Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D2296681	06/18/2024
Name of Provider or Supplier	**Street Address, City, State**	
Resonance Laboratories, Llc	729 E Pass Rd Ste G, Gulfport, MS	

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
D5800	POSTANALYTIC SYSTEMS CFR(s): 493.1290 Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7) that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the postanalytic systems and correct identified problems as specified in 493. 1299 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation of laboratory equipment, interview with processing personnel, and review of the laboratory's genetic test reports, the laboratory failed to monitor and evaluate the overall quality of the postanalytic systems and correct identified problems as specified in 493.1299, when the laboratory test reports did not include the name and address of the laboratory location where the tests were performed. Refer to D5805.
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 observation of laboratory equipment, interview with processing personnel, and review of the laboratory's genetic test reports, all five, of the five laboratory test reports reviewed, did not include the name and address of the laboratory location where the tests were performed. Findings include: 1. Observation of laboratory equipment on 6/18/2024 at 4:30 p.m. revealed the Thermo Fisher IonTorrent Ion GeneStudio S5 Semiconductor Sequencer and the IonTorrent Ion One Touch were not in use for laboratory testing. 2. In an interview on 6/18/2024 at 4:35 p.m., the laboratory's processing personnel stated the genetic testing on all patient samples, received at the laboratory, was performed by a reference laboratory, and the results from the reference laboratory were printed on the patient test reports to be sent to ordering providers. 3. Review of five patient genetic test reports revealed the patient test reports included the name and address of Resonance Laboratories, LLC, from which the samples were referred. All five, of the five test reports on the patients listed below, did not include the name and address of the laboratory location where the tests were performed: Patient ID #00000183-1, collection date 5/09/2024. Patient ID #00000187-1, collection date 5/13/2024. Patient ID #00000198-1, collection date 5/10 /2024. Patient ID #00000204-1, collection date 5/24/2024. Patient ID #00000205-1, collection date 5/24/2024.