

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2009082	(X3) Date Survey Completed 12/17/2020
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	
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: The laboratory failed to maintain satisfactory performance in 3 out of 4 proficiency testing (PT) events for the analyte Triiodothyronine (T3) resulting in a 2nd unsuccessful PT. (Refer to D2107)</p>
D2107	<p>ENDOCRINOLOGY CFR(s): 493.843(f)</p>

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 review of the Centers for Medicare and Medicaid Services (CMS) CASPER report 155/153 and the College of American Pathologist (CAP) performance summary revealed the laboratory failed to achieve successful performance for the analyte Triiodothyronine (T3) in the 3rd event 2019, 1st and 3rd event 2020 resulting in the 2nd unsuccessful PT occurrence. The findings include: 1. Review of the CMS CASPER report 155/153 revealed a score of 0% for the 3rd event 2019, a score of 20% for the 1st event 2020 and a score of 0% for the 3rd event 2020 for the analyte T3. 2. Review of the CAP performance summary report revealed a score of 0% for the 3rd event 2019, a score of 20% for the 1st event 2020 and a score of 0% for the 3rd event 2020 for the analyte T3.

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:

The Laboratory Director failed to ensure the laboratory follow the May 15, 2020 plan of correction (POC) for the 1st unsuccessful proficiency testing (PT).

D6004

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(a)(b)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on record review of the May 15, 2020 plan of correction (POC) from the 1st unsuccessful proficiency testing (PT) and the December 3rd 2020 laboratory's PT Failure Investigation form, the laboratory director failed to ensure the laboratory manager follow their proficiency testing protocol for the analyte Triiodothyronine (T3) in 2020. The findings include: 1. Review of the May 15, 2020 POC revealed the laboratory manager will review all testing results being submitted to the College of American Pathologist (CAP) for correctness prior to submission to CAP. 2. Review of the laboratory's PT Failure Investigation form confirmed the laboratory manager

failed to review the results for correctness prior to submission to CAP for the 3rd event 2020 for the analyte T3 resulting in a 2nd Unsuccessful PT occurrence for 2020.