Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0473397	09/30/2022
Name of Provider or Supplier	**Street Address, City, State**	
Ascension St John Sapulpa	Attn Laboratory, Sapulpa, 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 09/27,28,29,30/2022. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the director of laboratory quality and laboratory manager at the conclusion of the survey.
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 policies and procedures and interview with the director of laboratory quality, the laboratory failed to have a step by step procedure for one of eight procedures reviewed. Findings include: (1) On 09/27/2022 at 11:00 am, the

	director of laboratory quality stated urine microscopic testing was performed in the laboratory; (2) On 09/28/2022, a review of the urine microscopic procedure titled, "Routine Urinalysis Clinitek Advantus" under the heading "Microscopic Examination Reporting" did not specify the speed and time to process the specimens in the centrifuge for microscopic examination of the sediment; (3) The procedure was reviewed with the director of laboratory quality who stated on 09/28/2022 at 09:47 am, the procedure did not include the speed and time the urines were to be processed for microscopic analysis.
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 policies and interview with the director of laboratory quality, the laboratory failed to ensure five of five policies had been approved, signed, and dated by the current laboratory director. Findings include: (1) On 09/27/2022 at 11:00 am, the director of laboratory qualify stated the following testing were performed in the laboratory and IQCP's (Individualized Quality Control Plans) had been developed for the test systems: (a) Urine Drug Screen Testing using the Redwood Toxicology test kit; (b) Sodium, Potassium, Ionized Calcium, Glucose, BUN, Creatinine, and CO2 testing using the Chem 8+ cartridge and the iSTAT 1 analyzer; (c) Troponin I testing using the TnI cartridge and the iSTAT 1 analyzer; (d) BNP (B-type Natriuretic Peptide) testing using the BNP cartridge and the iSTAT 1 analyzer; (e) Blood Gas (pH, pCO2, and pO2) testing using the CG4+ cartridge and the iSTAT 1 analyzer. (2) On 09/28/2022 at 01:20 pm, the director of laboratory quality stated the start date for the current laboratory director was June 2021; (3) A review of the above IQCP's identified the QCP (Quality Control Plan) for the test systems had not been approved, signed, and dated by the current laboratory director; (4) The records were reviewed with the director of laboratory quality who stated on 09/28/2022 at 01:35 pm, the QCP's for the above test systems had not been approved, signed, and dated by the current laboratory director.
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 director of laboratory quality, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures for one of five analyzers. Findings include: (1) On 09/28/2022 at 11:20 am, the director of laboratory quality stated the laboratory performed PT/INR (Prothrombin Time/International Normalized Ratio), PTT (Partial Thromboplastin Time), and D-dimer testing using the Stago Satellite analyzer; (2) On 09/29/2022, a review of the manufacturer's maintenance log showed the following manufacturer required quarterly maintenance procedure: (a)

	Replace Air Filters (3) A review of the maintenance logs from June 2021 through August 2022 identified the quarterly maintenance had not been documented as performed: (a) Between 06/24/21-12/20/21 (b) After 03/31/2022 and to date (4) The records were reviewed with the director of laboratory quality who stated on 09/29 /2022 at 02:04 pm, the quarterly maintenance had not been documented as performed as stated above.
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 and interview with the director of laboratory quality, the laboratory failed to perform quality control as stated in the IQCP's for four of five test methods. Findings include: (1) On 09/28/2022 at 11:00 am, the director of laboratory quality stated the laboratory performed the following testing and IQCP's (Individualized Quality Control Plans) had been developed for the test systems: (a) Sodium, Potassium, Ionized Calcium, Glucose, BUN, Creatinine, and CO2 testing were performed using the Chem 8+ cartridge and the iSTAT 1 analyzer; (b) Troponin I testing was performed using the TnI cartridge and the iSTAT 1 analyzer; (c) BNP (B-type Natriuretic Peptide) testing was performed using the BNP cartridge and the iSTAT 1 analyzer; (d) Blood Gas (pH, pCO2, pO2) testing was performed using the CG4+ cartridge and the iSTAT 1 analyzer. (2) A review of the QCP's (Quality Control Plans) for the above IQCP's identified the following: (a) Chem 8+ - The IQCP had been dated as approved on 09/22/2020. Two levels of QC (quality control) materials were to be tested on a monthly basis; (b) Troponin I - The IQCP had been dated as approved on on 08/22/2018. Two levels of QC materials were to be tested on a monthly basis; (c) BNP - The IQCP had been dated as approved on 08/22/2018. Two levels of QC materials were to be tested on a monthly basis; (d) Blood Gas - The IQCP had been dated as approved on 08/22/2018. Two levels of QC materials were to be tested on a monthly basis. (3) A review of QC records for the test systems from August 2021 through August 2022 identified that QC testing had not been performed as stated in the QCP's as follows: (a) Chem 8+ - There was no documentation to prove QC had been performed between: (i) 10/06/2021 and 12/24/2021 (ii) 12/24/21 and 02 /25/22 (iii) 04/07/22 and 06/01/22 (b) Troponin I - There was no documentation to prove QC had been performed between: (i) 12/21/21 and 02/06/22 (ii) 04/12/22 and 07 /15/22 (c) BNP - There was no documentation to prove QC had been performed between: (i) 12/21/21 and 02/11/22 (ii) 04/12/22 and 07/15/22 (d) Blood Gas - There was no documentation to prove QC had been performed between: (i) 04/12/22 and 06 /01/22 (4) The records were reviewed with the director of laboratory quality who stated on 06/28/2022 at 04:53 pm, QC had not been performed as stated above.
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 director of laboratory quality, the laboratory failed to follow their policy for monitoring the effectiveness of their IQCP for four of five test systems. Findings include: (1) On 09/28/2022 at 11:00 am, the director of laboratory quality stated the laboratory performed the following testing and IQCP's (Individualized Quality Control Plans) had been developed for the test systems: (a) Urine Drug Screen Testing using the Redwood Toxicology test kit; (b) Troponin I testing using the TnI cartridge and the iSTAT 1 analyzer; (c) BNP (B-type Natriuretic Peptide) testing using the BNP cartridge and the iSTAT 1 analyzer; (d) Blood Gas (pH, pCO2, pO2) testing using the CG4+ cartridge and the iSTAT 1 analyzer. (2) A review of the IQCP's identified that QA (Quality Assessment) reviews of the QCP's (Quality Control Plans) were to be performed on an annual basis; (3) A review of records for the test systems for 2020, 2021, and to date in 2022 revealed the following: (a) Urine Drug Screen - The IQCP had been approved on 03/28/2017. There was no documentation QA reviews had been performed between 01/24/2020 and 06/22/2022; (b) Troponin I - The IQCP had been approved on 08/22/2018. There was no documentation QA reviews had been performed between 01/24/2020 and 06/22 /2022; (c) BNP - The IQCP had been approved on 08/22/2018. There was no documentation QA reviews had been performed between 01/24/2020 and 06/22/2022; (d) Blood Gas - The IQCP had been approved on 11/18/2020. There was no documentation QA reviews had been performed since the implementation of the test system. (4) The records were reviewed with the director of laboratory quality who stated on 09/28/2022 at 02:41 pm, annual QA reviews had not been documented as performed as stated above.