Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2143481	06/05/2020
Name of Provider or Supplier	**Street Address, City, State**	
Premier Acute Care Services, Llc	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 off-site Clinical Laboratory Improvement Amendments (CLIA) complaint investigation (Complaint #VA00048959) was conducted for Premier Acute Care Services, LLC on May 27, 2020 to June 5, 2020 by a Medical Facilities Inspector from the Virginia Department of Health, Office of Licensure and Certification. Deficiencies cited are as follows:
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 a review of manufacturer's package insert, policies/procedures, Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA), available patient and quality control (QC) logs, and interviews, the laboratory failed to: 1. document monitoring temperatures to ensure proper storage of the CoronaChek COVID-19 IgG/IgM test cassettes and kit reagents in the drive through laboratory set up from April 8, 2020 to the date of the initiated complaint survey May 27, 2020; 2. evaluate and verify the performance specifications of the non FDA approved CoronaChek COVID-19 IgG/IgM test method prior to reporting two thousand one hundred forty-three (2,143) patient results from 4/8/20 to 5/27/20; 3. document performance of a negative and positive control for the non FDA approved CoronaChek COVID-19 IgG/IgM test method for each day of patient testing from 4/8 /20 to 5/27/20 while reporting 2,143 patient results . See D5413, D5423, D5449.

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 interviews, review of manufacturer's package insert and policies/procedures, the laboratory failed to document monitoring of temperatures to ensure proper storage of the CoronaChek COVID-19 IgG/IgM test cassettes and kit reagents while reporting two thousand one hundred forty-three (2,143) patient results from April 8, 2020 to the date of the initiated complaint survey May 27, 2020. Findings include: 1. During an interview with the owner, lab director, medical director, and operations manager during a telephone conference call on 5/27/20 at approximately 12:30 PM, the inspector asked for a description of the patient COVID-19 IgG/IgM testing process. The operations manager described a drive through laboratory set up: "We take appointments for the COVID testing. This operation takes place in a drive through testing process in our facility's parking area. Our appointments are directed to the drive through area and are tested at their appointment time slot. The client does not exit their car. After client is identified, blood is drawn by finger-stick, and the blood is applied to the test cartridge, read by lab testing personnel, and a provider interacts with the client and reports the COVID test reading. The test kits are taken from our facility each day of testing and are stored in a cooler outside in the drive through lab setting." 2. Review of the CLIAWAIVED, INC CoronaChek COVID-19 IgG/IgM package insert revealed manufacturer's instructions: "Storage and Stability: store at room temperature or refrigerated (2-30 degrees Celsius), do not freeze. 3. Review of the laboratory's procedure ("PACS Urgent Care Procedure: COVID-19 Antibody Testing") revealed instructions "Storage and Stability: store at room temperature or refrigerated (2-30 degrees Celsius), do not freeze". 4. Review of the available daily temperature logs from 4/8/20 to 5/27/20 revealed no documentation of recording the laboratory's drive through cooler storage of the CoronaChek cassettes. The inspector requested to review documentation of monitoring the storage temperature. No documentation was available for review. 5. In an interview on June 1, 2020 at 1:00 PM, the operations manager confirmed the above 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 review of the Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA), interviews, available patient and quality control (QC) logs, the laboratory failed to evaluate, verify/validate the performance specifications of the non FDA approved CoronaChek COVID-19 IgG/IgM test method prior to reporting two thousand one hundred forty-three (2,143) patient results from April 8, 2020 to the date of the initiated complaint survey May 27, 2020. Findings include: 1. Review of the FDA's published listing of COVID-19 EUA granted for SARS CoV-2 antibody testing as of 5/27/20 revealed no EUA granted for CLIAWAIVED, INC CoronaChek COVID-19 IgG/IgM test method. The CoronaChek COVID-19 IgG/IgM test method classification as of 5/27/20 was high complexity. 2. During an interview with the owner, lab director, medical director, and operations manager during a telephone conference call on 5/27/20 at approximately 12:30 PM, the inspector asked for a description of the laboratory's QC protocols and to review documentation of in-house validation procedures for the high complexity COVID-19 test kits. The LD stated, at approximately 1:00 PM: "We use the test cassette's internal QC. We do not run additional negative or positive QC material. We cannot find tests that have the FDA's EUA. The only test kits that we have been able to purchase due to the high demand are the CoronaChek cassettes from the CLIAWAIVED distributor. We reviewed and use the manufacturer's validation study listed in the package inserts. We did not perform our own validation." 3. Review of the patient test and QC logs revealed that the laboratory reported 2,143 COVID-19 IgG/IgM results while performing zero (0) external negative or positive controls for the timeframe of 4/8/20 to 5/27/20. No records of a validation study were available for review. 4. In an interview on June 1, 2020 at 1:00 PM, the operations manager confirmed the above findings.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA), interviews, and review of available patient and quality control (QC) logs, the laboratory failed to document performance of negative and positive controls for the non FDA approved CoronaChek COVID-19 IgG/IgM test method while reporting two thousand one hundred forty-three (2,143) patient results from April 8, 2020 to the date of the initiated complaint survey May 27, 2020. Findings include: 1. Review of the FDA's published listing of COVID-19 EUA granted for SARS CoV-2 antibody testing as of 5/27/20 revealed no EUA for CLIAWAIVED, INC CoronaChek COVID-19 IgG/IgM test method. The CoronaChek COVID-19 IgG /IgM test method classification as of 5/27/20 was high complexity. 2. During an interview with the owner, lab director, medical director, and operations manager during a telephone conference call on 5/27/20 at approximately 12:30 PM, the inspector asked for a description of the laboratory's QC protocols for the high

	complexity COVID-19 test kits. The LD stated, at approximately 1:00 PM: "We use the test cassette's internal QC. We do not run additional negative or positive QC material". 3. Review of the patient test and QC logs revealed that the laboratory reported 2,143 COVID-19 IgG/IgM results while performing zero (0) external negative or positive controls for the timeframe of 4/8/20 to 5/27/20 . 4. In an interview on June 1, 2020 at 1:00 PM, the operations manager confirmed the above findings.
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 a review of the Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA), available patient and quality control (QC) logs, policies and procedures, temperature logs, Centers for Medicare and Medicaid Services Laboratory Personnel Report Form (CMS 209), available laboratory personnel files, and interviews, the laboratory director (LD) failed to: 1. ensure validation/verification performance procedures were performed for the non FDA approved CoronaChek COVID-19 IgG/IgM test method prior to reporting two thousand one hundred forty-three (2,143) patient results from April 8, 2020 to the date of the initiated complaint survey May 27, 2020; 2. ensure that QC policies were established and followed for the non FDA approved CoronaChek COVID-19 IgG/IgM test from April 8, 2020 to the date of the initiated complaint survey May 27, 2020; 3. ensure that quality assurance (QA) policies were established and maintained for the non FDA approved CoronaChek COVID-19 IgG/IgM test process from April 8, 2020 to the date of the initiated complaint survey May 27, 2020; 4. ensure that the laboratory retained evidence of education ensuring testing personnel qualifications and competency assessment for one (1) of two (2) testing personnel responsible for performing non FDA approved CoronaChek COVID-19 IgG/IgM test method during the timeframe of April 8, 2020 to the date of the initiated complaint survey May 27, 2020. See D6086, D6093, D6094, D6102.
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 a review of the Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA), available patient and quality control (QC) logs, and interviews, the laboratory director (LD) failed to ensure validation/verification performance procedures were performed for the non FDA approved CoronaChek COVID-19 IgG /IgM test method prior to reporting two thousand one hundred forty-three (2,143) patient results from April 8, 2020 to the date of the initiated complaint survey May 27, 2020. Findings include: 1. Review of the FDA's published listing of COVID-19 EUA granted for SARS CoV-2 antibody testing as of 5/27/20 revealed no EUA for

	CLIAWAIVED, INC CoronaChek COVID-19 IgG/IgM test method. The CoronaChek COVID-19 IgG/IgM test method classification as of 5/27/20 was high complexity. 2. Review of the patient test and QC logs revealed that the laboratory reported 2,143 COVID-19 IgG/IgM results while performing zero (0) external negative or positive controls for the timeframe of 4/8/20 to 5/27/20 . 3. During an interview with the owner, lab director, medical director, and operations manager during a telephone conference call on 5/27/20 at approximately 12:30 PM, the inspector asked for a description and review of documentation of in-house validation procedures for the high complexity COVID-19 test kits. The LD stated, at approximately 1:00 PM: "We use the test cassette's internal QC. We do not run additional negative or positive QC material. We cannot find tests that have the FDA's EUA. We reviewed and use the manufacturer's validation study listed in the package inserts." No records of validation study were available for review. 4. In an interview on June 1, 2020 at 1:00 PM, the operations manager confirmed the above findings.
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 a review of the Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA), interviews, review of available patient and quality control (QC) logs, policies and procedures, the laboratory director (LD) failed to ensure that QC policies were established and followed from April 8, 2020 to the date of the initiated complaint survey May 27, 2020. Findings include: 1. Review of the FDA's published listing of COVID-19 EUA granted for SARS CoV-2 antibody testing as of 5 /27/20 revealed no EUA for CoronaChek COVID-19 IgG/IgM test method (distributed by CLIAWAIVED, INC and manufactured in China by Hangzhou Biotest). The CoronaChek COVID-19 IgG/IgM test method classification as of 5/27 /20 was high complexity. 2. During an interview with the owner, LD, medical director, and operations manager during a telephone conference call on 5/27/20 at approximately 12:30 PM, the inspector asked for a description of the laboratory's daily QC protocols for the high complexity COVID-19 test kits. The LD stated, at approximately 1:00 PM: "We use the test cassette's internal QC. We do not use additional QC material". 3. Review of the patient test and QC logs revealed that the laboratory reported 2,143 COVID-19 IgG/IgM results while performing zero (0) external negative or positive controls for the timeframe of 4/8/20 to 5/27/20 . 4. Review of the laboratory's available policy and procedures revealed no written approved QC policy for the CoronaChek COVID-19 IgG/IgM testing system. 5. In an interview on June 1, 2020 at 1:00 PM, the operations manager confirmed the above findings.
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 a review of the Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA), available patient and quality control (QC) logs, manufacturer's package insert, temperature logs, and interviews, the laboratory director (LD) failed to ensure that quality assurance (QA) policies were established and maintained for the non FDA approved CoronaChek COVID-19 IgG/IgM test method prior to reporting two thousand one hundred forty-three (2,143) patient results from April 8, 2020 to the date of the initiated complaint survey May 27, 2020. Findings include: 1. Review of the FDA's published listing of COVID-19 EUA granted for SARS CoV-2 antibody testing as of 5/27/20 revealed no EUA for CLIAWAIVED, INC CoronaChek COVID-19 IgG/IgM test method. The CoronaChek COVID-19 IgG/IgM test method classification as of 5/27/20 was high complexity. 2. Review of the patient test and QC logs revealed that the laboratory reported 2,143 COVID-19 IgG/IgM results while performing zero (0) external negative or positive controls for the timeframe of 4/8/20 to 5/27/20 . 3. Review of the CLIAWAIVED, INC CoronaChek COVID-19 IgG/IgM package insert revealed manufacturer's instructions: "Storage and Stability: store at room temperature or refrigerated (2-30 degrees Celsius), do not freeze". 4. Review of the available daily temperature logs from 4/8/20 to 5/27/20 revealed no documentation of recording the laboratory's drive through cooler storage of the CoronaChek cassettes. The inspector requested to review documentation of monitoring the storage temperature. No documentation was available for review. 5. During an interview with the operations manager during a telephone conference call on 6/1/20 at approximately 1:00 PM, the inspector asked for a description of the laboratory's QA policies. The operations manager stated at approximately 1:15 PM: "We do not have a laboratory QA policy". 6. In an interview on June 1, 2020 at 1:00 PM, the operations manager confirmed the above findings.
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 a review of the Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA), Centers for Medicare and Medicaid Services Laboratory Personnel Report Form (CMS 209), available laboratory personnel files, and interviews, the laboratory director (LD) did not ensure that the laboratory retained evidence of education ensuring testing personnel qualifications and competency assessment for one (1) of two (2) testing personnel responsible for performing non FDA approved CoronaChek COVID-19 IgG/IgM test method during the timeframe of April 8, 2020 to the date of the initiated complaint survey May 27, 2020. Findings include: 1. Review of the FDA's published listing of COVID-19 EUA granted for SARS CoV-2 antibody testing as of 5/27/20 revealed no EUA for CLIAWAIVED, INC CoronaChek COVID-19 IgG/IgM test method. The CoronaChek COVID-19 IgG /IgM test method classification as of 5/27/20 was high complexity. 2. Review of the laboratory's CMS 209 form revealed 2 testing personnel (TP) identified as performing CoronaChek COVID-19 IgG/IgM patient testing during the timeframe of 4/8/20 to 5

	/27/20. 3. Review of the available laboratory personnel records revealed no evidence of required education documentation or a CoronaChek COVID-19 IgG/IgM test competency assessment for TP A. The inspector requested to review the education documentation and training/competency assessment for TP A. No records were available for review. See Personnel Code Sheet attached. 4. In an interview on June 1, 2020 at 1:00 PM, the operations manager confirmed the above findings. The operations manager stated: "We have diploma documentation and training record for one of the two personnel. We do not have a training competency check or diploma for the other testing personnel. I have left a telephone message with the one lacking documents to request the diploma or a transcript. She is no longer employed with us."
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on a review of the Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA), Centers for Medicare and Medicaid Services Laboratory Personnel Report Form (CMS 209), available laboratory personnel files, and interviews, the laboratory failed to retain evidence of education ensuring testing personnel qualifications for one (1) of two (2) testing personnel. See D6171.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved

by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:
Based on a review of the Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA), Centers for Medicare and Medicaid Services Laboratory Personnel Report Form (CMS 209), available laboratory personnel files, and interviews, the laboratory failed to retain evidence of education ensuring testing personnel qualifications for one (1) of two (2) testing personnel. Findings include: 1. Review of the FDA's published listing of COVID-19 EUA granted for SARS CoV-2 antibody testing as of 5/27/20 revealed no EUA for CLIAWAIVED, INC CoronaChek COVID-19 IgG/IgM test method. The CoronaChek COVID-19 IgG/IgM test method classification as of 5/27/20 was high complexity. 2. Review of the laboratory's CMS 209 form revealed 2 testing personnel (TP) identified as performing CoronaChek COVID-19 IgG/IgM patient testing during the timeframe of 4/8/20 to 5/27/20. 3. Review of the available laboratory personnel records revealed no evidence of required education documentation for TP A. The inspector requested to review the education documentation for TP A. No record was available for review. See Personnel Code Sheet attached. 4. In an interview on June 1, 2020 at 1:00 PM, the operations manager confirmed the above findings. The operations manager stated: ""We have diploma documentation and training record for one of the two personnel. We do not have a training competency check or diploma for the other testing personnel. I have left a telephone message with the one lacking documents to request the diploma or a transcript. She is no longer employed with us." We have diploma documentation for one of the two personnel. We have a resume for the other testing personnel. I have left a telephone message with the one lacking documents to request the diploma or a transcript. She is no longer employed with us."