Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0865696	09/10/2020
Name of Provider or Supplier	**Street Address, City, State**	
Joseph A George Md Pc	1848 Biddle Avenue, Wyandotte, MI	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: . Based on record review and interview with the Laboratory Director, the laboratory failed to enroll in a proficiency testing program for urine creatinine testing for 9 (January 2020 to September 2020) of 9 months. Findings include: 1. An interview on 9 /10/20 at 8:56 am with the Laboratory Director revealed the laboratory started patient testing on 1/9/20. 2. A record review of the laboratory's established "Proficiency Testing" policy revealed a section stating, "The lab will enroll and participate in Proficiency Testing on an annual basis. Enrollment should occur by December of the preceding year. All regulated analytes must be enrolled in proficiency testing." 3. A review of the "Michigan Department of Licensing & Regulatory Affairs CLIA Annual Test Menu" form provided by the laboratory revealed the laboratory had not enrolled in proficiency testing for urine creatinine testing. 4. A record review of the laboratory's documents revealed a lack of proficiency testing records for urine creatinine testing. 5. The surveyor requested proficiency testing records for 2020 on 9 /10/20 at 9:41 am and the records were not made available. 6. An interview on 9/10 /20 at 9:41 am with the Laboratory Director confirmed the laboratory was not enrolled in a proficiency testing program for urine creatinine testing for 2020.

D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: . Based on observation, record review, and interviews, the laboratory failed to ensure positive identification and optimum integrity of patient's specimens for toxicology testing from the time of collection through the completion of reporting results for 22 of 22 patient aliquots observed by the surveyor. Findings include: 1. An observation by the surveyor on 9/10/20 at 9:05 am revealed a test tube rack of 22 uncapped, uncovered specimen aliquots in which 12 aliquots had a first name written on the tube and 10 aliquots were blank. 2. An interview with Testing Personnel #1 on 9/10/20 at 9: 05 am revealed the specimens had been aliquoted earlier in the morning and had been in the refrigerator uncapped, uncovered, and unlabeled for approximately 2 hours. 3. A review of the laboratory's established "Internal Quality Control" procedure revealed a section titled "Specimens" which states, "Use only the specimen described in the individual test instructions. Be sure that the specimen has been properly collected, stored, and labeled with patient's first and last name as well as the date of collection." 4. An interview with the Laboratory Director on 9/10/20 at 9:05 am confirmed the urine specimen aliquots in the refrigerator were uncapped, uncovered, and not labeled according to the laboratory's procedure.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director, the laboratory failed to ensure test requisitions for urine toxicology testing contained the patient's date of birth and the tests to be performed for 9 (Patients 1-9) of 9 patient testing records audited. Findings include: 1. A review of patient testing records revealed test requisitions for urine toxicology testing did not include the patients' date of birth and the tests to be performed for the following patients with results reported: a. Patient 1 performed on 2/12/20 b. Patient 2 performed on 3/11/20 c. Patient 3 performed on 4/29

	/20 d. Patient 4 performed on 5/28/20 e. Patient 5 performed on 6/9/20 f. Patient 6 performed on 7/1/20 g. Patient 7 performed on 7/7/20 h. Patient 8 performed on 8/3 /20 i. Patient 9 performed on 9/2/20 2. An interview on 9/10/20 at 11:03 am with the Laboratory Director confirmed the test requisitions did not contain patients' date of birth or the tests to be performed.
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 record review and interview with the Laboratory Director, the laboratory failed to have written procedures for each assay performed for 9 (January 2020 to September 2020) of 9 months since the laboratory has started testing patients. Findings include: 1. An interview on 9/10/20 at 8:56 am with the Laboratory Director revealed the laboratory started patient testing on 1/9/20. 2. A review of the laboratory's established procedure manual revealed a lack of procedures to perform the following tests listed on the "Michigan Department of Licensing & Regulatory Affairs CLIA Annual Test Menu" form provided by the laboratory: a. 6-Acetylmorphine b. Amphetamines c. Benzodiazepine d. Buprenorphine e. Cocaine f. Creatinine g. Methadone h. Oxycodone i. Opiates 3. The surveyor requested the approved procedures to perform the assays listed above on 9/10/20 at 10:15 am and they were not made available. 4. An interview on 9/10/20 at 11:03 am with the Laboratory Director confirmed the laboratory did not have procedures established for performing the tests listed above.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

	This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director, the laboratory failed to perform urine creatinine calibration verification at least every 6 months for 1 (July 2020) of 2 calibration verification events required. Findings include: 1. A record review of the laboratory's verification of urine creatinine testing revealed calibration verification was performed on 1/8/20. 2. On 9/10/20 at 10:13 am the surveyor requested the urine creatinine calibration verification documentation and the calibration verification procedures, and they were not made available. 3. An interview on 9/10/20 at 10:13 am with the Laboratory Director confirmed urine creatinine calibration verification procedures were not performed every 6 months.
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: . A. Based on record review and interview with the Laboratory Director, the laboratory failed to issue corrected reports for 45 patients receiving urine toxicology testing when Oxycodone quality control was out of range. Findings include: 1. A review of quality control records revealed Oxycodone quality control testing did not pass on 2/12/20. 2. A review of the laboratory's corrective action from the 2/12/20 quality control failure revealed the laboratory had 45 patients' testing repeated. 3. A review of Patient 1's chart revealed the original report dated 2/12/20 and repeated report dated 2/24/20 did not contain information about Oxycodone reporting errors from 2/12/20, that the 2/24/20 report was the corrected report to the 2/12/20 initial report, or that the ordering physician was notified of the Oxycodone reporting errors. 4. A review of the laboratory's established "In-House Laboratory Error Correction Procedure" revealed a section stating, "The laboratory technician will be notified when a lab error is found. the technician will then correct the error and initial the report form. The ordering physician will then be notified and he will also initial the report form. All errors will be described on the lab error report form and records will be saved for two years. 5. An interview on 9/10/20 at 11:03 am with the Laboratory Director confirmed the laboratory did not follow its procedure while correcting patient test reports. B. Based on record review and interview with the Laboratory Director, the laboratory failed to follow laboratory procedure when correcting a patient test report for 1 (Patient 1) of 9 patients reviewed. Findings include: 1. A review of patient testing records revealed Patient 1 had the last name crossed out with a different last name next to it. 2. A review of the laboratory's established "In-House Laboratory Error Correction Procedure" revealed a section stating, "The laboratory technician will be notified when a lab error is found. the technician will then correct the error and initial the report form. The ordering physician will then be notified and he will also initial the report form. All errors will be described on the lab error report form and

	records will be saved for two years. 3. An interview on 9/10/20 at 10:13 am with the Laboratory Director confirmed the laboratory did not follow its procedure while correcting patient test reports.