

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D1099219	(X3) Date Survey Completed 04/21/2026
Name of Provider or Supplier Oregon Fertility Institute	Street Address, City, State 9370 Sw Greenburg Rd Suite 412, Portland, OR	
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	Based on the desk review of proficiency testing (PT) from 2025 through 2026 performed on 04/21/2026, the laboratory failed to meet the following conditions, resulting in noninitial unsuccessful PT participation: D2016 - 42 CFR 493.803 Condition: Successful participation (proficiency testing) D6000 - 42 CFR 493.1403 Condition: Laboratories performing moderate complexity testing; 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 a desk review of proficiency testing (PT) records from the Certification and Survey Provider Enhance Reporting (CASPER) 0155 report and AAB Medical Laboratory Evaluation (AAB-MLE) proficiency testing records, the laboratory failed

	to successfully participate in a proficiency testing program approved by HHS. The laboratory failed to successfully participate in the subspecialty of Endocrinology for the analyte Follicle Stimulating Hormone (FSH). Refer to D2107.
D2107	ENDOCRINOLOGY CFR(s): 493.843(f) (f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a proficiency testing desk review of CASPER 0155 report and AAB-Medical Laboratory Evaluation 2025 and 2026 proficiency testing records, the laboratory failed to achieve satisfactory performance (80% or greater) for the same analyte in three of four consecutive testing events in the subspecialty of Endocrinology for the analyte follicle stimulating hormone (FSH). Findings include: 1. Review of the CASPER 0155 report revealed the following results: 2025 AAB-MLE Event 1 - FSH result 20% 2025 AAB-MLE Event 3 - FSH result 20% 2026 AAB-MLE Event 1 - FSH result 20% 2. A review of the AAB-Medical Laboratory Evaluation 2025 and 2026 proficiency testing records confirmed the laboratory failed to achieve satisfactory performance. 3. Interview with the laboratory director (LD) through email on 4/21/2026 at 11:00am confirmed the results.
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 proficiency testing desk review of CASPER 0155D report and AAB-Medical Laboratory Evaluation 2025 and 2026 records, the laboratory director (LD) failed to provide overall management and direction of the laboratory services. The LD failed to ensure the overall quality of the proficiency testing performance on three (3) testing events in the subspecialty of Endocrinology. 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 proficiency testing desk review of CASPER 0155D report and AAB-Medical Laboratory Evaluation proficiency summary report of 2025 and 2026 records, the laboratory director failed to ensure that proficiency test (PT) samples for follicle stimulating hormone (FSH) in the subspecialty of Endocrinology were tested as required under subpart H. Refer to D2107.