Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0959181	07/20/2022
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 July 19, 2022 and July 20, 2022 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of reagent instructions for use (IFU), laboratory quality control (QC) worksheets, patient results, and confirmed in interview, the laboratory failed to follow manufacturer's instruction by documenting reagent acceptability, lot numbers, and expiration dates for each day of use for 28 of 28 days, and 24 of 28 days, respectively, reviewed between October 26, 2021 and December 6, 2021. The findings include: 1. Review of the "corQC Test System Control", for quality control of blood bank reagents, IFU, section "Test Method" had the following instructions: "1. Prior to performing daily QC testing, inspect all reagents under test (ABO reagents, Rh reagents, ect.) for evidence of contamination or deterioration (ie, marked turbidity of Blood Grouping Reagents, ect), hemolysis of Reagent Red Blood Cells). Record the lot number and expiration date of each reagent and observations on the corQC Data Sheet." 2. Review of the blood bank "corQC Data Sheet" for daily QC from October 26, 2021, to December 6, 2021, did not indicate reagent appearance or performance, for the following ten reagents in use, as specified for 28 of 28 days where patient testing was performed. Anti-A Anti-B Anti-D Rh-Hr Control Reverse Grouping Cells (A-cells) Reverse Grouping Cells (B-cells) Screening Cells Potentiator Anti-Human Serum Coombs Control Cells 3. Review of the blood bank daily QC worksheets, titled "corQC Data Sheet", did not include daily documentation of reagent lot and expiration

	dates for each day of patient testing. On each worksheet reviewed from October 26, 2021, to December 6 2021, the lot numbers and expiration dates were handwritten into the first column/day out of seven available on the worksheet for the daily record. For example, QC was performed and documented on 11/9/2021 to 11/12/2021 without daily documentation of reagent lot and expiration dates. Surveyor queried 07/19/2022 at 15:15 hours, as to the laboratory's record process. The laboratory director (LD) stated that the laboratory records every lot and expiration date at the beginning of each sheet and that they will record the lot number and expiration date of any new bottle opened during the six testing days following the initial record. The following two weeks did not include reagent lot and expiration documentation, for the following reagents. Week of 11/4/2021 - 11/12/2021 listed the Anti-B reagent, lot 306037, with an expiration date of 11/5/2021 with no documentation of reagent change for Anti-B Lot 306037-1 once it passes the 11/4/2021 expiration date. 22 Patients were tested with Anti-B Lot 306037-1 that had an expiration date of 11/4/2021 from 11/5/2021 - 11/12/2021: 11/5/2021: 3 Patients 109494 109485 109495 11/8/2021: 3 Patients 109529 109528 109538 11/9/2021: 4 Patients 109547 109554 109562 109566 11/10 /2022: 7 Patients 109598 109570 109572 109575 109585 109598 109590 11/11/2021: 3 Patients 109615 109610 109624 11/12/2021: 2 Patients 109631 109632 Week of 11 /15/2021 - 11/23/2021 documented the reverse grouping cells reagent as 111376, exp 12/3/2021 with no documentation of the 2nd reverse grouping cells. The following 33 patients were tested without documentation of the lot and expiration date of the 2nd reverse grouping cells from 11/15/2021 to 11/24/2021: 11/15/2021: 3 Patients 109653 109656 109661 11/16/2021: 5 Patients 109680 109691 109692 109694 109697 11/17 /2021: 6 Patients 109713 109715 109727 109728 109729 109731 11/18/2021: 4 Patients 109728 109732 109738 109747 11/19/2021: 5 Patients 109767 109753 109754 109759 109766 11/22/2021: 5 Patients 109787 109779 109782 109767 109795 11/23/2021: 5 Patients 109802 109805 109810 109814 109829 4. In an interview on 7/19/2022 at 15:15 hours, in the laboratory, the laboratory director confirmed that there was no documentation of reagent lot and expiration dates, or reagent acceptability, during QC for each day of patient testing.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's calibration verification procedure, calibration verification records for 2021 and 2022, and interview with the Laboratory Director, the laboratory failed to perform calibration verification for three of three assays reviewed (Sodium, Potassium, and Chloride) at least every six months between 2021 and 2022. The findings included: 1. Review of the laboratory's procedure titled "Calibration Verification", stated: "Procedure: Ace Axcel - Calibration verification will be performed every six months using a linearity kit to include low, mid, and high values." 2. Based on review of installation and calibration verification records, the instrument's reportable range was verified and approved by the Laboratory Director on 1/14/2021 and calibration verification procedures were performed on 9/22/2021 (elapsed time 8 months, 8 days). 3.At 11:00 hours on 7/20/2022 in the laboratory, the surveyor requested calibration verification documentation for 2022. The laboratory director confirmed the laboratory had not performed any calibration verification studies since the September 2021 studies. The elapsed time between 9/22/2021 and date of the survey, July 20, 2022, was 9 months and 28 days.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the Bio-Rad Liquichek Immunoassay Plus Control instructions for use, laboratory quality control records, and interview with facility personnel, the laboratory failed to accurately define acceptability criteria for three of three levels of control material in use. The findings included: 1. Based on review of the Bio-Rad Liquichek Immunoassay Plus Control Levels 1, 2, and 3 instructions for the use, under "Assignment of Values", the document states: "The mean values and corresponding plus/minus 3SD ranges in the Assignment of Values Data Charts (available separately) were derived from replicate analysis and are specific for this lot of product. " 2. Based on review of the laboratory's quality control limits, the laboratory had adopted the plus/minus 3SD ranges of the Bio-Rad controls and had set the limits as plus/minus 2 SD. Examples: Bio-Rad Liquichek Immunoassay Plus Control Level 3 (lot 85293) Analyte: TSH plus/minus 3SD ranges provided as guides from manufacturer: 24.1-34.5, SD equals 1.73 For this control, the laboratory had the plus /minus 2 SD limits set at 26.7332 - 37.1332, with a stated SD of 2.6 Bio-Rad Liquichek Immunoassay Plus Control Level 1 (lot 85291) Analyte: Progesterone plus /minus 3SD ranges provided as guides from manufacturer: 0.302-1.16, SD equals

	0.143 For this control, the laboratory had the plus/minus 2 SD limits set at 0.339 - 1.579, with a stated SD of 0.31 Bio-Rad Liquichek Immunoassay Plus Control Level 2 (lot 85292) Analyte: TSH plus/minus 3SD ranges provided as guides from manufacturer: 4.48-6.38, SD equals 0..316 For this control, the laboratory had the plus /minus 2 SD limits set at 5.01-6.89 , with a stated SD of 0.47 Lot numbers 85291, 85292, and 85293 were in used by the laboratory from October 2021 through the date of the survey, July 20, 2022. 3. In an interview at 15:00 hours on July 19, 2022 in the laboratory, the Laboratory Director stated that the laboratory had been using the provided plus or minus 3SD ranges in place of what the laboratory had thought was plus or minus 2SD for acceptability criteria. Key: SD - Standard deviation TSH - Thyroid Stimulating Hormone