Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D2047655	01/18/2022
Name of Provider or Supplier	**Street Address, City, State**	
Amerathon Health Llc Dba American Health	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to follow its corrective action policy for three of three corrected tests (sodium, potassium, and chloride) performed on one of one chemistry analyzer (Beckman Coulter Model AU5800, Serial # 2018013706) for one (PT#4) of six patients reviewed. Findings include: 1. On 01/07/2022 at 9:54 AM, SP2 confirmed the chemistry analyzer (Beckman Coulter Model AU5800, Serial # 2018013706) was inoperable from 11/1/2021 to 11/2/2021 due to repairs being performed from the morning of 11/1/2021 until approximately 14: 00 on 11/2/2021 2. A Beckman Coulter work summary for the AU5800 chemistry analyzer repair on 11/1/2021 and 11/2/2021 stated that the laboratory reported high sodium and potassium results on 11/1/2021 at 10:29 AM. 3. Review of six medical records indicated that PT#4 had critical lab results for potassium (5.9 mEq/L), sodium (187 mEq/L), and chloride (133 mEq/L) reported by the AU5800 chemistry analyzer on 10/29/2021 at 14:05. PT#4's medical report indicated that these results were corrected to non-critical laboratory results on 11/02/2021 at 00:45. 4. The laboratory policy "Detecting and Correcting Patient Reports and Correcting Lab Records", approved by the laboratory director on 4/8/2021, included procedures for correcting "erroneous or wrong lab results" that specified that "The general Lab tech or Supervisor will call the [patient's] facility and alert them of the corrected report...if it has significantly changed and affects patient care. Otherwise, (sic) the corrected report will be automatically sent to the client via the LIS fax system". 5. PT#4's accession audit history and accession call history included a fax of the corrected report being sent on 11/02/2021 at 01:32 AM, but these audits did not indicate that PT#4's facility

	was called and alerted of the corrected report. 6. On 01/17/2022 at 1:30 PM, SP1 indicated that there was no documentation of the changed sodium, potassium, and chloride results in PT#4's STAT Connect Accession Call History because the corrected values were not critical, and only critical results are put into the call queue. 7. On 01/18/2022 at 3:30 PM, upon request for clarification on how the laboratory alerted PT#4's facility of the corrected results, SP1 did not provide evidence of a call being made to the facility after 10/30/2021. 8. Annual test volume for sodium 1,366,086, potassium 1,368,546, and chloride 1,365,953.