Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2005746	03/05/2019
Name of Provider or Supplier	**Street Address, City, State**	
Houston Bay Area Fertility Center	9 Professional Park Drive, Suite C, Webster, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor observations, manufacturer's instructions, and confirmed in interview, the laboratory failed to document the revised expiration date for the Cliniqa liquid QC [quality control] Immunoassay controls for Estradiol testing on the Biomeriux MiniVidas analyzer. Findings were: 1. Surveyor observations on 03/05/19 at 0940 hours in the laboratory revealed opened bottles of quality control with no documentation of the revised expiration date stored in the refrigerator. Cliniqa liquid QC Immunoassay Controls (Ref 94101) lot 1706090A, exp 02/2021 lot 1706092A, exp 02/2021 2. Review of the package insert for the Clinqa liquid QC Immunoassay Controls (Ref 94101, 32928_06 1/18/13) revealed under storage and stability "Once opened, vials of control are stable for 30 days when stored tightly capped at 2-8 24C." 3. An interview with the lab director on 03/05/19 at 1025 hours in her office confirmed the above findings. She acknowledged that the testing person should document the revised expiration.
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 policies, laboratory records, and confirmed in interview, the laboratory failed to document twice annually the calibration verification for Progesterone, HcG, and Estradiol testing on the Biomeriux MiniVidas analyzer for 2017 and 2018. Findings were: 1. Review of the laboratory policy Calibration Verification Procedure revealed "CLIA regulations require calibration verification at least every 6 months..." 2. Review of the laboratory records available revealed the laboratory performed calibration verification for Progesterone, HcG and Estradiol on 05/25/17. No documentation of the second calibration verification for 2017 was provided by the end of survey on 03/05/19. 3. Review of the laboratory records available revealed the laboratory performed calibration verification for Estradiol on 11 /14/18. No documentation of the second calibration verification for 2018 was provided by the end of survey on 03/05/19. 4. An interview with the lab director on 03 /05/19 at 1020 hours confirmed the above findings. She stated that "since [the laboratory] has a low volume, [service representative] told [her] the laboratory doesn't have to perform [calibration verification] twice annually."