Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0698192	12/15/2020
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	The laboratory was found out of compliance with the CLIA regulations. The condition not met was: 493.1240 D5300 Preanalytic Systems 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. 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.
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 College of American Pathologists proficiency testing records form 2020 and staff interview, it was revealed that the laboratory failed to verify the accuracy of the unregulated analyte Sperm Morphology twice annually in 2020 to ensure accurate and reliable test results. Findings include: 1. A review of the laboratory's College of American Pathologists proficiency testing records from 2020 revealed the laboratory failed to verify the accuracy of Sperm Morphology twice annually by receiving a 0% for the Semen Analysis first event 2020. 2. An interview with the general supervisor (as indicated on the CMS 209 form, signed by the laboratory director on 10/30/20) on 12/15/20 at 10:50 a.m. in the office, after review of the records, confirmed the above findings.

D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, a review of the laboratory's American Association of Bioanalysts proficiency testing records from 2019, and staff interview, it was revealed that the laboratory failed to have documentation of performing corrective actions for the unregulated analyte Sperm Viability in the Embryology, Andrology & Fetal second event for 2019. Findings include: 1. A review of the laboratory's policy titled 'Quality Control Program' revealed the following: "All 'unacceptable' proficiency testing results must be investigated and corrective actions must be initiated immediately. Corrective actions must be appropriate to the nature and magnitude of the problem. Corrective action may consist of staff education, instrument recalibration, change in procedures, institution of new clerical checks, and /or discontinuation of patient testing for the analyte or discipline in question, or any other appropriate measures as determined by the laboratory director or designee." 2. A review of the laboratory's American Association of Bioanalysts proficiency testing records from 2019 revealed the laboratory received a score of 50% for the analyte Sperm Viability in the Embryology, Andrology & Fetal second event for 2019. 3. The laboratory was asked to provide documentation of corrective action performed for the Sperm Viability second event. No documentation was provided. 4. An interview with the general supervisor (as indicated on the CMS 209 form, signed by the laboratory director on 10/30/20) on 12/15/20 at 10:50 a.m. in the office, after review of the records, confirmed the above findings.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a review of the laboratory's records and staff interview, it was revealed that the laboratory failed to monitor and detect problems in pre-analytic systems. Findings include: 1. The laboratory failed to follow its policy for not accepting patient samples that had no documentation of a collection time. (Refer to D5311 I) 2. The laboratory failed to have documentation of following its policy for not accepting patient's semen analysis samples that were collected more than an hour before receiving the specimen in the laboratory. (Refer to D5311 II)
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3)

	Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: I. Based on a review of the laboratory's policies, a random review of patient test records from September 2020 to November 2020, and staff interview, it was revealed that the laboratory failed to follow its policy 2 of 20 times from September 2020 to November for not accepting patient samples that had no documentation of a collection time. Findings include: 1. A review of the laboratory's policy titled 'Laboratory Policy for Sample Collection' revealed the following: "Specimens falling into any of the categories listed below will not be accepted by the Laboratory for examination: -Improperly labeled specimens (no date and time of collection, no initials of collector)" 2. A random review of patient test records from September 2020 to November 2020 revealed the following 2 patient samples that were resulted when no collection time was given: Patient 163427 Collection time: not given Received 9/16/20 11:20 a.m. Semen extraction Patient 165248 Collection time: not given Received 11/24/20 2:31 p.m. Post vasectomy semen analysis 3. An interview with the general supervisor (as indicated on the CMS 209 form, signed by the laboratory director on 10/30/20) on 12/15/20 at 12:15 p.m. in the office, after review of the records, confirmed the above findings. II. Based on a review of the laboratory's policies, a random review of patient test reports from October 2020 and November 2020, and staff interview, it was revealed that the laboratory failed to have documentation of following its policy 4 of 4 times for not accepting patient's semen analysis samples that were collected more than an hour before receiving the specimen in the laboratory. Findings include: 1. A review of the laboratory's policy titled 'Laboratory Policy for Sample Collection' revealed the following: "Specimens falling into any of the categories listed below will not be accepted by the Laboratory for examination: -All specimens for semen analysis, culture, coagulation and urinalysis must arrive in the Laboratory within one hour of collection to assure specimen integrity." 2. A random review of patient test reports from October 2020 to November 2020 revealed the following 4 patients were resulted even though the semen analysis samples were received in the laboratory after one hour from the time of collection: Patient 164626 Resulted 10/13/20 Time collected 9:38 a.m. Time received 10:41 a.m. Elapsed time 1 hour 3 minutes Patient 165102 Resulted 11/12/20 Time collected 8:40 a.m. Time received 9:50 a.m. Elapsed time 1 hour 10 minutes Patient 165181 Resulted 11/18/20 Time collected 10:49 a.m. Time received 2:54 p.m. Elapsed time 4 hours 5 minutes Patient 165258 Resulted 11/25/20 Time collected 10:15 a.m. Time received 11:22 a.m. Elapsed time 1 hour 7 minutes 3. An interview with the general supervisor (as indicated on the CMS 209 form, signed by the laboratory director on 10/30/20) on 12/15/20 at 12:15 p.m. in the office, after review of the records, confirmed the above findings.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by:

	Based on a review of the laboratory's quality assessment records from 2020 and staff interview, it was revealed that the laboratory's quality assessment plan failed to identify issues with preanalytic systems. Findings include: 1. The laboratory failed to follow its policy for not accepting patient samples that had no documentation of a collection time. (Refer to D5311 I) 2. The laboratory failed to have documentation of following its policy for not accepting patient's semen analysis samples that were collected more than an hour before receiving the specimen in the laboratory. (Refer to D5311 II)
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 define control procedures for quality control testing for Oxidation-Reduction Potential in patient's semen samples run on the MiOXSYS analyzer. (Refer to D5403) 2. The laboratory failed to have documentation of complete establishment studies for Oxidation-Reduction Potential testing on the MiOXSYS analyzer. (Refer to D5423) 3. The laboratory failed to have a method in place to monitor quality control values over time for the MiOXSYS analyzer. (Refer to D5441) 4. The laboratory failed to ensure at least two levels of quality control were acceptable prior to testing patients for Oxidation-Reduction Potential (ORP) on the MiOXSYS analyzer. (Refer to D5447)
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

	This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and staff interview, it was revealed that the laboratory failed to define control procedures for quality control testing for Oxidation-Reduction Potential in patient's semen samples run on the MiOXSYS analyzer. Findings include: 1. A review of the laboratory's policy titled 'Oxidation-Reduction Potential Measurement in Ejaculated Semen Samples' revealed the following: "Quality Control Good laboratory practice recommends the use of the control materials. Users should follow the appropriate federal, state, and local guidelines concerning the running of external controls. MiOXSYS external control solution kits are supplied separately by the vendor. It is recommended that each new lot or shipment of MiOXSYS Sensors be verified upon receipt and before use. Testing of external controls should be performed thereafter in accordance with appropriate federal, state, and local guidelines." 2. Further review of the laboratory's policy titled 'Oxidation-Reduction Potential Measurement in Ejaculated Semen Samples' revealed there was no documentation of the following: - frequency of control testing - corrective action for failed quality controls 3. An interview with the general supervisor (as indicated on the CMS 209 form, signed by the laboratory director on 10 /30/20) on 12/15/20 at 11:50 a.m. in the office, confirmed the above findings.
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 MiOXSYS System Package Insert, a review of the FDA website, a review of the laboratory's establishment studies, and staff interview, it was revealed that the laboratory failed to have documentation of complete establishment studies for Oxidation-Reduction Potential testing on the MiOXSYS analyzer. Findings include: 1. A review of the MiOXSYS System Package Insert (100335, rev 006) revealed the following: 'NOT FOR SALE IN USA." 2. A review of the FDA website for categorization of tests, the MiOXSYS analyzer used for testing Oxidation-Reduction Potential was not available for categorization of complexity, therefore the kit/test was high complexity. 3. A review of the laboratory's establishment studies for the MiOXSYS analyzer (serial number:03100-309) revealed the laboratory failed to have documentation of the following studies: - Accuracy - Analytical sensitivity - Analytical specificity including interfering substances - Reference intervals (normal values) - Reportable range 4. The laboratory was asked to provide the establishment studies for Oxidation-Reduction Potential testing on the MiOXSYS analyzer. No documentation was provided. 5. The laboratory reported performing 60 Oxidation Reduction Potential tests annually using the MiOXSYS analyzer. 6. An interview with

	general supervisor (as indicated on the CMS 209 form, signed by the laboratory director on 10/30/20) on 12/15/20 at 11:00 a.m. in the office, after review of the records, confirmed the above findings.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, a review of the laboratory's quality control records from May 2019 to November 2020, and staff interview, it was revealed the laboratory failed to have a method in place to monitor quality control values over time for 2 of 2 lot numbers to detect shifts and trends for testing on the MiOXSYS analyzer. Findings include: 1. A review of the laboratory's policy titled 'Oxidation-Reduction Potential Measurement in Ejaculated Semen Samples' revealed the following: "Quality Control Good laboratory practice recommends the use of the control materials. Users should follow the appropriate federal, state, and local guidelines concerning the running of external controls. MiOXSYS external control solution kits are supplied separately by the vendor. It is recommended that each new lot or shipment of MiOXSYS Sensors be verified upon receipt and before use. Testing of external controls should be performed thereafter in accordance with appropriate federal, state, and local guidelines." 2. A review of the laboratory's quality control records from May 2019 to November 2020 revealed the laboratory failed to have documentation of monitoring quality control values over time for the following 2 lot numbers: Low Control lot number: 100776 High Control lot number: 100277 3. The laboratory was asked to provide documentation of monitoring the control values over time for shifts and trends. No documentation was provided. 4. An interview with the general supervisor (as indicated on the CMS 209 form, signed by the laboratory director on 10/30/20) on 12/15/20 at 11:15 a.m. in the office revealed the laboratory only assessed quality control values each day and did not monitor or evaluate values over time for shifts or trends. This confirmed the above findings.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on a review of the MiOXSYS External Control Solutions Package Insert, a random review of the laboratory's quality control records, a random review of patient test reports, and staff interview, it was revealed that the laboratory failed to ensure at least two levels of quality control were acceptable prior to testing patients for Oxidation-Reduction Potential (ORP) on the MiOXSYS analyzer for 5 of 121 days from March 2020 to June 2020. Findings include: 1. A review of the MiOXSYS External Control Solutions Package Insert (100278 rev 003) revealed the following: "Good laboratory practice recommend the use of external quality control checks. Users should follow the appropriate federal, state, and local guidelines concerning the running of external controls. Valid test results interpretation range should be as follows: External High Control Range: 91 - 117 mV External Low Control Range: 33 - 70 mV When unacceptable quality control values are obtained, all test results should be considered invalid." 2. A random review of the laboratory's quality control records from March 2020 to June 2020 revealed the following 5 days when only one level of quality control was acceptable : Date: 3/18/20 Low control 68.1 (acceptable) High control 129.2 Date: 6/17/20 Low control 72.9 High control 111.4 (acceptable) Date: 6 /19/20 Low control 73.5 High control 112.5 (acceptable) Date: 6/23/20 Low control 75.7 High control 113.8 (acceptable) Date: 6/29/20 Low control 80.3 High control 112.3 (acceptable) 3. A random review of patient test reports revealed the following 6 patient samples were resulted when only one level of quality control was acceptable: Patient: 162499 Resulted: 3/18/20 ORP = 6.11 Patient: 163124 Resulted: 6/17/20 ORP = 1.02 Patient: 6/19/20 Resulted: 6/19/20 ORP = 0.2 Patient: 163167 Resulted: 6 /23/20 ORP = 1.97 Patient: 163241 Resulted: 6/29/20 ORP = 2.22 Patient: 163245 Resulted: 6/29/20 ORP = 1.7 4. An interview with the general supervisor (as indicated on the CMS 209 form, signed by the laboratory director on 10/30/20) on 12/15/20 at 11:50 a.m. in the office, after review of the records, confirmed the above findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of the laboratory's quality assessment records and staff interview, it was revealed the laboratory's quality assessment plan failed to identify and correct problems in analytic systems. Findings include: 1. The laboratory failed to define control procedures for quality control testing for Oxidation-Reduction Potential in patient's semen samples run on the MiOXSYS analyzer. (Refer to D5403) 2. The laboratory failed to have documentation of complete establishment studies for Oxidation-Reduction Potential testing on the MiOXSYS analyzer. (Refer to D5423) 3. The laboratory failed to have a method in place to monitor quality control values over time for the MiOXSYS analyzer. (Refer to D5441) 4. The laboratory failed to ensure at least two levels of quality control were acceptable prior to testing patients for Oxidation-Reduction Potential (ORP) on the MiOXSYS analyzer. (Refer to D5447)
D5813	TEST REPORT CFR(s): 493.1291(g)

	The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, a random review of patient test reports, and staff interview, it was revealed that the laboratory failed to have documentation of notifying providers of panic values for 4 of 6 patient test reports reviewed between March 2020 and June 2020. Findings include: 1. A review of the laboratory's policy titled "Oxidation-Reduction Potential Measurement in Ejaculated Semen Samples" revealed the following panic value for the Oxidation-Reduction Potential (ORP) test run on the MiOXSYS analyzer: "Results Panic Values: >1.36/10 sperm/mL." 2. A review of patient test reports from March 2020 to June 2020 revealed the following 4 patient test reports with no documentation of notifying the providers of the panic values: Patient 162499 Resulted 3/18/20 ORP = 6.11 Patient 163167 Resulted 6/23/20 ORP = 1.97 Patient 163241 Resulted 6/29/20 ORP = 2.22 Patient 163245 Resulted 6 /29/20 OPR = 1.7 3. An interview with the general supervisor (as indicated on the CMS 209 form, signed by the laboratory director on 10/30/20) on 12/15/20 at 12:25 p. m. in the office, after review of the records, confirmed the above findings.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on a review of the laboratory's records and staff interview, it was revealed the laboratory director failed to ensure preanalytic systems were followed to ensure quality testing. Findings include: 1. The laboratory director failed to ensure the laboratory followed its policy for not accepting patient samples that had no documentation of a collection time. (Refer to D5311 I) 2. The laboratory director failed to ensure the laboratory followed its policy for not accepting patient's semen analysis samples that were collected more than an hour before receiving the specimen in the laboratory. (Refer to D5311 II)
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 the studies for the Oxidation-Reduction Potential testing on the MioXSYS anlayzer were complete prior to performing patient testing. (refer to D5423)

D6097	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that patient test results are reported only when the system is functioning properly. This STANDARD is not met as evidenced by: Based on review of the laboratory's records and staff interview, it was revealed the laboratory director failed to ensure the laboratory failed to ensure at least two levels of quality control were acceptable prior to testing patients. (Refer to D5447).