

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0933746	(X3) Date Survey Completed 06/23/2021
Name of Provider or Supplier Community Health Clinic Pc	Street Address, City, State 5705 Redbud Hwy, Honaker, 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 (Honaker) on June 21, 2021 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: The laboratory was not in compliance with the following 42 CFR part 493 CLIA Regulations: D3000 - 42 C.F.R. 493-1100 Condition: Facility Administration, 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.
D3000	<p>FACILITY ADMINISTRATION CFR(s): 493.1100</p> <p>Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.</p> <p>This CONDITION is not met as evidenced by: **REPEAT DEFICIENCY** Based on a review of quality control (QC) records, instrument maintenance records, lack of documentation, and interview, the laboratory failed to retain the manufacturer's package inserts (PI) documenting Complete Blood Cell (CBC) count QC acceptable ranges for the "Coulter AcT Diff Control Plus" and "Sysmex Eightcheck 3WP" control materials utilized from 07/1/19 up to 06/02/21. Refer to D3031.</p>

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:

****REPEAT DEFICIENCY**** Based on a review of quality control (QC) records, instrument maintenance records, lack of documentation, and interview, the laboratory failed to retain the manufacturer's package inserts (PI) documenting Complete Blood Cell (CBC) count QC acceptable ranges for the "Coulter AcT Diff Control Plus" and "Sysmex Eightcheck 3WP" control materials utilized from 07/1/19 up to 06/02/21. Nine QC lot numbers for the 21 months reviewed. Findings include: 1. Review of the QC and instrument maintenance records revealed the laboratory utilized the Beckman Coulter AcT Diff hematology analyzer from 07/01/19 up to 09/22/20 and the Sysmex XP 300 hematology analyzer from 09/22/20 up to 06/21/21. 2. Review of the instrument QC printouts revealed the laboratory received and utilized 6 lot numbers of the "Coulter AcT Diff Control Plus" QC materials from 07/01/19 up to 09/22/20. The following QC lot numbers lacked documentation of acceptable ranges or manufacturer's PI: 067800 (077800, 087800) expiration date 10/17/19, 068200 (078200, 088200) expiration date 12/12/19, 068900 (078900, 088900) expiration date 03/09/20, 069600 (079600, 089600) expiration date 06/15/20, 067600 (077600, 087600) expiration date 08/24/20 and 068200 (078200, 088200) expiration date 11/19/20. Review of the instrument QC printouts revealed the laboratory received and utilized 3 lot numbers of the "Sysmex Eightcheck 3WP" QC materials from 09/22/19 up to 06/02/21. The following QC lot numbers lacked documentation of acceptable ranges or manufacturer's PI: 02520710 (11,12) expiration date 12/16/20, 03360710 (11, 12) expiration date 03/10/21 and 10540710 (11, 12) expiration date 06/02/21. The inspector requested to review the manufacturer's PI for the above-specified QC lot number. The documents were not available for review at the date of survey on 06/21/21. 3. An exit interview with the laboratory director at approximately 1:30 PM on June 21, 2021 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 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, quality assurance (QA) check lists, daily patient logs, patient results, lack of documentation, plan of corrections submitted

for 2017 and 2019, and interview, the laboratory failed to: 1. Ensure that the Quality Control (QC) materials were not utilized beyond manufacturer's expiration date on 12/3/19 and 12/4/19 (Refer to D5417); 2. Provide documentation of the daily and weekly maintenance performed from 10/03/20 up to 04/24/21 on the Sysmex XP-300 hematology analyzer (Refer to D5429); 3. Provide documentation of performance of hematology daily QC procedures on 06/26/20 reporting 4 patients ****REPEAT DEFICIENCY**** (Refer to D5447); 4. 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); 5. Ensure that the correct assigned values, expected ranges, lot number and expiration date were entered into the hematology analyzer ****REPEAT DEFICIENCY**** (Refer to D5469); 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 ****REPEAT DEFICIENCY**** (Refer to D5791); and 7. Document the type of SARS-CoV-2 (COVID-19) testing performed on eight (8) of 8 patients reports reviewed (Refer to D5805).

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:
Based on the review of the hematology analyzer Quick Reference Guide, quality control (QC) records, daily patient log, lack of documentation, and an interview, the laboratory failed to ensure that the QC materials were not utilized beyond manufacturer's expiration date on 12/3/19 and 12/4/19, reporting 19 patients. Findings include: 1. Review of daily QC printouts from the Beckman Coulter AcT Diff 2 hematology analyzer revealed the lab received and utilized lot number 068200 (Abnormal Low), 078200 (Normal), 088200 (Abnormal High), expiration date of 12/02/19 on 10/01/19. Daily instrument QC printouts for 12/03/19 and 12/04/19 revealed the same lot number but an expiration date of 12/06/19. On 12/05/19, the lab entered values for lot number 068900 (Abnormal Low), 078900 (Normal), and 088900 (Abnormal High), expiration date 03/09/20. 2. Daily patient testing log revealed 6 patients were reported on 12/03/19 and 13 patients reported on 12/04/19. 3. Documentation of manufacturer's package insert for lot numbers were not available for review upon request. Refer to D3031. The December Quality Assurance checklist lacked documentation of review of monthly QC procedures by the lab director (signed 12/31/19). Refer to D5793. The lab was unable to demonstrate that lot number 068200 (Abnormal Low), 078200 (Normal), 088200 (Abnormal High) was not utilized beyond the manufacturer's expiration date on 12/3/19 and 12/4/19 reporting 19 patients. 4. An exit interview with the laboratory director on 06/21/21 at approximately 1:30 PM confirmed the 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 interview, the laboratory failed to provide documentation of the daily maintenance performed for eight (8) days from 10/03/20 and up to 02/25/21 and weekly maintenance performed for eight weeks from 10/12/20 up to 04/24/21 on the Sysmex XP-300 hematology analyzer at the date of survey on 06/21/21. Findings include: 1. The laboratory utilizes the Sysmex XP-300 hematology analyzer (serial number B6627) to perform Complete Blood Counts (CBC). Review of monthly maintenance logs from 09/22/20 up to date of survey on 06/21/21 revealed lack of documentation for the following: Daily Maintenance- 10/03/20, 11/7/20, 11/21/20 and 11/28/20, 12/19/20, and 2/06/21, 2/13/21 and 2/25/21. Eight days. Weekly Maintenance- 10/12-17/20, 10/26-31/20, 03/1-6/21, 03/22-27/21, 03/29-04/03/21, 04/05-10/21, 04/12-17/21 and 04/19-24/21. Eight weeks. 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 (approved by lab director on 10/17/07): "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 (page 21) revealed the maintenance procedures to include performing daily shutdown, verify background, verify vacuum/pressure and check trap chamber and weekly maintenance of performance of cleaning SRV Tray procedures. 4. An exit interview with the lab director on 06/21/21 at approximately 1:30 PM confirmed the 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:
 REPEAT DEFICIENCY Based on the review of policy and procedures (P&P), record review, lack of documentation, Plan of Correction Form 2567 (POC) submitted on 04/04/19, and interview, the laboratory failed to follow the POC submitted on 04/04/19 and provide documentation of performing the hematology daily quality control (QC) procedures on 06/26/20 reporting 4 patients at the date of survey on 06/21/21. Findings include: 1. The laboratory utilized the Beckman Coulter AcT Diff 2 hematology analyzer 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 07/01/19 and up to 06/21/21 (to include maintenance records and daily patient logs) revealed lack of documentation of daily QC procedures for following date: 06/26/2020- 4 patients. The QC documents were not available for review upon request. 3. The POC submitted and

signed by the lab director on 04/04/19 stated on page 11: "the importance of running QC before patient testing has been emphasized by lab consultant and training done. All copies of QC shall be available for review." The attached "Summary of Major Corrective Actions Taken and Implemented (dated April 4, 2019) stated: 4) the lab tech personnel has been trained by the lab consultant about the importance of running Quality controls every 8 hours before the patient testing and keeping its records in a separate QC log folder." 4. An exit interview with the lab director on 06/21/21 at approximately 1:30 PM confirmed the 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, and lack of documentation, and interview, 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-seven (87) of 87 days, reporting 196 patients from 07/15/20 until 05/17/21. 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. Review of the daily patient logs revealed that 196 patients were tested and resulted on 87 days from 07/15/20 until 05/17/21. 4. An exit interview with the laboratory director on 06/21/21 at approximately 1:30 PM, the inspector requested to review the daily external positive and negative QC documents for the dates of use from 07/15/20 until 05/17/21. They stated, "We did not know that this kit needed QC. We do not have those documents." The lab lacked documentation of the requested QC.

D5469

CONTROL PROCEDURES

CFR(s): 493.1256(d)(10)(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--

Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

****REPEAT DEFICIENCY**** Based on the review of the hematology analyzer Quick Reference Guide, quality control (QC) records, Plan of Correction Form 2567 (POC) submitted for survey findings on 02/20/19, CPT billing statement, and an interview, the laboratory failed to follow the POC submitted 04/11/17 and ensure that the correct assigned values, expected ranges, lot number and expiration date were entered into the hematology analyzer for the new QC materials utilized from 08/24/20 up to 09/22/20, reporting two-hundred and eighty (280) patient results. Findings include: 1. Review of the Beckman Coulter AcT Diff 2 Hematology analyzer Quick Reference Guide reveals that laboratories are to manually enter the assigned values, expected ranges, lot number and expiration date of new lot numbers of quality control materials from the package inserts prior to use. 2. Review of the daily QC records (Coulter 4C Plus Cell Control) from 06/16/20 through 09/22/20 revealed the following: Lot number 067600 (Abnormal Low), 077600 (Normal), 087600 (Abnormal High) - expiration date of 08/24/20. Assigned values, expected ranges, lot number and expiration date entered into the hematology analyzer and placed into use on 06/15/20. The laboratory received and utilized one (1) different lot number of QC materials on 08/25/20. Daily QC printouts revealed Abnormal Low QC (lot 068200 exp 11/09/20) was entered into the analyzer on 08/25/20. The Normal and Abnormal High lot numbers and expiration dates were not changed/updated. The laboratory was unable to demonstrate that the correct values and expected ranges were updated for the new Normal and Abnormal High control materials. The laboratory accepted daily QC results based on expired values, lot number and expiration date from 08/25/20 up to 09/22/20. 3. CPT billing statement for the timeframe of 08/25/20-09/22/20 revealed 280 patients tested and resulted. 4. The corrected POC submitted on 04/11/17 (original signature date by the lab director on 02/20/17) page 15 stated, "Lab director will be responsible for ensuring the correct values are placed in the instrument in the future." 5. An exit interview with the laboratory director on 06/21/21 at approximately 1:30 PM confirmed the findings.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

****REPEAT DEFICIENCY**** Based on the review of policy and procedures (P&P),

quality assurance (QA) check lists, lack of documentation, Plan of Correction Form 2567 submitted on 04/04/19, and interview, the current QA procedure failed to identify and address analytic issues in the specialty of hematology from 07/01/19 and up to the date of survey on 06/21/21 and failed to follow the Plan Of Correction (POC) submitted on 04/04/19 (Refer to D5417, D5429, D5447, D5449, D5469, D5805, D6065 and D6029). Findings include: 1. Review of P&P, quality control (QC) records, daily patient logs, CPT billing statements and testing personnel records revealed the following analytic issues in the specialty of hematology: - Lack of documentation of the review of old and new QC lot numbers for the Beckman Coulter AcT Diff 2 hematology analyzer (Refer to D5417), - Lack of documentation of the daily and weekly Sysmex XP-300 analyzer maintenance (Refer to D5429), - Lack of documentation of performance of the Coulter 4C Plus QC materials on 06/26/20 (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), - Lack of correct QC data to include assigned values, expected ranges, lot number and expiration date entered into the Beckman Coulter AcT Diff 2 hematology analyzer (Refer to D5469), - Lack of documentation of the type of SARS-CoV-2 (COVID-19) testing performed on eight (8) of 8 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 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: Orientation and training documentation; proof of education; competency assessment review; required controls, calibration and maintenance have been performed; calibration and maintenance documents have been reviewed; tests have been properly ordered, recorded and reported; and the director has reviewed and associated remedial actions taken. 4. Review of the QA checklists revealed testing personnel and lab consultant completed the checklists and the lab director signed eight (April-October) documents in 2019; the lab director signatures only for November and December 2019. The lab director signed all twelve documents in 2020 and the five documents from 01/01/21 up to 05/31/21. There was no documentation of issues or problems by the lab director on the 19 checklists (November/December 2019, January-December 2020 and January-May 2021). 5. Review of the POC submitted and signed on 04/11/19 stated on pages 17: "Quarterly Quality Assurance meeting with lab staff, consultant to address all relevant lab operation topics to be done and minutes verified by lab director. Records kept for minimum 2 years." In addition, the submitted POC on page 20 stated, "D6022- The lab director has hired a lab consultant to assist in revamping the review, document all lab procedures, competency of lab personnel and comply with regulations." There was no documentation available for review upon request of the quarterly quality assurance meetings and consultant reviews from November 2019 and up to the date of survey on 06/21/21 (19 months). 6. An exit interview with the laboratory director on 06/21/21 at approximately 1:30 PM confirmed the 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 interview, the laboratory failed document the type of SARS-CoV-2 (COVID-19) testing performed on eight (8) of 8 patients reports reviewed from 01/01/21-04/16/21. Findings include: 1. Review of 8 patient COVID test results revealed hand-written "COVID Neg or Pos" on the hematology Complete Blood Count (CBC) result printouts 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 methods. 2. An exit interview with the laboratory director on 06 /21/21 at approximately 1:30 PM confirmed the patient COVID-19 results lacked documentation of test method.

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 2017 and 2019 Plan of Correction Form 2567, record review, policy and procedures (P&P), quality control (QC) records, manufacturer's Food and Drug Administration's (FDA) Emergency Use Authorizations (EUA), manufacturer's instructions for use (IUF), daily patient logs, CPT billing statement, patient test results, quality assessment (QA) checklists, Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, lack of documentation, and interview, the laboratory director failed to: 1. 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), 2. 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), 3. ensure testing personnel documented the type of SARS-CoV-2 (COVID-19) testing performed (Refer to D6026), 4. follow the established policy and ensure that one (1) of 1 new TP had documented training and competency assessments prior to performing patient testing procedures for hematology (Refer to D6029).

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:
****REPEAT DEFICIENCY**** A. Based on record review, policy and procedures (P&P), quality control (QC) records, patient data logs, CPT billing statement, quality assessment (QA) checklists, Plan of Correction (POC) Form 2567 submitted on 04/04 /19, and interview, 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 D5417, D5429, D5447, D5469 and D5791). 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, and lack of documentation, and interview, 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-seven (87) of 87 days, reporting 196 patients from 07/15/20 until 05 /17/21. (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 interview, the laboratory director failed to ensure testing personnel documented the type of SARS-CoV-2 (COVID-19) testing performed on eight (8) of 8 patients reports reviewed from 01/01/21-04/16/21. (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:
Based on the review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, policy and procedures (P&P), and interview, the laboratory director failed to follow the established policy and ensure that one (1) of 1 new TP had documented education records, training and competency assessments prior to performing patient testing procedures for hematology from 07/13/2020 up to 09/25/20. (Refer to D6065). Findings include: 1. Review of CLIA CMS-209 form revealed that TP E as new TP (See attached TP Code Sheet). 2. The inspector requested to review education records, training documentation and competency assessments on the above-mentioned TP. The documentation was not available for review at the date of survey on 06/21/21. (Refer to D6065). 3. Review of the policy and procedure manual revealed the following statement (signed by the laboratory director December 2016): "Testing personnel: Testing personnel will meet the qualifications specified in 42 CFR part 493.1423. New testing personnel will be evaluated with forms from Appendix 1 prior to assignment in the lab." 4. An exit interview with the laboratory director on 06/21/21 at approximately 1:30 PM confirmed the 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 interview, the laboratory failed to retain education qualifications for one (1) of 5 TP in 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 interview, the laboratory failed to retain education qualifications for one (1) of 1 TP in 2020. Findings include: 1.

Review of proficiency testing records, hematology maintenance records and the CLIA 209 form, 5 TP performed patient testing in the specialty of hematology from 04/01/19 up to the date of survey 06/21/21. See attached personnel code sheet. 2. The inspector requested to review the education qualifications, at minimal high diploma or transcripts, for the 5 TP. The laboratory was unable to provide the requested documents for TP E. 3. An exit interview with the laboratory director on 06/21/21 at approximately 1:30 PM confirmed the findings.