Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 49D2162379	**(X3) Date Survey Completed** 06/25/2020
Name of Provider or Supplier Northern Virginia Carenow Urgent Care Llc	**Street Address, City, State** 12214 W Broad Street, Richmond, 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 CLIA complaint investigation was conducted at Bettermed Urgent Care-Short Pump from May 27, 2020 up to June 25, 2020 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Specific deficiencies cited are as follows:
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on review of the Virginia State Board of Health Regulations and the Federal Coronavirus Aid, Relief, and Economic Security (CARES) Act, telephone interviews with the Director of Clinical Operations and the Chief Operating Officer (COO), and review of available patient test logs, the laboratory failed to report positive patient test results for the 2019 novel Coronavirus (COVID-19) antibody in accordance with State and Federal requirements for forty-seven (47) of nine hundred and eighty-four (984) patients from April 27, 2020 through May 28, 2020. Findings include: 1. Review of the Commonwealth of Virginia State Board of Health November 2018, Regulations for Disease Reporting and Control (page 10) revealed the following statements: "12 VAC 5-90-80. Lists of diseases that shall be reported. A. Reportable disease list. The board declares suspected or confirmed cases of the following named diseases, toxic effects, and conditions to be reportable by the persons enumerated in 12VAC5-90-90. Conditions identified by an asterisk (*) require immediate communication to the local health department by the most rapid means available upon suspicion or confirmation, as defined in subsection C of this section. *Coronavirus infection, severe C. Reportable diseases requiring rapid communication. Certain of the diseases in the list of reportable diseases because of their extremely contagious nature, potential for

	greater harm, or availability of a specific intervention that must be administered in a timely manner require immediate identification and control. Reporting of persons confirmed or suspected of having these diseases, listed in this subsection, shall be made immediately by the most rapid means available, preferably by telephone to the local health department (page 13). Coronavirus infection, severe" 2. Review of the Coronavirus Aid, Relief, and Economic Security (CARES) Act Public Law 116-136, 18115(a) revealed the following statements: "requires every laboratory that performs or analyzes a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 to report the results from each such test to the Secretary of the Department of Health and Human Services (HHS). This document outlines the requirements for data submission to HHS as authorized under this law. In an effort to receive these data in the most efficient and effective manner, the Secretary is requiring that all data be reported through existing public health data reporting methods, described below. As a guiding principle, data should be sent to state or local public health departments using existing reporting channels (in accordance with state law or policies) to ensure rapid initiation of case investigations by those departments, concurrent to laboratory results being shared with an ordering provider, or patient as applicable." 3. An interview with the Director of Clinical Operations and the COO on May 28, 2020 at approximately 1 PM revealed the laboratory utilized two (2) non FDA approved COVID-19 test kits (Corona Check and Healgen COVID-19 IgG/IgM Antibody) to detect IgG/IgM antibodies to the 2019 novel Coronavirus (COVID-19) from 4/27/20 through 5/28/20. In addition, lack of communication to local and State health departments of patient test results for COVID-19 IgG/IgM antibody for the specified timeframe in accordance with the aforementioned State and Federal regulations. 4. Review of available patient test logs revealed the following patients reported as positive for COVID-19 IgG/IgM Antibody: 4/28/20- 5 patients, 4/29/20- 7 patients, 4/30/20- 2 patients, 5/1/20- 7 patients, 5/2/20- 2 patients, 5/3/20- 1 patient, 5 /4/20- 3 patients, 5/5/20- 3 patients, 5/6/20- 3 patients, 5/8/20- 3 patients, 5/9/20- 2 patients, 5/12/20- 2 patients, 5/14/20- 2 patients, 5/15/20- 1 patient, 5/21/20- 2 patients, 5/22/20- 1 patient and, 5/23/20- 1 patient. Total of 47 patients. 5. An interview with the Director of Clinical Operations and the COO on June 25, 2020 at approximately 11 AM confirmed the 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 logs of patient testing, quality control (QC), temperature monitoring, and lack of documentation, the laboratory failed to: 1. document monitoring of temperatures to ensure proper storage of Corona Check 2019-nCoV Ab Test Colloidial Gold and Healgen COVID-19 IgG/IgM Rapid Test Cassette kit reagents from 4/27/20 to 5/31/20; 2. evaluate and verify the performance specifications of two (2) non FDA approved COVID-19 IgG/IgM test methods prior to reporting nine

	hundred eighty-four (984) patient COVID-19 IgG/IgM antibody test results from 4/27 /20 to 5/31/20; 3. document performance of negative and positive external controls for 2 non FDA approved COVID-19 IgG/IgM test methods for each day of patient testing from 4/27/20 to 5/31/20 while reporting 984 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 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 record monitoring of temperatures to ensure proper storage of immunology kits /reagents while reporting nine hundred eighty-four (984) patient COVID-19 IgG/IgM antibody results from April 27, 2020 to May 31, 2020. Findings include: 1. In an email interview with the the Director of Clinical Operations and Chief Operating Officer (COO) on 5/27/20 at approximately 10:10 AM, it was revealed that the laboratory had been utilizing the following two (2) COVID-19 test kits (in a drive through testing setting) during the timeframe of 4/27/20 through the date of the offsite investigation: Corona Check 2019-nCoV Ab Test Colloidial Gold, manufactured in China by Innovita Tangshan Biological Technology Co. LTD and Healgen COVID-19 IgG/IgM Rapid Test Cassette manufactured by Healgen Scientific Limited Liability Company, Houston Texas. 2. Review of the FDA's published listing of COVID-19 EUA granted for SARS CoV-2 antibody testing on 5/27/20 revealed no EUA granted for the 2 kits outlined above. The Innovita Corona Check and Healgen COVID-19 IgG/IgM rapid test methods' classifications as of 5/27/20 were high complexity. 3. Review of the Innovita Corona Check package insert revealed manufacturer's instructions: "Storage and Stability: Store at 4-30 C (39.2-86 F)". Review of the Healgen COVID-19 IgG/IgM Rapid Test package insert revealed instructions that stated: "Storage and Stability: The kit can be stored at room temperature or refrigerated (2-30 degrees C/36-86 F); do not freeze". 4. Review of the laboratory's approved procedures ("BetterMed POC COVID-19 Healgen Antibody Testing" and "BetterMed POC COVID-19 Innovita Antibody Testing") revealed no instructions for monitoring temperatures for proper storage of kit/reagent. 5. Review of the available laboratory logs from 4/27/20 to 5/31/20 revealed 984 patient COVID-19 IgG/IgM antibody test results were reported. No temperature monitoring logs for the Corona Check or Healgen test kits conforming with the manufacturer's instructions were available for review. 6. During an email interview on 6/17/20, at approximately 10:30 AM, the inspectors requested clarification regarding temperature logs and dates of use for each test kit methods outlined above. The COO stated: "No temperatures were recorded for the storage areas. All antibody kits were delivered to our corporate office at 3200 Rockbridge St, Suite 103 Richmond, VA 23230. Each of our test sites had a limited appointment slot of 25-35 antibody tests per day. The

	number of kits were delivered to get them through a 7 day period, often times it would be more than that amount so they would just receive a box of the kits instead of loose kits. Regarding distribution, the kits were distributed to each site Tuesday mornings via our courier, Oribit. At times a site manager may stop by and pick up a box or a box of kits may be distributed by someone from our corporate office that may have been going to a site that needed some. Lot numbers of the boxes or individual kits were not tracked. Boxes of kits were simply handed out". The COO stated in the follow up email interview on 6/17/20, at approximately 12:52 PM: "BetterMed at Short Pump used Healgen antibody kits from 4/27/2020 - 5/12/2020 and Innovita antibody kits from 5/13/2020 - Present." 7. An interview with the director of clinical operations and COO on 6/25/20, at approximately 11:00 AM, 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 interviews, review of the Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA), available patient and quality control (QC) logs, and lack of documentation, the laboratory failed to evaluate, verify/validate the performance specifications of two (2) non FDA approved COVID-19 IgG/IgM test methods prior to reporting nine hundred eighty-four (984) patient COVID-19 antibody results from April 27, 2020 to May 31, 2020. Findings include: 1. In an email interview with the the Director of Clinical Operations and Chief Operating Officer (COO) on 5/27/20 at approximately 10:10 AM, it was revealed that the laboratory had been utilizing the following two (2) COVID-19 test kits (in a drive through testing setting) during the timeframe of 4/27/20 through the date of the offsite investigation: Corona Check 2019-nCoV Ab Test Colloidial Gold, manufactured in China by Innovita Tangshan Biological Technology Co. LTD and Healgen COVID-19 IgG/IgM Rapid Test Cassette manufactured by Healgen Scientific Limited Liability Company, Houston Texas. 2. Review of the FDA's published listing of COVID-19 EUA's granted for SARS CoV-2 antibody testing as of 5/27/20 revealed no EUA granted for the 2 kits outlined above. The Innovita Corona Check and Healgen COVID-19 IgG /IgM rapid test methods' classifications as of 5/27/20 were high complexity. 3. During the telephone conference call interview with the Director of Clinical Operations and COO on 5/28/20 at approximately 1 PM, the inspectors asked for a description of the laboratory's QC protocols, to review documentation of in-house validation procedures for both high complexity COVID-19 test kits, and patient test logs for each test method. The COO stated at approximately 1:30 PM: "We have ordered a different manufacturer COVID rapid test that has FDA EUA and the laboratory will be moving to those kits as soon as possible. We did not perform validation studies for the test kits

	we have been using. We rely on the manufacturer's validation. We use the internal built in QC. We did not purchase extra quality control materials." 4. Review of patient test and QC records revealed that the laboratory reported 984 patient COVID-19 IgG /IgM antibody test results from 4/27/20 to 5/31/20 while performing zero (0) negative or positive external controls. No records of validation studies were available for review. 5. The COO stated in the follow up email interview on 6/17/20, at approximately 12:52 PM: "BetterMed at Short Pump used Healgen antibody kits from 4/27/2020 - 5/12/2020 and Innovita antibody kits from 5/13/2020 - Present." 6. An interview with the director of clinical operations and COO on 6/25/20, at approximately 11:00 AM, 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 interviews, a review of the Food and Drug Administration's (FDA) Emergency Use Authorization (EUA), review of 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) materials for two (2) non FDA approved COVID-19 IgG/IgM test methods while reporting nine hundred eighty-four (984) patient COVID-19 antibody results from April 27, 2020 to May 31, 2020. Findings include: 1. In an email interview with the the Director of Clinical Operations and Chief Operating Officer (COO) on 5/27/20 at approximately 10:10 AM, it was revealed that the laboratory had been utilizing the following two (2) COVID-19 test kits (in a drive through testing setting) during the timeframe of 4/27/20 through the date of the offsite investigation: Corona Check 2019-nCoV Ab Test Colloidial Gold, manufactured in China by Innovita Tangshan Biological Technology Co. LTD and Healgen COVID-19 IgG/IgM Rapid Test Cassette manufactured by Healgen Scientific Limited Liability Company, Houston Texas. 2. Review of the FDA's published listing of COVID-19 EUA's granted for SARS CoV-2 antibody testing as of 5/27/20 revealed no EUA granted for the 2 test methods outlined above. The Innovita Corona Check and Healgen COVID-19 IgG/IgM rapid test methods' classifications as of 5/27/20 were high complexity. 3. In a telephone interview with the the Director of Clinical Operations and Chief Operating Officer (COO) on 5/28/20 at approximately 1:00 PM, the inspectors asked for a description of the laboratory's QC protocols and patient test logs for the 2 test methods outlined above. The COO stated at approximately 1:30 PM: "We use the internal built in QC. We did not purchase extra quality control materials." 4. Review of available patient and QC logs revealed that the facility reported 984 COVID-19 IgG/IgM results while performing zero (0) negative or positive external controls for each day of patient testing during the timeframe of 4/27/20 to 5/31/20. The inspectors requested clarification regarding dates of use for each test kit methods outlined above in an email interview on 6/17/20 at approximately 10:30 AM. The COO stated in the follow up email interview on 6/17 /20 at 12:52 PM: "BetterMed Short Pump used Healgen antibody kits from 4/27/2020

	- 5/12/2020 and Innovita antibody kits from 5/13/2020 - Present. No QC material was purchased." 5. An interview with the director of clinical operations and COO on 6/25 /20, at approximately 11:00 AM, 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 interviews, review of the Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA), available logs of patient testing, quality control (QC), temperature monitoring, policies and procedures, Laboratory Personnel Report Form (CLIA) (CMS-209 Form), available laboratory personnel files, and lack of documentation, the laboratory director failed to: 1. ensure validation/verification performance procedures were performed for two (2) non FDA approved COVID-19 IgG/IgM test methods prior to reporting nine hundred eighty-four (984) patient antibody results from 4/27/20 to 5/31/20; 2. ensure that QC policies were established and followed for 2 non FDA approved COVID-19 IgG/IgM test methods from 4/27 /20 to 5/31/20; 3. ensure that training and competency assessments were performed for Testing Personnel prior to testing and reporting patient results with the Healgen and Corona Check COVID-19 IgG/IgM Antibody test kits. See D6086, D6093, 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 interviews, review of the Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA), available patient testing, quality control (QC) logs, and lack of documentation, the laboratory director (LD) failed to ensure validation/verification performance procedures were performed for two (2) non FDA approved COVID-19 IgG/IgM test methods prior to reporting nine hundred eighty-four (984) patient antibody results from April 27, 2020 to May 31, 2020. Findings include: 1. In an email interview with the the Director of Clinical Operations and Chief Operating Officer (COO) on 5/27/20 at approximately 10:10 AM, it was revealed that the laboratory had been utilizing the following two (2) COVID-19 test kits (in a drive through testing setting) during the timeframe of 4/27/20 through the date of the offsite investigation: Corona Check 2019-nCoV Ab Test Colloidial Gold, manufactured in China by Innovita Tangshan Biological Technology Co. LTD and Healgen COVID-19 IgG/IgM Rapid Test Cassette manufactured by Healgen Scientific Limited Liability Company, Houston Texas. 2. Review of the FDA's published listing of COVID-19 EUA's granted for SARS CoV-2 antibody testing as of 5/27/20 revealed no EUA granted for the 2 test methods outlined above. The Innovita Corona Check and Healgen COVID-19 IgG/IgM rapid test methods' classifications as

	of 5/27/20 were high complexity. 3. In a telephone interview with the the Director of Clinical Operations and Chief Operating Officer (COO) on 5/28/20 at approximately 1:00 PM, the inspectors requested a description of the laboratory's QC protocols and to review documentation of in-house validation procedures for both high complexity COVID-19 test kits utilized. The COO stated at approximately 1:30 PM: "We have ordered a different manufacturer COVID rapid test that has FDA EUA and the laboratory will be moving to those kits as soon as possible. We did not perform validation studies for the test kits we have been using. We rely on the manufacturer's validation. We use the internal built in QC. We did not purchase extra quality control materials." 4. Review of the available patient test/QC logs revealed that the laboratory reported 984 patient COVID-19 IgG/IgM test results while performing zero (0) negative or positive external controls for the timeframe of 4/27/20 to 5/31/20. No records of validation studies approved by the LD were available for review. In an email interview on 6/17/20 at approximately 10:30 AM, the inspectors requested clarification regarding dates of use for each of the 2 immunology test kit methods in use for COVID-19 patient testing. The COO stated in a follow-up email on 6/17/20 at 12:52 PM: "BetterMed Short Pump used Healgen antibody kits from 4/27/2020 - 5/12 /2020 and Innovita antibody kits from 5/13/2020 - Present." 5. An interview with the director of clinical operations and COO on 6/25/20, at approximately 11:00 AM, 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 interviews, review of the Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA), available patient/quality control (QC) logs, policies and procedures, and lack of documentation, the laboratory director failed to ensure that QC policies were established and followed for COVID-19 immunology test kits while reporting nine hundred eighty-four (984) patient IgG/IgM antibody test results from April 27, 2020 to May 31, 2020. Findings include: 1. In an email interview with the the Director of Clinical Operations and Chief Operating Officer (COO) on 5/27/20 at approximately 10:10 AM, it was revealed that the laboratory had been utilizing the following two (2) COVID-19 test kits (in a drive through testing setting) during the timeframe of 4/27/20 through the date of the offsite investigation: Corona Check 2019-nCoV Ab Test Colloidial Gold, manufactured in China by Innovita Tangshan Biological Technology Co. LTD and Healgen COVID-19 IgG/IgM Rapid Test Cassette manufactured by Healgen Scientific Limited Liability Company, Houston Texas. 2. Review of the FDA's published listing of COVID-19 EUA's granted for SARS CoV-2 antibody testing as of 5/27/20 revealed no EUA granted for the 2 test methods outlined above. The Innovita Corona Check and Healgen COVID-19 IgG/IgM rapid test methods' classifications as of 5/27/20 were high complexity. 3. In a telephone interview with the the Director of Clinical Operations and Chief Operating Officer (COO) on 5/28/20 at approximately 1:00 PM, the inspectors asked for a description of the laboratory's QC protocols, patient test logs, and policy /procedures for the 2 test methods outlined above. The COO stated at approximately 1: 30 PM: "We use the internal built in QC. We did not purchase extra quality control materials." 4. Review of requested laboratory records revealed 984 COVID-19 IgG

	/IgM patient results were reported from 4/27/20 to 5/31/20. No records of verification of negative or positive external controls on each day of patient testing was available for review. 5. Review of the laboratory's provided policy and procedures revealed no written approved QC policy for the high complexity COVID-19 IgG/IgM test kits outlined above. 6. During an email interview on 6/17/20 at approximately 10:30 AM, the inspectors requested clarification regarding dates of use for the Innovita Corona Check and Healgen COVID-19 IgG/IgM rapid test methods. The COO stated in a follow up email on 6/17/20 at 12:52 PM: "BetterMed Short Pump used Healgen antibody kits from 4/27/2020 - 5/12/2020 and Innovita antibody kits from 5/13/2020 - Present. No QC material was purchased." 7. An interview with the director of clinical operations and COO on 6/25/20, at approximately 11:00 AM, 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: A. Based on a review of the Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA), Laboratory Personnel Report Form (CLIA) (CMS-209 Form), available testing personnel (TP) files, lack of documentation, and interviews, the laboratory director (LD) failed to ensure that training and competency assessments were performed for ten (10) of 12 TP prior to testing and reporting patient results with the Healgen COVID-19 IgG/IgM Antibody test kit. Dates of record review include 4 /27/20 up to 6/17/20. 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 Healgen COVID-19 IgG/IgM Antibody test method. In addition, test method classification was high complexity. The COO stated in a follow up email interview on 6/17/20 at approximately 12:52 PM that the "kit was in use from 4/27/20 to 5/12/20." 2. Review of the laboratory's CLIA CMS-209 Form revealed 12 TP identified as performing COVID-19 IgG/IgM patient testing. 3. Review of the available laboratory personnel records revealed a lack of documentation of training and competency assessment(s) for TP B, D- L prior to use of aforementioned kit (total of 10 TP). The inspector requested to review documentation and training/competency assessment for specified TP. No records were available for review. See Personnel Code Sheet attached. 4. An interview with the Director of Clinical Operations and the COO on 6 /25/20 at approximately 11 AM confirmed the findings. B. Based on a review of the Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA), Laboratory Personnel Report Form (CLIA) (CMS-209 Form), available testing personnel (TP) files, lack of documentation, and interviews, the laboratory director (LD) failed to ensure that training and competency assessments were performed for nine (9) of 12 TP prior to testing and reporting patient results with the Corona Check (Innovita) COVID-19 IgG/IgM Antibody test kit. Dates of record review include 4/27 /20 up to 6/17/20. 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 Corona Check (Innovita) COVID-19 IgG/IgM Antibody test method. In addition, test method classification was high complexity. The COO stated in a follow

	up email interview on 6/17/20 at approximately 12:52 PM that the "kit was in use from 5/13/20 to present." 2. Review of the laboratory's CLIA CMS-209 Form revealed 12 TP identified as performing COVID-19 IgG/IgM patient testing with the Corona Check (Innovita) COVID-19 IgG/IgM Antibody test method. 3. Review of the available laboratory personnel records revealed a lack of documentation of training and competency assessment(s) for TP B, D-H and J-L) prior to use of aforementioned kit (total of 9 TP). The inspector requested to review documentation and training /competency assessment for specified TP. No records were available for review. See Personnel Code Sheet attached. 4. An interview with the Director of Clinical Operations and the COO on 6/25/20 at approximately 11 AM confirmed the findings.
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), Laboratory Personnel Report Form (CLIA) (CMS-209 Form), available testing personnel (TP) files, lack of documentation, and interviews, the laboratory failed to ensure that four (4) of 12 TP qualified to perform high complexity testing from April 27, 2020 and up to June 17, 2020. 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), Laboratory Personnel Report Form (CLIA) (CMS-209 Form), available testing personnel (TP) files, lack of documentation, and interviews, the laboratory failed to ensure that four (4) of 12 TP qualified to perform high complexity testing from April 27, 2020 and up to June 17, 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 the Corona Check (Innovita) and Healgen COVID-19 IgG/IgM Antibody test method(s). In addition, test method(s) classification was high complexity. The COO stated in a follow up email interview on 6/17/20 at approximately 12:52 that "the Healgen COVID-19 IgG/IgM Antibody test method was in use from 4/27/20 to 5/12/20 and the Corona Check (Innovita) COVID-19 IgG/IgM Antibody test method was in use from 5/13/20 to present." 2. Review of the laboratory's CMS 209 form revealed 12 TP identified as performing COVID-19 IgG/IgM patient testing. 3. Review of the available laboratory personnel records revealed lack of documentation of education requirements for high complexity testing for TP B, G, I and L (total of 4 TP). See Personnel Code Sheet attached. 4. An interview with the Director of Clinical Operations and the COO on June 25, 2020 at approximately 11 AM confirmed the findings.