

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 37D0470183	<b>(X3) Date Survey Completed</b> 10/06/2020
<b>Name of Provider or Supplier</b> Saints Metro Medical Associates	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The recertification survey was performed on 10/06/2020. The laboratory was found out of compliance with the following CLIA regulations: 493.1421; D6063: Testing Personnel The findings were reviewed with testing person #1 at the conclusion of the survey.
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of policies and procedures, and interview with testing person #1, the laboratory failed to have written policies and procedures for assessing employee competency. Findings include: (1) During the survey, the surveyor reviewed the laboratory's policies and procedures. A policy that explained how employees were assessed for competency could not be located; (2) The surveyor asked testing person #1 if a competency policy was available for review. Testing person #1 stated to the surveyor on 10/06/2020 at 10:45 am, a policy had not been written. NOTE: For non-waived testing, the regulations require initial training, a semiannual evaluation during the first year, and an annual evaluation thereafter for each testing person for ensuring competency. The policy/procedure for evaluating competency must include, but is not limited to: *Direct observation of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing *Monitoring the recording and reporting of test results *Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records *Direct observation of performance of instrument maintenance</p>

and function checks \*Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples \*Assessment of problem solving skills

**D5217**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**

CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I 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 verify the accuracy of Wet Prep, KOH, and Urine Microscopic testing at least twice annually. Findings include: (1) At the beginning of the survey, testing person #1 stated to the following to the surveyor: (a) Wet Prep, KOH (Potassium Hydroxide) Prep, and Urine Microscopic testing were performed in the laboratory by 2 of the 5 testing persons (testing person #1 and testing person #3); (b) The procedure for verifying the accuracy of the testing twice annually consisted of the laboratory director reading a slide after the testing person, and documenting the findings to ensure they correlate. (2) The surveyor reviewed 2019 and 2020 records which showed the following: (a) Wet Prep - There was no documentation the laboratory director performed a second review for 2 of 3 dates when accuracy verification had been documented as performed: (i) 03/12/2019 - One slide had been reviewed, with the results documented by testing person #1, and one slide had been reviewed, with the results documented by testing person #2. There was no documentation the laboratory director reviewed the slides; (ii) 07/15/2019 - One slide had been reviewed, with the results documented by testing person #1, and one slide had been reviewed, with the results documented by testing person #2. There was no documentation the laboratory director reviewed the slides. (b) KOH Prep - There was no documentation the laboratory director performed a second review for 2 of 2 dates when accuracy verification had been documented as performed in 2019. In addition, there was no documentation the testing had been verified for accuracy after 07/24 /2019 and to date in 2020: (i) 03/26/2019 - One slide had been reviewed, with the results documented by testing person #1, and one slide had been reviewed, with the results documented by testing person #2. There was no documentation the laboratory director reviewed the slides; (ii) 07/24/2019 - One slide had been reviewed, with the results documented by testing person #1, and one slide had been reviewed, with the results documented by testing person #2. There was no documentation the laboratory director reviewed the slides. (c) Urine Microscopic Testing - There was no documentation the testing had been verified for accuracy in 2019 and to date in 2020. (3) The surveyor reviewed the findings with testing person #1, who stated on 10/06 /2020 at 11:20 am, there was no documentation to prove the testing had been verified for accuracy at least twice annually as stated above.

**D5401**

**PROCEDURE MANUAL**

CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:  
Based on a review of written policies and procedures, and interview with testing person #1, the laboratory failed to have written procedures for Wet Prep, KOH Prep, and Urine Microscopic testing. Findings include: (1) At the beginning of the survey, testing person #1 stated to the surveyor Wet Prep, KOH (Potassium Hydroxide) Prep, and Urine Microscopic testing were performed in the laboratory; (2) The surveyor reviewed the manual titled, "Policy and Procedure Manual" and was unable to locate written procedures for the above testing; (3) The surveyor reviewed the procedure manual with testing person #1, who stated on 10/06/2020 at 11:00 am, procedures had not been written for Wet Prep, KOH Prep and Urine Microscopic testing.

**D6049**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:  
Based on a review of records and interview with testing person #1, the technical consultant failed to ensure that evaluations included the review of test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records for 5 of 5 testing persons. Findings include: (1) At the beginning of the survey, testing person #1 stated to the surveyor CBC (Complete Blood Count) testing was performed on the Beckman Coulter AcT Diff2 analyzer; (2) The surveyor reviewed personnel records for 5 persons performing CBC testing, who had evaluations performed in 2020. For 5 of 5 persons, there was no evidence that the review of test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records had been included as part of the evaluations. The specific findings were: (a) Testing Person #1 - The evaluation form was completed on 01/21/2020; (b) Testing Person #2 - The evaluation form was completed on 02/06/2020; (c) Testing Person #3 - The evaluation form was completed on 02/06/2020; (d) Testing Person #4 - The evaluation form was completed on 07/29/2020; (e) Testing Person #5 - The evaluation form was completed on 07/29/2020. (3) The findings were discussed with testing person #1 who stated on 10/06/2020 at 10:55 am, there was no documentation to prove the evaluations above included the review of test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

**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 testing person #1, the laboratory

failed to ensure individuals who performed moderate complexity testing met the educational qualifications. Findings include: (1) The laboratory failed to ensure a 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 testing person #1 and testing person #5, the laboratory failed to ensure testing persons met the required educational qualifications to perform moderate complexity testing for 1 of 5 testing persons. Findings include: (1) At the beginning of the survey, testing person #1 stated to the surveyor CBC (Complete Blood Count) testing was performed on the Beckman Coulter AcT Diff2 analyzer by 5 testing persons (testing person #1, testing person #2, testing person #3, testing person #4, and testing person #5); (2) The surveyor reviewed personnel records for the above testing persons, with the following identified for testing person #5: (a) The testing person had been hired to perform moderate complexity testing on 07/26/2019; (b) The testing person had earned a Bachelor of Science in Nursing Degree from the Philippines; (c) There was no documentation to prove an evaluation of the person's credentials had been performed, by a nationally recognized organization, to determine the equivalency of their education compared to an education obtained in the United States, as stated at 493.2 (d). (3) The surveyor reviewed the findings with testing person #1 and testing person #5. Both stated an evaluation of the degree to determine the equivalency in the United States had not been performed.