

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0311957	(X3) Date Survey Completed 01/21/2025
Name of Provider or Supplier East Tennessee Pulmonary Associates	Street Address, City, State 800 Oak Ridge Turnpike C-200, Oak Ridge, TN	
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 a review of the Centers for Medicare and Medicaid Casper Report 155 (CMS 155) and the laboratory's 2024 College of American Pathologists (CAP) proficiency testing (PT) evaluation reports, the laboratory failed to maintain satisfactory participation for two out of three proficiency testing events for the Creatinine (CREAT) analyte (Refer to D2096) and the Routine Chemistry specialty (Refer to D2097) resulting in initial unsuccessful PT performance.</p>
D2096	<p>ROUTINE CHEMISTRY CFR(s): 493.841(f)</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.

This STANDARD is not met as evidenced by:

Based on a desk review of the CMS 155 and the laboratory's CAP PT evaluation reports, the laboratory failed to maintain satisfactory performance for two of three test events for the Creatinine (CREAT) analyte. The findings include: 1. A review of the CMS 155 report revealed the following unsatisfactory scores: -2024 Event 2: 0% for CREAT -2024 Event 3: 0% for CREAT 2. A review of the laboratory's 2024 CAP Routine Chemistry evaluation reports revealed the following unsatisfactory scores: -2024 Event 2: 0% for CREAT -2024 Event 3: 0% for CREAT

D2097

ROUTINE CHEMISTRY

CFR(s): 493.841(g)

(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on a desk review of the CMS 155 and the laboratory's CAP PT evaluation reports, the laboratory failed to achieve satisfactory performance for the overall specialty of Routine Chemistry in two of three PT events in 2024. The findings include: 1. A review of the CMS 155 report revealed the following unsatisfactory Routine Chemistry PT event scores: -2024 Event 2: 65% -2024 Event 3: 0% 2. A review of the laboratory's 2024 CAP Routine Chemistry evaluation reports revealed the following unsatisfactory Hematology event scores: -2024 Event 2: 65% -2024 Event 3: 0%