Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2184311	04/20/2026
Name of Provider or Supplier	**Street Address, City, State**	
Hope Fertility	3005 Royal Boulevard, South, Suite 220, Alpharetta, 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	A proficiency testing desk review was completed on April 20, 2026. At the time of the review, the laboratory was not in compliance with the Clinical Laboratory Improvement Amendments of 1988, 42 CFR 493.1 through 42 CFR 493.1780. The following condition deficiencies were cited: D2016 - 42 CFR 493.803 Condition: Successful participation [proficiency testing] D6000 - 42 CFR 493.1403 Condition: Moderate Complex Laboratory Director
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of the CASPER 155 report and review of the American Association

	of Bioanalysts (AAB) reports, the laboratory failed to maintain satisfactory proficiency testing (PT) participation for Luteinizing Hormone (LH) in 2025 event 3 and 2026 event 1, resulting in an initial unsuccessful participation for LH. Refer to D 2099
D2099	ENDOCRINOLOGY CFR(s): 493.843(b) (b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid (CMS) CASPER 155 report and review of American Association of Bioanalysts (AAB) reports, the laboratory failed to maintain satisfactory participation in two consecutive testing events (3rd event of 2025 and 1st event of 2026), resulting in an initial unsuccessful participation for Luteinizing Hormone (LH). Findings: 1. A review of Casper Report 155 revealed the laboratory failed LH on the following: 2025 Event 3 LH Score 0% 2026 Event 1 LH Score 0% 2. A review of the laboratory's AAB Reports confirmed the laboratory failed LH with the aforementioned scores.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of the CMS CASPER 155 report and review of American Association of Bioanalysts (AAB) reports, the laboratory director failed to provide overall management and direction for proficiency testing performance. The laboratory director failed to ensure proficiency testing samples were tested as required. Refer to D6016
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on review of the CMS CASPER Report 155 and the American Association of Bioanalysts (AAB) 2025 event 3 and 2026 event 1 PT evaluation reports, the laboratory director failed to ensure successful proficiency testing performance in Luteinizing Hormone (LH) in 2 of 3 (2025 event 3 and 2026 event 1), resulting in the initial unsuccessful participation for LH..