Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	28D1044038	12/28/2022
Name of Provider or Supplier	**Street Address, City, State**	
Methodist Physician Clinic - Diabetes And	7831 Chicago Court, Omaha, NE	

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
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory's Sysmex XP-300 procedure, quality assurance records, calibration verification records, and interview with the new technical consultant the laboratory failed to perform calibration on their hematology analyzer, Sysmex XP-300. 1. The laboratory's Sysmex XP-300 procedure states "calibration is performed at least every 6 months during preventative maintenance by field engineer." 2. Surveyor review of the laboratory's Quality Assurance Tracking Sheet for October 2020 and April 2021 revealed the laboratory checked off the box indicating calibration was performed on October 2020 and April 2021. 3. Surveyor review of calibration results of the Sysmex XP-300 revealed the calibration was performed on April 2020, February 2022, and August 2022. 4. Interview with the new technical consultant on 12/28/2022 at 10:28 AM confirmed the laboratory did not calibrate the Sysmex XP-300 every 6 months.
D5805	TEST REPORT CFR(s): 493.1291(c)

	The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on surveyor review of five laboratory test reports and interview with the technical consultant the laboratory failed to have the test report date on laboratory test reports. Findings are: 1. Surveyor review of five laboratory test reports revealed reports were missing the test report date. 2. Interview with the technical consultant on 12/28/2022 at 11:08 AM confirmed no test report date was included on the five laboratory test reports.
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 testing personnel competencies, CMS-209 form, and interview with the new technical consultant, as listed on the CMS-209 form, the laboratory failed to have the technical consultant position filled. 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 surveyor review of testing personnel annual competencies, CMS-209 form, and interview with the new technical consultant, as listed on the CMS-209 form, the laboratory failed to have the technical consultant position filled prior to October 13, 2022. Findings are: 1. Review of testing personnel competencies for 2022 and 2021 revealed no signature on the field for the technical consultant signature. 2. The CMS-209 form revealed the technical consultant role filled. 3. Interview with the technical consultant, as listed on the CMS-209, on 12/28/2022 at 9:53 AM revealed the technical consultant started this role after October 13, 2022. The technical consultant confirmed the laboratory failed to have the technical consultant role filled prior to October 13, 2022.