

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2040074	(X3) Date Survey Completed 06/18/2025
Name of Provider or Supplier Harris Medical Services, Llc	Street Address, City, State 3328 Jenkins Rd, Ste 200, Chattanooga, TN	
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 desk review survey conducted on 06/18/2025 of proficiency scores resulted in the following deficiencies. The laboratory was found to be out of compliance with the following conditions: D2016- 493.803 Condition: Successful participation D6000-493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director. .
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 a desk review survey of proficiency testing (PT) records from the Certification and Survey Provider Enhanced Reporting (CASPER) 0155 report and the American Proficiency Institute (API) proficiency testing records, the laboratory</p>

	<p>failed to successfully participate in the White Blood Cell (WBC) Count analyte and the Hematology specialty. Refer to D2130 and D2131. .</p>
<p>D2130</p>	<p>HEMATOLOGY 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 a proficiency testing desk review of the CASPER 0155 report and the API 2024 and 2025 PT records, the laboratory failed to achieve satisfactory performance (80% or better) for the same analyte in two out of three consecutive testing events in the specialty of Hematology for the White Blood Cell (WBC) Count analyte. The findings include: 1. A review of the CASPER 0155 report revealed the following results: 2024 Event Two: The laboratory received an unsatisfactory score of 0% for WBC Count 2025 Event One: The laboratory received an unsatisfactory score of 60% for WBC Count 2. A review of the API 2024 and 2025 proficiency testing records (2024 Hematology/Coagulation- 2nd Event and 2025 Hematology/Coagulation - 1st Event) confirmed that the laboratory received the above results. .</p>
<p>D2131</p>	<p>HEMATOLOGY 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 a proficiency testing desk review of the CASPER 0155 report and the API 2024 and 2025 PT records, the laboratory failed to achieve satisfactory overall performance (80% or better) in two out of three consecutive testing events for the specialty of Hematology. The findings include: 1. A review of the CASPER 0155 report revealed the following results: 2024 Event Two: The laboratory received an overall unsatisfactory score of 0% for Hematology 2025 Event One: The laboratory received an overall unsatisfactory score of 60% for Hematology 2. A review of the API 2024 and 2025 proficiency testing records (2024 Hematology/Coagulation- 2nd Event and 2025 Hematology/Coagulation - 1st Event) confirmed that the laboratory received the above results. .</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR 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 CASPER 0155 report and the API 2024 and 2025 records, the laboratory director failed to provide overall management</p>

and direction of the laboratory services. The laboratory director failed to ensure that proficiency testing samples were tested as required. 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 the CASPER 0155 report and the API 2024 and 2025 records, the laboratory director failed to ensure proficiency testing samples were tested as required. The laboratory director failed to ensure successful participation in an HHS approved proficiency testing program. Refer to D 2130 and D2131. .