

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D1049768	(X3) Date Survey Completed 11/04/2025
Name of Provider or Supplier Backus Outpatient Care Center Laboratory	Street Address, City, State 111 Salem Tpke, Norwich, CT	
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
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 record review of the 'CASPER Report 155D' from 'Centers for Medicare and Medicaid Services (CMS)' and the proficiency testing evaluation report from the College of American Pathologist (CAP), the laboratory failed to successfully participate in a proficiency testing (PT) program approved by CMS in the specialty of hematology. Refer to D2127.</p>
D2127	<p>HEMATOLOGY CFR(s): 493.851(d)</p>

(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to return proficiency testing (PT) results in a timely manner for the analyte #0845 prothrombin time in the specialty of hematology for 2025 - Event 3, resulting in an unsatisfactory performance. Findings include: 1. Record review on 11/04/2025 of the Centers for Medicare and Medicaid Services (CMS) 'CASPER Report 155D' revealed the laboratory obtained a PT score of 0% in 2025 - Event 3 for the analyte #0845 prothrombin time in the specialty of hematology. 2. Record review on 11/04/2025 of the laboratory's 'College of American Pathologists (CAP)' PT 'Original Evaluation' report for 'WP9-C 2025, Whole Blood Coagulation' revealed the following: a. 'Regulated Analyte: Prothrombin Time' b. 'Test Event: WP9-C' c. 'Score: 0/10' d. 'Percent: 0' e. 'Current Event Performance Interpretation: Unsatisfactory' f. 'Exception reason codes appearing in this evaluation: [40] = Results for this kit were not received' g. 'Kit Mail date: 08/25/2025' h. 'Results Due Date: 09/16/2025' i. 'Evaluation Date: 10/14/2025' Note: Lack of documentation of correction action to prevent recurrence. 3. Staff interview on 11/04/2025 at 10:15 AM with the laboratory's Technical Consultant #1 confirmed the above findings. 4. Staff interview on 11/07/2025 at 11:45 AM with a 'CAP Contact Center Agent' confirmed the above findings. He/she further commented that the laboratory submitted the results on 10/31/2025 over the phone. 5. The laboratory performs 85,610 prothrombin time tests annually in the specialty of hematology.

D5413

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

(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on surveyor observation, record review and staff interview, the laboratory failed to define and provide evidence of monitoring and documenting room temperature and humidity requirements in the specialty of hematology. Findings include: 1. Surveyor observation on 11/04/2025 at 10:45 AM of the laboratory's patient consultation rooms revealed the following in use: a. Four Roche Coaguchek XS Pro analyzers. b. Three Coaguchek XS PT Test Strip containers. 2. Record review on 11/04/2025 of the laboratory's maintenance records for 2024 and 2025 revealed lack of documentation of room temperature and humidity levels for the laboratory's patient consultation rooms. 3. Record review on 11/04/2025 of the 'Roche Coaguchek XS Pro' analyzer operators manual revealed the following acceptable operational conditions: a. Relative humidity requirement of 10% to 85% (non-condensing). b. Room temperature requirement of 15 to 32 degrees Celsius. 4. Record review on 11/04

/2025 of the 'Coaguchek XS PT Test Strips' instructions for use revealed an acceptable storage room temperature requirement of 2 to 30 degrees Celsius. 5. Staff interview on 11/04/2025 at 11:00 AM with the laboratory Technical Consultant #1 confirmed the above findings. 6. The laboratory performs 85,610 prothrombin time tests annually in the specialty of hematology.