Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D1012367	03/31/2022
Name of Provider or Supplier	**Street Address, City, State**	
Huntsville Reproductive Medicine Pc	20 Hughes Road Sutie 203, Madison, AL	

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
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on a review of American Association of Bioanalysts (AAB) Proficiency Testing (PT) records, Quality Assurance records, and an interview with the Technical Consultant, the laboratory failed to improve the PT performance for Insulin. This was noted for four out of eight PT events for Insulin. The findings include: 1) A review of AAB PT records revealed Insulin was not graded due to a lack of consensus for the following events: a) Chemistry Q1 2021 b) Chemistry Q2 2021 c) Chemistry Q3 2021 d) Chemistry Q1 2022 2) A review of the Quality Assurance records revealed corrective actions were performed for all events where Insulin was not graded, however, the analyte continued to be out of range according to the data submitted to AAB. The corrective action implemented for all four PT events was to review quality control data and calibrations records, which showed no issue with Insulin. The laboratory failed to implement and document any additional measures and investigations to determine a cause of the discrepancy between the laboratory's results and the results submitted to AAB by other laboratories, or implement another mechanism to to verify the accuracy of this non-regulated analyte. 3) During an interview on 03/31/2022 at 12:30 PM, the Technical Consultant was unsure about the issue with the AAB PT results for Insulin, but the quality control and calibration seemed to be acceptable.