Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2143229	06/10/2022
Name of Provider or Supplier	**Street Address, City, State**	
Healthy Connections, Inc - Hot Springs Central	3604 Central Avenue, Suite D, Hot Springs, AR	

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
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Through review of American Proficiency Testing Institute (API) laboratory files, laboratory policy and procedure and interview it was determined that the laboratory tested proficiency test samples in duplicate on four of four proficiency testing events in 2021 and 2022. Findings follow: A) Review of proficiency test instrument printouts for API Hematology/Coagulation 2021 event #3 ,API Hematology/Coagulation 2022 event #1, API Chemistry Core 2021 event #3 and API Chemistry Core 2022 event #1 revealed that all twenty specimens in the four events were tested in duplicate. B) In an interview on June 9, 2022 at 11:30 am, when asked the reason the proficiency test samples were tested in duplicate, the laboratory staff members, identified as numbers two and three on the CMS 209 form, stated it was because many of the proficiency test results were abnormal. C) Review of policy and procedure for testing revealed that there was no requirement for testing patients with abnormal results in duplicate. D) In an interview on June 9 2022 at 11:30 am the laboratory staff member, identified as number 3 on the CMS 209 form, stated that there was no policy requiring that patients with abnormal values be tested in duplicate and that all samples in the proficiency testing events identified above had been tested in duplicate.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (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. This STANDARD is not met as evidenced by: . Through review of quality control (QC) policy and procedure , QC results for September 2021 and January 2022, patient result reports, lack of documentation and interviews with laboratory staff it was determined that the laboratory failed to evaluate patient results back to the last successful performance of QC, on two of two occasions when QC failed criteria for acceptability for Serum Creatinine (CREAT) analysis and corrective action required changes affecting test system performance. Findings follow: A) Review of the laboratory policy and procedure revealed that action is to be taken when QC fails criteria for acceptability and stated when any control is outside the acceptable range do not report patient results. B) Review of QC records for (CREAT) test for September 2021 revealed that on 9/30/21 at 10:41 AM Alfa Wasserman Chemistry Control Level 1 lot # 1501 UNCM with acceptable limits of 1.58 to 1.98 was resulted as 2.31 which was greater than plus 2 standard deviations (SD) from the target value and Alfa Wasserman Chemistry Control Level 2 lot # 1166 UECM with acceptable limits of 6.71 to 8.19 was resulted as 9.66 which was greater than plus 2 SD from the target value. C) Review of documentation of corrective action for the event identified above revealed that the test system had been recalibrated which indicated a change in the test system operation. D) Review of QC results revealed that QC was acceptable on 9/30/21 at 11:16 am. E) Review of QC results revealed the previous acceptable QC results for CREAT testing was performed on 9/29/21 at 09:00 am. F) Review of patient result reports revealed that a CREAT tests were performed and reported on five patients, identified as numbers one through five on a separate patient identification list, between 9/29/21 after 09:00 am and 9/30/21 before 11:16 am. G) Upon request, the laboratory was unable to provide documentation that the patients identified above with CREAT results performed and resulted had been evaluated. H) Review of QC records for (CREAT) test for January 2022 revealed that on 1/27/22 at 08:42 AM Alfa Wasserman Chemistry Control Level 1 lot # 1501 UNCM with acceptable limits of 1.58 to 1.98 was resulted as 2.08 which was greater than plus 2 standard deviations (SD) from the target value and Alfa Wasserman Chemistry Control Level 2 lot # 1166 UECM with acceptable limits of 6.71 to 8.19 was resulted as 8.87which was greater than plus 2 SD from the target value. I) Review of documentation of corrective action for the event identified above revealed that the test system had been recalibrated which indicated a change in the test system operation. J) Review of QC results revealed that QC was acceptable on 1/27/22 at 09: 27 am. K) Review of QC results revealed the previous acceptable QC results for CREAT testing was performed on 1/26/22 at 09:00 am. L) Review of patient result reports revealed that a CREAT tests were performed and reported on one patient, identified as number six on a separate patient identification list, between 1/26/22 after 09:00 am and 1/27/22 before 09:27 am. M) Upon request, the laboratory was unable to provide documentation that the patients identified above with CREAT results performed and resulted had been evaluated. N) In an interview on 6/9/22 at 01:55 pm the laboratory staff member, identified as number three on the CMS 209 form, confirmed that the CREAT tests performed on 9/29/21 and 1/26/22 , identified above had not been evaluated and should have been.