

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 33D0654341	<b>(X3) Date Survey Completed</b> 01/14/2026
<b>Name of Provider or Supplier</b> Wadsworth Center-Biggs Laboratory	<b>Street Address, City, State</b> Nysdoh, Albany, NY	
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>	An onsite recertification survey was conducted January 14, 2026, with standard level deficiencies cited.
<b>D5311</b>	<p><b>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL</b> CFR(s): 493.1242(a)</p> <p>(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory' procedures, review of patient specimen temperature receiving logs, and interview with Technical Supervisor #3, the laboratory failed to follow their procedure for Perfluorooctanoic acid (PFOA) and Perfluorooctanesulfonic acid (PFOS) testing in October 2025 for 30 of 30 specimens as evidenced by: 1. In review of the laboratory's procedure, LOAC-812-APPB under criteria for acceptable specimens stated, " Improper specimen collection, handling and or labeling of container are criteria for rejection of the specimen for the department." Under Specimen requirements for freezing. "Specimens must be stored frozen at -20C or below." Temperature requirements for Serum section stated, " following the transfer of serum to the blue top storage containers, serum may remain at room temperature for up to 8 hours." 2. In review 30 of 30 patients received on October 27, 2025 all patients reviewed (30 of 30) were not within its acceptable transportation temperature per their procedure. They were recorded received at 14 degrees C. A random sampling of 3 of those 30 patients are as follows: a. Patient #IDR2500078377 was recorded as received on 10/27/2025 at 14 degrees C. The laboratory did not reject the specimen. b. Patient #IDR2500078378 was recorded as received on 10/27/2025 at</p>

14 degrees C. The laboratory did not reject the specimen. c. Patient #IDR2500078407 was recorded as received on 10/27/2025 at 14 degrees C. The laboratory did not reject the specimen. 3. In an interview at 1019, the Technical Supervisor #3 confirmed that the specimens received were not within the laboratory's defined acceptability, room temperature, which she defined as a range of 15-30 degrees C.

**D5417**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(d)

(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on direct observation , review of room temperature records in D250, interview with the Technical Supervisor #3, the laboratory failed to define room temperature ranges consistent with the manufacturer's storage requirements for five of five boxes of BD Red top tubes stored in 2025 and 2026 as evidenced by: 1. Observation at 1420 revealed five of five boxes (100 Each) BD vacutainer red top tubes lot#5241150 with the manufacturer's storage requirement of 4-25 degrees C. 2. Review of the D250 room temperature records from January 2025 to January 2026 showed temperature ranges of 15-30 degrees C for 2025. 3. In an interview with Technical supervisor #3 at 1422 confirmed the room temperature ranges differed from the manufacturer's storage requirement for the BD Vacutainer tubes.