

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D0678428	(X3) Date Survey Completed 12/02/2025
Name of Provider or Supplier Iu Health Lab Services Landmark Pediatrics	Street Address, City, State 350 S Landmark Ave, Bloomington, IN	
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 completed on 12/02/2025. It was determined that the following condition-level deficiencies existed: 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 the proficiency testing desk review (PTDR) of the CASPER report 0155D from the Centers for Medicare and Medicaid Services (CMS) data system and an email from the Technical Consultant (SP-1) on 11/26/25, the laboratory failed to</p>

	<p>achieve satisfactory performance for two consecutive testing events (Event 2/CAP-FH16-B=0% of 2025 and Event 3/CAP-FH16-C=60% of 2025) resulting in unsuccessful participation in the specialty of Hematology for the analyte, RBC (red blood cell). Refer to D2130. Legend: CAP=College of American Pathologist, FH16-B=Event 2, FH16-C=Event 3.</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 the proficiency testing desk review (PTDR) of the CASPER report 0155D from the Centers for Medicare and Medicaid Services (CMS) data system and an email from the Technical Consultant (SP-1) on 11/26/25, the laboratory failed to achieve satisfactory performance for two consecutive testing events (Event 2/CAP-FH16-B=0% of 2025 and Event 3/CAP-FH16-C=60% of 2025) resulting in unsuccessful participation in the specialty of Hematology for the analyte, RBC (red blood cell). Findings include: 1) Review of CASPER report 0155D indicated the following unsuccessful scores for the analyte RBC in the specialty of Hematology: a) Event 2/2025=0% b) Event 3/2025=60% 2) Email received on 11/26/25 at 3:57 pm from SP-1, confirmed the failing scores for the analyte, RBC on the College of American Pathologist (CAP) proficiency test results for Event 2 (FH16-B=0%) and Event 3 (FH16-C=60%) for 2025.</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 the proficiency testing desk review (PTDR) of the CASPER report 0155D from the Centers for Medicare and Medicaid Services (CMS) data system and an email from the Technical Consultant (SP-1) on 11/26/25, the laboratory director (SP-2) failed to ensure satisfactory performance for two consecutive testing events (Event 2/CAP-FH16-B=0% of 2025 and Event 3/CAP-FH16-C=60% of 2025) resulting in unsuccessful participation in the specialty of Hematology for the analyte, RBC (red blood cell). 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 surveyor proficiency testing desk review (PTDR) of the CASPER report</p>

0155D from the Centers for Medicare and Medicaid Services (CMS) data system and an email from the Technical Consultant (SP-1) on 11/26/25, the laboratory director (SP-2) failed to ensure satisfactory performance for two consecutive testing events (Event 2/CAP-FH16-B=0% of 2025 and Event 3/CAP-FH16-C=60% of 2025) resulting in unsuccessful participation in the specialty of Hematology for the analyte, RBC (red blood cell). Refer to D2130.