Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0470183	07/13/2022
Name of Provider or Supplier	**Street Address, City, State**	
Saints Metro Medical Associates	100 W. Main Suite 200, Oklahoma City, 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 07/13/2022. The laboratory was found out of compliance with the following CLIA Condition of Participation: 493.1421; D6063: Testing Personnel The findings were reviewed with the directive administrator and radiology/lab technician at the conclusion of the survey.
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 radiology/lab technician, the laboratory failed to ensure an attestation statement had been signed by the analyst(s) for one of four events. Findings include: (1) A review of the first, second, and third 2021; and first 2022 Hematology proficiency testing events revealed the following: (a) First 2021 Event - The attestation statement had not been signed by the analyst(s) who tested samples HEM 03, HEM 04, and HEM 05. (2) The records were reviewed with the radiology/lab technician who stated on 07/14/2022 at 11:30 am, the attestation had not been signed by all analyst(s) performing the testing event.
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 radiology/lab technician, the laboratory failed to review and evaluate proficiency testing results for one of four events. Findings include: (1) A review of 2021 and 2022 proficiency testing records revealed the following failures: (a) First 2022 Hematology Event (i) Hemoglobin - The laboratory failed the result for one of five samples (HEM-01) resulting in a score of 80%; (ii) MCH (Mean Corpuscular Hemoglobin) - The laboratory failed the result for one of five samples (HEM-01) resulting in a score of 80%; (iii) MCHC (Mean Corpuscular Hemoglobin Concentration) - The laboratory failed the result for one of five samples (HEM-01) resulting in a score of 80%. (2) A review of the records revealed no evidence proving corrective actions had been taken for the failures; (3) The records were reviewed with the radiology/lab technician who stated on 06/13 /2022 at 11:30 am, corrective actions had not been taken.
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 radiology/lab technician, the laboratory failed to evaluate the accuracy of testing when proficiency results had not been graded by the proficiency program for one of four Microscopy events reviewed. Findings include: (1) A review of 2021 and 2022 proficiency testing records revealed the following for one of four events: (a) First 2022 Event (i) KOH - One of one result (VKP-03) stated, "See Data Summary" under "Expected Result". There was no evidence the laboratory reviewed the "Participant Summary Report" to evaluate their result. (2) The records were reviewed with the radiology/lab technician who stated on 07/13/2022 at 11:35 am, the laboratory had not evaluated the result that was not graded by the proficiency testing program.
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 and interview with the radiology/lab technician, the laboratory failed to ensure the urine centrifuge was functioning properly for five of six function checks performed. Findings include: (1) On 07/13/2022 at 10:00 am, the radiology/lab technician stated the the following: (a) Urine sediment examinations were performed in the laboratory; (b) The specimens were processed in the LW Scientific Ultra 8S centrifuge at a speed of 1800 rpm (revolutions per minute) for 5 minutes; (c) The speed and timer were checked by an outside company on a quarterly basis. (2) A review of the centrifuge records for 2021 and to date in 2022 revealed the centrifuge timer had not been checked at the time urine specimens were processed for five of six checks as follows: (a) 04/16/2021 - The centrifuge timer had been checked at 10 minutes instead of five minutes; (b) 07/07/2021 - The centrifuge timer had been checked at 10 minutes instead of five minutes; (c) 10/22/2021 - The centrifuge timer had been checked at 10 minutes instead of five minutes; (d) 01/14/2022 - The centrifuge timer had been checked at 10 minutes instead of five minutes; (e) 04/07 /2022 - The centrifuge timer had been checked at 10 minutes instead of five minutes. (3) The findings were reviewed with the radiology/lab technician who stated on 07/13 /2022 at 12:30 pm, the timer had not been checked at the time urine specimens were processed.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on a review of records and interview with the radiology/lab technician, the laboratory failed to ensure an individual who performed moderate complexity testing met the educational qualifications for one of seven persons listed on the CMS-209. Findings include: (1) The laboratory failed to a ensure testing person met the educational qualifications. Refer to D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

	This STANDARD is not met as evidenced by: Based on a review of records and interview with the radiology/lab technician and directive administrator, the laboratory failed to ensure a testing person met the educational qualifications to perform moderate complexity testing for one of seven testing persons listed on the CMS-209. Findings include: (1) On 07/13/2022 at 10:00 am, the radiology/lab technician stated CBC (Complete Blood Count) testing was performed by seven testing persons as listed on the CMS-209, Laboratory Personnel Report: (2) A review of personnel records for testing person #6 revealed no evidence of an education document to ensure the individual met the moderate complexity personnel requirements; (3) The findings were reviewed with the directive administrator who stated on 07/13/2022 at 12:05 pm, the education document was not available.