Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2205785	06/14/2023
Name of Provider or Supplier	**Street Address, City, State**	
Center Of Reproductive Medicine Dba Shady Grove	9230 Katy Freeway #540, 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 applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories). 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. Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found in compliance with applicable CLIA conditions, and certification 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.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on surveyor's observations, review of manufacturer's instructions for use and staff interviews the laboratory failed to define and monitor storage conditions for one of one urine analysis test strips' container found in the facility's bathroom. Findings included: 1. Surveyor's observations on 06/14/2023 at 1445 hours revealed the following container of urine reagent strips stored in the facility's bathroom: McKesson Consult Diagnostics 10SG Urine Reagents Strips Lot: URS2050023 Expiration: 2024-07-24 The container did not have open date or amended expiration date documented. 2. Review of manufacturer's instructions for use for the McKesson Consult

	Diagnostics 10SG Urine Reagents Strips (no document number available) revealed: "STORAGE AND STABILITY Store as packaged in the closed canister or the sealed pouch either at room temperature or refrigerated (2-30C or 36-86F)." And, "Note: Once the canister has been opened, the remaining strips are stable for up to 3 months." 3. Further observations revealed there was no temperature monitoring device in the bathroom. 4. In an interview on 06/14/2023 at 1450 hours in the laboratory, the Technical Consultants number 1 and 2 (as indicated on submitted form CMS 209), confirmed that the bathroom did not have the temperature monitored, and stated that the laboratory did not define storage conditions for the urine strips since they were a waved test. Key: CMS - Centers for Medicare and Medicaid C - Degrees Celsius F - Degrees Fahrenheit
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: Based on review of the laboratory and patient test records from January to June 2023, and confirmed in interview, the laboratory failed to establish the specimen acceptability of one of two semen analysis collection cup (Protex). Findings included: 1. Random review of patient test records from January to June 2023 revealed one of ten patients had semen analysis performed using a Protex semen collection cup. 05/01 /2023 Sample #20231840 2. Review of the laboratory records revealed no documentation of the specimen collection, storage and preservation, acceptability and rejection for the above specimen container. 3. An interview with the TS#1 on 06/14 /2023 at 1400 hours in the laboratory confirmed the above findings. She stated the protex collection containers are validated for up to 5 hours. No documentation was provided as to the type of collection cup used nor the specimen stability.
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 review of the laboratory and patient test records from January to June 2023, and confirmed in interview, the laboratory quality assessment policies failed to monitor and identify the specimen acceptability of one of ten semen analysis reviewed. Findings included: 1. Review of the laboratory policy Semen Analysis under Sperm Motility and Progression, it stated "Motility and progression should be evaluated within one hour of collection." 2. Random review of patient test records from January to June 2023 revealed one of ten patients had semen motility performed after one hour of sample collection. 05/01/2023 Sample #20231840 collected 08:26

	AM; analyzed 11:20 AM, elapsed time 2 hours, 54 minutes 3. An interview with the TS#1 on 06/14/2023 at 1400 hours in the laboratory confirmed the above findings. She stated that they are working on determining the acceptability of specimens - one or two hours. However, she stated the protex collection containers are validated for up to 5 hours. No documentation was provided as to the type of collection tube used nor the specimen stability.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on surveyor observations, review of laboratory and patient test records, and confirmed in interview, the laboratory failed to follow its policy for determining sperm motility for one of one patient semen analysis observed. Findings included: 1. Review of the laboratory policy Semen Analysis under Motility and Progression, it stated "scan 6-10 fields on Slide #2, systemically grade 100 sperm as one of the following: a) rapid, progressive b) slow, sluggish, progressive c) non-progressive d) immotile Motility is reported as a percentage of moving sperm out of all sperm considered." 2. Surveyor observation on 06/14/2023 at 1050 hours in the laboratory revealed Testing Person #2 (TP#2) performed the semen analysis to include the semen motility for Patient #80257348. 3. An interview with TP#2 at 06/14/2023 at 1055 hours confirmed that she estimated the progression. She stated that she does not count each type of progression per the lab policy. 4. An interview with the TS#1 on 06/14 /2023 at 1340 hours in the laboratory confirmed the above findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on surveyor's observations, review of manufacturer's instructions for use and package labels, laboratory's policies/procedures and staff interview, the laboratory failed to define and monitor conditions for storage for one of one collection devices used in collecting samples for endocrinology testing. Findings included: 1. Surveyor's observations on 06/14/2023 at 1330 hours in the storage room revealed the following specimen collection devises stored on shelves: BD Vacutainer SST Blood Collection Tubes Lot: Expiration: # Boxes 2291657 2023-10-31 4 2291797 2023-10-31 5 Each box contained 100 tubes. 2. Review of manufacturer's instructions for use for BD Vacutainers (document 500030670, 03/2018) revealed: " Store tubes at 4-25C (39-

	77F), unless otherwise noted on the package label." 3. Review of the package label revealed storage temperature requirement to be 4-25C. 4. The laboratory was asked to provide documentation of monitoring storage room temperature and no such documentation was available for review prior to survey exit. 5. Review of laboratory's policies/procedures revealed the laboratory did not define temperatures and/or monitoring requirements for storage of specimen collection tubes. 6. In an interview on 06/14/2023 at 1335 hours in the laboratory, the Technical Consultants 1 and 2 (as indicated on the submitted form CMS 209), after review of the data, confirmed the findings. Key: CMS - Centers for Medicare and Medicaid C - Degrees Celsius F - Degrees Fahrenheit
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: A. Based on review of the laboratory records from January to June 2023, and confirmed in interview, the laboratory failed to document the verification records for one of one hematology tests (semen analysis count, motility, and morphology). Findings included: 1. Review of the laboratory records revealed the laboratory started semen analysis (count, motility, and morphology) testing in January 2023. 2. Review of laboratory records revealed no documentation of the verification studies for one of one test: semen analysis. No documentation of the count, motility, and morphology of semen analysis were available for review. 3. Review of the CMS116 revealed the laboratory performed 263 hematology tests annually. 4. An interview with the TS#2 on 06/14/2023 at 1010 hours in the office confirmed the above findings. 44698 B. Based on review of laboratory's test records, laboratory's submitted CMS form 116, test/instrument verification records and staff interview, the laboratory failed to document test verification components (accuracy, precision, reportable range) for five of five endocrinology tests performed by the laboratory on the Roche Cobas e411 analyzer upon its reinstatement into use. Findings included: 1. Review of laboratory's test records revealed the laboratory stopped patient testing in April 2021. In October of 2022 the laboratory placed the Roche Cobas e411 analyzer back in use in preparation for patient testing. Patient testing started in January 2023. 2. Review of laboratory's test records from January to June 2022 revealed the laboratory performed the following endocrinology tests on the Roche Cobas e411 analyzer: Estradiol Progesterone Luteinizing hormone (LH) Follicle-stimulating hormone (FSH) Human chorionic gonadotropin (HCG) 3. Review of laboratory's submitted CMS form 116 revealed the laboratory was estimated to perform 2,866 endocrinology tests annually. 4. Review of verification records for the above endocrinology tests revealed the laboratory completed method comparison studies for the tests performed on the Roche Cobas e411 analyzer between October and December 2022, bud did not document analysis of the obtained data for accuracy, precision and reportable range at time of placing the instrument back in use and prior to starting patient testing in January 2023. 5. In an interview on 06/14/2023 at 1430 hours in the laboratory, the laboratory's

	Technical Consultants 1 and 2 (as indicated on the submitted form CMS 209), after review of the data, confirmed the findings. Key: CMS - Centers for Medicare and Medicaid
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 and patient test records from January to June 2023, and confirmed in interview, the laboratory failed to establish the quality control requirements for one of one hematology test: semen analysis (motility). Findings included: 1. Review of random patient final reports in January to June 2023 revealed the following ten days when the laboratory performed semen analysis motility with no documentation of the motility quality control. 06/05/2023 ACC 20233179 05/10/2023 ACC 20232169 05/08/2023 ACC 20232061 04/04/2023 ACC 20231637 04/05/2023 ACC 20231243 03/22/2023 ACC 20231009 03/06/2023 ACC 20230680 02/06/2023 ID100413 01/17/2023 ID 100502 01/24/2023 ID 99071 2. Review of the laboratory policies revealed no documentation of the semen analysis motility requirement for quality control. 3. Review of the patient final reports confirmed that the above patient semen analysis testing included the motility. 4. An interview with the TS#1 on 06/14 /2023 at 1130 hours in the office confirmed the above findings.
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 observations, review of laboratory and patient test records, and confirmed in an interview, the laboratory failed to document the Diff Quick staining materials for intended reactivity each day of patient testing for ten of ten random patients reviewed in January to June 2023. The findings include: 1. In the laboratory walk-through on 06/14/2023 at 09:15 hours, the surveyor noted Diff Quick staining station used for semen morphology patient testing. 2. Review of the laboratory policy

	Kruger's Strict Morphology Semen Preparation did not include instructions or documentation of stain acceptability for Diff Quick. 3. Review of random patient final reports in January to June 2023 revealed the following ten patients had semen analysis morphology performed with no documentation of the Diff Quick stain quality. 06/05 /2023 ACC 20233179 05/10/2023 ACC 20232169 05/08/2023 ACC 20232061 04/04 /2023 ACC 20231637 04/05/2023 ACC 20231243 03/22/2023 ACC 20231009 03/06 /2023 ACC 20230680 02/06/2023 ID100413 01/17/2023 ID 100502 01/24/2023 ID 99071 4. In an interview on 06/14/2023 at 11:45 hours, in the office, the TS #2 confirmed that the Diff Quick stain acceptability had not been documented for the above days where patients had been tested.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on review of laboratory's test records, laboratory's submitted CMS form 116, test/instrument verification records and staff interview, the laboratory's Technical Consultants failed to ensure documentation of test verification components (accuracy, precision, reportable range) for five of five endocrinology tests performed by the laboratory on the Roche Cobas e411 analyzer upon its reinstatement into use was complete. Refer to D5421 B.
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 surveyor observations, review of the laboratory and patient test records from January to June 2023, and confirmed in interview, the Laboratory Director failed to ensure: a. The quality control requirements for one of one hematology test: semen analysis (motility) were established. Refer to D5469. b. The laboratory documented the Diff Quick staining materials for intended reactivity each day of patient testing. Refer to D5473.
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on review of the laboratory records from January to June 2023, and confirmed

	in interview, the laboratory's Technical Supervisors failed to ensure verification records for one of one hematology tests (semen analysis count, motility, and morphology) were documented. Refer to D5421 A.