Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D2122655	12/10/2020
Name of Provider or Supplier	**Street Address, City, State**	
Health Research Institute	505 Dimick Drive Ste 111, Fairfield, IA	

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
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of quality control records and confirmed by laboratory personnel identifier #3 (refer to the Laboratory Personnel Report) at approximately 3:30 pm on 12/10/2020, the laboratory failed to perform two levels of urine specific gravity quality control materials each day of patient testing for 11 out of 11 days in September-October 2020. The findings include: 1. The laboratory uses an Atago Digital Refractometer to perform urine specific gravity testing with each glyphosate and aminomethylphosphonic acid (AMPA) patient test. 2. The laboratory performed urine specific gravity testing on the following dates in September and October 2020: 9 /2, 9/11, 9/22, 9/24, 9/25, 9/29, 10/1, 10/5, 10/9, 10/15, and 10/27. 3. The laboratory performed urine specific gravity on a total of 51 patients during this time period. 4. At the time of the survey, personnel identifier #3 confirmed that the laboratory did not have quality control records for the above dates.