Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0698192	04/19/2022
Name of Provider or Supplier	**Street Address, City, State**	
Special Procedures Laboratory (Spl)	7200 Cambridge Street Rm B10-609, 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	A recertification survey was performed on 4/19/22. The laboratory was found out of compliance with the CLIA regulations. The condition not met was: 493.1250 D5400 Analytic Systems Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representatives were given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit.
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, the laboratory's American Association of Bioanalysts (AAB) proficiency testing records from 2021, and staff interview, it was revealed that the laboratory failed to test proficiency samples in the same manner it tested patient samples for 1 of 2 events in 2021 for Sperm Viability. Findings include: 1. A review of the laboratory's policy titled 'Quality Control Program' revealed the following: "Proficiency testing specimens must be handled and tested in a manner identical to patient specimens. Proficiency testing specimens must be tested the same number of times that patient samples are routinely tested." 2. A review of the laboratory's American Association of Bioanalysts (AAB) proficiency testing records for S2 Andrology & Embryology 2021 (second event) revealed three separate 'Semen

	Analysis Worksheets'. 3. Further review of the three worksheets revealed three different laboratory personnel tested the 2 proficiency testing samples for this event on 11/9/21. 4. An interview with the laboratory director on 4/19/22 at 10:15 a.m. in the conference room, revealed the laboratory did not have three different laboratory personnel test each patient sample for Sperm Viability testing in 2021. This confirmed the above findings.
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 on a review of the laboratory's accuracy assessment records and staff interview, it was revealed that the laboratory failed to have documentation of verifying the accuracy of two of eight tests performed by the laboratory, at least twice annually, in 2021. Findings include: 1. A review of the laboratory's accuracy assessment records titled 'Fructose Intra Lab Comparison' form and the 'Static Oxidation-Reduction Potential Worksheet' revealed the laboratory performed accuracy assessments for the two tests on the following days: Semen Fructose Test: 1/11/21 3/18/22 Oxidation-Reduction Potential (ORP) Test: 6/25/20 2. Further review of the accuracy assessment records revealed the following: Semen Fructose test - missing one accuracy assessment in 2021 ORP test- missing two accuracy assessments in 2021 3. An interview with the laboratory director on 4/19/22 at 10:55 a.m. in the conference room, after review of the records, confirmed the above findings.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a review of the laboratory's policies, review of laboratory records, and staff interview, it was revealed the laboratory failed to identify issues with analytic systems. Findings include: 1. The laboratory failed to have documentation of complete establishment studies for antisperm IgG and IgA antibody testing using the SpermMar Test. (refer to D5423)
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer

	must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on a review of the FDA website, the laboratory's establishment studies, the laboratory's testing records, and staff interview, it was revealed that the laboratory failed to have documentation of complete establishment studies for antisperm IgG and IgA antibody testing using the SpermMar Test. Findings include: 1. A review of the FDA website for categorization of tests, the SpermMar Test used for antisperm IgG and IgA antibody testing was not available for categorization of complexity, therefore the kit/test was high complexity. 2. A review of the laboratory's establishment studies for the SpermMar Test revealed the laboratory failed to have documentation of the following studies: - Accuracy - Precision - Analytical sensitivity - Analytical specificity including interfering substances - Reference intervals (normal values) - Reportable range 3. A review of the laboratory's testing records revealed the laboratory started testing for antisperm IgG and IgA antibodies in January 2021. 4. Further review of the laboratory's testing records revealed the laboratory performed 8 antisperm antibody tests in 2021 on the following patients using the SpermMar test: Patient: 0304997423 Date: 1/29/21 Patient: 0304354573 Date: 10/28/21 Patient: 0304826787 Date: 10/13/21 Patient: 0302151844 Date: 9/20/21 Patient: 0303864418 Date: 9/7/21 Patient: 0305070290 Date: 3/8/21 Patient: 0305125940 Date: 3/8/21 Patient: 0303719074 Date: 2/23/21 5. An interview with the laboratory director on 4 /19/22 at 1:00 p.m. in the conference room, after review of the records, confirmed the above findings. *NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 12/2020
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor observation, a review of the laboratory's policies, the laboratory's records, and staff interview, it was revealed that the laboratory failed to have documentation of testing the FertiPro VitalScreen stain, used for distinguishing immotile sperm from dead sperm, for intended reactivity each day of use in 2020 and 2021. Findings include: 1. Surveyor observation of the laboratory on 4/19/22 at 12:15 p.m. found the following box of FertiPro VitalScreen stain: FertiPro VitalScreen Lot: FP21VI05 Exp: 06/2023 2. A review of the laboratory's policy titled 'Vital Stain-Semen' revealed the following: "Positive control: The average alive should be lower than 5% of the percent motility recorded in the semen analysis. Negative control: The average percent alive should be 5% or less." 3. A review of the laboratory's records revealed no documentation of the intended reactivity for the stain each day of use in

	2020 and 2021. 4. A review of the laboratory's testing records revealed the laboratory performed 1 VitalScreen stain in 2020 and 3 VitalScreen stains in 2021. 5. An interview with the laboratory director on 4/19/22 at 12:15 p.m. in the conference room, after review of the records, confirmed the above findings.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on a review of the laboratory's establishment studies and staff interview, it was revealed the laboratory director failed to ensure establishment studies were complete prior to performing patient testing. (refer to D5423)
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted CMS 209 form, the laboratory's personnel files, and staff interview, it was revealed that the technical supervisor failed to perform competency assessments on two of three testing personnel performing high complexity testing in 2021. Findings include: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 4/19/22), revealed the laboratory identified 3 testing personnel performing high complexity testing in 2021. 2. A review of the laboratory's personnel records revealed that there was no documentation of the technical supervisor performing a competency assessment in 2021 on the following testing personnel: - Testing person #1 - Testing person #3 3. An interview with the laboratory director on 4/19/22 at 9:50 a.m. in the conference room, after review of the records, confirmed the above findings.