

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  04D1007429	<b>(X3) Date Survey Completed</b>  12/09/2020
<b>Name of Provider or Supplier</b>  Healthy Connections	<b>Street Address, City, State</b>  136 Health Park Drive, Mena, AR	
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>D5783</b>	<p><b>CORRECTIVE ACTIONS</b> CFR(s): 493.1282(b)(2)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.</p> <p>This STANDARD is not met as evidenced by: Through a review of QC reports for January, May, and October 2020, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to document corrective actions for unacceptable Calcium quality control results for one of seven chemistry tests reviewed for the Vitros chemistry test system. Survey findings include: A. In a review of Vitros QC Reports for January, May, and October 2020 it was determined on 5/6 through 5/7 Calcium Level 1 and Calcium Level 2 both failed multiple times before being within the acceptable range for the controls. Calcium Level 1 failed twenty-one consecutive times between 5/6/2020 at 12:41 and 5/7/2020 at 13:41. Calcium Level 2 failed twenty-two consecutive times between 5/6/2020 at 12:41 and 5/7/2020 at 13:41. There was no documentation, on the QC Reports, of actions taken to correct the failures. B. The surveyor requested documentation of corrective actions for the Calcium quality control failures in May 2020 but none were provided. C. In an interview, at 10:51 on 12/9/2020, laboratory employee #3 (as listed on the form CMS-209) stated that there was no documented corrective actions for the quality control failures on 5/6/2020 through 5/7/2020.</p>