Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0948582	02/09/2024
Name of Provider or Supplier	**Street Address, City, State**	
Arkansas Heart Hospital Clinic Llc- Little Rock	#7 Shackelford West, Little Rock, 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
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Through a review of the laboratory's "Chemistry Calibration and QC Policy", Chemistry Quality Control (QC) for January 2023, patient test records for January 2023, and interviews with laboratory staff, it was determined the laboratory reported patient's Sodium (NA) result when quality control was unacceptable. Survey findings include: A) Through a review of chemistry NA QC results for January 2023 it was determined that on 1/6/23 Biorad Multiqual lot# 45870 level 1 (acceptable range 111.6 to 116.4) at 6:51 a.m. was resulted as 118 with flags "2/3-2S?1-3S" and level 3 (acceptable range 151.8 to 163.8)was reported as 164 with a flag of "2/3-2/S. Level 1 was repeated at 07:01 a.m. as 119 with a flag "2-2S/2/3/3-2S/1-3S" and repeated at 07: 13 a.m. as 117 with a flag "1-2S. Records show that level 3 was not repeated on that date. B) A review of the laboratory test reports revealed that NA tests were performed and reported on 88 patients (identified as numbers 1 through 88 on a separate patient identification list) on 1/6/23. C) In an interview on 2/8/24 at 12:25 p.m. laboratory employee #1 (as listed on the form CMS-209) confirmed that on 1/6/23. QC for NA analysis was unacceptable and 88 patients had NA analysis performed and reported on that date
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: Through review of the user's manual for the Siemens Dimension chemistry analyzer, the temperature/humidity records, lack of documentation and interview with laboratory staff, it was determined that the laboratory performed patient testing on the dimension analyzer when humidity was below the manufacturer's specified operational range. Findings follow: A) Review of the manufacturer's user's manual for the Siemens Dimension chemistry analyzer revealed "relative humidity must be maintained at 20% to 80%". B) Review of the laboratory's "AHH Clinic Temperature and Humidity Log" for November and December 2023 revealed that the humidity was below 20% (at 16%) for 12 of 39 days of operation during the period. C) Upon request, the laboratory could not provide documentation of corrective action taken on the days identified above when relative humidity was below the manufacturer's requirement. D) During an interview on 2/9/24 at 08:48 a.m. the laboratory staff member (# 1 on the CMS 209 form) confirmed that humidity was below the manufacturer's required range on the 12 days indicated on the Temperature/Humidity Log and that no corrective action was taken.
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 a review of the "Chemistry Calibration and QC Policy, quality control (QC) results for January 2023, corrective action documentation, patient results, and interview it was determined that patient results were not evaluated to the last successful QC performance when QC failed and corrective action made changes in the test system operation. Findings follow: A) Review of the laboratory's "Chemistry Calibration and QC Policy" revealed that under the heading "Out of Limits Control" paragraph 3. stated "any patient testing since the last successful QC run must be validated". B) Through a review of chemistry QC results for January 2023 it was determined that on 1/30/23 Biorad Multiqual lot# 45870 level 3 for triglyceride (Trig) analysis (acceptable range 202.24 to 214.4). was resulted as 200 with flags "1-2S" at 6: 5 a.m , and level 3 was repeated . as 196 with a flag "2-2S/1-3S" at 07:18 a.m and repeated at 07:30 a.m. as 195 with a flag "1-2S/1-3S". C) Review of corrective action documentation for Trig analysis on that date revealed for the first three instances of QC failure corrective action consisted of repeating the QC procedure but on the final instance corrective action stated "changed reagent" which indicated a change in the testing system. D) Review of chemistry QC results for Trig analysis revealed that the last successful QC for Trig analysis was performed at 6:48 a.m. on 1/27/23. E) Review of patient results revealed that 35 Trig tests were performed and reported on 1 /27/23 (patient identified as numbers 89 through 123 on the separate patient identification list). F) In an interview on 2/8/24 at 01:45 p.m., the laboratory staff

	member (# 1 on hte CMS 209 form) confirmed that the Trig results reported on 1/27 /23 had not been evaluated.