Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D1093849	05/26/2021
Name of Provider or Supplier	**Street Address, City, State**	
Community Health Clinic	1957 Second Street, Richlands, 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 announced CLIA Recertification on-site survey was conducted at the Community Health Clinic (Richlands) on May 25, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The initial contact and entrance interview with laboratory conducted on April 19, 2021 with off-site record review of documentation on May 17, 2021. Specific deficiencies cited are as follows: The laboratory was not in compliance with the following 42 CFR part 493 CLIA Regulations: D5200 - 42 C.F.R. 493-1230 Condition: General Laboratory Systems, D5400 - 42 C.F.R. 493-1250 Condition: Analytic Systems, D6000 - 42 C.F.R. 493-1403 Condition: Moderate Complexity Laboratory Director and, D6063 - 42 C.F.R. 493-1421 Condition: Laboratory Testing Personnel.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: **REPEAT DEFICIENCY** Based on the review of proficiency testing (PT) records, lack of documentation, the laboratory's 2018 Plan of Correction Form 2567, and interview, the laboratory director failed to sign three (3) of six (6) attestation statements reviewed on the date of survey on 05/25/21. PT record review included 2019 and 2020 testing events. Findings include: 1. Review of the Medical Laboratory Evaluation (MLE) PT records for all three events in 2019 and 2020 revealed lack of documentation of signature by laboratory director for the 2020 MLE 1st, 2nd, and 3rd events (M1-M3) attestation statements. 2. Review of the laboratory's 2018 Plan of Correction Form 2567 (dated 01/10/19) revealed the lab would have 2 separate copies of PT documents signed and filed as remedial action. 3. An exit interview with the

	primary testing personnel on 05/25/21 at approximately 2:00 PM confirmed the above-listed findings. A phone interview with the laboratory director on 05/26/21 at approximately 3:50 PM confirmed the above-listed findings.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: A. Based on the review of proficiency testing (PT) records, lack of documentation, and interview, the laboratory failed to retain the attestation, testing documents and results for one (1) of 3 events in 2020 at the date of survey on 05/25/21. Findings include: 1. Review of the available Medical Laboratory Evaluation (MLE) PT records revealed lack of documentation of the attestation statement, hematology instrument data, and final results for the 2020 MLE 1st event. During an interview on 05/25/21 at approximately 1:30 PM, the inspector requested the PT records. The records were not available for review. 2. An exit interview with the primary testing personnel on 05/25 /21 at approximately 2:00 PM confirmed the findings. A phone interview with the laboratory director on 05/26/21 at approximately 3:50 PM confirmed the above-listed findings. B. Based on the review of proficiency testing (PT) records, lack of documentation, and interview, the laboratory failed to retain results from the PT company for three (3) of six (6) events reviewed at the date of survey on 05/25/21. Findings include: 1. Review of the available Medical Laboratory Evaluation (MLE) PT records revealed lack of documentation of the final results from MLE for the 2020 MLE 1st, 2nd, and 3rd events. During an interview on 05/25/21 at approximately 1:30 PM the inspector requested the PT records. The records were not available for review. 2. An exit interview with the primary testing personnel on 05/25/21 at approximately 2:00 PM confirmed the findings. A phone interview with the laboratory director on 05 /26/21 at approximately 3:50 PM confirmed the above-listed findings.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of quality control (QC) records, lack of documentation, and interview primary testing personnel (TP), the laboratory failed to retain the "Mintrol Quality Control " manufacturer's assay information inserts documenting Complete

	Blood Cell (CBC) count QC acceptable ranges for thirteen (13) of 14 lot numbers utilized from 01/01/19 and up to 05/25/21. Findings include: 1. Review of the laboratory's end of the QC lot instrument printouts and daily QC records from 01/01 /19 and up to 05/25/21 revealed the laboratory received and utilized 14 lot numbers of the "Mintrol QC" to perform daily QC procedures for the CBC testing. The following QC lot numbers lacked documentation of acceptable ranges or manufacturer's package inserts: MX- 415, 416, 417, 418, 419, 420, 421, 422, 423, 424, 425, 427 and 427. 2. An exit interview with the primary testing personnel on 05/25/21 at approximately 2: 00 PM confirmed the findings. A phone interview with the laboratory director on 05 /26/21 at approximately 3:50 PM confirmed the above-listed findings.
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 the review of the laboratory's 2018 Plan of Correction Form 2567, proficiency testing (PT) records, lack of documentation, and interviews, the laboratory failed to adhere to the 2018 Plan of Correction. Refer to D5211**REPEAT DEFICIENCY** Refer to D6000
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: **REPEAT DEFICIENCY** Based on the review of proficiency testing (PT) records, lack of documentation, the laboratory's 2018 Plan of Correction Form 2567, and interviews, the laboratory director failed to review and sign three (3) of six (6) PT results reviewed at the date of survey on 05/25/21. PT record review included 2019 and 2020 testing events. Findings include: 1. Review of the Medical Laboratory Evaluation (MLE) PT records for all three events in 2019 and 2020 revealed lack of documentation of signature by laboratory director for the 2020 MLE 1st, 2nd, and 3rd events (M1-M3) results. 2. Review of the laboratory's 2018 Plan of Correction Form 2567 (dated 01/10/19) revealed the lab would have 2 separate copies of PT documents signed and filed as remedial action. 3. An exit interview with the primary testing personnel on 05/25/21 at approximately 2:00 PM confirmed the findings. A phone interview with the laboratory director on 05/26/21 at approximately 3:50 PM 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 the review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), manufacturer's Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA), manufacturer's instructions for use (IFU), policy and procedures (P&P), monthly maintenance logs, manufacturer operator guide, hematology records, phone call with technical service, quality assurance (QA) check lists, daily patient logs, patient results, lack of documentation, and interviews, the laboratory failed to: 1. Provide a written policy for reporting patient SARS-CoV-2 (COVID-19) positive and negative results to the State agency (Refer to D5401), 2. Provide documentation of the completed Horiba ABX Micros 60 analyzer maintenance logs for January 2021- April 2021 (Refer to D5429), 3. Provide documentation of calibration procedures performed and reviewed every 6 months for the Horiba ABX Micros 60 analyzer in 2019 and 2020 (Refer to D5437), 4. Provide documentation of performance of hematology daily quality control (QC) procedures in the month of April 2020 (Refer to D5447), 5. Provide documentation of the performance of external positive and negative quality control (QC) materials for one (1) non FDA approved SARS-CoV-2 (COVID-19) IgG/IgM test method (Refer to D5449), 6. Ensure current QA procedure identified and addressed analytic issues in the specialty of hematology from 01/01/19 and up to the date of survey on 05/25/21 (Refer to D5793), and 7. Document the type of SARS-CoV-2 (COVID-19) testing performed on twelve (12) of 12 patients reports reviewed (Refer to D5805).
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 the review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), manufacturer's instructions for use (IFU), policy and procedures (P&P), lack of documentation, and interviews, the laboratory failed to have a written policy for reporting patient SARS-CoV-2 (COVID-19) positive and negative results to the State agency from 09/02/20 and up to the date of survey on 05/25/21. Findings include: 1. Review of the CMS 116 application revealed the laboratory performed COVID-19 testing. 2. The following statements were revealed upon review of the IFU's: Healgen COVID-19 IgG/IgM Rapid Test (whole blood/serum/plasma)- " Authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate." Access Bio CareStart COVID-19 Antigen nasopharyngeal or nasal swab- "Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and

	relevant public health authorities, as appropriate." 3. Review of the P&P revealed lack of documentation of policy or procedure for reporting patient COVID- 19 positive and negative test results to the local health department. 4. On 05/25/21 at approximately 2: 00 PM, the inspector requested the primary testing personnel provide a P&P for reporting patient COVID- 19 positive and negative test results to the local health department. They stated that there was no P&P available for review. They followed the IFU for performing testing. 5. An exit interview with the primary testing personnel on 05/25/21 at approximately 2:00 PM confirmed the findings. A phone interview with the laboratory director on 05/26/21 at approximately 3:50 PM confirmed the above-listed findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on the review of monthly maintenance logs, review of policy and procedures (P&P), manufacturer operator guide, lack of documentation and interviews, the laboratory failed to provide documentation of the daily and monthly maintenance performed on the Horiba ABX Micros 60 hematology analyzer from 01/01/21 and up to 04/30/21 (four months) at the date of survey on 05/25/21. Findings include: 1. The laboratory utilizes the Horiba ABX Micros 60 analyzer (serial number 604CS95933) to perform Complete Blood Counts (CBC). Review of monthly maintenance logs from 01/01/19 up to date of survey on 05/25/21 revealed lack of documentation of the completed maintenance logs for January 2021- April 2021. The inspector requested to review the monthly maintenance logs at the date of survey. The documents were not available for review. 2. Review of the P&P revealed the following statement: "CHC Clinic Laboratory Policy Sections; page 7" "Instrument function checks will be performed with frequency and procedure as directed by the manufacturer. They will be properly documented." 3. Review of the manufacturer operator's guide revealed the maintenance procedures to include performing daily start-up and shutdown, check reagent levels, check waste level and monthly performance of concentrated cleaning procedures. 4. An exit interview with the primary testing personnel on 05/25/21 at approximately 2:00 PM confirmed the findings. A phone interview with the laboratory director on 05/26/21 at approximately 3:50 PM confirmed the above-listed findings.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

	This STANDARD is not met as evidenced by: **REPEAT DEFICIENCY** Based on the review of hematology records, policy and procedures (P&P), phone call with technical service, and interviews, the laboratory failed to follow the manufacturer's requirement and the established P&P for performing Horiba ABX Micros 60 calibration procedures at least once every six (6) months in the calendar year 2019 and 2020. Findings include: 1. Review of the hematology records revealed that a service representative performed the calibration procedures for the Horiba ABX Micros 60 hematology instrument on 12/18/19, 08/03 /20 and 02/01/2021. There was no other calibration documentation available for review at the date of survey on 05/25/21 upon request. An interview with the primary testing personnel on 05/25/21 at approximately 12:30 PM revealed that they did not know that calibration procedures were to be done every 6 months. 2. Review of the policy and procedure manual revealed the following statement (signed by the laboratory director December 2016): "Calibration procedures- perform and document calibration procedures at least six (6) months and as recommended by the manufacturer." 3. A phone call with Horiba technical service at approximately 11:00 AM on 05/25/21 confirmed that the manufacturer requires calibration of the hematology instrument every 6 months. 4. An exit interview with the primary testing personnel on 05/25/21 at approximately 2:00 PM confirmed the findings. A phone interview with the laboratory director on 05/26/21 at approximately 3:50 PM confirmed the above-listed findings.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of policy and procedures (P&P), record review, lack of documentation and interviews, the laboratory failed to provide documentation of performing the hematology daily quality control (QC) procedures for twenty-one (21) of 21 dates reviewed in April 2020 reporting 273 patients at the date of survey on 05 /25/21. Findings include: 1. The laboratory utilizes the Horiba ABX Micros 60 analyzer (serial number 604CS95933) to perform Complete Blood Counts (CBC). Review of the laboratory's P&P (approved by the LD on 10/17/2007) revealed the following statements: "CHC Clinic Laboratory Policy Sections; page 6" "Control Procedures: Perform and document control procedures using two levels of control materials. For each, analyze each day for chemistry and each 8 hr for hematology so that test are run and also recommended by the manufacturer. No patient test results will be reported unless the control results are adequate." 2. Record review from 01/01 /19 and up to 04/30/21 (to include maintenance records and daily patient logs) revealed lack of documentation of daily QC procedures when reporting patients for following dates: 04/01/2020- 11 patients, 04/02/2020- 5 patients, 04/03/2020- 5 patients, 04/06/2020- 9 patients, 04/07/2020- 15 patients, 04/08/2020- 9 patients, 04/09 /2020- 23 patients, 04/10/2020- 8 patients, 04/13/2020- 12 patient, 04/14/2020- 5 patients, 04/15/2020- 13 patients, 04/16/2020- 10 patients, 04/17/2020- 18 patients, 04

	/20/2020- 19 patients, 04/21/2020- 22 patients, 04/22/2020- 16 patients, 04/23/2020- 21 patients, 04/24/2020- 18 patients, 04/27/2020- 14 patients, 04/28/2020- 8 patients and 04/29/2020- 13 patients. Total of 21 dates and 273 patients. 3. An exit interview with the primary testing personnel on 05/25/21 at approximately 2:00 PM confirmed the findings. A phone interview with the laboratory director on 05/26/21 at approximately 3:50 PM confirmed the above-listed 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 the review of manufacturer's Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA), manufacturer's instructions for use (IUF), daily patient logs, lack of documentation, and interviews, the laboratory failed to document performance of external positive and negative quality control (QC) materials for one (1) non FDA approved SARS-CoV-2 (COVID-19) IgG/IgM test method for eighty-five (85) of 85 days, reporting 215 patients from 07/22/20 until 03 /15/21. 1. Review of the FDA's published listing of COVID-19 EUA granted for SARS CoV-2 Antibody testing as of 05/26/21 for the Healgen COVID-19 IgG/IgM Rapid Test (whole blood/serum/plasma) revealed the following statement, "Testing is limited to laboratories certified under the Clinical Laboratory Amendments of 1988 (CLIA), 42 U.S.C. 263a, to perform moderate or high complexity tests." 2. Review of the IFU for the Healgen COVID-19 IgG/IgM Rapid Test (whole blood/serum/plasma) revealed the following statements, "The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) should not be used to diagnose acute SARS-CoV-2 infection. Testing is limited to laboratories certified under the Clinical Laboratory Amendments of 1988 (CLIA), 42 U.S.C. 263a, to perform moderate or high complexity tests." "Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance. Additional controls may be required according to guidelines or local, state, and/or federal regulations (such as 42 CFR 493.1256) or accrediting organizations." 3. In an interview with the primary testing personnel on 05/25/20 at approximately 1:00 PM, the inspector requested to review the daily external positive and negative QC documents for the dates of use from 07/22/20 until 03/15/21. The primary testing personnel stated "We did not know that this kit needed QC. We do not have those documents." The lab lacked documentation of the requested QC. 4. Review of the daily patient logs revealed that 215 patients were tested and resulted from 07/22/20 until 03/15/21. 5. An exit interview with the primary testing personnel on 05/25/21 at approximately 2:00 PM confirmed the findings. A phone interview with the laboratory director on 05/26/21 at approximately 3:50 PM confirmed the above-listed findings. They stated McKesson sales representative told them the kit was waived.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c)

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
Based on the review of policy and procedures (P&P), quality assurance (QA) check lists, lack of documentation and interviews, the current QA procedure failed to identify and address analytic issues in the specialty of hematology from 01/01/19 and up to the date of survey on 05/25/21 (Refer to D2009, D2015 part A and B, D5211, D5401, D5429, D5437, D5447, D5449, D5805, D6065 and D6029). Findings include: 1. Review of P&P, quality control (QC) records, calibration records, proficiency testing (PT) records, daily patient logs, and testing personnel records revealed the following analytic issues in the specialty of hematology: - Lack of documentation of the attestation statement, hematology instrument data, and results for the 2020 MLE 1st event (Refer to D2015 part A), - Lack of documentation of signature by laboratory director for the 2020 Medical Laboratory Evaluation (MLE) 1st, 2nd, and 3rd events (M1-M3) attestation statements (Refer to D2009), - Lack of documentation of the results from MLE for the 2020 MLE 1st, 2nd, and 3rd events (Refer to D2015 part B), - Lack of documentation of signature by laboratory director for the 2020 MLE 1st, 2nd, and 3rd events (M1-M3) results (Refer to D5211), - Lack of documentation of a written policy for reporting patient SARS-CoV-2 (COVID-19) positive and negative results to the State agency (Refer to D5401), - Lack of documentation of the completed Horiba ABX Micros 60 analyzer maintenance logs for January 2021- April 2021 (Refer to D5429), - Lack of documentation of calibration procedures performed and reviewed every 6 months for the Horiba ABX Micros 60 analyzer in 2019 and 2020 (Refer to D5437), - Lack of documentation of performance of hematology daily quality control (QC) procedures in the month of April 2020 (Refer to D5447), - Lack of documentation of the performance of external positive and negative quality control (QC) materials for one (1) non FDA approved SARS-CoV-2 (COVID-19) IgG/IgM test method (Refer to D5449), - Document the type of SARS-CoV-2 (COVID-19) testing performed on twelve (12) of 12 patients reports reviewed (Refer to D5805) and, - Lack of documentation of new testing personnel education requirement (Refer to D6065) and training and competency assessments prior to testing patients in 2019 and 2020 (Refer to D6029). 2. Review of the current P&P and quality assessment policy (signed by the LD on 04/12/2015) revealed the following statement: "Quality assurance review meeting with the lab staff and the clinical consultant will be held at least quarterly with written minutes kept for two years. The quality assurance program will assess at least patient test management, quality control, proficiency testing, consistency between testing sites and personnel." 3. The QA review revealed that the laboratory utilizes a quality assurance checklist that included the following statements: Write "Y" for Yes, "N" No or "NA" for not applicable to indicate the outcome of the assessed item. Items of assessment include but not limited: New personnel have completed a personnel file; testing analysts has been checked for competency prior to reporting patient results; new procedures have been reviewed and signed by the lab director within 30 days; required controls, calibration and maintenance have been performed; calibration and maintenance documents have been reviewed; tests have been properly ordered, recorded and reported; Proficiency Testing (PT) results have been reviewed; and the director has reviewed last month's QA review and associated remedial actions. 4. Review of the QA checklists revealed testing personnel completed the checklists and the lab director signed all twelve

	documents in 2019 and January/February 2020. There was no documentation of issues or problems by the lab director on the 14 checklists. The checklists for March-December 2020 (8 months) lacked documentation of review by the lab director. There were no QA checklists available for review for January-April 2021(4 months) upon request at the date of survey on 05/29/21 at approximately 2:20 PM. 5. An exit interview with the primary testing personnel on May 25, 2021 at approximately 2:00 PM confirmed the findings. A phone interview with the laboratory director on May 26, 2021 at approximately 3:50 PM confirmed the above-listed findings.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on the review of patient results, lack of documentation and interviews, the laboratory failed document the type of SARS-CoV-2 (COVID-19) testing performed on twelve (12) of 12 patients reports reviewed from 01/01/21-03/15/21. Findings include: 1. Review of 12 patient COVID test results revealed hand-written "COVID Neg" or "COVID (with a circle around - or +) on the hematology Complete Blood Count (CBC) result print outs and/or on the daily intake of lab test form. The COVID-19 results lacked documentation if the test performed was for Antigen (via CareStart COVID-19 Antigen nasopharyngeal or nasal swab) or Antibody (via Healgen COVID-19 IgG/IgM Rapid Test (whole blood/serum/plasma)) test method. 2. On 05/25/21 at approximately 12:30 PM, the inspector asked the primary testing personnel how they would be able to determine if the patient had a blood test or nasal swab test and was the results for COVID-19 antibody or antigen. They stated they could not tell the inspector if the results were for the antibody or antigen and they didn't think they did much testing with the antibody test method after receiving the antigen test method. 3. An exit interview with the primary testing personnel on 05/25/21 at approximately 2: 00 PM confirmed the findings. A phone interview with the laboratory director on 05 /26/21 at approximately 3:50 PM 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 the review of the laboratory's 2018 Plan of Correction Form 2567, proficiency testing (PT) records, record review, policy and procedures (P&P), quality control (QC) records, calibration records, manufacturer's Food and Drug

	Administration's (FDA) Emergency Use Authorizations (EUA), manufacturer's instructions for use (IFU), daily patient logs, patient test results, quality assessment (QA) checklists, the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, lack of documentation, and interviews, the laboratory director failed to: 1. Ensure staff maintained documentation of the MLE and sign MLE results (Refer to D6018), 2. Ensure that the established QC and QA P&P were followed and analytic issues were identified and addressed in the specialties of hematology (Refer to D6022, part A), 3. Ensure the performance of external positive and negative quality control (QC) materials for one (1) non FDA approved SARS-CoV-2 (COVID-19) IgG/IgM test method (Refer to D6022, part B), 4. Ensure the documentation of the type of SARS-CoV-2 (COVID-19) testing performed on twelve (12) of 12 patients reports reviewed from 01/01/21-03/15/21 (Refer to D6026), and 5. Follow the established policy and ensure that three (3) of 3 new TP had documented training and competency assessments prior to performing patient testing procedures for hematology from 01/01/2019 up to date of survey 05/25/21 (Refer to D6029).
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on the review of the laboratory's 2018 Plan of Correction Form 2567, proficiency testing (PT) records, lack of documentation, and interviews, the laboratory director failed to: 1. Sign attestation statements for all three (3) Medical Laboratory Evaluation (MLE) events in 2020 **REPEAT DEFICIENCY** (Refer to D2009), 2. Ensure staff maintained testing documentation of the MLE 2020 1st event (Refer to D2015, part A), 3. Ensure staff maintained documentation of MLE results for all three events in 2020 (Refer to D2015, part B), and 4. Review and sign all three results of the MLE events 2020 **REPEAT DEFICIENCY** (Refer to D5211).
D6022	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 and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: A. Based on record review, policy and procedures (P&P), quality control (QC) records, calibration records, patient data logs, quality assessment (QA) checklists, and interviews, the laboratory director failed to ensure that the established QC and QA

	P&P were followed and analytic issues were identified and addressed in the specialties of hematology (Refer to D5429, D5437, D5447 and D5793). B. Based on the review of manufacturer's Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA), manufacturer's instructions for use (IUF), daily patient logs, lack of documentation, and interviews, the laboratory director failed to ensure the performance of external positive and negative quality control (QC) materials for one (1) non FDA approved SARS-CoV-2 (COVID-19) IgG/IgM test method for eighty-five (85) of 85 days, reporting 215 patients from 07/22/20 until 03/15/21. (Refer to D5449).
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) 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)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on the review of patient results, lack of documentation and interviews, the laboratory director failed to ensure the documentation of the type of SARS-CoV-2 (COVID-19) testing performed on twelve (12) of 12 patients reports reviewed from 01 /01/21-03/15/21. (Refer to D5805).
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) 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: **REPEAT DEFICIENCY** Based on the review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, policy and procedures, and interviews, the laboratory director failed to follow the established policy and ensure that three (3) of 3 new TP had documented training and competency assessments prior to performing patient testing procedures for hematology from 01/01 /2019 up to date of survey 05/25/21 (Refer to D6065). Findings include: 1. Review of CLIA CMS-209 form revealed that TP B, C and D as new TP (See attached TP Code Sheet). 2. The inspector requested to review training documentation and competency assessments on the above-mentioned TP. The documentation was not available for review at the date of survey on 05/25/21. 3. Review of the policy and procedure manual revealed the following statement (signed by the laboratory director December 2016): "Testing personnel: New testing personnel will be evaluated with forms from

	Appendix 1 prior to assignment in the lab." 4. An exit interview with the primary testing personnel on 05/25/21 at approximately 2:00 PM confirmed the findings. A phone interview with the laboratory director on 05/26/21 at approximately 3:50 PM confirmed the above-listed findings.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on the review of proficiency testing records, hematology maintenance records, available testing personnel (TP) records, Laboratory Personnel Report Form (CLIA) (CMS-209 Form), policy and procedure (P&P) and interviews, the laboratory failed to retain education qualifications for four (4) of 6 TP in 2019 and 2020 (Refer to D6065).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy 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; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on the review of proficiency testing records, hematology maintenance records, available testing personnel (TP) records, Laboratory Personnel Report Form (CLIA) (CMS-209 Form), policy and procedure (P&P) and interviews, the laboratory failed to retain education qualifications for four (4) of 6 TP in 2019 and 2020. Findings include: 1. Review of proficiency testing records, hematology maintenance records and the CLIA 209 form, 6 TP performed patient testing in the specialty of hematology from 01/01/19 up to the date of survey 05/25/21. See attached personnel code sheet. 2. The inspector requested to review the education qualifications, at minimal high diploma or transcripts, for the 6 TP. The laboratory was unable to provide the requested documents for the following TP- B, C, D and G. 3. An exit interview with the primary testing personnel on 05/25/21 at approximately 2:00 PM confirmed the findings. A phone interview with the laboratory director on 05/26/21 at approximately 3:50 PM confirmed the above-listed findings.