

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0865696	(X3) Date Survey Completed 04/20/2022
Name of Provider or Supplier Joseph A George Md Pc	Street Address, City, State 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
D5022	<p>TOXICOLOGY CFR(s): 493.1213</p> <p>If the laboratory provides services in the subspecialty of Toxicology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: . Based on record review and interviews, the laboratory failed to meet the requirements for the specialty Toxicology as specified in 493.1230 through 493.1256 and 493.1281 through 493.1299. Findings include: 1. The laboratory failed to follow written policies to ensure patient specimens did not exceed specimen stability. Refer to D5203 A.</p>
D5203	<p>SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . A. Based on observation, record review, and interview with the Technical Consultant, the laboratory failed to follow written policies to ensure patient specimens did not exceed specimen stability for 7 (Patients 3-9) of 10 patient test records reviewed. Findings include: 1. A review of the laboratory's "Siemens Buprenorphine Assay" manufacturer instructions revealed a section titled "Specimen Collection and Preparation" stating, "If not analyzed immediately, specimens may be stored</p>

refrigerated or unrefrigerated for up to 5 days. After 5 days specimens should be frozen at -20 degrees C." 2. A review of the laboratory's "Siemens Oxycodone Assay" manufacturer instructions revealed a section titled "Specimen Collection and Preparation" stating, "If not analyzed immediately, specimens may be stored refrigerated or unrefrigerated for up to 7 days. After 7 days specimens should be stored at -20 degrees C." 3. A review of 10 patient test reports revealed the following patients had qualitative urine drug testing, including Buprenorphine and Oxycodone, after their specimens had gone beyond the manufacturer's specified stability: a. Patient #3 had a specimen collected on 2/8/22 and was tested on 2/14/22. b. Patient #4 had a specimen collected on 4/14/22 and had not been tested yet. c. Patient #5 had a specimen collected on 3/25/21 and was tested on 4/5/21. d. Patient #6 had a specimen collected on 11/25/20 and was tested on 12/8/20. e. Patient #7 had a specimen collected on 9/30/20 and was tested on 10/8/20. f. Patient #8 had a specimen collected on 7/23/20 and was tested on 8/3/20. g. Patient #9 had a specimen collected on 4/28/20 and was tested on 5/4/20. 4. An interview on 4/20/22 at 10:15 am with the Technical Consultant confirmed the laboratory stores its specimens refrigerated and the specimens had been tested beyond their manufacturer-specified stability. ***This is a repeated deficiency from the 9/10/20 initial survey***

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 Technical Consultant, the laboratory failed to use criteria verified or established by the laboratory to assess calibration verification acceptability for 2 (5/5/21 and 12/22/21) of 2 calibration verification testing events performed. Findings include: 1. A review of the laboratory's calibration verification records revealed a lack of acceptance criteria used to determine whether the calibration verification testing had passed or failed for the testing events on 5/5/21 and 12/22/21 for its urine creatinine testing. 2. A review of the laboratory's "Calibration Verification" policy revealed the laboratory did not establish criteria for calibration verification acceptability. 3. An interview on 4/20/22 at 11:18 am with the

Technical Consultant confirmed the laboratory had not verified or established criteria to assess calibration verification acceptability. ***This is a repeated deficiency from the 9/10/20 initial survey***