Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D2019908	02/14/2023
Name of Provider or Supplier	**Street Address, City, State**	
Hhri Cardiac Biomarker Trials Laboratory	914 South 8th Street, S3, Minneapolis, MN	

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
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the Technical Consultant failed to assess competency at least semi-annually during the first year of patient specimen testing for three of three testing personnel (TP) hired in 2021 and 2022. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor (GS) and Laboratory Director (LD) during a tour of the laboratory at 10:10 a.m. on February 14, 2023. 2. The Roche Cobas e 411 analyzer was observed as present and available for use during the tour. 3. Competency checks were required at hire and at 6 months for new employees and annually thereafter as established in the Competency Assessment Policy found in the Cardiac Biomarker Trials Quality Assurance and policy binder. 4. Semi-annual competency assessments were not found for TP1, TP2 or TP3 for the chemistry testing performed on the Roche Cobas e 411. TP1 and TP2 were hired in 2021, and TP3 was hired in 2022. Initial competencies as well as annual competencies were found. 5. The laboratory was unable to provide the missing documents upon request. 6. In an interview at 10:05 a.m. on February 14, 2023, the GS confirmed the above finding. .