Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2164611	11/16/2021
Name of Provider or Supplier	**Street Address, City, State**	
Cny Fertility Center	924 West Spring Street, Monroe, GA	

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
D0000	On January 7, 2022 an off site follow-up review was completed. The report revealed that corrective action was found to be acceptable and corrected. The facility is now in compliance with with all regulations.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on document review and staff interview, the laboratory failed to verify at least twice annually, the accuracy of Hematology specialty, semen analysis. Findings include: 1. Document review revealed there were no twice annual proficiency review for Hematology specialty(semen analysis) performed for 2019, 2020, and 2021 (January-November 2021). 2. During an interview with the Testing Personnel#1(CMS 209) on November 16, 2021, at approximately 12:30 PM, in the laboratory, confirmed there were no twice annual proficiency review performed for 2019, 2020, and 2020.
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 quality assessment (QA) document review and staff interview, the laboratory failed to document quality assessment activities as required. The Findings include: 1. Laboratory QA document review revealed the lack of a QA checklist documentation for 2019, 2020 and 2021(January-October 2021). 2. During an interview with Testing Personnel #1 (CMS 209) on November 16, 2021 at 12:45 PM, confirmed the lack of QA checklist documentation for 2019, 2020 and 2021(January-October 2021).
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on laboratory proficiency document review and interview with the Testing Personnel(TP), the Laboratory Director (LD) failed to perform twice annual proficiency for Hematology specialty testing. The Findings include: 1. Laboratory proficiency document review revealed the LD failed to perform twice annual proficiency testing for the Hematology specialty testing for semen analysis for 2019, 2020, and 2021. 2. During an interview with the Testing Personnel #1(CMS 209) on November 16, 2021 at approximately 12:25 PM, in the laboratory, confirmed the LD failed to perform twice annual proficiency for 2019, 2020, and 2021.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory record review and staff interview, the laboratory director (LD) failed to ensure that quality assessment and corrective actions were taken for the laboratory. Findings include: 1. Laboratory record review revealed the LD failed to provide a quality assessment checklist and corrective action for the overall laboratory. 2. During an interview with Testing Personnel, in the laboratory on November 16, 2021, at approximately 2:40 PM, confirmed the LD failed to review and provide a quality assessment checklist and corrective action for the laboratory.