Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2118892	07/08/2026
Name of Provider or Supplier	**Street Address, City, State**	
Vios Fertility Institute Chicago Wicker Park	1455 N Milwaukee Ave, Chicago, IL	

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 a desk review of proficiency testing records from the Certification and Survey Provider Enhanced Reporting (CASPER) database and verified with the proficiency testing provider, the laboratory was found to be out of compliance with the 42 C.F.R. Part 493 CLIA requirements for the following CONDITION level deficiencies: D2016 - 42 C.F.R. 493.803 Condition: Successful participation [proficiency testing] D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director;
D2005	ENROLLMENT CFR(s): 493.801(a)(4) (a)(4) Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act. This STANDARD is not met as evidenced by: Based on review of College of American Pathologists (CAP) Proficiency Testing e-Lab data records, lack of documentation, and interview with a CAP representative, the laboratory failed to authorize the release of CAP PT results to the Illinois Department of Public Health (IDPH) State Agency for the subspecialty of Endocrinology analyte Progesterone. Findings Include: 1. Review of the CAP PT e-LAB Solutions records for the IDPH State Agency lacked PT records for the laboratory. 2. Phone interview with a CAP laboratory representative on 07/07/2026 at 1:03pm confirmed the laboratory had their PT results for Progesterone set to do not report to the state agency.
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 proficiency testing desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile and College of American Pathologists (CAP) Proficiency Testing (PT) records, the laboratory failed to successfully participate in a proficiency testing program for the subspecialty of Endocrinology analyte Progesterone for two consecutive PT events in 2025/2026 (event 3 of 2025 and event 1 of 2026) resulting in the initial unsuccessful PT performance. 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 the Certification and Survey Provider Enhanced Reporting (CASPER) 0155D Report and College of American Pathologists (CAP) Proficiency Testing (PT) records, the laboratory failed to achieve satisfactory performance for the subspecialty of Endocrinology analyte Progesterone for two consecutive PT events in 2025/2026 (event 3 of 2025 and event 1 of 2026) resulting in the initial unsuccessful PT performance. Findings include: 1. Review of the CASPER Report 0155D, generated on 07-01-2026, the laboratory received the following unsatisfactory scores for the subspecialty of Endocrinology analyte Progesterone. Progesterone EVENT 3, 2025 - 0% Unsatisfactory EVENT 1, 2026 - 40% Unsatisfactory 2. Review of CAP PT evaluation reports (Y-C 2025 & Y-A 2026 Sex Hormones (Y)) confirmed the above unsatisfactory scores that resulted in the initial unsuccessful PT performance for the subspecialty of Endocrinology analyte Progesterone.
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 a proficiency testing desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile and College of American Pathologists (CAP) Proficiency Testing (PT) records, the laboratory director failed to ensure successful participation in their PT program for the subspecialty of Endocrinology analyte Progesterone resulting in the laboratory's initial unsuccessful PT performance. See 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 a proficiency testing desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile and College of American Pathologists (CAP) Proficiency Testing (PT) records, the laboratory director failed to ensure PT samples were tested as required to ensure successful participation in PT for the subspecialty of Endocrinology analyte Progesterone. Refer to 2107.