

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  04D2161175	<b>(X3) Date Survey Completed</b>  01/14/2026
<b>Name of Provider or Supplier</b>  Unity Health Harris Medical Clinic	<b>Street Address, City, State</b>  1200 Mclain St, Newport, AR	
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>	<p>A proficiency testing desk review was performed January 14th, 2026 and the laboratory was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: D2016 - 42 Code of Federal Regulations (C.F.R.) 493.803 Condition: Successful participation (proficiency testing) D6016 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director. The following acronyms will be utilized in this report: API - American Proficiency Institute CASPER - Certification and Survey Provider Enhanced Reporting CLIA - Clinical Laboratory Improvement Act CMS - Centers for Medicare and Medicaid Services HHS - Department of Health and Human Services WBC-DIFF - White Blood Cell Differential RBC - Rec Blood Cell Count HCT - Hematocrit HGB - Hemoglobin WBC - White Blood Cell Count PLT - Platelet</p>
<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 2025 CMS CASPER Reports 0155D, and API records (2025-2nd and 2025-3rd), the laboratory failed to achieve satisfactory performance in a proficiency program approved by the HHS for each specialty, subspecialty, and analyte or test in which the laboratory is certified under the CLIA. The laboratory failed to successfully participate in the specialty of Hematology for the analytes WBC-DIFF, RBC, HCT, HGB, WBC, and PLT. Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events is unsuccessful performance as cited at D2131 and 2130.</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 review of the CMS CASPER Reports 0155D and API proficiency testing results, the laboratory failed to achieve satisfactory performance for two of two consecutive testing events (2025-2 and 2025-3) proficiency testing for the analytes RBC, HCT, HGB, WBC, and PLT. Survey Findings follow: A. A review of CASPER 0155D reports revealed the following results for two of two testing events for RBC, HCT, HGB, WBC and PLT: RBC 2025-2:60% 2025-3:0% HCT 2025-2:60% 2025-3:0% HGB 2025-2:60% 2025-3:0% WBC 2025-2:60% 2025-3:0% PLT 2025-2:60% 2025-3:0% B. A review of CASPER 0155D reports revealed the following results for two of two testing events for WBC-DIFF: 2025-2: 67% 2025-3: 0% C. A review of API records confirmed the 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 CMS CASPER Reports 0155D and API proficiency testing results, the laboratory failed to achieve satisfactory performance for two of two consecutive testing events (2025-2 and 2025-3) proficiency testing for the specialty of hematology. Survey Findings follow: A. A review of CASPER 0155D reports revealed the following results for two of two testing events for overall hematology: 2025-2:61% 2025-3:0% B. A review of API records confirmed the findings.</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>

This CONDITION is not met as evidenced by:  
Based on review of CMS 0155D and API proficiency testing results for 2025, the laboratory director failed to provide overall management and direction of the laboratory services. The laboratory director failed to ensure that the proficiency testing samples are tested as required under Subpart H of this part. 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 review of the 2025 Casper CMS 0155D and API proficiency testing event results, the laboratory director failed to ensure the laboratory successfully participated in proficiency testing in an HHS approved proficiency testing program for WBC-DIFF, RBC, HCT, HGB, WBC, PLT and the specialty of Hematology. Refer to D2130 and D2131.