

<p>Statement of Deficiencies</p>	<p>(X1) Provider/Supplier/CLIA Identification Number 44D2009082</p>	<p>(X3) Date Survey Completed 08/18/2025</p>
<p>Name of Provider or Supplier American Health S, Llc</p>	<p>Street Address, City, State 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>		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
<p>D0000</p>	<p>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</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>

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 subspecialty of Toxicology and for the analytes Carbamazepine, Digoxin, Gentamicin, Phenobarbital, Phenytoin, Theophylline, Tobramycin, Valproic Acid, Alanine Aminotransferase (ALT) (SGPT), Albumin, Alkaline Phosphatase (Alk. Phos), Amylase, Aspartate Aminotransferase (AST) (SGOT), Bilirubin (Bili Total), Calcium (Ca Total), Chloride (Cl), Cholesterol Total, Cholesterol High-density lipoprotein (HDL) (Cholesterol, HDL), Creatine Kinase (CK Total), Creatinine, Glucose (Non-waived), Iron Total, Lactate Dehydrogenase (LDH Total), Magnesium (Mg), Potassium (K), Sodium (NA), Total Protein, Triglyceride (TRIGL), Blood Urea Nitrogen (BUN), and Uric Acid. Refer to D2096, D2118, and D2119.

D2096

ROUTINE CHEMISTRY
CFR(s): 493.841(f)

(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 PT desk review survey of the CASPER 0155 report and the CAP PT 2025 records (Events one and two), the laboratory failed to achieve satisfactory performance (80% or better) for the same analytes for two consecutive testing events in Routine Chemistry for the ALT (SGPT), Albumin, Alk. Phos, Amylase, AST (SGOT), Bili Total, Ca Total, Cl, Cholesterol Total, Cholesterol HDL, CK Total, Creatinine, Glucose (Non-Waived), Iron Total, LDH Total, Mg, K, Na, Total Protein, TRIGL, BUN, and Uric Acid analytes. The findings include: 1. A review of the CASPER 0155 report revealed the following results: 2025- Event One: The laboratory received an unsatisfactory score of 0% for ALT (SGPT), Albumin, Alk. Phos, Amylase, AST (SGOT), Bili Total, Ca Total, Cl, Cholesterol Total, Cholesterol HDL, CK Total, Creatinine, Glucose (Non-Waived), Iron Total, LDH Total, Mg, K, Na, Total Protein, TRIGL, BUN, and Uric Acid analytes. 2025- Event Two: The laboratory received an unsatisfactory score of 0% for ALT (SGPT), Albumin, Alk. Phos, Amylase, AST (SGOT), Bili Total, Ca Total, Cl, Cholesterol Total, Cholesterol HDL, CK Total, Creatinine, Glucose (Non-Waived), Iron Total, LDH Total, Mg, K, Na, Total Protein, TRIGL, BUN, and Uric Acid analytes. 2. A review of the CAP PT records (General Chemistry/Therapeutic Drugs C-A 2025 and C-B 2025) confirmed that the laboratory received the above results. Word Key: % - percent

D2118

TOXICOLOGY
CFR(s): 493.845(f)

(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 PT desk review survey of the CASPER 0155 report and the CAP PT 2025

records (Events one and two), the laboratory failed to achieve satisfactory performance (80% or better) for the same analytes for two consecutive testing events in the subspecialty of Toxicology for the Carbamazepine, Digoxin, Gentamicin, Phenobarbital, Phenytoin, Theophylline, Tobramycin, and Valproic Acid analytes. The findings include: 1. A review of the CASPER 0155 report revealed the following results: 2025- Event One: The laboratory received an unsatisfactory score of 0% for the Carbamazepine, Digoxin, Gentamicin, Phenobarbital, Phenytoin, Theophylline, Tobramycin, and Valproic Acid analytes. 2025- Event Two: The laboratory received an unsatisfactory score of 0% for the Carbamazepine, Digoxin, Gentamicin, Phenobarbital, Phenytoin, Theophylline, Tobramycin, and Valproic Acid analytes. 2. A review of the CAP PT records (General Chemistry/Therapeutic Drugs C-A 2025 and C-B 2025) confirmed that the laboratory received the above results.

D2119

TOXICOLOGY
CFR(s): 493.845(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 PT desk review of the CASPER 0155 report and the CAP PT 2025 records (Events one and two), the laboratory failed to achieve an overall satisfactory performance (80% or greater) for two consecutive testing events in the subspecialty of Toxicology. The findings include: 1. A review of the CASPER 0155 report revealed the following: 2025 Event One: The laboratory received an overall unsatisfactory score of 0% for Toxicology. 2025 Event Two: The laboratory received an overall unsatisfactory score of 0% for Toxicology. 2. A review of the CAP PT records (General Chemistry/Therapeutic Drugs C-A 2025 and C-B 2025) confirmed that the laboratory received the above results.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

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.

This CONDITION is not met as evidenced by:
Based on a PT desk review of the CASPER 0155 report and CAP 2025 records, 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 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 D2096, D2118, and D2119.