

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2051927	(X3) Date Survey Completed 10/14/2021
Name of Provider or Supplier Pan Laboratories	Street Address, City, State 15375 Barranca Pkwy Ste E101, Irvine, CA	
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	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: 2000 Failure to enroll Conditional Based on a review of the laboratory proficiency testing results in 2019 and 2020 and the lack of documentation related to proficiency testing (PT) program and an interview with the Technical Specialist (TS), it was determined that the laboratory failed to enroll in proficiency testing (PT) for Cycle 2 of 2019 for selected non-regulated analytes. The laboratory inspection occurred on 10/14/21 between 10 a.m. and 11:45 a.m. Findings include: 1. The split-sample PT testing results were reviewed for 2019 and 2020. 2. The TS indicated that they utilize Esoterix Laboratories (CLIA participant) for split-sample PT. 3. There were no split sample PT results for Cycle 2 of 2019 for the following analytes: - Gonadotropin Releasing Hormone - Anti-Annexin 5 - CEA Pancreatic Cyst Fluid - Androsterone, Serum - Beta Melanocyte Stimulating Hormone - Matrix Metalloproteinase-9 - Growth Hormone Binding Protein 4. At approximately 11:00 a.m. on 10/14/21, the TS affirmed that they did not have results for the indicated analyte PT testing for Cycle 2 2019. 5. Split level and AAB (American Association of Bioanalysts) PT results were complete for other analytes in 2019 and 2020.</p>
D6015	LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory proficiency testing results in 2019 and 2020 and the lack of documentation related to proficiency testing (PT) program and an interview with the Technical Specialist (TS), it was determined that the laboratory failed to enroll in proficiency testing (PT) for Cycle 2 of 2019 for selected non-regulated analytes. The laboratory inspection occurred on 10/14/21 between 10 a.m. and 11:45 a.m. Findings include: 1. The laboratory director did not ensure that the laboratory was enrolled in an HHS approved proficiency program for each testing cycle. 2. See D 2000.