Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D2087820	08/23/2024
Name of Provider or Supplier	**Street Address, City, State**	
Bloom Reproductive Institute, Pllc	8415 N Pima Rd, Ste 290, Scottsdale, AZ	

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 proficiency testing desk review survey performed on August 23, 2024, the laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCIES: D2016 - 42 C.F.R. 493.803 Condition: Successful Participation D6000 - 42 C.F.R. 493.1403 Condition: Laboratory Director, moderate complexity
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 Certification and Survey Enhanced Reporting (CASPER) 155 report and AAB-Medical Laboratory Evaluation, the laboratory failed to successfully participate in three of three consecutive testing events in the subspecialty of

	Endocrinology for the regulated analyte Thyroid Stimulating Hormone (TSH) in 2023 and 2024, resulting in non-initial unsuccessful performance. Refer to D2096. 1. The laboratory's PT performance was unsatisfactory for the third event of 2023 as indicated below: - TSH - 0% 2. The laboratory's PT performance was unsatisfactory for the first event of 2024 as indicated below: - TSH - 40% 3. The laboratory's PT performance was unsatisfactory for the second event of 2024 as indicated below: - TSH - 60%
D2107	ENDOCRINOLOGY CFR(s): 493.843(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 review of the CASPER 155 report and AAB-Medical Laboratory Evaluation. PT records from 2023 and 2024, the laboratory failed to achieve satisfactory performance (80% or greater) for three of three consecutive testing events in the subspecialty of Endocrinology for the regulated analyte Thyroid Stimulating Hormone (TSH). Findings include: 1. A review of the CASPER 155 report revealed the following unsatisfactory scores: 2023 event 3, TSH 0% 2024 event 1, TSH 40% 2024 event 2, TSH 60% 2. A review of the proficiency testing scores from AAB-Medical Laboratory Evaluation. (2023 and 2024) confirmed the above findings.
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 CASPER-0155 Individual Laboratory Report and AAB-Medical Laboratory Evaluation 2023 and 2024 records, the laboratory director 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) 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)(i) Ensure that 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 CASPER-0155 and AAB-Medical

	Laboratory Evaluation 2023-3, 2024-1, and 2024-2 evaluation reports, the laboratory director failed to ensure successful participation in an HHS approved proficiency testing program. Refer to D2096.