

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D1042264	(X3) Date Survey Completed 04/26/2023
Name of Provider or Supplier Great Lakes Labs, Llc	Street Address, City, State 1051 Transport Dr, Valparaiso, IN	
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to establish a policy /procedure or perform twice annual accuracy verification for one of one assay (PGX - Pharmacogenomics DNA Isolation) not included in subpart I from March 2020 to April 26, 2023. Findings include: 1) Review of "Enclosure I TEST METHODOLOGY AND ANNUAL TEST VOLUME LOG," signed and dated by the laboratory director on 4/23/2023, indicated PGX (Pharmacogenomics DNA Isolation) testing was being performed on the Agena BioScience instrument to detect appropriate medication for patients. 2) Upon request for a policy/procedure for twice annual verification of PGX testing on 4/26/23 at 3:15 pm, SP-3 (Testing Person) indicated none was available. SP-3 confirmed the last PGX test was reported on 4/8 /2022. No PGX testing has occurred in 2023. 3) Medical record review indicated the following patients had PGX testing performed: PT=patient PT Report Date a) PT#13 4 /8/2022 b) PT#14 3/24/2022 4) During interview on 4/26/23 at 3:30 pm, SP-1 (General Supervisor) confirmed the laboratory failed to establish a policy/procedure for twice annual verification of PGX testing (not included in Subpart I). SP-1 further indicated testing occurred beginning 3/20/20. No policy/procedure was in place for twice annual verification in 2020 to April 26, 2023, and no twice annual verification occurred in 2020 through 2022. The laboratory plans to continue PGX testing in 2023. 5) Approximate annual test volume for PGX Testing is 5.</p>