Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0857440	01/04/2018
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 findings were reviewed with the laboratory manager at the conclusion of the survey.
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 manager, the laboratory failed to thoroughly review and evaluate proficiency testing results. Findings include: FAILURES (1) At the beginning of the survey, surveyor #2 reviewed 2016 and 2017 proficiency testing records. The following was identified: (a) 2016 Chemistry Group 2 - 1st event (i) ALT (Alanine Aminotransferase) The laboratory received a score of 80% (failed 1 of 5 results). There was no evidence that corrective action had been taken for the failed result in order to identify the cause of the failure; (ii) Na (Sodium) - The laboratory received a score of 80% (failed 1 of 5 results). There was no evidence that corrective action had been taken for the failed result in order to identify the cause of the failure. (b) 2016 Hematology - 2nd Event (i) Hemoglobin - The laboratory received a score of 80% (failed 1 of 5 results). There was no evidence that corrective action had been taken for the failed result in order to identify the cause of the failure. (c) 2016 Chemistry Group 2 - 3rd event (i) ALT (Alanine Aminotransferase) The laboratory received a score of 80% (failed 1 of 5 results). There was no evidence that corrective action had been taken for the failed result in order to identify the cause of the failure. (d) 2017 Chemistry Core - 1st event (i) ALT (Alanine Aminotransferase) The laboratory received a score of 80% (failed 1 of 5 results). There was no evidence that corrective action had been taken for the failed result in order to identify the cause of the failure. (e) 2017 Chemistry Core - 2nd event (i) ALT (Alanine Aminotransferase) The laboratory received a score of

	80% (failed 1 of 5 results). There was no evidence that corrective action had been taken for the failed result in order to identify the cause of the failure. (f) 2017 Hematology - 1st event (i) MPV (Mean Platelet Volume) The laboratory received a score of 40% (failed 3 of 5 results). There was no evidence that corrective action had been taked for the failed results in order to identify the cause of the failure; (ii) Vaginal Wet Preparation The laboratory received a score of 0% (failed 1 of 1 result). There was no evidence that corrective action had been taken for the failed result in order to identify the cause of the failure. (2) The surveyors reviewed the above findings with laboratory manger who stated the proficiency testing had not been thoroughly addressed. BIAS (1) At the beginning of the survey, surveyor #2 reviewed 2016 and 2017 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) 2016 Hematology -3rd event (i) RDW (Red Cell Distribution Width) - 3 of 5 results exhibited a negative bias (aa) ABT-12- SDI -3.2 (bb) ABT-13- SDI -2.3 (cc) ABT- 14 - SDI -2.2 (b) 2017 Hematology - 1st event (i) MCHC (Mean Corpuscular Hemoglobin Concentration) - 5 of 5 exhibited a positive bias (aa) ABT-01 - SDI 3.0 (bb) ABT-02 - SDI 2.7 (cc) ABT-03 - SDI 3.0 (dd) ABT-04 - SDI 2.5 (ee) ABT-05 - SDI 2.4 (ii) MCV (Mean Corpuscular Volume) - 5 of 5 exhibited a negative bias (aa) ABT-01 - SDI -2.0 (bb) ABT-02 - SDI -2.2 (cc) ABT-03 - SDI -2.5 (dd) ABT-04 - SDI -2.2 (ee) ABT-05 - SDI -2.1 (iii) MPV (Mean Platelet Volume) - 5 of 5 exhibited a negative bias (aa) ABT-01 - SDI -2.9 (bb) ABT-02 - SDI -3.9 (cc) ABT-03 - SDI -4.0 (dd) ABT-04 - SDI -4.2 (ee) ABT-05 - SDI -3.1 (iv) RDW - 5 of 5 exhibited a negative bias (aa) ABT-01 - SDI -2.7 (bb) ABT-02 - SDI -2.7 (cc) ABT-03 - SDI -2.8 (dd) ABT-04 - SDI -3.0 (ee) ABT-05 - SDI -2.6 (2) The surveyors reviewed the above findings with laboratory manager who stated the biases had not been thoroughly addressed.
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 a review of written policies and interview with the laboratory manager, the laboratory failed to ensure policies and procedures had been approved, signed, and dated by the current laboratory director. Findings include: (1) At the beginning of the survey, the laboratory manager stated the following to the surveyors: (a) The laboratory performed Strep A Screen testing using the Quidel QuickVue + Strep A test kit; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) The laboratory manager stated to surveyor #1 the start date for the current laboratory director was in July 2017; (3) Surveyor #1 reviewed the IQCP and identified the QCP (Quality Control Plan) portion had not been approved, signed, and dated by the current laboratory director; (4) Surveyor #1 reviewed the records with the laboratory manager who agreed the QCP had not been approved, signed, and dated by the current laboratory director.
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2).

	This STANDARD is not met as evidenced by: Based on a review of the policy and procedure manual and interview with the laboratory manager, the laboratory failed to ensure written procedures no longer in use had been discontinued. Findings include: (1) During the survey, the surveyors reviewed the policy and procedure manual titled, "Lab Test Technical Manual". A procedure titled, "Coaguchek XS" and a procedure titled, "Sediplast ESR System" were identified; (2) The surveyors asked the laboratory manager if the above procedures were currently in use. The laboratory manager stated the procedures had been discontinued, but had not been indicated as discontinued. NOTE: 493.1105(a)(2) requires that discontinued procedures be maintained for at least 2 years.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory manager, the laboratory failed to follow the manufacturer's instructions for Strep A Screen testing. Findings include: (1) At the beginning of the survey, the laboratory manager stated to the surveyors Strep A Screen testing was performed using the Quidel QuickVue + Strep A test kit; (2) Surveyor #1 reviewed the manufacturer's package insert for the Strep A Screen test kit. Under the heading "Limitations" it stated, (a) "Additional follow-up testing using the culture method is recommended if the QuickVue+ test result is negative". (3) The surveyors asked the laboratory manager if the laboratory ensured a follow-up culture was performed when the Strep A Screen result was negative. The laboratory manager stated specimens were sent to the reference laboratory for a follow-culture when the Strep A Screen result was negative in patients 18 years old and younger; (4) Surveyor #1 then reviewed the Group A Strep test log for testing performed from January through December 2017 and identified that follow-up culture testing had not been performed for 42 of 42 patients 19 years and older as follows: (a) 60 year old patient tested on 01 /03/17 (b) 45 year old patient tested on 01/04/17 (c) 27 year old patient tested on 01/10 /17 (d) 58 year old patient tested on 01/23/17 (e) 66 year old patient tested on 01/31 /17 (f) 29 year old patient tested on 02/07/17 (g) 24 year old patient tested on 02/10/17 (h) 35 year old patient tested on 02/14/17 (i) 59 year old patient tested on 02/23/17 (j) 64 year old patient tested on 02/28/17 (k) 35 year old patient tested on 03/03/17 (l) 42 year old patient tested on 03/10/17 (m) 29 year old patient tested on 03/15/17 (n) 48 year old patient tested on 03/28/17 (o) 58 year old patient tested on 04/10/17 (p) 48 year old patient tested on 04/19/17 (q) 20 year old patient tested on 04/28/17 (r) 23 year old patient tested on 05/01/17 (s) 54 year old patient tested on 05/10/17 (t) 29 year old patient tested on 06/02/17 (u) 37 year old patient tested on 06/13/17 (v) 39 year old patient tested on 06/30/17 (w) 64 year old patient tested on 07/07/17 (x) 60 year old patient tested on 07/28/17 (y) 52 year old patient tested on 08/02/17 (z) 78 year old patient tested on 08/28/17 (aa) 26 year old patient tested on 08/31/17 (bb) 55 year old patient tested on 09/06/17 (cc) 22 year old patient tested on 09/14/17 (dd) 49 year old patient tested on 09/20/17 (ee) 36 year old patient tested on 10/03/17 (ff) 35

	year old patient tested on 10/24/17 (gg) 23 year old patient tested on 10/31/17 (hh) 52 year old patient tested on 11/02/17 (ii) 28 year old patient tested on 11/16/17 (jj) 27 year old patient tested on 11/30/17 (kk) 19 year old patient tested on 12/01/17 (ll) 52 year old patient tested on 12/05/17 (mm) 31 year old patient tested on 12/12/17 (nn) 39 year old patient tested on 12/19/17 (oo) 58 year old patient tested on 12/21/17 (pp) 75 year old patient tested on 12/27/17 (4) The surveyors reviewed the findings with the laboratory manager who stated follow-up culture testing had not been performed for the patients above.
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, and interview with the laboratory manager, the laboratory failed to ensure equipment was stored as required by the manufacturer. Findings include: (1) At the beginning of the survey, the laboratory manager stated to the surveyors Albumin, Alkaline Phosphatase, ALT, AST, BUN, Calcium, Chloride, CK (Creatine Kinase), CO2, Cholesterol, Creatinine, Direct Bilirubin, Glucose, HDL (High Density Lipoprotein) Cholesterol, Potassium, Sodium, Total Bilirubin, Total Protein, and Triglyceride testing were performed on the Ortho Vitros 250 analyzer; (2) Later during the survey, surveyor #1 reviewed the manufacturer's environmental requirements for the analyzer. The manufacturer required the relative humidity be maintained within the range of 15-75%; (3) Surveyor #1 then reviewed laboratory humidity records from September 2016 through December 2017 which verified the humidity readings were less than 15% for 5 of 17 months as follows: (a) December 2016 - 11 of 20 humidity readings were documented as less than 15% (days 01,08,09,14,15,16,19,20,21,22,30) (b) January 2017 - 6 of 18 humidity readings were documented as less than 15% (days 04,05,26,27,30,31); (c) February 2017 - 3 of 19 humidity readings were documented as less than 15% (days 01,02,03) (d) March 2017 - 2 of 23 humidity readings were documented as less than 15% (days 03,08) (e) December 2017 - 10 of 18 humidity readings were documented as less than 15% (days 06,07,08,11,12,13,14,15,27,29) (4) The surveyors reviewed the records with the laboratory manager who stated the humidity of the laboratory had been maintained below 15% as indicated above.
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 manager, the laboratory failed to ensure equipment maintenace was performed as required by the manufacturer. Findings include: (1) At the beginning of the survey, the laboratory manager stated to the surveyors Albumin, Alkaline Phosphatase, ALT, AST, BUN, Calcium, Chloride, CK (Creatine Kinase), CO2, Cholesterol, Creatinine, Direct Bilirubin, Glucose, HDL (High Density Lipoprotein) Cholesterol, Potassium, Sodium, Total Bilirubin, Total Protein, and Triglyceride testing were performed on the Ortho Vitros 250 analyzer; (2) Surveyor #2 reviewed the 2016 and 2017 (24 months) manufacturer's maintenance logs for the analyzer. Surveyor #2 identified the following: (a) Daily - The manufactuer required 16 daily maintenance procedures. (i) Two daily maintenance procedures (Install new Reference Fluid disposable reservoir and Clean Reference Fluid cover/seal) had not been documented as performed for the month of February 2016. (b) Weekly - The manufacturer required 8 weekly maintenance procedures. The weekly maintenance had not been performed between: (i) 06/17/2016 and 06/30/2016 (ii) 11/18/2016 and 12/02/2016 (iii) 02/10/2017 and 02/24/2017 (3) The surveyors reviewed the records with the laboratory manager who stated there was no evidence the above maintenance had been performed as required.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to perform calibration verification procedures at least once every 6 months. Findings include: (1) At the beginning of the survey, the laboratory manager stated to the surveyors routine chemistry testing, which included the analytes Sodium, Potassium and Chloride were performed on the Ortho Vitros 250 analyzer; (2) Surveyor #2 reviewed 2016 and 2017 calibration verification records (since the routine calibration procedures for the above analytes included less than three levels, calibration verification procedures, using three or more levels of calibration materials that included a low, mid, and high value, were required every six months). There was

	no evidence calibration verification procedures had been performed between 01/15 /2016 and 02/27/2017; (3) Surveyor #2 reviewed the records with the laboratory manager who stated calibration verification procedures had not been performed every six months.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records, written policies, and interview with the laboratory manager, the laboratory failed to follow written quality control policies. Findings include: (1) At the beginning of the survey, the laboratory manager stated the following to the surveyors: (a) The laboratory performed Strep A Screen testing using the Quidel QuickVue + Strep A test kit; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) Surveyor #1 reviewed the IQCP (Individualized Quality Control Plan) that had been developed for the test system. The QCP (Quality Control Plan) portion of the IQCP required 2 levels of external quality control materials be tested "Once each calendar week and with each new box"; (3) Surveyor #1 then reviewed quality control records from January 2017 through December 2017 and identified the laboratory failed to follow the written QCP of performing quality control testing once each calendar week. Quality control testing had not been performed between: (a) 03/20/17 and 04/03/17 (b) 05/10/17 and 06/02 /17 (c) 07/13/17 and 07/26/17 (d) 07/31/17 and 08/21/17 (4) The findings were reviewed with the laboratory manager who stated the laboratory had not performed quality control testing as required by the QCP.
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 manager, the laboratory failed to follow the manufacturer's quality control instructions. Findings include: (1) At the beginning of the survey, the laboratory manager stated the following to the surveyors: (a) CBC (Complete Blood Count) testing was performed using the Abbott Cell Dyn Ruby analyzer; (b) Three levels of Cell-Dyn 26 Plus quality control (QC) materials were performed each day of patient testing. (2) Later during the survey, surveyor #1 reviewed the following

	manufacturer's instructions: (a) The QC package insert stated, "The mean range does not represent standard deviations (SD)"; (b) An instruction sheet provided by the manufacturer titled, "Establishing Quality Control Means and Limits" provided instructions to the laboratory for establishing laboratory means and limits for new lot numbers of control materials. (3) Surveyor #1 then reviewed QC records for testing performed from 04/12/17 through the day of the survey. It was identified the laboratory had used the package insert ranges, instead of laboratory established ranges, to determine acceptability of QC results for 4 of 5 lot numbers: (a) Low, Normal, and High control lot #7086 used from 04/12/17 through 06/09/17 (b) Low, Normal, and High control lot #7142 used from 06/02/17 through 08/04/17 (c) Low, Normal, and High control lot #7198 used from 08/01/17 through 09/29/17 (d) Low, Normal, and High control lot #7254 used from 09/25/17 through 11/22/17 (4) Surveyor #1 reviewed the findings with the laboratory manager who stated the laboratory had used the package insert ranges instead of laboratory established ranges for determining acceptability of QC results. NOTE: D5479 was cited on the recertification survey performed on 03/22/16.
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 and interview with the laboratory manager, the laboratory failed to follow their policy for monitoring the effectiveness of their IQCP. Findings include: (1) At the beginning of the survey, the laboratory manager stated the following to the surveyors: (a) The laboratory performed Strep A Screen testing using the Quidel QuickVue + Strep A test kit; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) Surveyor #1 reviewed the IQCP (dated as effective 01/07/16). The QA (Quality Assessment) portion of the IQCP stated, "The IQCP will be reviewed at least annually by the Technical Consultant and/or Medical Director with the laboratory manager"; (3) Surveyor #1 then reviewed records for the Strep A Screen testing. There was no evidence of a QA review for the IQCP since its effective date of 01/07/16; (4) Surveyor #1 reviewed the records with the laboratory manager and asked if an annual QA review had been performed. The laboratory manager stated an annual QA review had not been performed.
D6054	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 at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the technical consultant failed to evaluate testing persons performing moderate complexity testing

	at least annually. Findings include: (1) At the beginning of the survey, surveyor #2 reviewed personnel records for 3 persons who performed testing in 2016 and 2017. For 3 of 3 persons there was no evidence annual evaluations had been performed as follows: (a) 2017 (i) Testing Person #1 (ii) Testing Person #2 (iii) Testing Person #3 (2) The surveyors reviewed the findings with the laboratory manager, who stated the annual evaluations had not been performed in 2017 for the testing persons.