

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0468338	(X3) Date Survey Completed 06/09/2026
Name of Provider or Supplier Baxter Health Fulton County Hospital	Street Address, City, State 679 N Main St, Salem, AR	
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 was performed June 9th, 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) D6000 - 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 INF MONO - Infectious Mononucleosis
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 the 2025 and 2026 CMS CASPER Reports 0155D, and API records (2025-2 and 2026-1), 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 immunology for the analyte INF MONO, and the overall specialty of General Immunology. Failure to achieve satisfactory performance for the same analyte or test in two of three consecutive testing events is unsuccessful performance as cited at D2084. Failure to achieve overall satisfactory performance for the same specialty in two of consecutive testing events is unsuccessful performance as cited at D2076.</p>
D2076	<p>GENERAL IMMUNOLOGY CFR(s): 493.837(b)</p> <p>(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of the 2025 and 2026 CMS CASPER Reports 0155D and API proficiency testing results, the laboratory failed to achieve overall satisfactory performance for two of three consecutive testing events (2025-2 and 2026-1) of proficiency testing for the specialty of General Immunology. Survey Findings follow: A. A review of CASPER 0155D reports revealed the following results for two of three testing events for the overall score in general immunology: 2025-2: 0% 2026-1: 60% B. A review of API records confirmed the findings.</p>
D2084	<p>GENERAL IMMUNOLOGY CFR(s): 493.837(f)</p> <p>(f) Failure to achieve satisfactory performance for the same analyte or test in 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 2025 and 2026 CMS CASPER Reports 0155D and API proficiency testing results, the laboratory failed to achieve satisfactory performance for two of three consecutive testing events (2025-2 and 2026-1) proficiency testing for the analyte INF MONO. Survey Findings follow: A. A review of CASPER 0155D reports revealed the following results for two of three testing events for INF MONO: 2025-2: 0% 2026-1: 60% B. A review of API records confirmed the findings.</p>
D6000	<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>

This CONDITION is not met as evidenced by:
Based on review of CMS 0155D and API proficiency testing results for 2025 and 2026, 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 the 2025 and 2026 proficiency testing event results, the laboratory director failed to ensure the laboratory successfully participated in proficiency testing for the Immunology test INF MONO and the overall specialty of General Immunology . Refer to D2076 and D2084.