Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0698192	(X3) Date Survey Completed 03/01/2024
Name of Provider or Supplier Special Procedures Laboratory (Spl)	**Street Address, City, State** 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on the review of the laboratory's AAB/MLE proficiency testing records in 2023 and confirmed in an interview, the laboratory failed to document 2 of 2 attestation statements for Embrology, Andrology & Fetal events. The findings were: 1. Review of the laboratory's AAB/MLE proficiency testing records in 2023 revealed no documentation of attestation statements for 2 of 2 Embrology, Andrology & Fetal events. Embrology, Andrology & Fetal events S1 2023 Embrology, Andrology & Fetal events S2 2023 2. In an interview on 2/27/2024 at 12:10 pm in a conference room, the laboratory director confirmed the above findings. Key: AAB=American Association of Bioanalysis MLE=Medical Laboratory Evaluation
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.

	This STANDARD is not met as evidenced by: Based on the review of the CAP proficiency testing in 2023, CAP participant summary, and confirmed in an interview, the laboratory failed to have documentation of evaluting result returned as "See Note [26]" for 1 of 2 Semen Analysis Glass Slides events. The findings were: 1. Review of the CAP proficiency testing in 2023 revealed 2 of 2 samples in 1 of 2 Semen Analysis Glass Slides events had "See Note [26]". SEM1-B 2023 Semen Analysis Glass Slides Test Method: Sperm morphology, qual SEM-15 Your Grade: See Note [26] SEM-16 Your Grade: See Note [26] 2. Review of the CAP participant summary titled Surveys and Anatomic Pathology Education Programs for Semen Analysis Glass Slides SEM1-B 2023 event reveled under Actions Laboratories Should Take when a PT Result is Not Graded revealed the following, "Code: 26 Exception Reason Code Description: Educational challenge Action Required: Review participant summary for comparative results and document performance accordingly...." 3. Review of the CAP proficiency testing for the event of SEM1-B 2023 Semen Analysis Glass Slides revealed no documentation of evaluting result for 2 of 2 samples. SEM1-B 2023 Semen Analysis Glass Slides SEM-15 Your result: Abnormal Expected result: Abnormal SEM-16 Your result: Normal Expected result: Normal 4. In an interview on 2/27/2024 at 11:45 am in a conference room, the laboratory director confirmed the above findings. Key: CAP=College of American Pathologists PT=Proficiency testing