Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0857440	10/10/2019
Name of Provider or Supplier	**Street Address, City, State**	
Black Hawk Health Center	356110 E 930 Road, Stroud, OK	

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	The recertification survey was performed 10/10/19. The laboratory was found out of compliance with the following CLIA regulations: 493.1215: D5024: Condition: Hematology 493.1403: D6000: Condition: Laboratory Director, Moderate Complexity 493.1409: D6033: Condition: Technical Consultant, Moderate Complexity The findings were reviewed with laboratory supervisor at the conclusion of the survey.
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on a review of records, manufacturer's instructions, written policies and procedures, observation, and interview with the laboratory supervisor, the laboratory failed to meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299 for the specialty of Hematology. Findings include: (1) The laboratory failed to thoroughly address Hematology proficiency testing responses that obtained biases and failed to take corrective action for proficiency testing failures. Refer to D5211; (2) The laboratory failed to have a written policy and procedure that included complete quality control practices and included the correct normal reference intervals for Complete Blood Count testing. Refer to D5403; (3) The laboratory failed to ensure blood collection tubes had been stored as required by the manufacturer. Refer to D5413; (4) The laboratory failed to perform maintenance procedures as required by the manufacturer. Refer to D5429; (5) The laboratory failed to follow the manufacturer's specifications for quality control materials. Refer to D5479; (6) The laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791.

D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor, the laboratory failed to have a written technical consultant and clinical consultant competency policy based on the job responsibilities as listed in Subpart M. Findings include: (1) At the beginning of the survey, the surveyors reviewed personnel records for competency assessments performed during 2018 and to date in 2019. There was no evidence competencies had been performed for the technical consultant and the clinical consultant, based on their job responsibilities; (2) The surveyors asked the laboratory supervisor if a written policy to evaluate the technical consultant and clinical consultant based on job responsibilities was available and if competencies had been performed during the review period. The laboratory supervisor stated a policy to evaluate the technical consultant and clinical consultant based on job responsibilities had not been written; and competencies had not been performed.
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: Based on a review of records and interview with the laboratory supervisor, the laboratory failed to thoroughly review and evaluate proficiency testing results. Findings include: BIASES (1) At the beginning of the survey, the laboratory supervisor stated to the surveyors the laboratory performed the following testing: (a) CBC (Complete Blood Count) (WBC-White Blood Count, RBC-Red Blood Count, MCV-Mean Corpuscular Volume, RDW-Red Cell Distribution Width, Automated WBC differential in percentages and numbers (Neutrophils, Lymphocytes, Basophils, etc.), Platelet count, etc.); (b) Chemistry (i.e., ALT (Alanine Aminotransferase), AST (Aspartate Aminotransferase), Cholesterol, CK (Creatinine Kinase), CO2 (Carbon dioxide), BUN (Blood Urea Nitrogen), LDL (Low Density Lipoprotein), etc.) using the Ortho Vitros 250 analyzer. (2) During the survey, the surveyors reviewed 2018 and 2019 proficiency testing records. The following biases (the biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency testing program) were identified: (a) 2018 Hematology First Event: (i) MCV - 5 of 5 results exhibited a Negative bias: (aa) ABT-01: SDI -2.3 (bb) ABT-02: SDI -2.2 (cc) ABT-03: SDI -2.3 (dd) ABT-04: SDI -2.5 (ee) ABT-05: SDI -2.2 (b) 2018 Hematology Second Event: (i) RDW - 5 of 5 results exhibited a Negative bias: (aa) ABT-06: SDI -2.7 (bb) ABT-07: SDI -2.8 (cc) ABT-08: SDI -2.7 (dd) ABT-09: SDI -2.5 (ee) ABT-10: SDI -2.3 (c) 2018 Chemistry Core Second Event: (i) ALT - 2 of 5 results exhibited a Negative bias: (aa) CH-07: SDI - 2.3 (bb) CH-09: SDI -2.1 (d) 2018 Hematology Third Event: (i) Basophils (Percentage) - 3 of 5 results exhibited a Positive bias: (aa) ABT-12: SDI 2.2 (bb) ABT-13: SDI 2.7 (cc) ABT-15: SDI 2.5 (e) Chemistry Core Third Event: (i) AST - 5 of 5 results exhibited a Negative bias: (aa) CH-11: SDI -2.3

	(bb) CH-12: SDI -2.5 (cc) CH-13: SDI -2.0 (dd) CH-14: SDI -2.5 (ee) CH-15: SDI -2.6 (f) 2019 Chemistry Core First Event: (i) Cholesterol - 2 of 5 results exhibited a Positive bias: (aa) CH-01: SDI 2.4 (bb) CH-02: SDI 2.3 (ii) CK - 4 of 5 results exhibited a Negative bias: (aa) CH-01: SDI -2.3 (bb) CH-02: SDI -2.9 (cc) CH-03: SDI -3.2 (dd) CH-05: SDI -2.8 (iii) CO2 - 5 of 5 results exhibited a Negative bias: (aa) CH-01: SDI -2.2 (bb) CH-02: SDI -2.5 (cc) CH-03: SDI -2.3 (dd) CH-04: SDI -2.8 (ee) CH-05: SDI -1.6 (g) 2019 Hematology Second Event: (i) MCV - 5 of 5 results exhibited a Positive bias: (aa) ABT-06: SDI 2.3 (bb) ABT-07: SDI 2.3 (cc) ABT-08: SDI 2.2 (dd) ABT-09: SDI 2.4 (ee) ABT-10: SDI 2.2 (h) 2019 Chemistry Core Second Event: (i) BUN - 3 of 5 results exhibited a Negative bias: (aa) CH-06: SDI -2.7 (bb) CH-07: SDI -2.7 (cc) CH-09: SDI -1.9 (2) The surveyors reviewed the records again and identified although corrective action (i.e., sample rerun, calibration performed, watching analyte for future trends/shifts) was noted, there was no documentation the laboratory had reviewed maintenance records, quality control results, reagent stability, and patient results performed during the same time frame as the proficiency testing to determine the cause of the biased proficiency results listed above; (3) The surveyors reviewed the findings with laboratory supervisor who stated the biases had not been thoroughly addressed. FAILURES CHEMISTRY CORE (1) During the review of proficiency testing records, the following failures were identified: (a) 2018 Chemistry Core First Event - ALT: (i) The laboratory failed the result for 1 of 5 samples (CH-02) and attained a score of 80%; (ii) Although a note in the records stated, "Should be reanalyzed," there was no evidence further investigation was performed to determine the cause of the failure. (b) 2018 Chemistry Core Second Event - LDL (Calculated): (i) The laboratory failed 1 of 5 samples (CH-06) and attained a score of 80%; (ii) Although a note in the records stated, "Suggest rerunning Trig and Chol to recalculate LDL in future," there was no evidence further investigation was performed to determine the cause of the failure. (2) The surveyors asked the laboratory supervisor if there was additional documentation which proved the laboratory performed further investigation to determine the cause of the failures listed above. The laboratory supervisor stated to the surveyors there was no additional documentation. VAGINAL WET PREPS (1) At the begining of the survey, the laboratory supervisor stated to the surveyors the laboratory performed Vaginal wet prep testing; (2) During the survey, the surveyors reviewed proficiency testing and identifed the following failure for Vaginal wet prep testing: (a) 2018 Second Event: (i) The laboratory failed the result for Sample VA-02 and obtained a score of 0%; (ii) The laboratory's result was, "Clue Cells seen." The proficiency testing program's expected result was, "No yeast, Trich. or clue cells;" (ii) There was no documentation in the records the laboratory took corrective action (i.e., review answer, review photographs, retraining of testing persons, etc.) for the failure. (3) The surveyors asked the laboratory supervisor if there was additional documentation which proved the laboratory took corrective action for the failed result. The laboratory supervisor stated to the surveyors there was no additional documentation. NOTE: D5211 was cited on the previous recertification survey 01/04/18.
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 a review of records and interview with the laboratory supervisor, the laboratory failed to verify the accuracy of testing when the proficiency testing program did not evaluate submitted results. Findings include: (1) At the beginning of the survey, the laboratory supervisor stated to the surveyors the laboratory performed the following microscopic testing: (a) Urine sediment examination (b) Vaginal wet prep examination for fungal elements (e.g. yeast) (2) The surveyors reviewed proficiency testing records from 2018 and 2019 and identified in the First 2019 Event, the proficiency testing program had not evaluated the responses as follows: (a) Urine sediment examination: (i) Although the laboratory obtained a score of 100%, the result of 1 of the laboratory's 2 response (UA-02) had not been evaluated by the proficiency testing program, due to "No Consensus"; (ii) In addition, the laboratory's response was "Fiber." The proficiency testing program's acceptable response was "see Data Summary"; (iii) There was no documentation located in the records which verified the laboratory identified the response had not been graded, obtained the Data Summary, and performed a self-evaluation of their response. (b) Vaginal wet prep examination: (i) Although the laboratory obtained a score of 100%, the result of 1 of the laboratory's 1 response (VKP-01) had not been evaluated by the proficiency testing program, due to "No Consensus"; (ii) In addition, the laboratory's result was "No Yeast Seen." The proficiency testing program's acceptable response range was "see Data Summary"; (iii) There was no documentation located in the records which verified the laboratory identified the response had not been graded, obtained the Data Summary, and performed a self-evaluation of their response. (3) The surveyors then reviewed the proficiency testing program's "Performance Evaluation Sheet," which stated that, "Laboratories should review the Performance Summary and Comparative Evaluation thoroughly for failures or 'not graded' analytes. Laboratories are responsible for documenting and performing corrective action for failures and must perform a self-evaluation using statistics presented in the Participant Data Summary for samples that have not been graded."; (4) The surveyors asked the laboratory supervisor if the laboratory had performed a self-evaluation of the non-graded results to verify the accuracy of the testing. The laboratory supervisor reviewed the records and stated the laboratory had not identified the responses not evaluated by the proficiency program, had not obtained the Data Summary, and had not performed a self-evaluation of their responses to verify accuracy of the testing.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on a review of records, written policy and procedure, and interview with the laboratory supervisor, the laboratory failed to have an ongoing mechanism for performing general laboratory systems quality assessment. Findings include: (1) It was determined the laboratory did not have a mechanism for performing quality assessment of general laboratory systems due to the following issues identified during the survey: (a) The laboratory failed to have a written technical consultant and clinical consultant competency policy based on the job responsibilities as listed in Subpart M.

	Refer to D5209; (b) The laboratory failed to thoroughly review and evaluate proficiency testing results. Refer to D5211; (c) The laboratory failed to review and evaluate proficiency testing results which had not been evaluated. Refer to D5215.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of records, written policies and procedures, and interview with the laboratory supervisor, the laboratory failed to have a written policy and procedure that included all aspects of Hematology testing. Findings include: QUALITY CONTROL (1) At the beginning of the survey, the laboratory supervisor stated to the surveyors the laboratory used the Cell Dyn Ruby Hematology analyzer to perform CBC (Complete Blood Count) testing (i.e. WBC-White Blood Count, RBC-Red Blood Count, Hematocrit, Hemoglobin, Platelet, etc); (2) The surveyors reviewed the laboratory's written CBC policy and procedure and identified the written policy and procedure did not include complete practices for Hematology QC (Quality Control) testing performed: (a) Identification of the QC materials used (b) Frequency of QC performance (c) Establishment of QC limits (d) Criteria for acceptable QC results (e) Corrective action to take for QC results that fail to meet the laboratory's criteria for acceptability (3) The surveyors reviewed the findings with the laboratory supervisor and asked the laboratory supervisor if the laboratory had a written policy and procedure which included the items listed above. The laboratory supervisor stated to the surveyors the laboratory did not have a written policy and procedure that included complete QC practices for Hematology. REFERENCE INTERVALS (1) During the survey, the surveyors reviewed patient CBC test reports. The test reports included the following normal reference intervals for each analyte: (a) Adult Male: (i) RBC: 3.9-5.4 (ii) Hemoglobin: 11.1-14.4 (iii) Hematocrit: 31-42 (iv) MCH (Mean Corpuscular Hemoglobin): 21-31 (v) MCHC (Mean Corpuscular Hemoglobin Concentration): 30-37 (vi) MCV (Mean Corpuscular Volume): 69-88 (b) Adult Female: (i) RBC: 4.2-5.4 (ii) Hemoglobin: 11.5-16.0 (iii) Hematocrit: 37-47 (iv) MCH: 27-32 (v) MCHC: 32-36 (vi) MCV: 80-96 (2) The surveyors then reviewed the laboratory's written policy and procedure for CBC testing. The surveyors identified the normal reference intervals provided on the patient test reports, did not match the normal reference

	intervals in the policy and procedure, which were as follows: (a) Adult Male: (i) RBC: 4.6-6.0 (ii) Hemoglobin: 14.0-18.0 (iii) Hematocrit: 40-54 (iv) MCH: 26-32 (v) MCHC: 32-36 (vi) MCV: 80-94 (b) Adult Female: (i) RBC: 4.0-5.4 (ii) Hemoglobin: 12.0-15.0 (iii) Hematocrit: 35-49 (iv) MCH: 26-32 (v) MCHC: 32-36 (vi) MCV: 80-94 (3) The surveyors reviewed the findings with the laboratory supervisor who stated to the surveyors, the laboratory's normal reference intervals for CBC testing did not match the normal reference intervals included in the laboratory's written policy and procedure.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, observation, and interview with the laboratory supervisor, the laboratory failed to ensure blood collection tubes had been stored as required by the manufacturer. Findings include: (1) During the survey, the surveyors observed the laboratory draw room adjacent to the laboratory. The laboratory supervisor stated to the surveyors the door between the draw room and the laboratory was closed when patients were present; (2) Surveyor #1 identified the following testing materials stored in the draw room: (a) BD Vacutainer K2 EDTA blood collection tubes (75 tubes, Lot #8249511) for CBC (Complete Blood Count) testing; (b) BD Vacutainer SST blood collection tubes (25 tubes Lot #9036654) used for chemistry testing; (c) BD Vacutainer Lithium Heparin amber microtainer blood collection tubes (6 tubes, Lot #9158941) were used for Direct Bilirubin and Total Bilirubin testing. (3) Later during the survey, surveyor #1 reviewed the manufacturer's environmental requirements for the blood collection tubes. The manufacturer required the blood collection tubes listed above be stored at a temperature between 4 and 25 degrees C (Centigrade); (4) Surveyor #2 asked the laboratory supervisor if the draw room temperature was monitored to ensure the manufacturer's temperature requirements had been met. The laboratory supervisor stated to the surveyors, the temperature of the draw room had not been monitored. NOTE: D5413 was cited on the previous recertification survey performed 01/14/18.
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 a review of records, manufacturer's instructions, and interview with the laboratory supervisor, the laboratory failed to perform maintenance procedures as

	required by the manufacturer. Findings include: (1) At the beginning of the survey, the laboratory supervisor stated to the surveyors CBC (Complete Blood Count) (i.e. RBC-Red Blood Count; Hemoglobin, Hematocrit, Platelet Count, etc.) was performed using the Cell Dyn Ruby hematology analyzer; (2) The surveyors reviewed the manufacturer's instructions for the analyzer and identified the manufacturer required the loader components be cleaned on a weekly basis; (3) The surveyors then reviewed maintenance records from October 2018 through September 2019. There was no documentation the weekly maintenance procedure had been performed between 06/25 /19 and 07/08/19; (4) The surveyors reviewed the findings with the laboratory supervisor who stated to the surveyors, there was no documentation the weekly maintenance had been performed as listed above.
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory supervisor, the laboratory failed to follow the manufacturer's specifications for quality control materials. Findings include: (1) At the beginning of the survey, the laboratory supervisor stated to the surveyor the laboratory used the Cell Dyn Ruby hematology analyzer to perform CBC (Complete Blood Count) testing (i.e. WBC-White Blood Count, RBC-Red Blood Count, Hematocrit, Hemoglobin, Platelet, etc.). In addition, 3 levels (Low, Normal, and High) of Cell Dyn 26 Plus QC (Quality Control) materials were analyzed each day of patient testing; (2) Records were reviewed for QC materials tested from October 2018 through September 2019. It was identified the laboratory used the manufacturer's guideline ranges instead of establishing their own means and limits for 6 of the 8 QC lot numbers used during the review period: (a) Lot #8225; Low, Normal, and High: From 08/27/18 to 10/26/18 (b) Lot #8281; Low, Normal, and High: From 10/26/18 to 12/03/18 (c) Lot #8337; Low, Normal, and High: From 12/17/18 to 01/23/19 (d) Lot #9084; Low, Normal, and High: From 04/04/19 to 06/07/19 (e) Lot #9140; Low, Normal, and High: From 06/10 /19 to 06/27/19 (f) Lot #9196; Low, Normal, and High: From 08/03/19 to 08/05/19 (3) The surveyors then reviewed the manufacturer's instructions (package insert) for the control materials. The package insert included a mean assay value and mean range for each level and analyte. It stated, "The mean range does not represent standard deviations (SD)."; (4) The surveyors reviewed the records with the laboratory supervisor who stated to the surveyors, the laboratory utilized the manufacturer's package insert values and failed to establish their own means and acceptable ranges for the control material lot numbers, as listed above. NOTE: D5413 was cited on the previous recertification survey performed 01/14/18.
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: Based on a review of records, manufacturer's instructions, written policies and procedures, observation, and interview with the laboratory supervisor, the laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. Findings include: (1) It was determined the laboratory did not have an effective mechanism for performing analytic quality assessment because of the following issues identified during the survey: (a) The laboratory failed to have a written policy and procedure that included all aspects of Hematology testing. Refer to D5403; (b) The laboratory failed to ensure materials had been stored as required. Refer to D5413; (c) The laboratory failed to perform maintenance procedures as required by the manufacturer. Refer to D5429; (d) The laboratory failed to follow the manufacturer's specifications for quality control materials. Refer to D5479. NOTE: D5791 was cited on the previous recertification survey performed 01/04/18.
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 a review of records and interview with the laboratory supervisor, the laboratory failed to ensure patient test reports included the name of the laboratory. Findings include: (1) At the beginning of the survey, the laboratory supervisor stated to the surveyors the laboratory performed the following testing: (a) CBC (Complete Blood Count) testing (i.e. WBC-White Blood Count, RBC-Red Blood Count, Hematocrit, Hemoglobin, Platelet, etc.) was performed using the Cell Dyn Ruby hematology analyzer; (b) CMP (Comprehensive Metabolic Panel) testing (Albumin, Alkaline Phosphatase, ALT (Alanine Aminotransferase), AST (Aspartate Aminotransferase), Calcium, Carbon Dioxide, Chloride, Creatinine, Glucose, Sodium, Total Bilirubin, and Total Protein) was performed using the Orthos Vitros 250 analyzer; (c) Lipid Profile (Total Cholesterol, HDL (High Density Lipoprotein), LDL (Low Density Lipoprotein), Triglycerides) testing using the Orthos Vitros 250 analyzer; (d) Microscopic examination of urine sediment. (2) The surveyors reviewed test reports for 4 patients: (a) Patient #9952: CMP, Lipid Profile, and CBC testing was performed 10/10/19. The name of the laboratory on the report was, "Black Hawk Clinic," (b) Patient #766: CBC testing was performed 10/10/19. The name of the laboratory on the report was, "Black Hawk Clinic," (c) Patient #11435: Microscopic examination of urine was performed on 10/10/19. The name of the laboratory on the report was, "Black Hawk Clinic," (d) Patient #11374: CBC testing was performed 09 /26/19. The name of the laboratory on the report was, "Black Hawk Clinic." (3) It was identified the name of the laboratory on the patient reports, did not match the name of the laboratory listed on the CLIA certificate: Black Hawk Health Center; (4) The

	surveyors reviewed the findings with the laboratory supervisor, who stated to the surveyors the name on the test reports did not match the name on the CLIA certificate.
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 a review of records, manufacturer's instructions, written policies and procedures, observation, and interview with the laboratory supervisor, the laboratory director failed to provide overall management and direction of the laboratory in accordance with 493.1407 of this subpart. Findings include: (1) The laboratory director failed to ensure the laboratory performed test methods as required by the manufacturer to ensure accurate and reliable results were reported. Refer to D6014; (2) The laboratory director failed to attest the laboratory performed proficiency testing samples in the same manner as patient specimens, as required under Subpart H. Refer to D6016; (3) The laboratory director failed to ensure proficiency testing results were reviewed and evaluated. Refer to D6018; (4) The laboratory director failed to ensure a quality control program had been established and maintained to assure the quality of laboratory services provided by the laboratory. Refer to D6020; (5) The laboratory director failed to ensure the laboratory had an ongoing mechanism for performing effective analytic quality assessment. Refer to D6021; (6) The laboratory director failed to ensure the laboratory had written policies and procedures that included all aspects of testing. Refer to D6031.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, observation, and interview with the laboratory supervisor, the laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results were reported. Findings included: (1) The laboratory director failed to ensure the laboratory stored blood collection tubes as required by the manufacturer. Refer to D5413; (2) The laboratory failed to perform maintenance procedures as required by the manufacturer. Refer to D5429; (3) The laboratory director failed to ensure the laboratory followed the manufacturer's quality control specifications. Refer to D5479.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)

	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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor, the laboratory director failed to attest at the time of testing, proficiency testing samples were tested in the same manner as patient specimens, as required under Subpart H. Findings include: (1) At the beginning of the survey, the surveyors reviewed the Laboratory Personnel Record (Form 209) which listed an individual who served as the technical consultant; (2) The surveyors identified a written policy from the laboratory director that delegated the responsibility for signing proficiency testing attestation statements to the individual listed on the Form 209 as the technical consultant; (3) The surveyors reviewed the 2018 and 2019 Hematology and Chemistry Core proficiency testing records. It was identified for 7 of the 10 events performed, the attestation statements had been signed between 3 weeks to 7 weeks after the samples had been tested (not within a time frame to attest at the time of testing, the proficiency samples had been tested as required): (a) Hematology: (i) First 2018 Event: The samples were tested on 03/28/18 and the attestation statement had not been signed by the technical consultant until 04/19/18; (ii) First 2019 Event: The samples were tested on 03/29/19 and the attestation statement had not been signed by the technical consultant until 04 /26/19; (b) Chemistry Core: (i) First 2018 Event: The samples were tested on 02/09/18 and the attestation statement had not been signed by the technical consultant until 03 /02/18; (ii) Third 2018 Event: The samples were tested on 09/14/18 and the attestation statement had not been signed by the technical consultant until 10/09/18; (iii) First 2019 Event: The samples were tested on 02/01/19 and the attestation statement had not been signed by the technical consultant until 03/22/19; (iv) Second 2019 Event: The samples were tested on 05/30/19 and the attestation statement had not been signed by the technical consultant until 06/29/19; (v) Third 2019 Event: The samples were tested on 09/12/19 and the attestation statement had not been signed by the technical consultant until 10/04/19. (4) The surveyors reviewed the findings with the laboratory supervisor and explained that attestation statements must be signed within a time frame to definitively attest to the fact proficiency samples were tested in the same manner as patient specimens.
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 a review of records and interview with the laboratory supervisor, the

	laboratory director failed to ensure proficiency testing reports were thoroughly reviewed to evaluate the laboratory's performance and to identify any problems that required corrective action. Findings include: (1) The laboratory director failed to ensure proficiency testing results were reviewed and evaluated, and failed to ensure corrective action was taken for proficiency testing failures. Refer to D5211; (2) The laboratory director failed to ensure the accuracy of testing when the proficiency testing program had not evaluated submitted results. Refer to D5215.
D6020	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 program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, observation, and interview with the laboratory supervisor, the laboratory director failed to ensure a quality control program had been established and maintained to assure the quality of laboratory services provided by the laboratory. Findings include: (1) The laboratory director failed to ensure the laboratory followed the manufacturer's specifications for quality control materials. Refer to D5479.
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, written policies and procedures, observation, and interview with the laboratory supervisor, the laboratory director failed to ensure an effective quality assessment program had been established and maintained. Findings include: (1) The laboratory director failed to ensure the laboratory had an ongoing mechanism for performing general laboratory systems quality assessment. Refer to D5291; (2) The laboratory director failed to ensure the laboratory had an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on a review of records, written policies and procedures, and interview with the laboratory supervisor, the laboratory director failed to ensure the laboratory's written policy and procedure was followed as required for accurate and reliable results, and the laboratory director failed to ensure the laboratory had a written policy and procedure that included all aspects of testing. Findings include: (1) The laboratory director failed to ensure the laboratory had a written policy and procedure that included all aspects of Hematology testing. Refer to D5403.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records, manufacturer's instructions, written policies and procedures, observation, and interview with the laboratory supervisor, the technical consultant failed to provide technical oversight in accordance with 493.1413 of this subpart. Findings include: (1) The technical consultant failed to ensure the establishment and maintenance of acceptable levels of analytic performance. Refer to D6042; (2) The technical consultant failed to ensure testing persons were evaluated to assure they were competent in performing test procedures and able to report test results accurately and proficiently. Refer to D6046.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, written policies and procedures, observation, and interview with the laboratory supervisor, the technical consultant failed to ensure the establishment and maintenance of acceptable levels of analytic performance. Findings include: (1) The technical consultant failed to ensure the laboratory had policies and procedures for all aspects of testing. Refer to D5403; (2) The technical consultant failed to ensure the laboratory stored testing materials as required by the manufacturer. Refer to D5413; (3) The technical consultant failed to ensure the laboratory performed maintenance procedures as required by the manufacturer. Refer to D5429; (4) The technical consultant failed to ensure the

	laboratory followed the manufacturer's specifications for quality control materials. Refer to D5479; (5) The technical consultant failed to ensure patient test reports included the name of the laboratory. Refer to D5805.
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 a review of records and interview with the laboratory supervisor, the technical consultant failed to evaluate testing personnel to assure they were competent in performing test procedures and able to report test results accurately and proficiently. Findings include: (1) At the beginning of the survey, the laboratory supervisor stated to the surveyors the laboratory performed the following moderate complexity patient testing: (a) CBC (Complete Blood Count) (i.e. WBC-White Blood Count, RBC-Red Blood Count, Hemoglobin, Hematocrit, Platelet Count, automated WBC differential in number and percentages for Neutrophils, Lymphocytes, Monocytes, Eosinophils, and Basophils, etc.) (b) Vaginal wet prep examinations (c) Microscopic urinalysis (2) The surveyors reviewed the Laboratory Personnel Report (Form CMS-209) completed by the laboratory prior to the survey. The form listed 2 testing persons who performed the moderate complexity testing in the laboratory: Laboratory supervisor and testing person #1; (3) The surveyors reviewed the competency evaluations of the testing personnel from January 2018 through the survey. There was no evidence 2 of the 2 testing persons had been evaluated for testing performance and ability to report test results accurately and proficiently for Vaginal wet prep examinations and Microscopic urinalysis testing during the review period: (a) Laboratory supervisor: (i) Annual competency performed 01/03/18 did not include an evaluation of Vaginal wet prep examination performance; (ii) Annual competency performed 12/14/18 did not include an evaluation of Vaginal wet prep examination and Microscopic urinalysis performance. (b) Testing person #2: (i) The annual competencies performed on 02/02/18 and 12/14/18 did not include an evaluation of Vaginal wet prep examination and Microscopic urinalysis performance. (4) The surveyors reviewed the findings with the laboratory supervisor who stated to the surveyors there was no documentation the competencies included the evaluation of testing performance of Vaginal wet prep examinations and Microscopic urinalysis, as listed above