

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0999095	(X3) Date Survey Completed 06/11/2019
Name of Provider or Supplier Houston Ivf DbA Ccrm Houston	Street Address, City, State 929 Gessner Rd, Suite 2300, 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	An unannounced onsite investigation of complaint TX00316509 was conducted on 06/11/2019. Based on the investigation completed on 06/11/2019, this facility was found to be out of compliance with CLIA regulations. Immediate jeopardy findings were identified. The conditions not met were: D2000 - 42 C.F.R. 493.801 Enrollment And Testing Of Samples; D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director; D6033 - 42 C.F.R. 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant; Complaint TX00316509 was substantiated. Actual survey date was 06/11/19 and 06/21/19, with several email correspondence requesting documentation received 06/14/19 and 06/18/19. The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit.
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the American Association of Bioanalysts (AAB) proficiency testing (PT) records , facility procedure manual and confirmed in interview the facility engaged in inter-laboratory communications pertaining to the results of proficiency testing samples prior to the date by which the laboratory must report proficiency</p>

testing results to the program for the testing event in which the samples were sent. Refer to D2011

D2011

TESTING OF PROFICIENCY TESTING SAMPLES

CFR(s): 493.801(b)(3)

Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample (s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program.

This STANDARD is not met as evidenced by:

I. Based on review of the laboratory's policy and review of the 2017 to 2019 American Association of Bioanalysts (AAB) proficiency testing records, interview with the AAB technical support representative, and confirmed in interview with the laboratory manager, the laboratory engaged in inter-laboratory communications with Houston IVF-Medical Center 45D2102384 prior to the submission date for 2 of 5 testing events (2019 AAB 1st event and 2017 AAB 2nd event). A) 2019 AAB 1st event B) 2017 AAB 2nd event Findings included: A) 2019 AAB 1st event 1. Review of the laboratory's policy External and Internal Proficiency Testing Policy revealed "the technician performing the proficiency testing will avoid any inter-laboratory communication regarding proficiency testing samples during the PT event. This is to ensure maximum integrity of the proficiency testing process in out laboratory. We do NOT send any of our PT material to another lab for referral testing or reflex testing... no contact is to be made with other testing labs regarding proficiency test results until after our lab results have been submitted." 2. Review of 2019 AAB 1st event PT records for Andrology and Embryology 2019 with a submission cut-off date of 04/18 /19 included the following for Houston IVF 45D0999095: a) An attestation for the test Sperm Count was signed by the laboratory manager, who is the same lab manager for both laboratories, who attested "the undersigned analyst attests that samples were tested in the same manner as patient samples" on 4/17/19. b) Review of the AAB result worksheet for Sperm Count revealed 2 post it notes with the following counts: 1st post it note: "13, 20, 14, 21, 15, 17, 13, 15, 13" for a total of "157" "13, 18, 18, 19, 18, 16, 18, 18, 13, 14" for a total of "166" both counts averaged to "161" 2nd post it note: "23, 18, 21, 20, 14, 27, 22, 18, 21,17" for a total of "201" There are also annotations with crossed out numbers of "27, 19, 20, 18" "23, 26, 23, 17, 21, 20, 17, 17, 21, 25" for a total of "210" both counts averaged to "205" c) An interview with an AAB technical support representative on 06/18/19 at 1100 hours revealed the results submitted online on 4/17/19 at 1311 hours that correlated with the above worksheet for Sperm Count . Specimen 1 - 205 Specimen 2 - 161 3. Review of 2019 AAB 1st event PT records for Andrology and Embryology 2019 with a submission cut-off date of 04/18/19 included the following for Houston IVF-Medical Center 45D2102384: a) Review of the AAB 1st event PT records for Andrology and Embryology 2019 for Houston IVF-Medical Center 45D2102384 revealed 2 sets of AAB worksheets for Sperm Count: one form with the Houston IVF-Medical Center 45D2102384 address and one form with the Houston IVF 45D0999095. Both forms had different results for Specimen 1 and Specimen 2: Houston IVF-Medical Center 45D2102384 result worksheet performed by the primary testing person at the Medical Center location for

Sperm Count: Specimen 1 - 123 Specimen 2 - 171 Houston IVF 45D0999095 result worksheet with the laboratory manager's name written on the upper right hand corner had the following results for Sperm Count: Specimen 1 - 205 Specimen 2 - 161 b) An attestation for the test Sperm Count was signed by the laboratory manager, who is the laboratory manager for both locations, who attested "the undersigned analyst attests that samples were tested in the same manner as patient samples" on 4/17/19 for Houston IVF-Medical Center 45D2102384. c) An interview with an AAB technical support representative on 06/18/19 at 1100 hours revealed Houston IVF-Medical Center 45D2102384 submitted the same results on 04/17/19 at 1325 hours as the Houston IVF 45D0999095 worksheet: Specimen 1 - 205 and Specimen 2 - 161. d) Review of the results submitted for AAB for Houston IVF-Medical Center 45D2102384 revealed the results did not match the worksheet for Houston IVF-Medical Center 45D2102384; however, the submitted results correlated with the above results from the Houston IVF 45D0999095 worksheet. 4. Review of the submission dates and times provided via phone interview with the AAB technical support representative revealed both Houston IVF 45D0999095 and Houston IVF-Medical Center 45D2102384 had the same results submitted on the same date 4/17/19 and 14 minutes apart. 5. Review of the attestation statements for both Houston IVF 45D0999095 and Houston IVF-Medical Center 45D2102384 revealed the laboratory manager attested to performing the same tests for the same PT event for 2 separate laboratories. 6. An interview with the laboratory manager on 06/21/19 at 0915 hours in the laboratory confirmed the above findings. She also confirmed that she submitted the PT results for both locations. 7. The laboratory communicated Sperm count with another laboratory (Houston IVF-Medical Center 45D2102384) via duplicate results prior to the April 18 submission cutoff date for 2019 AAB 1st event for Andrology and Embryology. B) 2017 AAB 2nd event 1. Review of the laboratory's policy External and Internal Proficiency Testing Policy revealed "the technician performing the proficiency testing will avoid any inter-laboratory communication regarding proficiency testing samples during the PT event. This is to ensure maximum integrity of the proficiency testing process in our laboratory. We do NOT send any of our PT material to another lab for referral testing or reflex testing...no contact is to be made with other testing labs regarding proficiency test results until after our lab results have been submitted." 2. Review of 2017 AAB 2nd event PT records for Andrology and Embryology 2019 with a submission cut-off date of 11/15/17 included the following for Houston IVF 45D0999095: a) An attestation for the 2017 AAB 2nd event was signed by the laboratory manager, who is the laboratory manager for both laboratories who attested "the undersigned analyst attests that samples were tested in the same manner as patient samples" on 11/14/17. b) Review of the AAB worksheet for Houston IVF 45D0999095 revealed the following results: Sperm Count: Specimen 1 - 10; Specimen 2 - 155 Sperm Morphology: Specimen 1 - 18; Specimen 2 - 10 Sperm Motility: Specimen 1 - 50; Specimen 2 - 79 Sperm Viability: Specimen 1 - 27; Specimen 2 - 57 c) An interview with an AAB technical support representative on 06/18/19 at 1100 hours revealed the results were submitted on 11/14/17 at 1445 hours. Review of the submitted results correlated with the above results. 3. Review of 2017 AAB 2nd event PT records for Andrology and Embryology 2017 with a submission cut-off date of 11/15/17 included the following for Houston IVF-Medical Center 45D2102384 : a) Review of the AAB 2nd event PT records for Andrology and Embryology 2017 for Houston IVF-Medical Center 45D2102384 revealed the following worksheets with the Houston IVF 45D0999095 address and the following results: Sperm Count: Specimen 1 - originally 39 and marked off and a 12 written; Specimen 2 - 159 Sperm Morphology: Specimen 1 - 13; Specimen 2 - 9 Sperm Motility: Specimen 1 - originally 16 and marked off and a 43 written; Specimen 2 - 75 Sperm Viability: Specimen 1 - 20; Specimen 2 - 48 b) Review of the above

worksheets revealed 2 fax stamps on the upper left hand corner of each page with the following annotation: "11/14/17 03:38 Houston IVF 7132550509" and "Nov 08 2017 03:01 PM HP Fax" c) An attestation for 2017 AAB 2nd event was signed by the primary testing person who attested "the undersigned analyst attests that samples were tested in the same manner as patient samples" on 11/14/17 for Houston IVF-Medical Center 45D2102384. d) An interview with an AAB technical support representative on 06/18/19 at 1100 hours revealed Houston IVF-Medical Center 45D2102384 submitted the results on 11/14/17 at 1613 hours. e) Review of the results submitted to AAB for Houston IVF-Medical Center 45D2102384 correlated with the worksheets with the name and address for Houston IVF 45D0999095. 4. Review of the submission dates and times provided via phone interview with the AAB technical support representative revealed both Houston IVF 45D0999095 and Houston IVF-Medical Center 45D2102384 had similar results submitted on the same date 11/14/17 and 88 minutes apart. 5. An interview with the laboratory manager on 06/21/19 at 0915 hours in the laboratory confirmed the above findings. She confirmed that she submitted the PT results for both locations. 6. The laboratory communicated with another laboratory (Houston IVF-Medical Center 45D2102384) the results prior to the November 15, 2017 submission cutoff date for 2017 AAB 2nd event for Andrology and Embryology. II. Based on review of the laboratory's policy and review of the 2017 to 2019 American Association of Bioanalysts (AAB) proficiency testing records, interview with the AAB technical support representative, and confirmed with the laboratory manager, the laboratory engaged in inter-laboratory communications with Houston IVF-Medical Center 45D2102384 and Houston IVF- Sugarland 45D2161660 prior to the submission date for 1 of 1 testing event (2019 AAB 1st event). The laboratory manager had access to and knowledge of the PT results for all locations. Findings were: 1. Review of the laboratory's policy External and Internal Proficiency Testing Policy revealed "the technician performing the proficiency testing will avoid any inter-laboratory communication regarding proficiency testing samples during the PT event. This is to ensure maximum integrity of the proficiency testing process in out laboratory. We do NOT send any of our PT material to another lab for referral testing or reflex testing...no contact is to be made with other testing labs regarding proficiency test results until after our lab results have been submitted." 2. An interview with an AAB technical support representative on 06/18/19 at 1100 hours revealed the results were submitted online on 4/17/19 at 1311 hours for Houston IVF 45D0999095 for the 2019 1st event. 3. An interview with an AAB technical support representative on 06/18/19 at 1100 hours revealed the results were submitted online on 4/17/19 at 1325 hours for Houston IVF-Medical Center 45D2102384 for the 2019 1st event. 4. An interview with an AAB technical support representative on 06/18/19 at 1100 hours revealed the results were submitted online on 4/17/19 at 1339 hours for Houston IVF -Sugarland 45D2161660 for the 2019 1st event. 5. An interview with the laboratory manager on 06/21/19 at 0915 hours in the laboratory confirmed that she entered all PT results for all locations. She acknowledged that she had access to and knowledge of the PT results for all locations. 6. The laboratory engaged in inter-laboratory communication with both sister laboratories (Houston IVF-Medical Center 45D2102384 and Houston IVF -Sugarland 45D2161660) prior to the April 18 submission cutoff date for 2019 AAB 1st event for Andrology and Embryology.

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.

	<p>This CONDITION is not met as evidenced by: Based on review of American Association of Bioanalysts (AAB) proficiency testing records, and confirmed in interview, the laboratory director failed to provide overall management and direction of the laboratory. Refer to D6016</p>
<p>D6016</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</p> <p>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;</p> <p>This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) records and confirmed in interview, the Laboratory Director had not ensured that proficiency testing samples were tested as required and did not engage in any inter-laboratory communications pertaining to the results of proficiency testing samples. (Refer to D2011-I, II)</p>
<p>D6033</p>	<p>TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the laboratory's proficiency testing records, facility procedures, record review and staff interview, it was revealed that the Technical Consultant failed to provide technical and scientific oversight. (Refer to D6036)</p>
<p>D6036</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413</p> <p>The technical consultant is responsible for the technical and scientific oversight of the laboratory.</p> <p>This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) records, instrument printouts, and confirmed in interview, the Technical Consultant failed to provide technical oversight and ensure the laboratory did not engage in any inter-laboratory communications pertaining to the results of proficiency testing samples. (Refer to D2011)</p>