

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  15D0955355	<b>(X3) Date Survey Completed</b>  10/23/2025
<b>Name of Provider or Supplier</b>  Fort Wayne Endocrinology	<b>Street Address, City, State</b>  5010 W Jefferson Blvd, Fort Wayne, IN	
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>	A proficiency testing desk review survey was completed on 10/23/2025. 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
<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 surveyor proficiency testing (PT) desk review of the laboratory PT records, the American Proficiency Institute (API) Evaluation Reports, and CASPER Report 0155D from the Centers for Medicare and Medicaid Services (CMS) data system, and</p>

emails from SP-1 (General Supervisor, Technical Supervisor, Testing Personnel) on 10/24/2025, the laboratory failed to achieve satisfactory performance in two consecutive testing events (Event 1 of 2025 and Event 2 of 2025) resulting in unsuccessful participation in the subspecialty of General Immunology and the analyte C-Reactive Protein (CRP) in 2025. Refer to D2076.

**D2076**

**GENERAL IMMUNOLOGY**  
CFR(s): 493.837(b)

(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

This STANDARD is not met as evidenced by:  
Based on surveyor proficiency testing (PT) desk review of the laboratory PT records, the American Proficiency Institute (API) Evaluation Reports, CASPER reports 0153D and 0155D from the Centers for Medicare and Medicaid Services (CMS) data system, and emails from SP-1 (General Supervisor, Technical Supervisor, Testing Personnel) on 10/24/2025, the laboratory failed to score at least 80 percent in two consecutive events (Event 1 of 2025 and Event 2 of 2025) resulting in unsatisfactory performance in the subspecialty of General Immunology and the analyte of C-Reactive Protein (CRP) in 2025. Findings included: 1. Review of "Casper Report 0155D," run date 10/21/2025 indicated a score of 40% for event 1 2025 and 60% for event 2 2025 for and General Immunology and C-Reactive Protein (CRP) as reported by API. 2. Review of the "Enclosure 1 Test Methodology and Annual Test Volume Log", signed by the laboratory director on 6/24/2025, indicated C-Reactive Protein (CRP), was listed as analyte "CRP-HS" with an annual test volume of 1,000. 3. Upon email requests for PT report for 2025, Event 1 and 2 on 10/23/2025 at 12:29 pm, SP-1 provided API Performance Evaluation Reports for "2025 Immunology/ Immunohematology -1st event" and "2025 Immunology/ Immunohematology -2nd event". 4. Review of the API Proficiency Testing Performance Evaluation for "2025 Immunology/ Immunohematology -1st event", detailed the following for CRP: a) Part 2 of 4, Page 1 of 1 "Performance Summary 2025 Immunology/ Immunohematology-1st Event" showed a score of 40% for CRP (high sensitivity). b) Part 3 of 4, page 1 of 1 "Comparative Evaluation 2025 Immunology/ Immunohematology - 1st Event" indicated five samples were reported for C Reactive Protein (high sensitivity {hs}) and the following samples were unacceptable: 1. Sample HS-02 2. Sample HS-03 3. Sample HS-05 5. Review of the API Proficiency Testing Performance Evaluation for "2025 Immunology/ Immunohematology -2nd event", detailed the following for CRP: a) Part 2 of 4, Page 1 of 1 "Performance Summary 2025 Immunology/ Immunohematology- 2nd Event" showed a score of 60% for CRP (High Sensitivity). b) Part 3 of 4, page 1 of 1 "Comparative Evaluation 2025 Immunology/ Immunohematology - 2nd Event" indicated five samples were reported for C Reactive Protein (hs) and the following samples were unacceptable: 1. Sample HS-06 2. Sample HS-08

**D6000**

**MODERATE COMPLEXITY LABORATORY DIRECTOR**  
CFR(s): 493.1403

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.

This CONDITION is not met as evidenced by:  
Based on surveyor proficiency testing (PT) desk review of the laboratory PT records, the American Proficiency Institute (API) Evaluation Reports, and CASPER Report 0155D from the Centers for Medicare and Medicaid Services (CMS) data system, and emails from SP-1 (General Supervisor, Technical Supervisor, Testing Personnel) on 10/24/2025, the laboratory director failed to ensure that the laboratory scored at least 80 percent in two consecutive events (Event 1 of 2025 and Event 2 of 2025) resulting in unsuccessful participation in the subspecialty of General Immunology and the analyte of C-Reactive Protein (CRP) in 2025. 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 surveyor proficiency testing (PT) desk review of the laboratory PT records, the American Proficiency Institute (API) Evaluation Reports, and CASPER Report 0155D from the Centers for Medicare and Medicaid Services (CMS) data system, and emails from SP-1 (General Supervisor, Technical Supervisor, Testing Personnel) on 10/24/2025, the laboratory director failed to ensure that the laboratory scored at least 80 percent in two consecutive events (Event 1 of 2025 and Event 2 of 2025) resulting in unsuccessful participation in the subspecialty of General Immunology and the analyte of C-Reactive Protein (CRP) in 2025. Refer to D2076.