Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0050874	07/25/2023
Name of Provider or Supplier	**Street Address, City, State**	
Osu University Health Services	1202 West Farm Road, Stillwater, 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 on 07/24,25,2023. The laboratory was found out of compliance with the following CLIA Conditions: 493.493.801; D2000: Enrollment and Testing of Samples 493.1409; D6034: Technical Consultant The findings were reviewed with the facility director, associate director of clinical operations, laboratory director, and testing person #1 during an exit conference performed at the conclusion of the survey.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a review of records and interview with the laboratory director and testing person #1, the laboratory failed to enroll in a proficiency testing program for RPR (Rapid Plasma Reagin) testing for five of five events and Qualitative Serum Pregnancy testing for four of five events reviewed. Findings include: (1) On 07/24 /2023, a review proficiency testing records for 2021 (third event), 2022 (first, second, and third events) and to date in 2023 (first event) identified no evidence the laboratory was enrolled in proficiency testing for RPR testing for five of five events and Qualitative Serum Pregnancy testing for four of five events; (2) The records were reviewed with the laboratory director and testing person #1 who stated on 07/24/2023 at 02:30 pm, the laboratory had not enrolled in proficiency testing as stated above; (3)

	A review of the test volume list completed for the survey identified the laboratory performed approximately 491 RPR tests and 229 Qualitative Serum Pregnancy tests annually.
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 records and interview with the laboratory director and testing person #1, the laboratory failed to ensure proficiency testing records had been maintained; and failed to ensure proficiency testing attestation statements had been signed by the laboratory director and/or testing person for four of eight events reviewed. Findings include: (1) On 07/24/2023, a review of 2022 and 2023 proficiency testing records identified the following for three of eight events: (a) 2022 Hematology/Coagulation - First Event (i) The attestation statement had not been signed by the laboratory director and testing person(s); (ii) A copy of the results submitted to the proficiency testing program had not been maintained. (b) 2022 Microbiology - First Event (i) The attestation statement had not been signed by the laboratory director and testing person(s); (ii) A copy of the results submitted to the proficiency testing program had not been maintained. (c) 2023 Microbiology - First Event (i) A copy of the results submitted to the proficiency testing program had not been maintained. (d) 2023 Hematology/Coagulation - First Event (i) A copy of the results submitted to the proficiency testing program had not been maintained. (2) The findings were reviewed with the laboratory director and testing person #1. Both stated on 07/24/2023 at 12:40 pm, the attestation statements had not been signed and records not maintained as stated above.
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 written procedures, manufacturer's package insert, and interview with the laboratory director and testing person #1, laboratory failed to have procedures to include step-by-step performance and complete control procedures for one of one procedure reviewed. Findings include: (1) On 07/24/2023 at 03:30 pm, the laboratory director and testing person # 1 stated qualitative sickle cell testing was performed using the Streck Sickledex and blood samples; (2) A review of the package insert and "Standard Operating Procedure for Streck Sickledex Hgb Solubility Testing" identified; (a) Under the heading "Instructions for Use" the package insert stated, "If the whole blood Hematocrit is less than or equal to 15%, centrifuge the sample for 5-10 minutes at 1200 rpm"; (i) The written procedure did not include information for handling patients with less than or equal to 15% Hematocrit. (b) Under the heading "Summary and Principles" the package insert stated, "Clinical laboratories are required to establish quality control programs for automated, semi automated and manual procedures used for in vitro diagnostic testing of whole blood specimens" (i) The written procedure stated, "5.1 Perform regular quality control checks on the Streck Sickledex test as recommended by the manufacturer. 5.2 Follow the manufacturer's instructions for running internal quality controls checks of external proficiency testing, as applicable. 5.3 Record and document quality control results accurately." (ii) The procedure did not include the frequency quality control was to be performed. (c) Under the heading "Instructions for Use" the package insert stated, "Allow the working solution in the test tubes to warm to room temperature (18 C to 30 C) for a minimum of 10 minutes before use. The use of reagents below room temperature can give false results." (i) The procedure did not include information to warm the working solution in the test tubes to room temperature (18 C to 30 C) for a minimum of 10 minutes before use. (3) The findings were reviewed with the laboratory director and testing person #1. Both stated on 07/24/2023 at 03:30 pm, the procedure did not include the information as stated 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 observation and interview with the laboratory director and testing person #1, the laboratory failed to ensure collection swabs were stored as required in 19 of 19 patient rooms; and failed to ensure blood collection tubes were stored as required in

	one of one draw room. Findings include: COLLECTION SWABS (1) Observation of a patient room (#135) and interview with testing person #1 on 07/24/2023 at 10:05 am, identified the following: (a) Five eSwab COPA N Collection Preservation tubes, lot #N0234300, storage temperature of 5-25 degrees C (Centigrade). The swabs were used to collect specimens to send to a reference laboratory; (b) Three Aptima Unisex Swab Collection Kits, lot #362900V, storage temperature of 15-30 degrees C. The swabs were used to collect specimens to send to a reference laboratory; (c) One Swab Collection Kit, lot #318Q09, storage temperature of 2-30 degrees C. The swab was used to collect specimens to perform Neisseria gonorrhoeae and Chlamydia trachomatis testing using the Cepheid analyzer; (d) Two Collection Swabs, lot #220522900, storage temperature of 2-30 degrees C. The swabs were used to collect specimens to perform Neisseria gonorrhoeae and Chlamydia trachomatis testing using the Cepheid analyzer. (2) Interview with testing person #1 on 07/24/2023 at 10:07 am, confirmed the following: (a) Collection swabs, identical to the above, were stored in 19 patient rooms; (b) The temperature of the patient rooms was not being monitored. BLOOD COLLECTION TUBES (1) On 07/25/2023 at 09:40 am, observation of the draw room identified the following examples of blood collection tubes, stored in the room: (a) BD Vacutainer K2 EDTA 7.2 mg tubes - 52 tubes of lot #2259065; storage requirement of 4-25 degrees C (Centigrade); (b) BD Vacutainer SST tubes - 49 tubes of lot #308825; storage requirement of 4-25 degrees C; (c) BD Vacutainer PST Gel and Lithium Heparin tubes - 33 tubes of lot #2259093; storage requirement of 4-25 degrees C; (d) BD Vacutainer SST tubes - 25 tubes of lot #3093369; storage requirement of 4-25 degrees C. (2) Interview with the laboratory director and testing person #1 on 07/25/2023 at 11:25 am confirmed the laboratory was not monitoring the temperature of the draw room. 48517 Based on a review of records, manufacturer's instructions, and interview with the technical consultant, the laboratory failed to ensure the laboratory temperature was maintained as required by the manufacturer of the the ASI RPR (Rapid Plasma Reagin) card test for syphilis. Findings include: (1) On 07/24/2023 at 11:30 am, testing person #1 stated RPR testing was performed using the ASI RPR card test for syphilis; (2) A review of the package insert for the test system identified the manufacturer required a temperature range of 20-30 degrees Celsius; (3) A review of temperature records from January 2022 through June 2023 identified the acceptable temperature range defined by the laboratory was 15-30 degrees Celsius; (4) The records were reviewed with the technical consultant who stated on 07/24/2023 at 11:30 am, the laboratory acceptable temperature range would not detect an out of range temperature, as stated in the ASI RPR package insert.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on a review of the manufacturer's package insert, observation, and interview with testing person #1, the laboratory failed to document the open date and the contents of the ASI RPR (Rapid Plasma Reagin) carbon antigen dropping bottle. Findings include: (1) On 07/25/2023 at 11:50 am, testing person #1 stated the following: (a) RPR testing was performed using the ASI RPR Card Test for Syphilis;

	(b) The carbon antigen dropper bottle was utilized each day of patient testing. (2) Observation of the current ASI RPR test kit (ASI RPR Card Test for Syphilis lot #3C28R3, exp 12/31/24) on 06/25/2023 at 09:35 am, identified the dropping bottle had not been dated with the open date, modified expiration date, or the contents; (3) Review of the manufacturer's package insert under "Storage Instructions" showed the carbon antigen was stable for one month in the dropping bottle after opening; (4) The dropping bottle was shown to testing person #1 who stated on 07/25/2023 at 09:35 am, the dropping bottle had not been dated when opened and labeled with the contents.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation and interview with the laboratory director, the laboratory failed to ensure expired supplies were not available for use. Findings include: (1) Observation of the draw room on 07/25/2023 at 05:30 pm, identified the following expired collection tubes that appeared to be available for use: (a) Two BD Vacutainer SST tubes - lot #2145652 with an expiration date of 05/31/2023. (2) Interview with the laboratory director on 07/25/2023 at 05:30 pm. confirmed the BD Vacutainer SST tubes were available for use. 48517 Based on observation and interview with the laboratory director and testing person #1, the laboratory failed to ensure 19 of 19 COVID test kits, one of one bottle of Acetic Acid Solution, and one of one container of deionized water had not exceeded their expiration dates. Findings include: COVID TEST KITS (1) On 07/24/2023 at 09:20 am, observation of the lab coat closet in the laboratory, identified the following expired test kits that appeared to be available for use: (a) 19 boxes of Quidel QuickVue SARS COVID test kits, lot #70669 with an expiration date of 02/10/2022. (2) The laboratory director and testing person #1 stated on 07/24/2023 at 09:25 am, the test kits were available for use. ACETIC ACID SOLUTION (1) On 07/24/2023 at 09:50 am, observation of the laboratory identified the following expired reagent on the counter next to the microscope that appeared to be available for use: (a) One bottle of EDM Acetic Acid Solution lot #1119 with an expiration date of 04/29/2023. (2) Interview with the laboratory director and testing person #1 on 07/24/2023 at 09:55 am confirmed the reagent was used when performing urine microscopic testing and was available for use. DEIONIZED WATER (1) On 07/24/2023 at 10:05 am, the laboratory director and testing person #1 stated RPR (rapid plasma reagin) testing was performed using the ASI RPR Card Test for Syphilis; (2) Observation of the laboratory on 07/24/2023 at 01:28 identified the following expired material that appeared to be available for use: (a) One container of Deionized Water with an expiration date of 02/06/2020. (3) Interview with the laboratory director and testing person #1 on 07/24/2023 at 01:30 pm confirmed the Deionized Water was used to clean the carbon antigen dispensing needle for RPR testing and was available for use.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory

	must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with testing person #1, the laboratory failed to perform needle accuracy checks as defined by the manufacturer for the ASI RPR (Rapid Plasma Reagin) Card test for syphilis. Findings include: (1) On 07/24/2023 at 11:59 am, testing person #1 stated the following: (a) The laboratory performed RPR testing using the ASI RPR Card test for syphilis: (b) A needle accuracy check was performed each day of testing, by attaching the needle to the dropper bottle and counting 30 drops into the sink. (2) A review of the package insert for the ASI RPR test card for syphilis stated, "To perform accuracy check of the needle, attach the needle to a 1 or 3 ml syringe, fill the syringe with the antigen suspension and, holding the syringe in a vertical position, count the number of drops in 0.5 ml. The needle is considered satisfactory if 30 + or - one drop are obtained in 0.5 ml"; (3) On 07/24/2023 at 11:59 am testing person #1 confirmed they were not using a syringe to check the volume dispensed by the needle.
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: Based on a review of records, policies and procedures, and interview with the laboratory director and testing person #1, the laboratory failed to define a written function check protocol to ensure one of one timer was functioning properly. Findings include: (1) On 07/24/2023 at 03:45 pm, testing person #1 stated the following: (a) The laboratory performed Sickle Cell testing using the Streck Sickledex test kit; (b) The blood specimens were allowed to stand at room temperature (18 to 30 C) for at least 6 minutes (timed using the CDN504Q17R timer). (2) A function check protocol that defined the frequency of the timer checks and the acceptable limits for the checks could not be located; (3) On 07/24/2023 at 03:48 pm, testing person # 1 stated the laboratory did not have a written function check protocol but the timer was checked at least annually; (4) A review of the timer maintenance records from 2021 to the current date identified an accuracy check had not been performed since 11/08/2021; (5) The findings were reviewed with the laboratory director and testing person #1. Both stated on 07/24/2023 at 03:50 pm, the laboratory did not have a protocol for checking the accuracy of the timer and checks had not been performed as stated above. 48517 Based on a review of records, policies and procedures, and interview with the laboratory director, the laboratory failed to follow their written protocol for ensuring the urine centrifuge was functioning properly for two of two function checks performed during the review period of October 2021 through the current date. Finding

	include: (1) On 07/24/2023 at 04:30 pm, testing person #1 stated the following: (a) Urine sediment examinations were performed; (b) The specimens were processed in the Drucker Horizon centrifuge at a speed of 1700 rpm (revolutions per minute) for 5 minutes; (2) A review of the centrifuge function check records confirmed the centrifuge speed and timer were checked annually; (3) A review of the procedure titled, "Equipment maintenance", stated "A digital timer will be set for five minutes for urine specimens spun in the L.W. Scientific Ultra Select Centrifuge"; (4) A review of centrifuge function check records during 2021 through the current date identified the centrifuge timer had not been checked at time urines were processed for two of two checks performed as follows: (a) 10/20/2021 - The timer had been checked at ten minutes; (b) 10/11/2022 - The timer had been checked at ten minutes. (5) The records were reviewed with the laboratory director who stated on 07/24/2023 at 04:40 pm, the laboratory had not followed their policy.
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 and interview with the laboratory manager, the technical consultant failed to provide technical supervision in accordance with 493.1413 of this subpart. Findings include: (1) The technical consultant failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications for one of two testing persons. Refer to D6035; (2) The technical consultant failed to ensure competency evaluations for moderate complexity testing had been performed semiannually during the first year of testing for one of two testing persons. Refer to D6053.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated

	specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director, the technical consultant failed to ensure the individual who performed the duties and responsibilities of the technical consultant met the qualifications to perform competency evaluations for one of two moderate complexity testing persons. Findings include: (1) On 06/24/2023 a review of semi-annual competency evaluations for two persons identified that one of two testing persons (testing person #2) had a competency evaluation that was performed on 05/24/2023 by an individual who did not meet the regulatory qualifications of a technical consultant: (2) The records were reviewed with the laboratory director and testing person #1. Both stated on 06/24 /2023 at 11:10 am, the competency evaluation for testing person #2 had been performed by an individual who did not meet the qualifications of a technical consultant.
D6053	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 semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director and testing person #1, the technical consultant failed to ensure competency evaluations for moderate complexity testing had been performed semiannually during the first year of testing for one of two testing persons performing testing during 2022 through the current date. Findings include: (1) On 06/24/2023 a review of personnel records for two persons hired to perform moderate complexity testing after the previous recertification survey identified no evidence a semi-annual competency had been performed for one of two persons: (a) Testing Person #1 - The initial training was complete on 01/27/2022. There was no evidence a competency evaluation had been performed until 05/24/2023. (2) The records were reviewed with the laboratory director and testing person #1. Both stated on 06/24/2023 at 11:10 am, a semiannual competency evaluation had not been performed.