Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0453314	10/08/2018
Name of Provider or Supplier	**Street Address, City, State**	
Ob Gyn Of Southwest Kansas	222 W 15th, Liberal, KS	

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
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 a review of lab policies and procedures, proficiency testing (PT) records during calendar years 2017 and 2018 through the PT provider, American Proficiency Institute (API) and staff interview, the laboratory failed to document each step in the testing and reporting of results for all proficiency test samples. Findings were: 1. A review of the laboratory's proficiency API records showed the Laboratory Director and Testing Person's failed to sign the Attestation Statement for the following testing events: Hematology/Coagulation - 2018: 1st event; 2017: 1st and 2nd event 2. This was confirmed with interview with testing personnel #2 (refer to Testing Personnel Report (CMS-209)) at 10:06 am on October 8, 2018.
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 lack of documents and interview with testing personnel #2 at 10:56 am on October 8, 2018, the laboratory failed to follow policies and procedures to assess the testing personnel's competency.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based upon direct observation during a tour of the laboratory, review of manufacturer's reagent labels and staff interview, the laboratory failed to ensure that reagents and supplies in use were not expired. Findings were: 1. During a tour of the lab the surveyors observed the following expired reagents, tubes, and supplies: 10% KOH bottles. lot. 1300913 expired 1/2015 was observed on the counter. Stored in the cupboard were additional 10% KOH reagent bottles with the following lots: lot. 67586 expired 9/9/11; lot. 1428213 expired 9/30/2014; lot. 1633413 expired 11/29 /2017; and two bottles of lot. 1724206 expired 8/30/2018 without open dates. Reagent grade water: lot. 1400908 expired 1/15/2016 Alere Hemopoint #2 Optics Cleaner: lot. 18352 expired 10/2016 single package and lot. 152101 expired 10/2016 five pack. Alere Viral Negative (-) Control Swab: lot. 074844 expired 07/2017 HemoTrol Level 1: lot. 63165 expired 4/2018 and Level 3: lot. 63667 expired 4/2018 Hemoccult developer (10 bottles total): lot. 22 expired 1/2016; lot. 51604H expired 11/2016; lot. 54375H expired 6/2017; lot. 55729H expired 11/2017 Purple EDTA specimen blood tubes: lot. 6216521 expired 12/31/2017; lot. 6253682 expired 1/31/2018; lot. 7033587 expired 6/30/2018; lot. 7067949 expired 7/31/2018 - lot found in phlebotomy station EDTA microtainer: lot. 5660911 expired 8/2018 Green Lithium Heparin specimen blood tubes: lot. 6040958 expired 6/2017; lot. 6313692 expired 3/31/2018 found in phlebotomy station Lacto Phenol Cotton Blue Mounting Fluid: lot. K06A61 expired 10/2009 HemoCue Glucose 201 25 Microcuvettes - Glucose 201: Lid not fastened on top of bottle. HemoCue AB, Ref. 110706: lot. 1805133 expired 6/15/2018 was opened 10/1 with no year documented. Bottle had no open expiration date noted on "once opened - Expiry date" line. 2. The above findings were confirmed by interview with testing personnel #2, refer to Testing Personnel Report (CMS-209), at 08:24 am on October 8, 2018, in the laboratory.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must

	be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Review of urinalysis policy/procedure, equipment maintenance records and interview with staff reveals that the laboratory failed to define function check protocols for all equipment as required. Findings include: 1. Centrifuge VWR Clinical 200 Serial Number (S/N): 68105096 with lid broke about three months ago at which time they started using the Adams Physicians Compact Centrifuge without a lid, S/N: 31676. Last documented tachometer on centrifuge VWR Clinical 200 results were performed on 4/4/2016 and 8/22/2016 for setting 1500 and 3000 revolutions per minute (rpm). Documented centrifuge range was 1500 +/- 30 and 3200 +/- 64 rpm. 2. At the time of the survey, there were no documentation of tachometer checks for the Adams Physicians Compact Centrifuge during 2017 or 2018 or the urine centrifuge, Van Seal, S/N: 876. 3. Review of tachometer laser certificate of calibration provided to surveyor at time of survey, serial number 904713 was due 8/11/2011. 4. Review of urinalysis microscopic procedure states to centrifuge urine specimen for 1500 rpm for 5 minutes. 5. At the time of the survey, there were no documentation of service or maintenance performed for the microscopes or centrifuge for 2016, 2017, or 2018. 6. The above findings were verified by interview with the testing personnel #2, refer to Testing Personnel Report (CMS-209), at 10:45 am on October 8, 2018 in the laboratory.