

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2005337	(X3) Date Survey Completed 02/27/2025
Name of Provider or Supplier Bay Ob-Gyn Pc	Street Address, City, State 2736 Ocean Avenue Suite 1a, Brooklyn, NY	
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
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 Centers for Medicare & Medicaid Services (CMS) Proficiency Testing (PT) Certification and Survey Provider Enhanced Reporting system (CASPER 0155D) and American Proficiency Institute (API) PT summary reports, the laboratory failed to successfully participate in the CMS approved PT program for the Endocrinology subspecialty for four of four consecutive testing events in the Progesterone and two consecutive events in the Luteinizing Hormone (LH) test analytes in 2024 and 2025 resulting in unsuccessful 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 CMS PT CASPER 0155D and API PT summary reports from 2024 and 2025 as well as interview with the Testing Personnel (TP), the laboratory failed to achieve satisfactory performance (80% or greater) in the Endocrinology subspecialty for the Progesterone and LH test analytes. FINDINGS: a. A review of the CASPER 155 report revealed the following unsatisfactory score: 1. Progesterone Test Analyte: 2025 First Event = 40% b. A review of the API (2024 and 2025) reports revealed the following unsatisfactory scores: 1. Progesterone Test Analyte: 2024 First Event = 0% 2024 Second Event = 50% 2024 Third Event = 50% 2025 First Event = 40% 2. LH Test Analyte: 2024 Second Event = 0% 2024 Third Event = 0% c. The TP confirmed the findings on February 27th, 2025, at 11:00 A.M.
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 CMS PT CASPER 0155D and API PT summary reports from 2024 and 2025, the Laboratory Director (LD) failed to provide overall management and direction of the laboratory services. 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 CMS PT CASPER 0155D and API PT 2024-1, 2024-2, 2024-3, and 2025-1 summary reports, the LD failed to ensure successful participation in an HHS approved PT program. Refer to D2107.