

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D1100953	(X3) Date Survey Completed 09/08/2023
Name of Provider or Supplier Renal Consultants Pllc	Street Address, City, State 24 Maccorkle Avenue Sw Suite 201, South Charleston, WV	
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
D0000	A proficiency testing (PT) desk review was performed for Renal Consultants PLLC on September 8, 2023, by the West Virginia Office of Laboratory Services. The laboratory PT evaluations with the American Proficiency Institute (API) were reviewed for compliance with the Federal Clinical Laboratory Improvement Amendments (CLIA) regulations under 42 CFR 493. Specific deficiencies are explained below.
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 review of the proficiency testing (PT) records from the American</p>

Proficiency Institute (API) and the CMS CASPER 153D Unsuccessful PT Report, the laboratory failed to successfully participate in PT for the analyte #0765 CELL ID or WBC DIFF for two of three consecutive events. Findings: 1. CMS CASPER 153D report revealed the following unsuccessful participation in two of three consecutive events for analyte #0765 CELL ID or WBC DIFF: 28% Event 3 2022 40% Event 2 2023 2. API evaluation summary confirmed the unsatisfactory scores of 28% and 40% in two of three consecutive events for the analyte #0765 WBC DIFF and the unsuccessful performance of the laboratory.

D2131

HEMATOLOGY
CFR(s): 493.851(g)

Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:
Based on review of the proficiency testing (PT) records from the American Proficiency Institute (API) and CMS CASPER 155D Individual Laboratory Profile (PT Report), the laboratory produced unsatisfactory results for analyte #0765 WBC DIFF for two of three consecutive testing events. Findings: 1. Review of API evaluation scores and CASPER 155D identified the following unsatisfactory scores for analyte #0765 WBC DIFF: 28% Event 3 2022 40% Event 2 2023