Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D2019908	01/15/2019
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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed ensure all personnel who routinely perform testing on patient samples were included in testing proficiency testing (PT) samples. Findings are as follows: 1. The laboratory performed Chemistry testing as indicated by the General Supervisor (GS) during a tour of the laboratory on 01/15/19 at 12:40 p.m. The GS indicated she and Testing Personnel 1 routinely performed testing on patient samples. 2. The laboratory enrolled in a PT program for testing Creatine Kinase-MB with the College of American Pathologists (CAP). 3. The GS performed all testing on the CAP samples from 4 of 4 PT events completed in the timeframe reviewed, 08/18/17 through date of survey. 4. In an interview on 01/15/19 at 2:00 p.m., the GS confirmed the above finding.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for

	acceptability. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to ensure the test report included the name and address of the laboratory location (c)(2). Findings are as follows: 1. The laboratory performed Chemistry testing as indicated by the General Supervisor (GS) during a tour of the laboratory on 01/15/19 at 12:40 p.m. 2. Test reports for the patients listed below were reviewed on date of survey. Patient ID Date of testing 1391714 01/04/18 0675555 11/05/18 3. The name and address of the laboratory was not indicated on the test reports for the patients listed above. 4. In an interview on 01/15/19 at 3:50 p.m., the GS confirmed the above finding.