Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D1080642	09/28/2018
Name of Provider or Supplier	**Street Address, City, State**	
American Health Associates, Inc	1070 Asheville Highway, Spartanburg, SC	

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	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (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. This CONDITION is not met as evidenced by: During an onsite recertification survey on 09/28/2018, based on the CASPER 155D report and proficency testing results review from American Proficiency Institute (API), the laboratory failed to successfully participate in proficiency testing for the sub-specialty of routine chemistry, the analyte digoxin, for two of three consecutive proficiency events (2017, Event A and Event C). See D2087.
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a)

	Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: During an onsite recertification survey performed on 09/28/2018, based on the CASPER 155D report review and onsite proficiency testing results review from College of American Pathologists (CAP) proficiency testing, the laboratory failed to attain a satisfactory score of at least 80% for digoxin for two of three consecutive proficiency testing events. Findings include: 1. The CASPER 155D report revealed the following scores for your laboratory's digoxin: a. 2017, Event A: 0% b. 2017, Event C: 0% 2. The scores were confirmed by review of the graded CAP results. Scores less than 80% for this analyte indicates unsatisfactory performance. A failure of this analyte for two consecutive or two out of three consecutive testing events is scored as unsuccessful.