Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2113679	12/15/2022
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Reproductive And Urologic Procedures	7200 Cambridge Room 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 representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. 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 CMS Southern Operations Branch-Dallas for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on surveyor's observations in the laboratory, review of material safety data sheets for laboratory's chemicals, review of the laboratory's policies and procedures and staff interview, it was determined the laboratory failed to establish and follow safety protocols for storage and handling of laboratory's chemicals and reagents. Findings included: 1. Surveyor's observations on 12/15/2022 at 1110 hours in the laboratory revealed the following chemicals stored in a flammable cabinet under the desk: Fisher Chemical Methanol - 1 liter (L), 2 bottles Fisher Chemical Hydrochloric Acid - 500 milliliters (ml) Fisher Chemical Glacial Acetic Acid - 500 ml ThermoScientific 10% Neutral Buffered Formalin - 3.8 L 2. Review of chemical

	Safety Data Sheets (SDS) for the above chemicals revealed: Methanol (S25426A, 2015): "7. Handling and Storage ...Keep awy from open flames, hot surfaces and sources of ignition. Flamables area. Incompatible Materials. Strong oxidizing agents. Strong acids. Acid anhydrates.Acid Chlorides. Strog bases. Metals. Peroxides." Hydrochloric Acid (S25857, 2015): "7. Handling and Storage ...Store away from incompatible materials... ...10. Stabiliy and reactivity Reactivity: reacts violently with bases. ... Reacts violently with oxidants. ... Incompatible materials: Bases, Amines, Alkali metals, Metals, permanganates (potassium permanganate), Fluorine, Metal acetylides, Hexalithium disilicide." Glacial Acetic Acid (S25118, 2015) "7. Handling and Storage ...Keep awy from heat, sparks and flame.... Incompatible Materials: ...10. Stabiliy and reactivity ... Incompatible materials: Strong oxidizing agents, Strong Bases, Metals" 10% Neutral Buffered Formalin (S21828, 2015) "7. Handling and Storage ...Keep awy from heat and sources of ignition. ...10. Stabiliy and reactivity ... Incompatible materials: Strong oxidizing agents. Strong acids. Strong bases. 3. Review of the laboratory's policies and procedures revealed there was no safety considerations mentioned regarding storage requirements for the above chemicals. 4. In an interview on 12/15/2022 at 1115 hours in the laboratory, the Laboratory Director confirmed the above chemicals should not have been stored together.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of the laboratory's quality control records for 2021 and 2022 for the Beckman Coulter Dxi600 chemistry analyzer and staff interview, it was determined the laboratory failed to follow its own policy for two of two chemistry controls' lot rollovers during the 2021-2022 interval. Findings included: 1. Review of laboratory's "Policy on programming of lot-specific analyte control ranges into the DxI600 analyzer for Quality Control" revealed: "Prior to discontinuation of a control lot, and prior to beginning the use of a new control lot, we must overlap both lots to obtain at least 20 data points from the new lot while the old lot is still used as control." 2. Review of the laboratory's quality control records for 2021 and 2022 for the Beckman Coulter Dxi600 chemistry analyzer revealed the following controls' lot rollover studies: February 2022 Study: Old Control Lot 85290 Tested: 09/2021 to 02/01/2022 New Control Lot 85300 Tested: 02/01/2022 to 12/2 /2022 Points of QC overlap/rollover: 1 (on 02/01/2022) The study did not have 20 overlapping points of rollover study as per laboratory's protocol. November 2022 Study: Old Control Lot 85300 Tested; 02/01/2022 to 12/2/2022 New Control Lot 85320 Tested: 11/16/2022 to current (12/15/2022) Points of QC overlap/rollover: 12

	(11/16/2022 to 12/02/2022) The study did not have 20 overlapping points of rollover study as per laboratory's protocol. 3. In an interview on 12/15/2022 at 1250 hours in the conference room, the Laboratory Director, after review of the data, confirmed the 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 review of the laboratory's quality assurance (QA) records for 2021 and 2022, review of laboratory's control rollover studies for the Beckman Coulter Dxi600 chemistry analyzer, review of the laboratory's policies and staff interview, it was determined the laboratory's QA failed to identify and correct issues with Beckman Coulter control rollovers. Refer to D5469.
D6052	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(vi) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills. This STANDARD is not met as evidenced by: Based on review of laboratory's submitted Form 209, review of personnel records for 2021 and 2022, and staff interview, it was determined the laboratory's Technical Consultant failed to address problem solving skills in the competency assessments for one of one Testing Personnel performing moderate complexity testing. Findings included: 1. Review of laboratory's submitted Form 209 revealed the laboratory employed one Testing Person performing moderate complexity testing; Testing Person number 1 (TP1). 2. Review of personnel records for 2021 and 2022 revealed the competency assessments for the one Testing Person performing high complexity testing did not have problem solving skills component assessed in 2021 and 2022. Competencies missing the required component were: TP1: Competency assessed on 01 /05/2021 and 12/14/2022 3. In an interview on 12/15/2022 at 1000 hours in the conference room, the Laboratory Director confirmed the findings.
D6084	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions provide a safe environment in which employees are protected from physical, chemical, and biological hazards. This STANDARD is not met as evidenced by: Based on surveyor's observations in the laboratory, review of material safety data sheets for laboratory's chemicals, review of the laboratory's policies and procedures

	and staff interview, it was determined the Laboratory Director failed to ensure laboratory's environment provided protection from chemical hazards. Refer to D3011.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assurance records for 2021 and 2022, review of laboratory's control rollover studies for the Beckman Coulter Dxi600 chemistry analyzer, review of the laboratory's policies and staff interview, it was determined the Laboratory Director failed to ensure laboratory's quality control was maintained. Refer to D5469.
D6126	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(vi) The procedures for evaluation of the competency of the staff must include, but are not limted to assessment of problem solving skills. This STANDARD is not met as evidenced by: Based on review of laboratory's submitted Form 209, review of personnel records for 2021 and 2022, and staff interview it was determined the laboratory's Technical Supervisor failed to address problem solving skills in the competency assessments for two of two Testing Personnel performing high complexity testing. Findings included: 1. Review of laboratory's submitted Form 209 revealed the laboratory employed two Testing Personnel performing high complexity testing; testing person number 2 (TP2) and testing person number 3 (TP3). 2. Review of personnel records for 2021 and 2022 revealed the competency assessments for the two Testing Personnel performing high complexity testing did not have problem solving skills component assessed in 2022. Competencies missing the required component were: TP2: Competency assessed on 02 /14/2022 TP3: Competency assessed on 04/11/2022 and 10/20/2022 3. In an interview on 12/15/2022 at 1000 hours in the conference room, the Laboratory Director confirmed the findings.