

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2009082	(X3) Date Survey Completed 12/12/2025
Name of Provider or Supplier American Health S, Llc	Street Address, City, State 5380 Hickory Hollow Parkway, Suite 120, Antioch, 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
D0000	The following deficiencies are a result of a desk review of proficiency testing (PT) scores obtained from the Certification and Survey Provider Enhanced Reporting (CASPER) 0155 report and verified with the College of American Pathologists (CAP) PT agency. The facility was found to be out of compliance with the following CONDITION LEVEL DEFICIENCIES: 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 .
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:</p>

	<p>Based on a desk review of PT scores from the CASPER 0155 report and the CAP PT 2025 records, the laboratory failed to successfully participate in a PT program approved by the Health and Human Services (HHS), for each specialty, subspecialty, and analyte or test in which the laboratory is certified under Clinical Laboratory Improvement Amendments (CLIA). The laboratory failed to successfully participate in the specialty of Routine Chemistry and for the analyte Triiodothyronine. Refer to D2097 and D2107. .</p>
<p>D2097</p>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(g)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on a desk review of the CASPER 0155 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 2025. The findings include: 1. A review of the CMS 155 report revealed the following unsatisfactory Routine Chemistry PT event scores: -2025 Event 1: 12% -2025 Event 2: 12% 2. A review of the CAP 2025 PT records (Ligand General K-A 2025 and K-B 2025) confirmed that the laboratory received the above results. .</p>
<p>D2107</p>	<p>ENDOCRINOLOGY CFR(s): 493.843(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 a desk review of the CASPER 0155 and the laboratory's 2025 CAP PT evaluation reports (Events 1 and 2), the laboratory failed to achieve satisfactory performance (80% or better) for the same analyte in two consecutive testing events for the Triiodothyronine analyte in 2025. The findings include: 1. A review of the CASPER 0155 report revealed the following results: - 2025 Event 1: The laboratory received a 0% score for Triiodothyronine. - 2025 Event 2: The laboratory received a 0% score for Triiodothyronine 2. A review of the CAP PT records (Ligand General K-A 2025 and K-B 2025) confirmed that the laboratory received the above results. .</p>
<p>D6000</p>	<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> <p>This CONDITION is not met as evidenced by: Based on a PT desk review of the CASPER 0155 report and CAP PT 2025 records,</p>

the laboratory director failed to provide overall management and direction of the laboratory services. The laboratory director failed to ensure PT samples were tested as required. 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 a PT desk review of the CASPER 0155 report and CAP PT 2025 records, the laboratory director failed to ensure PT samples were tested as required. The laboratory director failed to ensure successful participation in an HHS-approved PT program. Refer to D2097 and D2107.