

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2194915	(X3) Date Survey Completed 10/10/2022
Name of Provider or Supplier Phenomix Health Inc	Street Address, City, State 46701 Commerce Center Dr, Plymouth, 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
D2006	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director and Testing Personnel #2, the laboratory failed to treat proficiency testing samples in the same manner as it tests patient samples for 4 (ZE-A, T-A, C-A, and C-B) of 4 proficiency testing events reviewed. Findings include: 1. A review of the laboratory's College of American Pathologists' Proficiency Testing documentation revealed a lack of test reports for the proficiency testing samples showing the results going through the laboratory's laboratory information management system for the following testing events: a. 2022 ZE-A b. 2022 T-A c. 2022 C-A d. 2022 C-B 2. An interview on 10/10/22 at 1:57 pm with Testing Personnel #2 and the Laboratory Director revealed the data from the proficiency testing samples are not exported back through the laboratory's information management system, like a patient would have been, but are instead immediately entered into the proficiency testing website.</p>
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p>

This STANDARD is not met as evidenced by:
. Based on record review and interview with the Laboratory Director, the laboratory failed to document the evaluation of ungraded proficiency testing results for 3 (ZE-A, T-A, and C-A) of 4 proficiency testing events reviewed. Findings include: 1. A review of the laboratory's College of American Pathologists' Proficiency Testing documentation revealed the following events had ungraded results from the proficiency testing provider and a lack of a documented evaluation of the laboratory's results to verify its accuracy of testing: a. 2022 ZE-A b. 2022 T-A c. 2022 C-A 2. An interview on 10/10/22 at 2:10 pm with the Laboratory Director confirmed the laboratory had not performed and documented the ungraded results from the proficiency testing provider for the events listed above.

D5293

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1239(b)(c)

(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.

This STANDARD is not met as evidenced by:
. Based on record review and interview with the Laboratory Director, the laboratory failed to document quality assessment activities for 4 (December 2021 to April 2022) of 4 months reviewed. Findings include: 1. A review of the laboratory's "Quality Management Plan" revealed a section stating, "The Quality Management Program evaluates and monitors the quality and appropriateness of services it provides. The goal is to ensure the accuracy, precision and reliability of results originating from the Laboratory for the physicians who refer patients for patient medication profiling and therapeutic drug monitoring. Management, administration, statistical analysis and preventative/corrective action in part form the core of the Quality Management Program. The prevention of quality problems rather than the detection and correction of problems after they occur is facilitated by an ongoing monitoring process" and a section stating, "Schedule reviews and conduct them according to the schedule. a Perform all monthly quality management activities listed on the review schedule." 2. A review of the laboratory's records revealed a lack of documentation showing the laboratory had been performing quality assessment monitoring as part of its quality management plan. 3. An interview on 10/10/22 at 1:56 pm with the Laboratory Director confirmed the laboratory had not documented its quality assessment reviews as part of the quality management plan.