

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D0704110	(X3) Date Survey Completed 08/29/2023
Name of Provider or Supplier Nih Niddk Pecrb Decrs	Street Address, City, State 1550 E Indian School Rd, Phoenix, AZ	
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
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on the number and severity of the deficiency cited herein, the Condition: Successful [Proficiency Testing] Participation was not met. The laboratory failed to successfully participate in a proficiency testing program approved by CMS for each analyte or test in which the laboratory is certified under CLIA (see D2096).</p>
D2096	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</p> <p>Failure to achieve satisfactory performance for the same analyte or test in two</p>

consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on laboratory personnel interviews and proficiency testing record review on August 29, 2023 at 09:30 am, the laboratory failed to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive proficiency testing events. Findings included: a. First Occurrences of Unsuccessful Proficiency Testing Performance: i. For the following analytes or tests, the laboratory failed to achieve satisfactory proficiency testing performance (i.e., obtain a minimum proficiency testing score of 80%) in two consecutive proficiency testing events or two out of three consecutive proficiency testing events constituting first occurrences of unsuccessful proficiency testing performance: ALT (SGPT), Albumin, ALP, AST (SGOT), Bilirubin - total, Calcium - total, Chloride, Cholesterol - total, Creatinine, Glucose (non-waived), Potassium, Sodium, Total Protein, Triglyceride, BUN, and Uric Acid. ii. For these analytes or tests, the laboratory received scores of 0% for the third event of 2022 and scores of 0% for the first event of 2023. b. Subsequent Occurrence of Unsuccessful Proficiency Testing Performance: i. For the following analyte or test, the laboratory failed to achieve satisfactory proficiency testing performance (i.e., obtain a minimum proficiency testing score of 80%) in two consecutive proficiency testing events or two out of three consecutive proficiency testing events constituting a subsequent occurrence of unsuccessful proficiency testing performance: Cholesterol - HDL. ii. For this analyte, the laboratory received a score of 0% for the third event of 2022, a score of 0% for the first event of 2023, and 60% for the second event of 2023. c. According to laboratory records, the laboratory performs and reports approximately 15,500 patient routine chemistry tests annually.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on the number and severity of the deficiency cited herein, the Condition: Laboratories Performing Moderate Complexity Testing - Laboratory Director was not met. The laboratory director failed to ensure that proficiency testing samples were tested as required under Subpart H of this part (see D6016).

D6016

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(i)

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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:
Based on laboratory personnel interviews and proficiency testing record review on August 29, 2023 at 09:30 am, the laboratory director failed to ensure that proficiency testing samples were tested as required under Subpart H of this part. Findings included: The laboratory failed to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive proficiency testing events. See D2016.