

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  15D2047655	<b>(X3) Date Survey Completed</b>  07/28/2020
<b>Name of Provider or Supplier</b>  Amerathon Health Llc DbA American Health	<b>Street Address, City, State</b>  10204 Lantern Road, Fishers, IN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> 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: Based on document review and interview, the laboratory failed to successfully participate in the College of American Pathologists (CAP) proficiency testing (PT) program for lactate dehydrogenase (LDH). The laboratory had two consecutive unsatisfactory testing events (Events 1 and 2, 2020). (Refer to D2096.)</p>
<b>D2096</b>	<p><b>ROUTINE CHEMISTRY</b> CFR(s): 493.841(f)</p> <p>Failure to achieve satisfactory performance for the same analyte or test in two</p>

consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on document review and interview, the laboratory failed to achieve a proficiency testing (PT) score of 80% or higher for lactate dehydrogenase (LDH) testing during two consecutive PT events (Event 1, 2020 and Event 2, 2020), resulting in unsatisfactory performance. Findings included: 1. Review of "CASPER Report 0155D" indicated the laboratory received a score of 0% during PT testing events 1 and 2, 2020 for LDH testing. 2. In interview on 7-28-2020 at 3:15 PM, SP1, Laboratory Manager, acknowledged the laboratory received a score of 0% during PT events 1, 2020 and 2, 2020 for LDH testing.