-CoV-2 (COVID-19) positive and negative results to the state agency during the timeframe of January 2021 to the date of the inspection on May 20, 2021. Findings include: 1. During a tour of the facility's exterior rapid COVID-19 test building (located in the back parking lot of the medical office) on 5/20/21 at approximately 1:15 PM, the inspector requested a listing of the facility's COVID-19 test methods. The office manager outlined that the laboratory utilized Access Bio CareStart COVID-19 test kits for rapid antigen testing in the drive through and also provided RightSign Covid 19 IgG/IgM and Abbott ID Now rapid COVID-19 testing in the main medical building laboratory 2. Review of the FDA's published listing of EUA's granted for SARS CoV-2 testing as of 05/21/21 revealed an EUA was granted for the test methods outlined above. The FDA listing included each manufacturer's package insert / IFU which outlined Conditions of Authorization for the Laboratory as: "All laboratories using this test must follow standard confirmatory

	testing and reporting guidelines according to appropriate public health authorities. Laboratories using product will have a process in place for reporting test results to healthcare providers and to public health authorities, as appropriate". 3. Review of the policies and procedures revealed no documentation of a policy for reporting patient COVID-19 results to the state agency. The inspector inquired of the reporting protocols to ensure all patient sample results were reported to the Virginia Department of Health (VDH). No policy was available for review. The office manager stated at approximately 3:00 PM on 05/21/21: "We are in contact by telephone and fax to our county health department and report all positive COVID-19 results. We have not reported negatives. Our lab manual does not have a policy related to reporting COVID-19 results." 4. An interview with the laboratory's office manager on 5/25/21 at 11:00 AM confirmed the above listed findings.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a tour, interviews, review of package insert, Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA), manufacturer's instructions for use (IFU), and policies and procedures, the laboratory directors (LD #1 and #2) failed to document approval and review of the laboratory's modifications of the manufacturer's procedure for rapid Access Bio CareStart COVID-19 antigen testing during the five month review timeframe (January to May 2021). Findings include: 1. During a tour of the facility's temporary exterior rapid COVID-19 test building on 5/20/21 at approximately 1:00 PM, the inspector noted two (2) Access Bio CareStart COVID-19 test kits (Lot Number CH21A03, expiration date 06/2021) in use for rapid antigen detection for the drive through testing setting. The inspector noted seventeen (17) opened, ready to use, CareStart test cassette devices lined up in a plastic container on the mobile unit test counter. The inspector inquired of the arrangement of test cassettes and how long they had been opened. The office manager stated at approximately 1:15 PM: "We have used the antigen test kits for rapid testing since early January 2021 and our clients like for the process to be as quick as possible. The pre-opened test cartridges makes it a quicker test process. I am not sure when these were opened but it was done to speed up the process for our clients." The inspector requested to review the approved test procedure. The office manager provided a package insert. 2. Review of the manufacturer's CareStart package insert revealed the following instructions: Warnings and Precautions: "Immediately use after removing the test device from the sealed pouch. In order to obtain accurate results, the test must follow this package insert"; Storage and Stability Instructions: "The test device must remain in the sealed pouch until use"; Test Procedure Notes: "Remove the CareStart COVD-19 Antigen test device and extraction vial from its foil pouch immediately before testing"; Limitations: "Failure to follow the instructions for use may adversely affect test performance and/or invalidate the test result". The inspector noted that the package insert lacked director signature of approval. 3. Review of the FDA EUA and IFU revealed the Authorized Laboratory instructions: "Deviations from the authorized procedures are not permitted. All operators using the product must be appropriately trained in performing and interpreting the results and use in accordance with authorized labeling". 4. Review of the laboratory's procedure manual revealed no approved procedure for the modified COVID-19 test method outlined above (opening

	test devices in advance of testing). The inspector requested to review documentation of LD approval for the modified procedure. No record was available for review. The inspector inquired on 5/20/21 at 4 PM via an email to the director (LD # 1) and the Chief Operations Officer (COO) regarding approval of procedures. LD # 1 stated on 5 /20/21 at approximately 5 PM: "I am no longer the lab director employed for this lab as I had resigned about 4 months ago. I am unsure of who has replaced me at this time." The COO stated on 5/21/21 at approximately 8:25 AM: "I will have the new director contact you today. LD #2 stated on 5/24/21 at approximately 3:00 PM: "I started as lab director on April 1, 2021 and have not been onsite or reviewed the procedures yet. I have asked the office manager to scan the procedures to me so that I can review them." (See Personnel Code Sheet) 5. An interview with the laboratory's office manager on 5/25/21 at 11:00 AM confirmed the above listed findings.
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: A. Based on a tour, interviews, review of the Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA), manufacturer's instructions for use (IFU), available patient and quality control (QC) logs, and lack of documentation, the laboratory failed to document performance of negative and positive external quality control (QC) for Access Bio CareStart COVID-19 antigen test kits according to manufacturer's instructions while reporting four thousand three hundred fifty (4,350) rapid patient results from January 7, 2021 to May 20, 2021. Findings include: 1. During a tour of the facility's temporary exterior rapid COVID-19 test building, on 5 /20/21 at approximately 1:00 PM, the inspector noted two (2) Access Bio CareStart COVID-19 test kits (Lot Number CH21A03, expiration date 06/2021) in use for rapid antigen detection for the drive through testing setting. The office manager stated at approximately 1:15 PM: "We have used the antigen test kits for rapid testing since early January 2021". 2. Review of the FDA's published listing of EUA's granted for COVID-19 testing as of 05/20/21 revealed an EUA was granted for the test method outlined above on 10/8/2020 and revised on 4/12/21. The FDA listing included the manufacturer's IFU which stated "The CareStart COVID-19 Antigen test includes Positive and Negative external control swabs. The product requires that all quality control must generate expected results in order for the test kit to be considered valid". 3. Review of the available monthly patient and QC logs from 1/07/21 to the date of the inspection revealed no record that positive or negative external control swabs were assayed and verified in the following months: January -one thousand three hundred forty-eight (1,348 patients tested); February - nine hundred eighty-five (985); March - eight hundred sixty (860); April - seven hundred ninety-one (791); May - three hundred sixty-six (366); a total of 4,350 patient tests. The inspector requested to review QC documentation for the CareStart COVID-19 Antigen test kits utilized for the patient testing outlined above. No documentation was available for review. 4. In an interview with the laboratory's office manager on 5/20/21 at 3:00 PM the above listed findings were confirmed. B. Based on a tour, review of manufacturer's guide, lack of documentation, patient test logs, and an interview, the laboratory failed to document performance of Abbott ID Now analyzer cleaning maintenance according to

manufacturer's instructions for seven (7) of 7 analyzers while reporting one thousand five hundred (1,500) patient results during the review timeframe of January 7, 2021 to May 20, 2021. Findings include: 1. During a tour of the facility, on 5/20/21 at approximately 1:15 PM, the inspector requested a listing of the facility's COVID-19 test methods. The office manager outlined that the laboratory utilized Access Bio CareStart COVID-19 test kits for rapid antigen testing in the drive through and also provided RightSign Covid 19 IgG/IgM and Abbott ID Now rapid COVID-19 testing inside the main medical building laboratory. 2. During a tour of the Abbott ID Now testing area (an exam room adjacent to the main laboratory) at approximately 2:00 PM, the inspector noted 7 Abbott ID Now analyzers lined up on a patient exam table. The manager stated at approximately 2:05 PM: "We did not have enough room in the main lab to set up these instruments. We are only using two of these analyzers at this time." The inspector noted the serial numbers (SN) of the analyzers: 1AA0D91C, A253D91C, FBA9D91C, AEBDD91C, 3EB5D91C, 444CD91C, D38FD91C. The inspector noted signs of residue staining (exterior and interior) on both of the two "in use" analyzers (SN 1AA0D91C and A253D91C). 3. Review of the Abbott ID Now users guide under Precautions and Warnings revealed statement: "Due to the high sensitivity of the assays run on the instrument, contamination of the work area with previous positive samples may cause false positive results. Clean instruments and surrounding surfaces according to instructions provided in Section 1.6 Maintenance and Cleaning." The inspector requested to review cleaning records/logs for the ID Now analyzers outlined above. No documentation was available for review. 4. The inspector requested to review the patient result logs for the Abbott ID Now COVID-19 testing area for the timeframe of January to May 20, 2021. The office manager provided the patient result data for the number of tests resulted as 1,500 resulted. 5. In an interview with the laboratory's office manager on 5/20/21 at 3:00 PM the above listed findings were confirmed. C. Based on a tour, interviews, review of package insert, the Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA), manufacturer's instructions for use (IFU), and lack of documentation, the laboratory failed to follow the manufacturer's instructions for handling of the AccessBio CareStart COVID-19 test cassette devices during the timeframe of January 2021 to May 20, 2021. Findings include: 1. During a tour of the facility's temporary exterior rapid COVID-19 test building on 5/20/21 at approximately 1:15 PM, the inspector noted seventeen (17) opened ready to use CareStart test cassette devices lined up in a plastic container on the mobile unit test counter. The inspector inquired of the arrangement of test cassettes and how long they had been opened. The manager stated: "Our clients like for the process to be as quick as possible and pre-opened test cartridges makes it a quicker test process. I am not sure when these were opened but it was done to speed up the process for our clients." The inspector inquired if the practice of pre-opening test cassette devices was a lab director approved procedure step and/or if it was within the manufacturer's guidelines. The manager did not respond. The inspector requested to review the approved test procedure. The office manager provided a package insert. 2. Review of the manufacturer's CareStart package insert revealed: Warnings and Precautions: "Immediately use after removing the test device from the sealed pouch. In order to obtain accurate results, the test must follow this package insert"; Storage and Stability Instructions: "The test device must remain in the sealed pouch until use"; Test Procedure Notes: "Remove the CareStart COVD-19 Antigen test device and extraction vial from its foil pouch immediately before testing"; Limitations: "Failure to follow the instructions for use may adversely affect test performance and/or invalidate the test result". 3. Review of the FDA EUA and IFU revealed the Authorized Laboratory instructions: "Deviations from the authorized procedures are not permitted. All operators using the product must be appropriately trained in performing and interpreting the results and use in accordance

	with authorized labeling". 4. An interview with the laboratory's office manager on 5/25 /21 at 11:00 AM confirmed the above listed findings.
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: Based on a tour, interviews, review of the Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA), manufacturer's package inserts, policies /procedures, available test logs, and lack of documentation, the laboratory failed to document monitoring of temperatures to ensure proper storage of immunology kits /reagents while reporting five thousand eight hundred fifty-five (5,855) patient COVID-19 test results from January 2, 2021 to May 20, 2021. Findings include: 1. During a tour of the facility's exterior rapid COVID-19 test building on 5/20/21 at approximately 1:15 PM, the inspector requested a listing of the facility's COVID-19 test methods. The office manager outlined that the laboratory utilized Access Bio CareStart COVID-19 test kits for rapid antigen testing in the drive through and also provided RightSign Covid 19 IgG/IgM and Abbott ID Now rapid COVID-19 testing in the main medical building laboratory. 2. Review of the FDA's published listing of EUA's granted for COVID-19 testing as of 05/20/21 revealed an EUA was granted for the test methods outlined: Access Bio CareStart EUA granted on 10/8/2020 and revised on 4/12/21; RightSign Covid 19 IgG/IgM granted on 6/4/20, revised 12/21/20; Abbott ID Now rapid COVID-19 granted on 3/27/20. Review of the FDA published listings also revealed each EUA released with statement: "Test has not been FDA cleared or approved, this test has been authorized by FDA under an EUA" and IFU Authorized Laboratory instruction statement: "Deviations from the authorized procedures are not permitted." 3. Review of the package inserts for the test methods outlined above revealed manufacturer's storage and stability instructions: CareStart - "Store the test kit as packaged between 1-30 C. Do not freeze any contents of the kit. Allow the devices, reagents and controls to equilibrate to room temperature (15-30 C) prior to testing."; RightSign - "Humidity and temperature adversely affect results. The kit can be stored at room temperature or refrigerated (2-30 C). The test cassette must remain in sealed pouch until use. Do not freeze."; Abbott ID - "Proper sample collection and storage are essential for correct results. Store kits at 2-30 C. Ensure all test components are at room temperature (15-30 C) before use". 4. Review of the laboratory's procedure manual revealed a quality assurance policy that stated (page 3): "We will ensure correct environmental conditions for all laboratory methods and supplies to ensure reliable operation and test results. Reagents are monitored for acceptable labeling and storage." The inspector requested to review temperature /humidity monitoring logs for the three (3) COVID-19 testing areas: Test area #1 (drive through building) for January to May 2021, Test area #2 (main laboratory room) for February to April 2021, Test area #3 (Abbott ID Now exam room) for January to May 2021. No records were available for review. 5. Review of the available patient test logs from 1/2/21 to 5/20/21 revealed 5,855 patient COVID-19

	test results were reported utilizing the test kits outlined above in testing areas 1, 2, 3. 6. During an interview on 5/20/21, at approximately 2:30 PM, the inspector requested clarification regarding temperature monitoring. The office manager stated: "I have temperature charts recorded for the main lab room for January 2021 and May 2021. I have not located the temperature charts for the other areas". 7. An interview with the laboratory's office manager on 5/25/21 at 11:00 AM confirmed the above listed findings.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on a tour, interviews, review of package insert, Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA), review of available patient and quality control (QC) logs, and lack of documentation, the laboratory failed to evaluate, verify /validate the performance specifications of a modified test procedure for Access Bio CareStart COVID-19 antigen test kits prior to reporting four thousand three hundred fifty (4,350) rapid patient results from January 7, 2021 to May 20, 2021. (See D5411 C.) Findings include: 1. During a tour of the facility's temporary exterior rapid COVID-19 test building on 5/20/21 at approximately 1:00 PM, the inspector noted two (2) Access Bio CareStart COVID-19 test kits (Lot Number CH21A03, expiration date 06/2021) in use for rapid antigen detection for the drive through testing setting. The inspector noted seventeen (17) opened ready to use CareStart test cassette devices lined up in a plastic container on the mobile unit test counter. The inspector inquired of the arrangement of test cassettes and how long they had been opened. The office manager stated at approximately 1:15 PM: "We have used the antigen test kits for rapid testing since early January 2021. Our clients like for the process to be as quick as possible and pre-opened test cartridges makes it a quicker test process. I am not sure when these were opened but it was done to speed up the process for our clients." The inspector inquired if the practice of pre-opening test cassette devices was a lab director approved procedure step and/or if it was within the manufacturer's guidelines. The manager did not respond. The inspector requested to review the approved test procedure. The office manager provided a package insert. 2. Review of the manufacturer's CareStart package insert revealed: Warnings and Precautions: "Immediately use after removing the test device from the sealed pouch. In order to obtain accurate results, the test must follow this package insert"; Storage and Stability Instructions: "The test device must remain in the sealed pouch until use"; Test Procedure Notes: "Remove the CareStart COVD-19 Antigen test device and extraction vial from its foil pouch immediately before testing"; Limitations: "Failure to follow the instructions for use may adversely affect test performance and/or invalidate the test result". 3. Review of the FDA EUA revealed IFU Authorized

	Laboratory instructions: "Deviations from the authorized procedures are not permitted. All operators using the product must be appropriately trained in performing and interpreting the results and use in accordance with authorized labeling". 4. The inspector requested to review an approved validation study for the modified high complexity CareStart COVID-19 test method. No documentation was available for review. 5. Review of the available monthly patient and QC logs from 1/07/21 to the date of the inspection revealed no record that positive or negative external control swabs were assayed and verified for the modified CareStart COVID-19 test practices in the following months: January -one thousand three hundred forty-eight (1,348 patients tested); February - nine hundred eighty-five (985); March - eight hundred sixty (860); April - seven hundred ninety-one (791); May - three hundred sixty-six (366); A total of 4,350 patient tests were resulted without an approved study verifying performance specifications and quality control documentation for the modified high complexity test method. 6. An interview with the laboratory's office manager on 5/25 /21 at 11:00 AM confirmed the above listed findings.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a tour, interviews, review of package insert, Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA), manufacturer's instructions for use (IFU), available patient and quality control (QC) logs, procedures and policy manual, and lack of documentation, the laboratory directors (LD #1, LD #2) failed to: (See Personnel Code Sheet) 1. ensure/evaluate that laboratory testing personnel performed patient Access Bio CareStart COVID-19 antigen testing according to manufacturer's instructions prior to reporting four thousand three hundred fifty (4,350) rapid patient results from January 7, 2021 to May 20, 2021; 2. ensure that a QC policy was established and monitored for rapid AccessBio CareStart COVID-19 Antigen patient testing from January 2021 to the date of the inspection on 5/20/21; 3. ensure that the quality assurance (QA) policies were maintained during the four months reviewed (January 2021 through May 20, 2021); 4. review and approve the laboratory policies and procedures after assuming the duties of LD on April 1, 2021 and up the date of the inspection on 5/20/21; See D6014, D6020, D6021, D6031.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on a tour, interviews, review of package insert, Food and Drug Administration's

	(FDA) Emergency Use Authorizations (EUA), manufacturer's instructions for use (IFU), available patient and quality control (QC) logs, and lack of documentation, the laboratory directors (LD #1, LD #2) failed to ensure/evaluate that the laboratory testing personnel performed patient Access Bio CareStart COVID-19 antigen testing according to manufacturer's instructions prior to reporting four thousand three hundred fifty (4,350) rapid patient results from January 7, 2021 to May 20, 2021. (See Personnel Code Sheet.) Findings include: 1. During a tour of the facility's temporary exterior rapid COVID-19 test building on 5/20/21 at approximately 1:00 PM, the inspector noted two (2) Access Bio CareStart COVID-19 test kits (Lot Number CH21A03, expiration date 06/2021) in use for rapid antigen detection for the drive through testing setting. The inspector noted seventeen (17) opened ready to use CareStart test cassette devices lined up in a plastic container on the mobile unit test counter. The inspector inquired of the arrangement of test cassettes and how long they had been opened. The manager stated: "Our clients like for the process to be as quick as possible and pre-opened test cartridges makes it a quicker test process. I am not sure when these were opened but it was done to speed up the process for our clients." The inspector inquired if the practice of pre-opening test cassette devices was a lab director approved procedure step and/or if it was within the manufacturer's guidelines. The manager did not respond. The inspector requested to review the approved test procedure and quality control (QC) records. The office manager stated at approximately 1:15 PM: "We have used the antigen test kits for rapid testing since early January 2021". The office manager provided a package insert. 2. Review of the manufacturer's CareStart package insert revealed: Warnings and Precautions: "Immediately use after removing the test device from the sealed pouch. In order to obtain accurate results, the test must follow this package insert"; Storage and Stability Instructions: "The test device must remain in the sealed pouch until use"; Test Procedure Notes: "Remove the CareStart COVD-19 Antigen test device and extraction vial from its foil pouch immediately before testing"; Limitations: "Failure to follow the instructions for use may adversely affect test performance and/or invalidate the test result". 3. Review of the FDA's published listing of EUA's granted for COVID-19 testing as of 05/20/21 revealed an EUA was granted for the test method outlined above on 10/8/2020 and revised on 4/12/21. The FDA listing included the manufacturer's IFU which stated: "The CareStart COVID-19 Antigen test includes Positive and Negative external control swabs. The product requires that all quality control must generate expected results in order for the test kit to be considered valid. Deviations from the authorized procedures are not permitted. All operators using the product must be appropriately trained in performing and interpreting the results and use in accordance with authorized labeling". 4. Review of the available monthly patient and QC logs from 1/07/21 to the date of the inspection revealed no record that positive or negative external control swab results were recorded as assayed and verified in the following months: January -one thousand three hundred forty-eight (1,348 patients tested); February - nine hundred eighty-five (985); March - eight hundred sixty (860); April - seven hundred ninety-one (791); May - three hundred sixty-six (366); a total of 4,350 patient test results recorded with zero (0) QC documentation available for review. 5. In an interview on 5/24/21 at approximately 4: 00 PM, LD #2 stated: "I started as lab director on April 1, 2021 and have not been onsite or reviewed the procedures yet. I have asked the office manager to scan the procedures to me so that I can review them. The test devices should not be opened ahead of testing." 6. An interview with the laboratory's office manager on 5/25/21 at 11:00 AM confirmed the above listed findings.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)

	The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a tour, review of the Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA), manufacturer's instructions for use (IFU), laboratory's policy and procedure manual, interviews, and lack of quality control (QC) records, the laboratory directors (LD #1, LD #2) failed to ensure that their quality control (QC) policy was monitored to identify quality failures for rapid AccessBio CareStart COVID-19 Antigen patient testing from January 2021 to the date of the inspection on May 20, 2021. (See Personnel Code Sheet.) Findings include: 1. During a tour of the facility's temporary exterior rapid COVID-19 test building (located in the back parking lot of the medical office) on 5/20/21 at approximately 1:00 PM, the inspector requested to review the approved test procedure for the AccessBio CareStart COVID-19 Antigen testing. The office manager stated that the laboratory used the manufacturer's instruction insert. 2. Review of the FDA's published listing of EUA's granted for COVID-19 testing as of 05/20/21 revealed an EUA was granted for AccessBio CareStart COVID-19 Antigen on 10/8/2020 and revised on 4/12/21. The FDA listing included the manufacturer's IFU which stated "The CareStart COVID-19 Antigen test includes Positive and Negative external control swabs. The product requires that all quality control must generate expected results in order for the test kit to be considered valid". 3. Review of the laboratory's policy and procedure manual revealed a written quality assurance (QA) policy (signed by LD #1, not dated) that outlined: "We have written collection of instructions for all tests performed by our lab. Included in these instructions are how to perform quality control". 4. Review of the laboratory's available QC and QA documentation from January 2021 through the date of the survey revealed no record that positive or negative external control swabs were assayed and verified as required for the CareStart antigen testing. The inspector requested LD QA reviews for the review timeframe. No records were available for review. 5. Review of the available monthly CareStart antigen patient logs from 1/07 /21 to the date of the inspection revealed: January -one thousand three hundred forty-eight (1,348 patients tested); February - nine hundred eighty-five (985); March - eight hundred sixty (860); April - seven hundred ninety-one (791); May - three hundred sixty-six (366); a total of 4,350 rapid patient tests reported while QC protocols were not maintained or evaluated by the LD. 6. An interview with the laboratory's office manager on 5/25/21 at 11:00 AM confirmed the above listed findings.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

	This STANDARD is not met as evidenced by: Based on a review of the laboratory's policy and procedure manual, temperature monitoring records, rapid COVID-19 quality control (QC) records, validation studies, interviews, and lack of documentation, the laboratory directors (LD #1, LD #2) failed to ensure that the quality assurance (QA) policies were maintained during the four months reviewed (January 2021 through May 20, 2021). See Personnel Code Sheet. Findings include: 1. Review of the laboratory's policy and procedure manual on 05/20 /21 revealed a written QA policy (signed by LD #1, not dated) that stated under categories: Analytic Phase Test Reagents and Supplies: "We will ensure correct environmental conditions for all laboratory methods and supplies to ensure reliable operation and test results. Reagents are monitored for acceptable labeling and storage." Procedure Manual: "We have written collection of instructions for all tests performed by our lab. Included in these instructions are how to perform quality control". Quality Control: "For each test system we have control procedures that monitor the accuracy of the analytical process. We perform quality control in the manner and at the frequency recommended by the manufacturer of each waived and non waived test method." Verification of Performance Specifications: "For modified methods or methods that are not FDA approved, we will establish our own performance specifications that include analytical sensitivity, specificity, and meet expected performance specifications." Post Analytic: "Frequency of QA reviews are at least once every three months". 2. The inspector requested to review QA reviews that included room temperature/humidity monitoring, QC, test validation studies, applicable instrument maintenance for the three (3) COVID-19 testing areas (drive through building, main laboratory room, Abbott ID Now exam room). No January to May 2021 QA documentation was available for review. 3. An interview with the laboratory's office manager on 5/25/21 at 11:00 AM confirmed the above listed findings.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) 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 a tour, review of the laboratory's procedure manual, and interviews, the laboratory director (LD #2) failed to review and approve the laboratory policies and procedures after assuming the duties of the laboratory oversight on April 1, 2021 and up the date of the inspection on May 20, 2021. (See Personnel Code Sheet.) Findings include: 1. During a tour of the facility's exterior rapid COVID-19 test building on 5 /20/21 at approximately 1:15 PM, the inspector requested a listing of the facility's COVID-19 test methods. The office manager outlined that the laboratory utilized Access Bio CareStart COVID-19 test kits for rapid antigen testing in the drive through and also provided RightSign Covid 19 IgG/IgM and Abbott ID Now rapid COVID-19 testing in the main medical building laboratory. 2. Review of the laboratory's procedure manual revealed no approved procedure for the three (3) COVID-19 test methods outlined above. The inspector requested to review record of LD approval.

	The office manager provided package inserts and stated on 5/20/21 at approximately 2: 00 PM: "Our director has not been onsite this year. We can reach out through conferencing and I can ask for the review of procedures. I will give you the director's email". 3. The inspector sent an email survey notification/inquiry to the director (LD # 1) and the Chief Operations Officer (COO) on 5/20/21 at 4 PM. LD # 1 was not able to provide any information regarding the mobile unit or laboratory oversight. LD # 1 stated on 5/20/21 at approximately 5 PM: "I wanted to inform you that I am no longer the lab director employed for this lab as I had resigned about 4 months ago. I am unsure of who has replaced me at this time." The COO responded to the inspector's inquiry regarding director oversight of the laboratory services on 5/21/21 at approximately 8:25 AM: "I will have the new director contact you today". An interview with LD #2 on 5/24/21 at approximately 3:00 PM revealed that the facility had not notified the state agency of the lab director change. LD #2 stated: "I will complete the required forms for director change and send to your office overnight. I started as lab director on April 1, 2021 and have not been onsite or reviewed the procedures yet. I have asked the office manager to scan the procedures to me so that I can review them." 4. An interview with the laboratory's office manager on 5/25/21 at 11:00 AM confirmed the above listed findings.