

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0672796	(X3) Date Survey Completed 02/07/2025
Name of Provider or Supplier Monmouth Hematology Oncology	Street Address, City, State 456 Chestnut Street, Lakewood, NJ	
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 desk review survey was performed on February 7, 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
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 CASPER report 155 and the American Proficiency Institute (API), the laboratory failed to successfully participate in four out of six Proficiency Testing (PT) events in the subspecialty Hematology for analyte Cell Identification or</p>

	<p>White blood Cell Differential resulting in non-initial unsuccessful performance. Refer to D2130.</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 review of the CASPER 155 report and graded results from American Proficiency Institute (API), the laboratory failed to achieve satisfactory performance (80% or greater) for four out of six events in the subspecialty Hematology for the analyte Cell Identification or White blood Cell Differential (CELL ID or WBC DIFF) resulting in non-initial unsuccessful performance. The findings include: 1) A review of the CASPER 155 report revealed the following. a) The laboratory scored 33% for CELL ID or WBC DIFF in event 1-2022. b) The laboratory scored 33% for CELL ID or WBC DIFF in event 2-2022. c) The laboratory scored 76% for CELL ID or WBC DIFF in event 1-2023. d) The laboratory scored 72% for CELL ID or WBC DIFF in event 3-2023. 2. A review of API graded results confirmed the laboratory failed four out of six Proficiency Testing (PT) events.</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 review of the CASPER 155 report and graded results from American Proficiency Institute (API), the Laboratory Director (LD) failed to provide overall management and direction to laboratory personnel to ensure that the Proficiency Testing (PT) surveys are performed satisfactorily and in compliance with Clinical Laboratory Improvement Amendments (CLIA) regulations. The findings include: 1. The LD failed to ensure PT surveys are performed satisfactorily and in compliance with CLIA regulations. Refer to D6016.</p>
<p>D6016</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</p> <p>(e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part;</p> <p>This STANDARD is not met as evidenced by: Based on a review of the CASPER 155 report and graded results from American Proficiency Institute (API), the Laboratory Director (LD) failed to ensure successful participation in a Department of Health and Human Services (DHHS) approved</p>

Proficiency Testing (PT) program for four out of six PT events for subspecialty Hematology for the analyte Cell Identification or White blood Cell Differential resulting in subsequent unsuccessful performance. Refer to D2130.