

<p>Statement of Deficiencies</p>	<p>(X1) Provider/Supplier/CLIA Identification Number</p> <p>44D2009082</p>	<p>(X3) Date Survey Completed</p> <p>01/07/2026</p>
<p>Name of Provider or Supplier</p> <p>American Health S, Llc</p>	<p>Street Address, City, State</p> <p>5380 Hickory Hollow Parkway, Suite 120, Antioch, TN</p>	
<p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p>		

<p>(X4) ID Prefix Tag</p>	<p>Summary Statement of Deficiencies</p>
<p>D0000</p>	<p>The following deficiencies are a result of a desk review survey of proficiency testing (PT) scores obtained from the Certification and Survey Provider Enhanced Reporting (CASPER) 0155 report and the College of American Pathologists (CAP) PT agency. The facility was found to be out of compliance with the conditions of the CLIA program. The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: D2016: 493.803 Condition: Successful participation. D6000: 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director.</p>
<p>D2016</p>	<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 the CASPER 0155 report and the 2025 CAP PT records, the laboratory failed to successfully participate in a proficiency testing program approved by HHS, for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. The laboratory failed to successfully participate in the subspecialty of Endocrinology and for the Thyroid-Stimulating Hormone (TSH) analyte. Refer to D2107 and D2108.</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 report and the 2025 CAP PT records (Events 1 and 3), the laboratory failed to achieve satisfactory performance (80% or better) for the same analyte in two of three consecutive testing events in the subspecialty of Endocrinology for the TSH analyte. The findings include: 1. A review of the CASPER 0155 report revealed a 0% score for the TSH analyte for 2025 Events 1 and 3. 2. A review of the CAP PT records confirmed the laboratory received the above results.</p>
<p>D2108</p>	<p>ENDOCRINOLOGY CFR(s): 493.843(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 report, CAP PT 2025 records (Events 1 and 3), and interviews, the laboratory failed to achieve an overall satisfactory performance (80% or greater) for two out of three consecutive testing events in the subspecialty of Endocrinology. The findings include: 1. A review of the CASPER 0155 report revealed that the laboratory received the following scores for the Endocrinology subspecialty: 2025 Event 1: 37% 2025 Event 3: 72% 2. A review of the 2025 CAP PT records (Events 1 and 3) revealed the laboratory received the following scores for the Endocrinology subspecialty: 2025 Event 1 (K-A Ligand-General): 38% 2025 Event 3 (Parathyroid Hormone (PTH)-C): 73% 3. A phone interview with the CAP customer support specialist on 01/05/2026 at 3:00 pm confirmed 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>

This CONDITION is not met as evidenced by:
Based on a desk review of the CASPER 0155 report and the 2025 CAP PT records, the laboratory director failed to provide overall management and direction of the laboratory services. The laboratory director failed to ensure proficiency testing 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 desk review of the CASPER 0155 report and the 2025 CAP PT records (Events 1 and 3), the laboratory director failed to ensure proficiency testing samples were tested as required. The laboratory director failed to ensure successful participation in an HHS approved proficiency testing program. Refer to D2107 and D2108.