

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0470183	(X3) Date Survey Completed 06/07/2018
Name of Provider or Supplier Saints Metro Medical Associates	Street Address, City, State 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 findings were reviewed with testing person #1 at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulations: 493.1409; D6033 Technical Consultant
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with testing person #1, the laboratory failed to thoroughly review and evaluate proficiency testing results. Findings include: (1) At the beginning of the survey, the surveyor reviewed 2016, 2017, and 2018 proficiency testing records. The following biases (the biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency testing program) were identified: (a) First 2018 Hematology Event (i) MCHC (Mean Corpuscular Hemoglobin Concentration) - 4 of 5 results exhibited a positive bias (aa) HEM - 01 - SDI 2.4 (bb) HEM - 02 - SDI 2.3 (cc) HEM - 03 - SDI 2.1 (dd) HEM - 05 - SDI 2.4 (2) The surveyor could not locate evidence in the records proving the biases had been identified and addressed; (3) The surveyor reviewed the above findings with testing person #1 who stated the biases had not been addressed.</p>
D5807	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.</p>

This STANDARD is not met as evidenced by:
Based on a review of records, and interview with testing person #1, the laboratory failed to ensure reference intervals were determined as appropriate for the laboratory's patient population. Findings include: (1) At the beginning of the survey, testing person #1 stated to the surveyor CBC (Complete Blood Count) testing was performed using the Beckman Coulter AcT Diff 2 analyzer; (2) Later during the survey, the surveyor reviewed two patient CBC reports - the first report was for an adult male patient with the testing performed on 06/07/18 at 10:55 am; the second report was for an adult female patient with the testing performed on 06/07/18 at 07:27 am. Both reports included the same reference intervals for the CBC parameters of RBC (Red Blood Cell), Hemoglobin, and Hematocrit, which were: (a) RBC - 4.00 - 6.00 10⁶/L (b) Hemoglobin - 11.0 - 18.0 g/dL (c) Hematocrit - 35 - 60% (3) The surveyor viewed the findings with testing person #1 who stated the patient reports did not include gender specific reference ranges. NOTE: Routinely, female reference intervals for the analytes RBC, Hemoglobin, and Hematocrit are lower than male reference intervals.

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 testing person #1, the technical consultant failed to provide technical oversight 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. Refer to D6035.

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 testing person #1, the technical consultant failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications. Findings include: (1) At the beginning of the survey, the surveyor reviewed records for 4 persons performing moderate complexity testing in 2016 and 2017. The records verified the evaluations for 4 of 4 persons had been performed by an individual who did not meet the regulatory qualification requirements of the technical consultant: (a) Testing Person #2 (i) The 07/28/16 evaluation had been performed by testing person #1 (this person had earned an associate degree); (ii) The 12/07/17 evaluation had been performed by testing person #1. (b) Testing Person #3 (i) The 12/07/16 evaluation had been performed by testing person #1; (ii) The 12/07/17 evaluation had been performed by testing person #1. (c) Testing Person #4 (i) The 12/07/16 evaluation had been performed by testing person #1; (ii) The 12/07/17 evaluation had been performed by testing person #1. (d) Testing Person #5 (i) The 12/07/16 evaluation had been performed by testing person #1; (ii) The 12/07/17 evaluation had been performed by testing person #1. (2) The surveyor explained to testing person #1 that all components of the competency evaluations must be performed by a person who qualifies as a technical consultant (an individual with a minimum of a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution, and at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service).