

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2153575	(X3) Date Survey Completed 04/27/2023
Name of Provider or Supplier Center Of Reproductive Medicine	Street Address, City, State 7400 Fannin St Ste 1180, 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 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.
D3037	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory's twice annual test accuracy verification (proficiency testing - PT) records for 2021, 2022 and 2023, and staff interview, the laboratory failed to retain all proficiency testing documents/records for one of ten PT events reviewed. Findings included: 1. Review of laboratory's PT records for 2021, 2022 and 2023 revealed the laboratory used the American Association of Bioanalysts as their PT provider. 2. Further review of the PT records revealed the laboratory did not retain complete PT documentation for one of ten events reviewed, S1 Andrology & Embriology 2022. The only document available for review for that event was the result evaluation form. There was no documentation of results, no data entry forms, no documentation of who performed the testing. 3. In an interview on 04/27/2023 at 1320</p>

hours in the office, the laboratory's Technical Supervisor number 1 (as evident on submitted form CMS-209), after review of the data, confirmed the findings. Key: CMS - Centers for Medicare and Medicaid

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES
CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:
Based on review of laboratory's submitted Laboratory Personnel Report (CLIA) - form CMS-209, laboratory's policies/procedures, laboratory's personnel records and staff interview, the laboratory failed to document personnel competency for 2 of 2 technical consultants/technical supervisors and one of one general supervisor as per its own policy. Findings included: 1. Review of laboratory's submitted form CMS-209 revealed the laboratory employed two personnel acting as both technical consultant (TC1 and TC2) and technical supervisor (TS1 and TS2). One of these individuals was also acting as a general supervisor (GS1). 2. Review of laboratory's "Policy for Personnel Assessment" (last reviewed January 2023) revealed: "A new employee will be assessed twice in the first year of employment and annually thereafter. The personnel assessment forms are designated for each job description." 3. Review of laboratory's personnel records revealed there was no competency assessment documented for the laboratory's two personnel holding the TC1/TS1/GS1 and TC2 /TS2 positions. 4. In an interview on 04/27/2023 at 1145 hours in the office, the laboratory's Technical Supervisor number 1 (as evident on submitted form CMS-209), after review of the data, confirmed the findings. Key: CMS - Centers for Medicare and Medicaid

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 the direct observation of the surveyor, the review of the manufacturer's package inserts, the laboratory's records from November 2022 to April 2023, and confirmed in an interview, the laboratory failed to follow the manufacturer's instructions to ensure the proper storage conditions for four of five reconstituted calibrators for Roche cobas e411 chemistry analyzer. The findings were: 1. Review of the manufacturer's package insert titled Progesterone III Calset (2015-09, V1.0 English) under Storage and stability revealed "Stability of the reconstituted calibrators: either at -20C 31 days (freeze only once)." 2. Review of the manufacturer's package insert titled Estradiol III Calset (2015-06, V2.0 English) under

Storage and stability revealed "Stability of the reconstituted calibrators: either at -20C 31 days (freeze only once)." 3. Review of the manufacturer's package insert titled FSH III Calset (2015-11, V11.0 English) under Storage and stability revealed "Stability of the reconstituted calibrators: at -20C 3 months (freeze only once)." 4. Review of the manufacturer's package insert titled LH III Calset (2015-11, V10.0 English) under Storage and stability revealed "Stability of the reconstituted calibrators: at -20C 3 months (freeze only once)." 5. Direct observation of the surveyor on 4/27/2023 at 12: 15 pm in the laboratory revealed the freezer temperature where reconstituted calibrators stored was -15C. Progesterone III Calset Lot# 61403902 Exp. 2023-06-30 Estradiol III Calset Lot#: 63133401 Exp. 2023-09-30 FSH Calset III Lot#: 57782902 Exp. 2023-12-31 LH Calset II Lot#: 65754601 Exp. 2023-11-30 6. Random review of the freezer temperature logs from November 2022 to April 2023 revealed the temperatures were out of manufacturer's ranges for 13 of 13 days reviewed. 11/9/2022 -18C 11/16/2022 -10C 12/5/2022 -19C 12/16/2022 -15C 1/18/2023 -16C 2/6/2023 -17 C 2/23/2023 -16C 3/20/2023 -17C 3/30/2023 -17C 4/10/2023 -18C 4/24/2023 -16C 4 /25/2023 -16C 4/26/2023 -16C 7. Review the patients for the above dates revealed 24 patients had tests performed after calibrations on Roche cobas e411 chemistry analyzer (SN:1480-18). 11/9/2022 FSH and LH were calibrated: 11/9/2022 Patient ID: 0460138 LH= (C)0.908/0.968 mIU/mL 11/9/2022 Patient ID: 0459602 LH= 6.14 mIU/mL 11/9/2022 Patient ID: 0458969 LH= 2.80 mIU/mL 11/9/2022 Patient ID: 0460155 LH= 4.87 mIU/mL FSH=5.87 mIU/mL 11/9/2022 Patient ID: 0460111 LH= 6.38 mIU/mL FSH=9.09 mIU/mL 11/9/2022 Patient ID: 0460296 LH= 10.76 mIU /mL FSH=11.13 mIU/mL 11/9/2022 Patient ID: 0459277 LH= 7.66 mIU/mL 11/9 /2022 Patient ID: 0458831 LH= 6.48 mIU/mL 11/9/2022 Patient ID: 0458929 LH= 2.08 mIU/mL 11/9/2022 Patient ID: 0460253 LH= 10.43 mIU/mL 11/9/2022 Patient ID: 0459223 LH= 10.59 mIU/mL 11/9/2022 Patient ID: 0460154 LH= 11.76 mIU/mL 11/9/2022 Patient ID: 0458804 LH= 3.78 mIU/mL 11/9/2022 Patient ID: 0459418 LH= 5.33 mIU/mL 11/9/2022 Patient ID: 0460169 LH= 3.11 mIU/mL FSH=11.01 mIU/mL 1/18/2023 FSH was calibrated: 1/18/2023 Patient ID: 0469792 FSH=6.07 mIU/mL 4/10/2023 Estradiol and Progesterone were calibrated: 4/10/2023 Patient ID: 85815 Estradiol= 1556 pg/mL Progesterone= 1.65 ng/mL 4/10/2023 Patient ID: 85826 Estradiol= 56.68 pg/mL Progesterone= 0.268 ng/mL 4/10/2023 Patient ID: 85827 Estradiol= 6058 pg/mL Progesterone= 0.852 ng/mL 4/10/2023 Patient ID: 85845 Estradiol= 3964 pg/mL Progesterone= 2.72 ng/mL 4/10/2023 Patient ID: 85866 Estradiol= 2819 pg/mL Progesterone= 1.42 ng/mL 4/10/2023 Patient ID: 85875 Estradiol= 33.87 pg/mL Progesterone= 0.338 ng/mL 4/10/2023 Patient ID: 85884 Estradiol= 663.4 pg/mL Progesterone= 0.286 ng/mL 4/10/2023 Patient ID: 85953 Progesterone= 0.296 ng/mL 8. An interview with the technical supervisor #1 on 4/27/2023 at 1:00 pm in a conference room confirmed the above findings. Key: LH=Luteinizing Hormone FSH=Follicle Stimulating Hormone

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:
A Based on the surveyor's direct observation, the laboratory's policy, the

manufacturer's package inserts, and confirmed in an interview, the laboratory failed to document revised expiration dates on reconstituted QC and calibrators for six of six lot numbers in use for Roche cobas e411 chemistry analyzer. A. BIO-RAD Lyphochek Immunoassay Plus Control B. Progesterone III Calset C. Estradiol III Calset D. FSH III Calset E. LH II Calset F. HCG+B Calset The findings were: 1. Review of the laboratory's policy titled Daily BioRad QC & QC net, revised on 5/7/2018, under STORAGE AND STABILITY revealed "After reconstituting and storing tightly capped at 2 to 8 degree Celsius, this product will be stable as follows: All analytes: 7 days." 2. Review of the manufacturer's package insert titled Lyphochek Immunoassay Plus Control (English.2023-02.1536-00S) under STORAGE AND STABILITY revealed "Reconstituted and Refrigerated: After reconstituting and storing tightly capped at 2 to 8C, this product will be stable as follows: All analytes: 7 days." 3. Review of the manufacturer's package insert titled Progesterone III Calset (2015-09, V1.0 English) under Storage and stability revealed "Stability of the reconstituted calibrators: either at -20C 31 days (freeze only once)." 4. Review of the manufacturer's package insert titled Estradiol III Calset (2015-06, V2.0 English) under Storage and stability revealed "Stability of the reconstituted calibrators: either at -20C 31 days (freeze only once)." 5. Review of the manufacturer's package insert titled FSH III Calset (2015-11, V11.0 English) under Storage and stability revealed "Stability of the reconstituted calibrators: at -20C 3 months (freeze only once)." 6. Review of the manufacturer's package insert titled LH III Calset (2015-11, V10.0 English) under Storage and stability revealed "Stability of the reconstituted calibrators: at -20C 3 months (freeze only once)." 7. Review of the manufacturer's package insert titled HCG+B Calset (2015-09, V10.0 English) under Storage and stability revealed "Stability of the reconstituted calibrators: at 2-8C 12 weeks." 8. Direct observation of the surveyor on 4/27/2023 at 12:15 pm in the laboratory revealed no revised expiration dates documented on the reconstituted QC and calibrators for six of six lot numbers in use. BIORAD Lyphochek Immunoassay Plus Control Lot#: 4042 Original expiration date: 2025-03-31 Reconstituted date: 04/26/2023 Progesterone III Calset Lot# 61403902 Original expiration date: 2023-06-30 Estradiol III Calset Lot#: 63133401 Original expiration date: 2023-09-30 FSH Calset III Lot#: 57782902 Original expiration date: 2023-12-31 LH Calset II Lot#: 65754601 Original expiration date: 2023-11-30 HCG+B Calset Lot# 64613901 Original expiration date: 2023-12-31 9. An interview with the technical supervisor #1 on 4/27/2023 at 12:55 pm in a conference room confirmed the above findings. Key: QC=Quality Control LH=Luteinizing Hormone FSH=Follicle Stimulating Hormone HCG=Human chorionic gonadotropin 44698 B. Based on surveyor's observations on 04/27/2023 at 1510 hours in the laboratory and staff interview, the laboratory failed to label 3 of 3 secondary containers of QuickLink III (DIFF QUICK) hematology stain reagents with reagent expiration dates. Findings included: 1. Surveyor's observations on 04/27/2023 at 1510 hours in the laboratory revealed the following solutions in secondary containers (staining jars) that had no expiration date annotated on the jars: QuickLink III Fixative Lot number: 6162 Expiration date: not specified QuickLink III Solution I Lot number: 2301 Expiration date: not specified QuickLink III Solution II Lot number: 1343 Expiration date: not specified 2. In an interview on 04/27/2023 at 1510 hours in the laboratory Testing Person number 3 (as evident on submitted form CMS-209), stated she was not aware that documentation of expiration dates was necessary if the lot number and solution's identity was documented on secondary containers. This confirmed the findings. Key: CMS - Centers for Medicare and Medicaid

D5433

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on surveyor's observations in the laboratory, review of laboratory's equipment maintenance records, equipment's manufacturer instructions for use manuals, laboratory's policies/procedures and staff interview, the laboratory failed to define and document maintenance procedures for one of one microscope used by the laboratory for semen analysis. Findings included: 1. Surveyor's observations on 04/27/2023 at 1510 hours in the laboratory revealed the laboratory used the following microscope for semen analysis procedures: Olympus BX41 Serial number: 7G21200 2. Review of laboratory's equipment maintenance records revealed there was no documentation of routine microscope maintenance performed by the laboratory. Third party preventive maintenance (PM) was documented as follows: Last PM: February 2023 Next PM: August 2023 3. Review of the manufacturer instructions for use "Olympus Instructions BX41 System Microscope" (document number Ax7474) revealed there were no specifications for routine maintenance and its frequency defined by the manufacturer. 4. Review of laboratory's policies/procedures revealed there was no policy/procedure in place defining the microscope's maintenance procedures or maintenance frequency. 5. In an interview on 04/27/2023 at 1545 hours in the office the laboratory's Technical Supervisor number 1 (as evident on 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 the review of the laboratory's policy, the manufacturer's package insert, the laboratory's QC records from January 2023 to March 2023, and confirmed in an interview, the laboratory failed to follow its own policy to establish one of one new lot number of QC acceptability for five of five analytes on Roche cobas e411 chemistry analyzer before putting the lot number in use. 1. Estradiol 2. FSH 3. hCG 4. LH 5.

Progesterone The findings were: 1. Review of the laboratory's policy titled QC Acceptable Range Verification, revised on 5/7/2018, under VERIFYING RANGE VALUES revealed "Upon the arrival of a new lot of BioRad Lyphochek Immunoassay Plus Control Levels 1, 2, and 3, a new range for each control must be established and verified." 2. Review of the manufacturer's package insert titled Lyphochek Immunoassay Plus Control (English. 2023-02.1536-00S) under Revision Date 2023-04-20 ->Indicates Revised Information revealed the manufacturer's acceptable ranges for each analyte. Level 1 Lot# 40421 Estradiol 63.8-108 pg/mL FSH 6.13-8.64 mIU/mL hCG 3.54-5.73 mIU/mL LH 1.23-1.97 mIU/mL Progesterone 0.330-0.915 ng/mL Level 2 Lot# 40422 Estradiol 142-206 pg/mL FSH 17.6-25.2 mIU/mL hCG 20.1-29.0 mIU/mL LH 17.8-24.2 mIU/mL Progesterone 8.23-11.8 ng/mL Level 3 Lot# 40423 Estradiol 312-418 pg/mL FSH 34.8-49.9 mIU/mL hCG 198-268 mIU/mL LH 61.4-82.7 mIU/mL Progesterone 21.9-30.6 ng/mL 3. Review of the laboratory's QC records from January 2023 to March 2023 revealed the laboratory's QC acceptable ranges were the same as the manufacturer's acceptable ranges for five of five analytes for Roche cobas e411 chemistry analyzer (SN: 1480-18). BIORAD Lyphochek Immunoassay Plus Control Lot#: 4042 Expiration date: 2025-03-31 Level 1 Lot# 40421 Level 2 Lot# 40422 Level 3 Lot# 40423 4. An interview with the technical supervisor #1 on 4/27/2023 at 11:45 am in a conference room confirmed the above findings. Key: QC=Quality Control hCG=Human chorionic gonadotropin LH=Luteinizing Hormone FSH=Follicle Stimulating Hormone

D5779

CORRECTIVE ACTIONS
CFR(s): 493.1282(a)

Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.

This STANDARD is not met as evidenced by:
Based on review of laboratory's twice annual accuracy verification (proficiency testing - PT) records for 2021, 2022 and 2023, review of laboratory's policies and procedures and staff interview, the laboratory failed to have in place policy/procedure for corrective action for proficiency testing failures. Findings included: 1. Review of laboratory's twice annual accuracy verification (PT) records revealed the laboratory used the American Association of Bioanalysts proficiency testing to verify its tests' accuracy. 2. Review of laboratory's American Association of Bioanalysts' PT records for 2021, 2022 and 2023 revealed the score for Leuteinizing Hormone (LH) in Q2 Chemistry 2022 event to be 50%. The laboratory documented result evaluation but did not document corrective action taken to ensure their results were accurate and/or to prevent recurrence of PT failure. 3. Review of laboratory's policy "Policy for Proficiency Testing" (last reviewed January of 2023) revealed the policy addressed corrective action (reevaluation) for analytes with no score or no consensus but did not address corrective action for analytes with unsatisfactory/failed results. 4. In an interview on 04/27/2023 at 1245 hours in the office, the laboratory's Technical Supervisor number 1 (as evident on submitted form CMS-209), after review of the data, confirmed the findings. Key: CMS - Centers for Medicare and Medicaid