

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D0546491	<b>(X3) Date Survey Completed</b>  05/01/2025
<b>Name of Provider or Supplier</b>  Comprehensive Urology Medical Group	<b>Street Address, City, State</b>  8631 W 3rd St Ste 1115e, Los Angeles, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A proficiency testing desk review survey was performed on 05/01/2025, the laboratory was found not in compliance with the following CONDITION LEVEL DEFICIENCIES D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing]; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director.
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> 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 Certification and Survey Provider Enhanced Reporting (CASPER) - 0155D and AAB-Medical Laboratory Evaluation (AAB) and American Proficiency Institute (API) records (2024-2, 2024-3, and 2025-1), the laboratory failed</p>

	<p>to successfully participate in a proficiency testing program approved by HHS for each specialty, subspecialty and analyte or test in which the laboratory is certified under CLIA, the laboratory failed to successfully participate in the specialty of Hematology for the analytes: RBC, HCT, HGB, WBC COUNT, and PLATELETS resulting in subsequent unsuccessful performances. Refer to D2130 and D2131.</p>
<p><b>D2130</b></p>	<p><b>HEMATOLOGY</b> CFR(s): 493.851(f)</p> <p>(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on desk review of Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile, API and AAB evaluation reports, the laboratory failed to achieve satisfactory performances for three consecutive events in 2024 and 2025, resulting in subsequent unsuccessful performances. The laboratory received the following scores: a. RBC, analyte: 2024-2 API 0%, 2024-3 API 0%, and 2025-1 AAB 0%; b. HCT, analyte: 2024-2 API 0%, 2024-3 API 0%, and 2025-1 AAB 0%; c. HGB, analyte: 2024-2 API 0%, 2024-3 API 0%, and 2025-1 AAB 0%; d. WBC COUNT, analyte: 2024-2 API 0%, 2024-3 API 0%, and 2025-1 AAB 0%; e. PLATELETS, analyte: 2024-2 API 0%; 2024-3 API 0%, and 2025-1 AAB 0%. A review of the 2024 and 2025 Proficiency Testing scores from API and AAB-Medical Laboratory Evaluation confirmed the above findings.</p>
<p><b>D2131</b></p>	<p><b>HEMATOLOGY</b> CFR(s): 493.851(g)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile and API and AAB evaluation reports, the laboratory failed to achieve overall testing event scores of satisfactory performance for consecutive events (2024-2, 2024-3, and 2025-1) resulting in subsequent unsuccessful for the specialty of Hematology. The finding include: Hematology: 2024-2 API 0%, 2024-3 API 0%, and 2025-1 AAB 0%;</p>
<p><b>D6000</b></p>	<p><b>MODERATE COMPLEXITY LABORATORY DIRECTOR</b> CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on a proficiency testing desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) - 0155D report API and AAB records for 2024-2,</p>

2024-3 and 2025-1 events, the laboratory director failed to provide overall management and a direction of the laboratory services. Refer to D6016.

**D6016**

**LABORATORY DIRECTOR RESPONSIBILITIES**

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

(e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:  
Based on a proficiency testing desk review of Certification and Survey Provider Enhanced Reporting (CASPER) - 0155D report API & AAB records for 2024-2, 2024-3 and 2025-1 events, the laboratory director failed to ensure successful participation in an HHS approved proficiency testing programs. Refer to D2130 and D2131.