Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0959181	09/21/2023
Name of Provider or Supplier	**Street Address, City, State**	
Southeast Texas Ob/Gyn Associates	755 N 11th Street Suite P4200, Beaumont, TX	

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	An onsite survey conducted 9/21/2023 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based upon review of proficiency testing records, policies and procedures, survey documents and interview of facility personnel, the laboratory failed to verify the accuracy of results for Trichomonas Vaginalis (TV) at least twice each year in 2022 and 2023. The findings included: 1. Review of the American Association of Bioanalysts (AAB/MLE) proficiency testing records for 2022 and 2023 found the laboratory had not enrolled in a proficiency testing program for Trichomonas Vaginalis tested using the Beckton Dickinson (BD) CTGCTV2 on the BD Max System. There was no other evidence of verification of accuracy of results available for review. 2. Review of the policy titled quality assessment found on page 2: "16. The laboratory participates in a proficiency testing program to assure the quality of test results." 3. Review of the survey documents provided found the laboratory recorded an annual test count of 137 patient specimens tested for Trichomonas Vaginalis. 4. During interview of the laboratory director conducted September 21, 2023 at 09:26 AM, she confirmed that the laboratory did not participate in a proficiency testing program for Trichomonas Vaginalis or have another means of verifying the accuracy of results at least twice each year in 2022 and 2023.
D6061	CLINICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1419(c)

	The clinical consultant must ensure that reports of test results include pertinent information required for specific patient interpretation. This STANDARD is not met as evidenced by: Based on a review of laboratory documents, patient final reports, laboratory policy, and confirmed in an interview, the clinical consultant failed to ensure that the patient reference range for mean platelet volume (MPV) was included in the final patient report for complete blood count's (CBC's) for 11 of 11 random patient reports reviewed from January to September 19, 2023. The findings included: 1. A review of the laboratory document titled "Clinical Consultant Responsibilities", prepared by the laboratory director (LD) on 9/3/2019 stated the following: "The clinical consultant provides consultation regarding the appropriateness of the testing ordered and interpretation of test results." Bullet point two: "-Ensure that test reports include pertinent information required for specific patient interpretation." 2. A review of 11 random patient final reports from January to September 19th, 2023, had the following patients with resulted MPV testing that did not include a reference range for the interpretation of results: Test Date - Patient #: MPV Result 1/31/2023 - 644240052: 8.1% 5/08/2023 - 644441400: 8.3% 5/11/2023 - 639209196: 6.8% 6/29/2023 - 639208252: 9.2% 7/26/2023 - 638204139: 7.1 % 8/09/2023 - 281439176: 8.5% 8/09 /2023 - 629301478: 8.0% 8/16/2023 - 253374829: 8.9% 8/21/2023 - 514047541: 8.6% 9/18/2023 - 452215239: 8.6% 9/19/2023 - 465654687: 7.9% 3. A review of the laboratory policy titled "Normal Reference Ranges", dated 8/8/2011, did not include a normal reference range for MPV testing. 4. In an interview on 9/21/2023 at 12:22 hours, in the laboratory, the LD confirmed that the reference range for MPV was not included on patient final reports for CBC testing.