Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0933746	02/27/2019
Name of Provider or Supplier	**Street Address, City, State**	
Community Health Clinic Pc	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 survey was conducted at the Community Health Clinic (Honaker site) on February 26 and 27, 2019 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:
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: Based on the review of proficiency testing (PT) records for all three (3) events in 2018 and an interview with the testing personnel and laboratory director, the laboratory failed to maintain documentation of the attestation statement and original instrument testing results for hematology and chemistry for the 3rd event in 2018. Findings include: 1. Review of the Medical Laboratory Evaluation (MLE) PT records for all 3 events in 2018 revealed the lack of the attestation statement and original instrument testing results for hematology and chemistry for the 3rd event in 2018. The inspector requested to review the above-mentioned documentation. The documents were not available for review. 2. An interview with the testing personnel and laboratory director on February 27, 2019 at approximately 3:25 PM confirmed the 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 the review instrument maintenance records, lack of documentation, policy and procedures (P&P) review, electronic medical record (EMR) patient data log, and interviews with the testing personnel (TP) and laboratory director (LD), the laboratory failed to retain daily quality control (QC) records for routine chemistry testing for twenty-nine (29) days from September 18, 2018 to December 31, 2018. Findings include: 1. The laboratory utilized the Alfa Wassermann Ace Alera chemistry analyzer to perform routine chemistry testing in 2018. The laboratory stopped testing with the analyzer May 21, 2018 and resumed patient testing on September 18, 2018. The laboratory discontinued use of the analyzer on December 31, 2018. 2. Review of the "Ace Alera Clinical Chemistry System" maintenance log from September through December 31, 2018 revealed the following dates in which the TP performed routine maintenance procedures prior to testing patients: 9/18, 26 and 29/2018, 10/01, 04, 05, 09, 12, 15, 16, 19, 22, 24 and 29/2018, 11/01, 12, 21, 26 and 30/2018, 12/5, 6, 8, 11, 13, 17, 19, 21, 26 and 29/2018. Total of 29 days. 3. Review of the laboratory's P&P 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. All quality control activity must be documented as described in the individual sections and these records retained for two year." The inspector requested to review QC documentation for the above-listed dates. The TP could not provide the daily QC records for review. 4. Review of the eClinical EMR data log revealed that the laboratory assayed three-hundred and twenty-four (324) patients from September 18, 2018 and up to December 31, 2018. 5. An interview with the TP and LD at approximately 3:25 PM on February 27, 2019 confirmed the findings.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the primary testing personnel and laboratory director, the laboratory failed to participate in the second event in 2018 and received a score of 0% for the routine chemistry module. Record review included all three (3) events in 2018. Findings include: 1. Medical Laboratory Evaluation (MLE) PT records for all 3 events in 2018 revealed the following statement for Event B: "failure to participate" and score of 0% for the

	routine chemistry module. 2. An interview with the primary testing personnel and laboratory director at approximately 3:25 PM on February 27, 2019 confirmed that the lab received a score of 0% for failure to participate.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on the review of proficiency testing (PT) records for all three (3) events in 2018 and an interview with the testing personnel and laboratory director, the laboratory failed to verify the accuracy twice a year for the testosterone analyte in 2018. Findings include: 1. The laboratory utilizes Medical Laboratory Evaluation (MLE) PT to verify the accuracy twice a year for the testosterone analyte. Review of the MLE PT records revealed that the laboratory received a "results unacceptable" response for all 3 events in 2018. The inspector requested to review a different method or documentation of verifying the accuracy of the above-mentioned analyte for 2018. The documentation was not available for review. 2. An interview with the testing personnel and laboratory director on February 27, 2019 at approximately 3:25 PM confirmed the findings and the staff was unaware that they did not received acceptable results for the testosterone analyte from the MLE PT.
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 record review, policy and procedures (P&P), quality control (QC) records, calibration records, patient data logs, quality assessment (QA) checklists, and interviews with the testing personnel (TP) and laboratory director (LD), the laboratory failed to 1) the LD failed to review and approve the procedure manual for the new chemistry analzyer (Cross Reference D5407); 2) verify the accuracy, reportable range and reference range of analytes assayed on the Beckman Coulter Access 2 analyzer prior to testing patients (Cross Reference D5421); 3) follow the established policy of performing calibration procedures for the hematology analyzer at least every six (6) months and contacting the manufacturer if calibration procedures failed (Cross Reference D5437); 4) follow the established P&P for performing daily quality control (QC) procedures for the analytes assayed on Beckman Coulter Access 2 analyzer prior to reporting patients (Cross Reference D5447 part A); 5) follow the established policy for performing hematology daily quality control (QC) procedures (Cross Reference D5447 part B); and 6) identify and address analytic issues in chemistry and hematology (Cross Reference D5791 part A and B).

D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on record review and interview with the testing personnel and laboratory director, the laboratory director failed to review and approve the procedure manual for the new Beckman Coulter Access 2 analyzer prior to performing patients on March 1, 2017. Findings include: 1. Record review for the Beckman Coulter Access 2 analyzer revealed that the laboratory installed the instrument on December 12, 2016 but did not begin patient testing until March 1, 2017. 2. The laboratory utilizes the manufacturer's operation guide as their policy and procedures for operating the instrument. There was no documentation by the laboratory director of review and approval of the operation guide at the dates of survey on February 26-27, 2019. 3. The laboratory director confirmed in an interview at approximately 3:25 PM on February 27, 2019 that he/she did not review and approve the procedures for the new Beckman Coulter Access 2 analyzer prior to testing patients on March 1, 2017.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review, lack of documentation and interview with the testing personnel (TP) and laboratory director (LD), the laboratory failed to verify the accuracy, reportable range and normal values (reference range) of the Vitamin D, Vitamin B12, Prostate Specific Antigen (PSA), Free Thyroxin (Free T4), Thyroid Stimulating Hormone 3rd generation (TSH3), and testosterone analytes assayed on the Beckman Coulter Access 2 analyzer prior to testing patients on March 1, 2017. Dates of record review include December 12, 2016 and up to February 27, 2019. Findings include: 1. Review of initial performance verification records for the Beckman Coulter Access 2 analyzer (serial number 511950) revealed that a service representative performed a linearity and precision study on December 12, 2016 for the Vitamin D, Vitamin B12, PSA, Free T4, TSH3, and testosterone analytes. Review of the linearity documentation for each analyte revealed the following statement: "Accuracy and reportable range were not evaluated in this experiment." There was no documentation of review by TP and LD. The inspector requested to review additional verification documentation for each of the above-specified analytes at approximately 11:00 AM on February 26, 2019. The documentation was not available for review. 2. An interview with the TP and LD at approximately 3:25 PM on February 27, 2019 confirmed the 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 record review, policy and procedures (P&P), and interview with testing personnel (TP) and laboratory director (LD), the laboratory failed to follow the established policy of performing calibration procedures for the Beckman Coulter AcT Diff 2 hematology analyzer at least every six (6) months for the calendar years 2017 and 2018 and contacting the manufacturer if calibration procedures failed. Findings include: 1. Review of the laboratory's P&P reveals the following statements: CHC Clinic Laboratory Policy Sections; page 5 (signed approved by LD on 04/12/2015) "Calibration Procedures: Perform and document calibration procedures at least six (6) months and as recommended by the manufacturer. If calibration fails contact manufacturer immediately." 2. Record review for the Beckman Coulter AcT Diff 2 hematology analyzer revealed calibration procedures performed on January 12, 2017 and March 16, 2018. No additional calibration documentation was available for review. The calibration performed on March 16, 2018 failed for the White Blood Cell and Red Blood Cell parameters. The inspector asked the TP in an interview at approximately 1:10 PM on February 27, 2019: "What did you do or did you contact the manufacturer due to the failed calibration?" He/she stated that they did not remember the calibration failure and no, they did not contact the manufacturer. 3. An interview with the TP and LD at approximately 3:25 PM on February 27, 2019 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** A. Based on tour of the laboratory, record review, interviews with the testing personnel (TP), policy and procedure (P&P) review, electronic medical record (EMR) patient data log, and an interview with the laboratory director (LD), the laboratory failed to follow the established P&P for performing daily quality control (QC) procedures for the Vitamin D, Vitamin B12, Prostate Specific Antigen (PSA), Free Thyroxin (Free T4), Thyroid Stimulating Hormone 3rd generation

(TSH3), and testosterone analytes assayed on Beckman Coulter Access 2 analyzer prior to reporting patients for one-hundred and six (106) days from February 28, 2018 and up to February 5, 2019. Findings include: 1. The tour of the laboratory revealed that the laboratory utilizes the Beckman Coulter Access 2 analyzer (serial number 511950) to assay Vitamin D, Vitamin B12, PSA, Free T4, TSH3, and testosterone analytes. An interview with TP at approximately 10:00 AM on February 26, 2019 revealed that he/she did not perform the QC procedures each day of patient testing since February 28, 2018. He/she stated that the lot number of QC materials changed on February 28, 2018. He/she could not find the manufacturer's stated assay ranges for the new lot number of QC materials (BioRad Liquichek Immunoassay Plus Control lot number 40960 exp 02/29/2020) as the ranges were not provided with the manufacturer's package insert of new QC materials. He/she stated that they did contact the manufacturer and BioRad technical service. The BioRad technical service informed the TP that the ranges were available on-line for download but the TP was unable to locate the website. He/she stated that they continued with patient testing without performing daily QC procedures, "time just got away from me". 2. In interview with TP at approximately 1:30 PM on February 25, 2019, he/she stated that they batch the specimens for testing and perform daily maintenance procedures each day they assay patient samples. Review of the analyzer's maintenance records revealed the following dates maintenance was performed: 02/28/2018, 03/ 03, 05, 09, 12, 16, 19, 21, 24 and 28, 2018, 04/02, 05, 09, 13, 16, 18, 20, 23, 26 and 30, 2018, 05/ 01, 04, 07, 10, 14, 17, 21, 24 and 28, 2018, 06/04, 06, 08, 11, 14, 18, 21 and 26, 2018, 07/02, 03, 05, 09, 10, 15, 17, 19, 23, 25 and 30, 2018, 08/01, 02, 06, 08, 13, 14, 17, 21, 24 and 28, 2018, 09/04, 07, 10, 14, 17, 20, 24 and 27, 2018, 10/02, 04, 08, 10, 15, 18, 22, 25 and 29, 2018, 11/01, 08, 12, 15, 19, 21, 26 and 30, 2018, 12/04, 06, 10, 11, 13, 17, 19, 21, 26 and 29, 2018, 01/02, 04, 05, 08, 10, 14, 16, 18, 21, 23, 25 and 28, 2019 and 02/05/2019. Total of one hundred and five (106) dates. 3. 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." 4. February 28, 2018 and up to January 31, 2019, the eClinical EMR data log revealed: TSH- Five hundred and twenty-four patients (524) resulted, Free T4- three hundred and ten (310) patients resulted, PSA- one hundred and seventy-four patients (174) resulted, Testosterone- ninety-three (93) patients resulted, Vitamin D- five hundred and seven (507) patients resulted and Vitamin B12- five hundred and seventeen (517) patients resulted. Total of two thousand one hundred and twenty-six patients (2,126) resulted. 5. An interview with the laboratory director at approximately 3:25 PM on February 27, 2019 confirmed the findings. He/she stated they did not know that daily QC procedures were not performed. B. Based on the review of policy and procedures (P&P), record review, and interview with the testing personnel (TP) and laboratory director (LD), the laboratory failed to follow the established policy for performing hematology daily quality control (QC) procedures for twenty-five (25) of two hundred and seventy-four (274) dates reviewed. Dates of record review include August 1, 2017 and up to April 30, 2018. Findings include: 1. The laboratory utilizes the Beckman Coulter AcT Diff 2 (serial number 434062) 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 August 1, 2017 and up to April 30, 2018 (to include maintenance records and patient data log) revealed lack of documentation of daily QC procedures prior to reporting patients for following dates: 08/07/2017- 2 patients, 08/08/2017- 6 patients, 08/09/2017- 5 patients, 08/09 /2017- 12 patients, 09/12/2017- 9 patients, 09/13/2017- 8 patients, 09/14/2017- 3 patients, 09/15/2017- 5 patients, 09/16/2017- 1 patient, 09/22/2017- 4 patients, 09/26 /2017- 3 patients, 10/17/2017- 3 patients, 10/18/2017- 5 patients, 10/27/2017- 9 patients, 11/09/2017- 9 patients, 11/144/2017- 4 patients, 11/18/2017- 3 patients, 11/28 /2017- 5 patients, 12/02/2017- 8 patients, 01/25/2018- 4 patients, 02/02/2018- 6 patients, 02/23/2018- 1 patient, 03/14/2018- 3 patients, 03/28/2018- 8 patients and 04 /26/2018- 5 patients. Total of 25 dates and 131 patients. 3. An interview with the TP and LD at approximately 3:25 PM on February 27, 2019 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: 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 with the testing personnel (TP) and laboratory director (LD), the current quality assurance P&P did not to identify and address analytic failures in the specialties of hematology and chemistry from January 1, 2017 and up to the dates of survey on February 26 and 27, 2019. Cross Reference D5407, D5421, D5437, and D5447. Findings include: 1. Record review, P&P, QC records, calibration records and patient data logs revealed the following analytic issues in the specialties of hematology and chemistry: - The laboratory director did not review and approve the procedure manual for the new Access 2 chemistry analzyer (Cross Reference D5407). - The laboratory did not verify the accuracy, reportable range and reference range of analytes assayed on the Beckman Coulter Access 2 analyzer prior to testing patients on March 1, 2017 (Cross Reference D5421). - TP failed to follow the established policy of performing calibration procedures in 2017 and 2018 and contacting the manufacturer if calibration procedures failed (Cross Reference D5437). - TP failed follow the established P&P for performing daily chemistry quality control (QC) procedures for analytes assayed on Beckman Coulter Access 2 analyzer prior to reporting patients from February 28, 2018 and up to February 5, 2019 (Cross Reference D5447 part A). - TP failed to follow the established policy for performing hematology daily quality control (QC) procedures (Cross Reference D5447 part B). 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." There was no documentation of quality assurance review meeting between the lab staff and the clinical consultant available for review upon request. 3. The QA review revealed that the laboratory utilizes a quality assurance checklist that included the following statements: "Write "Y" for Yes or "N" for No by an item to indicate the outcome of the assessed item. In the "Comments" area, explain how the

	assessment was done. Were charts reviewed, requisitions examined, for what period of time? List all significant findings. Summarize overall findings in the "Discussion" area on the last page. Were the findings satisfactory or unsatisfactory?" The LD signed the checklists indicating "Y" (yes) for review on the first of each month from January 1, 2017 and up to February 1, 2019 (total of 24 months). There was no documentation of issues or problems by the LD on the 24 checklists. 4. An interview with the TP and LD at approximately 3:25 PM on February 27, 2019 confirmed the findings. B. Based on the review of policy and procedures (P&P), quality assessment (QA) records and interview with the testing personnel (TP) and laboratory director (LD), the laboratory failed to follow the established QA policy for documenting and evaluating Levy-Jennings plots to identify shifts and trends in the hematology "4C plus Cell control" materials each month for twenty-four (24) of the 24 months reviewed. Findings include: 1. Review of the current P&P and quality assessment policy (signed by the LD on 04/122015) 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." There was no documentation of quality assurance review meeting between the lab staff and the clinical consultant available for review upon request. 2. The QA review also revealed that the LD signed a "monthly" QA checklist indicating "Y" (yes) for review on the first of each month from January 1, 2017 and up to January 31, 2019. The checklists included the evaluation of Levy-Jennings plots to identify shifts and trends in QC materials. The inspector requested to review the monthly plots for the hematology QC materials at approximately 1:15 PM on February 27, 2019. TP stated that they did not participate in the Beckman Coulter's Interlaboratory Quality Assurance Program (IQAP) or print the monthly Levy-Jennings or statistics to identify shifts or trends. 3. An interview with the LD at approximately 3:25 PM on February 27, 2019 confirmed that the 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 record review, policy and procedures (P&P), quality control (QC) records, calibration records, patient data logs, quality assessment (QA) checklists, and interviews with the testing personnel (TP) and laboratory director (LD), the laboratory director failed to 1) ensure the verification of the accuracy, reportable range and reference range of the analytes assayed on the Beckman Coulter Access 2 analyzer prior to testing patients (Cross Reference D6013); and 2) ensure that the established QC and QA P&P were followed and analytic issues were identified and addressed in the specialties of hematology and chemistry (Cross Reference D6022).
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform

	test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) 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 record review, lack of documentation and interview with the laboratory director (LD), the LD failed to ensure the verification of the accuracy, reportable range and reference range of the Vitamin D, Vitamin B12, Prostate Specific Antigen (PSA), Free Thyroxin (Free T4), Thyroid Stimulating Hormone 3rd generation (TSH3), and testosterone analytes assayed on the Beckman Coulter Access 2 analyzer prior to testing patients (Cross Reference D5421).
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: Based on record review, policy and procedures (P&P), quality control (QC) records, calibration records, patient data logs, quality assessment (QA) checklists, and interviews with the testing personnel (TP) and laboratory director (LD), 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 and chemistry (Cross Reference D5437, D5447 part A and B and D5791 part A and B).
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on the review of Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, and interviews with the TP and laboratory director (LD), the technical consultant failed to perform and document annual competency assessments for one (1) of one (1) TP in 2017 and 2018. Findings include: 1. Review of the CMS-209 form revealed that the LD also performs the duties of technical consultant that there was 1 TP performing patient testing in 2017 and 2018. See attached TP code sheet. 2. Review of TP A records revealed no documentation of competency assessments performed by the technical consultant in 2017 and 2018. The

	inspector requested the competency assessments. The documentation was not available for review. 3. An interview with the LD at approximately 3:25 PM on February 27, 2019 confirmed the findings.
D6055	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on the review of initial verification records, the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, and interview with the TP and laboratory director (LD), the technical consultant failed to review and approve the training documentation for one (1) of 1 TP for the new Beckman Coulter Access 2 chemistry analyzer in 2017. Findings include: 1. Review of the initial verification records for the new Beckman Coulter Access 2 chemistry analyzer revealed that the instrument was installed on December 12, 2016 and a service representative performed initial training documentation on February 28, 2017. 2. Review of the CMS-209 form revealed that the LD also performs the duties of technical consultant that there was 1 TP performing patient testing in 2017. See attached TP code sheet. 3. Review of TP A records revealed no documentation of evaluation by the technical consultant of the initial training records. 4. An interview with the LD at approximately 3:25 PM on February 27, 2019 confirmed the findings.