Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2102384	06/06/2019
Name of Provider or Supplier	**Street Address, City, State**	
Houston Ivf Med Center	7400 Fannin Suite 910, Houston, 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	The laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCIES: D2000 - 42 C.F.R. 493.801 Condition: Enrollment and Testing of Samples D6076 - 42 C.F.R. 493.1441 Condition: Laboratory Director; High complexity Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representative was given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider /supplier, the State Survey Agency (SA) should be notified immediately.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of the laboratory's proficiency testing records, and staff interview, it was revealed the laboratory reported proficiency testing results performed at a different facility (refer to D2013).

D2013

TESTING OF PROFICIENCY TESTING SAMPLES
CFR(s): 493.801(b)(4)

The laboratory must not send proficiency testing samples or portions of proficiency testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least one year. If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's American Association of Bioanalysts' proficiency testing records from 2017, 2018, and 2019, and staff interview, it was revealed the laboratory submitted proficiency testing results which were documented as belonging to a different facility. The findings were: 1. A review of the laboratory's American Association of Bioanalysts' (AAB) proficiency testing records from 2017 (events 2 and 3), 2018 (events 1, 2, and 3) and 2019 (event 1) revealed the laboratory had received faxed copies of proficiency testing worksheets with results filled in from its sister facility (45D0999095) for two events - 2017 event 2 and 2019 event 1. Each worksheet had the name, address, CLIA number and AAB number of the sister facility. These faxed worksheets had the following results filled in prior to faxing: a) 2017 event 2 Sperm Motility Specimen 1: 56 crossed out and replaced with 43 Specimen 2: 75 Sperm Count, video Specimen 1: 39 crossed out and replaced with 12 Specimen 2: 159 b) 2019 event 1 Sperm Motility Specimen 1: 16 crossed out and replaced with 43 Specimen 2: 75 Sperm Count, video Specimen 1: 39 crossed out and replaced with 12 Specimen 2: 159 Sperm Morphology, digital slide Specimen 1: 13 Specimen 2: 9 2. A review of the laboratory's own proficiency testing worksheets revealed the laboratory performed analysis of the proficiency testing specimens and documented their own results as: a) 2017 event 2 Sperm Motility No worksheets Sperm Count, video No worksheets Note: Sperm Cell ID, Forward Progression - semiquant, and Sperm Viability were reported by the laboratory without worksheets from either facility. b) 2019 event 1 Sperm Motility Specimen 1: 77 Specimen 2: 59 Sperm Count, video Specimen 1: 123 Specimen 2: 171 Sperm Morphology, digital slide Specimen 1: 13 Specimen 2: 6 3. A review of the laboratory's reported results which were scored by the proficiency testing agency revealed each of the results identified as coming from the other laboratory (CLIA 45D0999095). The results from the worksheets filled out by this facility (45D2102384) were not submitted. a) 2017 event 2 Sperm Motility Specimen 1: 80 Specimen 2: 76 Sperm Count, video Specimen 1: 205 Specimen 2: 161 b) 2019 event 1 Sperm Motility Specimen 1: 43 Specimen 2: 75 Sperm Count, video Specimen 1: 12 Specimen 2: 159 Sperm Morphology, digital slide Specimen 1: 13 Specimen 2: 9 4. An interview with the general supervisor on 06/21/2019 at 0915 hours in the conference room revealed she received proficiency testing worksheets from 3 facilities and entered them into the

	proficiency testing agency's website one right after the other. She stated she must have mixed up the forms. This confirmed the findings.
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 the manufacturer's instructions for the Bioscreen QC-Beads, review of the laboratory's quality control records from March 2019, April 2019, and May 2019, and staff interview, it was revealed the laboratory failed to have documentation of following the manufacturer's instructions for evaluating the acceptability of controls. The findings were: 1. A review of the manufacturer's instructions for the Bioscreen QC-Beads (revision 1/8/18) under the section titled "Procedure for Manual Counting of QC-Beads" revealed:"7. Calculate the concentration of beads according to the counting chamber manufacturer's instructions. 8. Repeat steps 1 -7 using a fresh aliquot of beads. 9. Compare the two results. If the results are within 10% of each other, then average the two counts." 10. The average count should be within the range of the Expected Values." 2. A review of the laboratory's quality control records from March 2019, April 2019, and May 2019, identified the following instances where the results of the two reading were not within the required 10% of each other. Examples are: a) March 2019 03/01 low control: reading 1: 28 reading 2: 33 % difference: 16.4% 03/04 high control reading 1: 62 reading 2: 55 % difference: 12.0 03/05 low control: reading 1: 31 reading 2: 27 % difference: 13.8% 03/06 low control: reading 1: 32 reading 2: 26 % difference: 20.7% 03/07 low control: reading 1: 31 reading 2: 28 % difference: 10.2% 03/08 low control: reading 1: 34 reading 2: 30 % difference: 12.5% 03/12 low control: reading 1: 33 reading 2: 29 % difference: 12.9% 03/18 low control: reading 1: 26 reading 2: 31 % difference: 17.5% high control: reading 1: 62 reading 2: 58 % difference: 10.2% 03/20 low control: reading 1: 32 reading 2: 27 % difference: 16.9% 03/21 low control: reading 1: 29 reading 2: 33 % difference: 12.9% 03/22 low control: reading 1: 26 reading 2: 34 % difference: 26.7% 03/27 low control: reading 1: 31 reading 2: 27 % difference: 13.8% 03/29 low control: reading 1: 31 reading 2: 27 % difference: 13.8% high control: reading 1: 62 reading 2: 54 % difference: 13.8% b) April 2019 04/01 low control: reading 1: 33 reading 2: 29 % difference: 12.4% 04/04 low control: reading 1: 27 reading 2: 33 % difference: 20.0% 04/05 low control: reading 1: 31 reading 2: 26 % difference: 17.5% 04/08 low control: reading 1: 30 reading 2: 27 % difference: 10.5% 04/09 low control: reading 1: 26 reading 2: 33 % difference: 23.7% 04/10 high control: reading 1: 54 reading 2: 61 % difference: 12.2% 04/18 low control: reading 1: 27 reading 2: 31 % difference: 13.8% 04/25 low control: reading 1: 31 reading 2: 27 % difference: 13.8% 04/26 low control: reading 1: 30 reading 2: 26 % difference: 14.3% 04/30 low control: reading 1: 29 reading 2: 25 % difference: 14.8% c) May 2019 05/07 low control: reading 1: 27 reading 2: 33 % difference: 20.0% 05/08 low control: reading 1: 30 reading 2: 26 % difference: 14.3% 05/10 low control: reading 1: 28 reading 2: 31 % difference: 10.2% high control: reading 1: 61 reading 2: 55 % difference: 10.3% 05/13 low control: reading 1: 32 reading 2: 26 % difference: 20.7% 05/14 low control: reading 1: 33 reading 2: 29 % difference: 12.9% high control: reading 1: 64 reading 2: 56 % difference: 13.3% 05/21 low control: reading 1: 33

	reading 2: 27 % difference: 20.0% 05/23 high control: reading 1: 55 reading 2: 66 % difference: 18.2% 05/30 low control: reading 1: 29 reading 2: 33 % difference: 12.9% 05/31 low control: reading 1: 28 reading 2: 33 % difference: 16.4% 3. An interview with general supervisor on 06/06/2019 at 0934 hours in the conference room revealed the laboratory was unaware of the requirement for the two controls to be within 10% of each other to be acceptable. She stated the laboratory would read each control twice and make sure both readings were within the acceptable range provided by the manufacturer, but did not ensure the two reading were within 10% of each other. This confirmed the findings.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's American Association of Bioanalysts' proficiency testing records, and staff interview, it was revealed the laboratory director failed to ensure proficiency testing samples were tested and reported are required (refer to D6089).
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure 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 the laboratory's American Association of Bioanalysts' proficiency testing records and staff interview, it was revealed the laboratory director failed to ensure the laboratory did not report proficiency testing results from a second facility (refer to D2011).