

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0940439	(X3) Date Survey Completed 04/21/2021
Name of Provider or Supplier Cooper Institute Reproductive Laboratory	Street Address, City, State 7500 Beechnut St, # 308, 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 conditions not met were: D5400 - 42 C.F.R. 493.1250 Condition: 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.
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the American Association of Bioanalysts (AAB) attestation forms, a review of the laboratory's AAB proficiency testing records from 2019 and 2021, and staff interview, it was revealed that the laboratory failed to have documentation of the laboratory director or designee signing 4 of 7 attestation statements for 2019 and 2021. Findings include: 1. A review of the AAB attestation form revealed the following: "In addition to the analysts' signature, one of the following must sign once for all analytes reported on this form: Director, Technical Consultant, or Technical Supervisor." 2. A review of the laboratory's AAB proficiency testing records from 2019 and 2021 revealed the following 4 events were missing the laboratory director or designee's signature on the attestation forms: - Q3 Chemistry 2019 (third event) - Q2 Chemistry 2019 (second event) - Q1 Chemistry 2021 (first event) - Q1 Nonchemistry 2021 (first event) 3. An interview with laboratory director on 4/21/21 at 12:15 p.m. in the break room, after review of the records, confirmed the above findings.</p>

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 a review of the American Association of Bioanalysts (AAB) website, a review of the laboratory's AAB proficiency testing records for 2019 and 2020 and staff interview, it was revealed that the laboratory failed to have documentation of verifying the accuracy of analytes that were not graded by the proficiency testing program for 4 of 4 events in 2019 and 2020. Findings include: 1. A review of the Frequently Asked Questions section found on the AAB website (<https://www.aab-pts.org/faq#4>) stated the following: " ? = This score may not truly evaluate performance for this specimen which was not graded because of a lack of participant consensus. You have received a default score of 100 for this sample because our statistical checks indicated your group was not valid. If you are outside the given acceptable range, you either need to justify why this range is not appropriate or treat this as a miss requiring corrective action." 2. A review of the laboratory's AAB results for 2019 and 2020 revealed the following 4 events that had analytes that were scored as not graded with a '?' next to the reported value: a) Embryology, Andrology & Fetal S1 2019 (first event): - Embryology Grading Day 5- Inner Cell Mass Compaction Reported: Complete Acceptable response: Incomplete - Sperm Count video Reported value: 221 Acceptable range: 107 - 198 - Sperm Count video Reported value: 206 Acceptable range: 100 - 186 b) Embryology, Andrology & Fetal S2 2019 (second event): - Sperm Motility Forward Progression Reported value: 31 Acceptable range: 38 - 63 - Sperm Motility Forward Progression, Semiquant Reported: Good progressive motility Acceptable response: Progressive, but sluggish c) Embryology, Andrology & Fetal S1 2020 (first event): - Sperm Count video Reported value: 167 Acceptable range: 82 - 151 - Sperm Motility Forward Progression Reported value: 27 Acceptable range: 36 - 60 d) Embryology, Andrology & Fetal S2 2020 (second event): - Sperm Motility Forward Progression Reported value: 24 Acceptable range: 25 - 49 3. Further review of the AAB proficiency testing results listed above revealed there was no documentation of corrective action being performed when the reported values were outside of the acceptable range or did not match the acceptable response. 4. An interview with the laboratory director on 4/21/21 at 12:15 p.m. in the break room, after review of the records, confirmed the above findings.

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 policies, a review of the laboratory's records, and staff interview, it was revealed that the laboratory failed to have documentation of performing twice annual accuracy assessments in 2020 for 1 of 7 unregulated analytes tested on the Roche Cobas e 411 analyzer. Findings include: 1. A review laboratory's policy titled 'External and Internal Quality Assessment' revealed the following: "When

external proficiency testing materials are not available, the semi-annual alternative performance assessment process should be integrated within the routine workload." 2. The laboratory was asked to provide documentation of assessing the accuracy, twice annually, for AMH on the Roche Cobas e 411 analyzer. No documentation was provided. 3. An interview with the laboratory director on 4/22/21 at 1:00 p.m. in the break room, after review of the records, stated that American Association of Bioanalysts (AAB) does not offer proficiency testing samples for AMH testing and that because of this, the twice annual assessments for AMH were never done. This confirmed the above findings.

D5291

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory's Quality Assurance Plan, a review of the laboratory's records, and staff interview, it was revealed the laboratory failed to have documentation of monitoring and assessing, and when indicated, correcting problems identified in the general laboratory systems. Findings include: 1. A review of the laboratory's Quality Assurance Plan revealed the laboratory will perform the following quarterly reviews: "Proficiency Testing - Appropriate corrective action taken for all PT analytes." 2. A review of the laboratory's records from April 12, 2019 (effective date) to April 21, 2021 (the day of the survey) revealed the laboratory failed to have documentation of monitoring, assessing, and correcting problems for the quality indicators specified in its policy. 3. An interview with the laboratory director on 4/22/21 at 12:30 p.m. in the break room, after review of the records, confirmed the above findings. Key: PT = Proficiency testing

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 a review of the Operator's Manual for the Roche Cobas e 411 analyzer, a random review of patient test records from October 2020 to November 2020, and staff interview, it was revealed that the laboratory failed to follow the manufacturer's instructions for resolving flags on patient results run on the Roche Cobas e 411 analyzer for 4 of 42 results reviewed between October 2020 to November 2020. Findings include: 1. A review of the Operator's Manual for the Roche Cobas e 411 (Version 3.2) revealed the following: " Troubleshooting data problems '>Test' = The sample concentration is too high. Manually dilute the sample, rerun the sample.

'CarOvr' = Carryover between tests. Rerun the sample." 2. A random review of the laboratory's patient test records from October 2020 to November 2020 revealed the following patient's results with flags present on the report and there was no documentation of following the manufacturer's instructions for resolving the flags prior to resulting: Date: 10/19/20 Patient ID: OB 'CarOvr' flag for Luteinizing Hormone - No documentation of a rerun Date: 11/16/20 Patient ID: MM '>Test' flag for Estradiol - No documentation of a dilution or rerun Date: 11/24/20 Patient ID: EC '>Test' flag for Estradiol - No documentation of a dilution or rerun Date: 11/25/20 Patient ID: HN '>Test' flag for Progesterone - No documentation of a dilution or rerun

3. An interview with the laboratory director on 4/22/21 at 11:35 a.m. in the break room, after review of the records, confirmed the above findings.

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 manufacturer's instructions, 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 have documentation of the laboratory director signing and approving 8 of 28 laboratory procedures (refer to D5407). 2. The laboratory failed to have documentation of performing an accuracy study for 1 endocrinology analyte tested on the Cobas e 411 analyzer (refer to D5421 I). 3. The laboratory failed to have documentation of performing reference range verification studies for 9 endocrinology analytes tested on the Cobas e411 analyzer (refer to D5421 II). 4. The laboratory failed to have documentation of performing the required monthly maintenance procedures on the Roche Cobas e 411 analyzer (refer to D5429). 5. The laboratory failed to have a method in place to monitor quality control values over time to detect shifts and trends for 10 analytes tested on the Roche Cobas e 411 analyzer (refer to D5441). 6. The laboratory failed to have documentation of running two levels of quality control material for each day of patient testing on the Roche Cobas e 411 analyzer (refer to D5447 I). 7. The laboratory failed to ensure at least two levels of quality control were acceptable prior to testing patients for Estradiol testing on the Roche Cobas e 411 analyzer (refer to D5447 II). 8. The laboratory failed to verify new lot numbers of quality control for endocrinology testing on the Roche Cobas e 411 analyzer before placing them into use (refer to D5469). 9. The laboratory failed to document the duplicate bead counts for each level of control, making sure the two concentrations were within 10% of each other (refer to D5479). 10. The laboratory failed to have documentation of monitoring and assessing, and when indicated, correct problems identified in the analytic systems (refer to D5791).

D5407

PROCEDURE MANUAL
CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the

current laboratory director before use.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's policies, a review of the laboratory's procedure manual, a review of the laboratory's submitted CMS 116 application, and staff interview, it was revealed that the laboratory failed to have documentation of the laboratory director signing and approving 8 of 28 laboratory procedures. Findings include: 1. A review of the laboratory's policy titled 'Document Control' revealed the following: "The Cooper Institute maintains a document control/management system to assure that: a) All policies and procedure manuals are current b) Personnel have access to policies/procedures relevant to their job performance c) All policies /procedures are authorized by the laboratory director or his/her designee d) Policies and procedures are reviewed at least annually by the laboratory director or his/her designee" 2. A review of the laboratory's procedure manual revealed the following 8 policies with no documentation of the laboratory director's signature of approval or review: - Chemical Safety - Laboratory Quality Control - Quality Indicators for Cooper Institute Laboratory Equipment - Cryopreservation Using Liquid Nitrogen - Laboratory Security - Exposure Control Plan - IVF Laboratory Back-Up Capabilities - Verification of Patient Identity 3. A review of the laboratory's submitted CMS 116 application listed the laboratory's effective date as 4/12/2019. 4. An interview with the laboratory director on 4/22/21 at 1:30 p.m. in the break room, after review of the records, confirmed the above findings.

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:

I. Based on a review of the laboratory's verification studies for the Roche Cobas e 411 analyzer, and staff interview, it was revealed that the laboratory failed to have documentation of performing an accuracy study for 1 of 10 endocrinology analytes tested on the Cobas e 411 analyzer. Findings include: 1. A review of the laboratory's verification studies for the Cobas e 411 (Serial Number: 66Y225) revealed the verification studies were performed in September 2020. 2. Further review of the verification studies revealed no documentation of an accuracy study for the analyte anti-mullerian (AMH). 3. An interview with the laboratory director on 4/22/21 at 11:15 a.m. in the break room, after review of the records, confirmed the studies were never done. II. Based on a review of the laboratory's verification studies for the Cobas e 411 analyzer, a review of patient test records, and staff interview, it was revealed that the laboratory failed to have documentation of performing reference range verification studies (verifying that the reference ranges are appropriate to use for its patient population) for 9 of 10 endocrinology analytes tested on the Cobas e411 analyzer. Findings include: 1. A review of the laboratory's verification studies for the Cobas e 411 (Serial Number: 66Y225) revealed the verification studies were

performed in September 2020. 2. A review of patient test records revealed the following reference ranges for 9 analytes tested on the Cobas e 411: a) LH (luteinizing hormone) 0.110 - 198.0 mIU/mL b) FSH (Follicle-stimulating hormone) 0.110 - 198.0 mIU/mL c) HCG BETA (Beta-Human Chorionic Gonadotropin) 0.000 - 1.00 mIU/mL d) Progesterone 0.055 - 59.0 ng/mL e) Estradiol 5.10 - 2950 pg/mL f) Thyroid Stimulating Hormone (TSH) 0.270 - 4.20 uIU/mL g) Free Tyroxine (FT4) 0.932 - 1.71 ng/dL h) Anti-mullerian Hormone (AMH) 0.030 - 23.00 ng/mL i) Vitamin D 5.0 - 60.00 ng/mL 3. Further review of the laboratory's verification studies for the Roche Cobas e 411 analyzer revealed the laboratory failed to have documentation of verifying the above listed reference ranges. 4. An interview with the laboratory director on 4/22/21 at 12:10 p.m. in the break room, after review of the records, confirmed the studies were never done.

D5429

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

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
 Based on a review of the Operator's Manual for the Roche Cobas e 411 analyzer, a review of the laboratory's installation records, a review of the laboratory's Cobas e 411 Maintenance Logs, and staff interview, it was revealed the laboratory failed to have documentation of performing the required monthly maintenance procedures on the Roche Cobas e 411 analyzer for 5 of 7 months in 2020 and 2021. Findings include: 1. A review of the Operator's Manual for the Roche Cobas e 411 analyzer (Version 3.2) states the following preventative monthly maintenance is required: "Monthly - Replace the pinch valve tubing" 2. A review of the laboratory's installation records revealed the Roche Cobas e 411 analyzer (Serial number 66Y225) was installed in September 2020. 3. A review of the laboratory's 'Cobas e 411 Maintenance Logs' from September 2020 to March 2021 revealed the following 5 months where the required monthly maintenance was not documented as being performed: October 2020 November 2020 December 2020 January 2021 February 2021 4. An interview with testing person #1 (as indicated on the CMS 209 form) on 4/22/21 at 11:20 a.m. in the laboratory, 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 quality control records for the Roche Cobas e 411 analyzer from September 2020 to March 2021 and staff interview, it was revealed that the laboratory failed to have a method in place to monitor quality control values over time to detect shifts and trends for 10 of 10 analytes tested on the Roche Cobas e 411 analyzer. Findings include: 1. A review of the laboratory's quality control records from September 2020 to March 2021 revealed the laboratory ran 2 levels of quality control material, once a day, each day of patient testing for the following 10 analytes: Estradiol Progesterone Follicle Stimulating Hormone Luteinizing Hormone Human Chorionic Gonadotropin Thyroid Stimulating Hormone Free T4 (Thyroxine) Vitamin D Anti-SARS CoV-2 Anti-Mullerian Hormone 2. Further review of the quality control records revealed the laboratory failed to have a method in place for monitoring and evaluating quality control results over time for the above listed analytes. 3. An interview with the laboratory director on 4/22/21 at 10:50 a.m. in the break room 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:
I. Based on a review of the laboratory's quality control records for the Roche Cobas e 411 analyzer for March 2021, a review of patient test records, and staff interview, it was revealed that the laboratory failed to have documentation of running two levels of quality control material for each day of patient testing for 5 of 31 days in March 2021 on the Roche Cobas e 411 analyzer. Findings include: 1. A review of the laboratory's quality control records for the Roche Cobas e 411 analyzer from March 2021 revealed the laboratory failed to have documentation of running two levels of quality control material each day of patient testing for the following analytes: Date: 3/3/21 PreciControl U1 was run for FSH Date: 3/4/21 PreciControl U1 was run for FSH, LH, or Progesterone Date: 3/9/21 PreciControl U2 was not run for FSH or Progesterone Date: 3/15/21 PreciControl U1 was run for FSH, LH, or Progesterone Date: 3/19/21 PreciControl U1 was run for FSH or Progesterone * There was no documentation of a second level of quality control material being run on the dates and for the analytes listed above. 2. A review of patient test records from March 2021 revealed the following patient's samples were result on days when only one level of quality control was run on the Roche Cobas e 411 analyzer: Date: 3/3/21 Patient ID: 11/4/86 FSH result: 11.0 mIU/mL Date: 3/4/21 Patient ID: 2/15/85 FSH result: 5.77 mIU/mL LH result: 6.24 mIU/mL Progesterone result: 0.405 ng/mL Date: 3/9/21 Patient ID: 1/7/93 FSH result: 6.06 mIU/mL Progesterone result: 0.585 ng/mL Date: 3/9/21 Patient ID: 11/15/93 FSH result: 7.49 mIU/mL Progesterone result: 0.208 ng/mL Date: 3/9/21 Patient ID: 8/29/98 FSH result: 14.04 mIU/mL Progesterone result: 0.793 ng/mL Date: 3/15/21 Patient ID: 8/3/87 FSH result: 8.06 mIU/mL Progesterone result: 0.260 ng/mL LH result: 4.41 mIU/mL Date: 3/15/21 Patient ID: 8/3/76 FSH result: 14.46 mIU/mL Progesterone result: 0.151 ng/mL LH result: 6.49 mIU/mL Date: 3/19/21

Patient ID: 2/7/76 FSH result: 10.84 mIU/mL Progesterone result: 0.241 ng/mL Date: 3/19/21 Patient ID: 11/10/79 FSH result: 4.80 mIU/mL Progesterone result: 0.340 ng/mL 3. An interview with the laboratory director on 4/22/21 at 11:20 a.m. in the break room, after review of the records, stated that only one level of quality control material was run on a few of the analytes for cost saving purposes. This confirmed the above findings. Key: FSH = Follicle Stimulating Hormone LH = Luteinizing Hormone II. Based on a review of the Roche Cobas e 411 Operator's Manual, a random review of the laboratory's quality control records for March 2021, 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 Estradiol testing on the Roche Cobas e 411 analyzer for 2 of 31 days from March 2021. Findings include: 1. A review of the Roche Cobas e 411 Operator's Manual (Version 3.2) revealed the following: "Before you test patient samples, perform QC to check the performance of the analyzer. After you perform QC tests, validate them." 2. A random review of the laboratory's quality control records from March 2021 revealed the following 2 days when only one level of quality control was acceptable for Estradiol testing: Date: 3/9/21 PreciControl U1 for Estradiol = 66.91 (acceptable range: 66.92 - 124.3) - unacceptable PreciControl U2 for Estradiol acceptable Date: 3/19/21 PreciControl U1 for Estradiol acceptable PreciControl U2 for Estradiol = 342.7 (acceptable range: 364.0 - 676.0) - unacceptable 3. A random review of patient test reports revealed the following 3 patient samples were resulted for Estradiol when only one level of quality control was acceptable: Date: 3/3/21 Patient ID: 11/4/86 Estradiol result: 18.80 pg/mL Date: 3/19/21 Patient ID: 2/7/76 Estradiol: 107.1 pg/mL Date: 3/19/21 Patient ID: 11/10/79 Estradiol: 74.89 pg/mL 4. An interview with testing person #1 (as indicated on the CMS 209 form) on 4/22/21 at 10:00 a.m. in the laboratory, after review of the records, stated that when the control are out of range, he takes the quality control results to the laboratory director for approval or disapproval. If the laboratory director approves the quality control results, whether out of range or not, it is ok to run the patient samples. This confirmed the above findings. Key: QC = Quality Control

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 a review of the laboratory's quality control records for the Roche Cobas e 411 analyzer from September 2020 to April 2021 and staff interview, it was revealed that the laboratory failed to verify new lot numbers of quality control for endocrinology testing on the Roche Cobas e 411 analyzer before placing them into

use. Findings include: 1. A review of the laboratory's quality control records for the Roche Cobas e 411 analyzer (serial number: 66Y225) from September 2020 to April 2021 revealed there was no documentation of the laboratory performing lot to lot verifications for the following lot numbers of external quality control materials: a) Elecsys Vitamin D Level V0 Lot Number: 416978 Level V2 Lot Number: 416980 b) PreciControl Varia Level V0 Lot Number: 479256 Level V2 Lot Number: 479269 c) PreciControl Universal Level U1 Lot Number: 411864 Level U2 Lot Number: 411868 2. An interview with the laboratory director on 4/22/21 at 11:19 a.m. in the break room, after review of the records, confirmed the above findings.

D5479

CONTROL PROCEDURES

CFR(s): 493.1256(e)(5)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of the manufacturer's instructions for the QC- Beads for sperm counting, a review of the laboratory's Andrology/Blood Lab QC logs for January 2021 to March 2021, and staff interview, it was revealed the laboratory failed to document the duplicate bead counts for each level of control, making sure the two concentrations were within 10% of each other, for 3 of 3 months in 2021. Findings include: 1. A review of the manufacturer's instructions for the QC- Beads (1/3/13) revealed the following steps for performing quality control testing: "Count the beads using a standard counting procedure for counting sperm. 1. Invert the bottle several times to resuspend the Hi QC-Beads. 2. Using a pipette, remove the volume recommended for the counting chamber you are using. 3. Pipette the bead suspension into the counting chamber. 4. Immediately recap the bottle. 5. Wait about 5 minutes to allow the beads to stop moving and then observe using a microscope. 6. Count at least 200 beads. 7. Calculate the concentration of beads according to the counting chamber manufacturer ' s instructions. 8. Repeat steps 1- 7 using a fresh aliquot of beads. 9. Compare the two results. If the results are within 10% of each other, then average the two counts. 10. The average count should be within the range of the Expected Values. If the results are not within this range, then repeat steps 1-9. 11. Repeat steps 1-10 using the Lo QC-Beads." 2. A review of the laboratory's Andrology/Blood Lab QC logs for January 2021 to March 2021 revealed there was no documentation of the individual counts for each level of QC beads, verifying that the two counts were within 10% of each other. 3. An interview with testing person #1 (as indicated on the CMS 209 form) on 4/22/21 at 9:15 a.m. in the laboratory, 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 Assurance Plan, a review of the laboratory's records, and staff interview, it was revealed the laboratory failed to have documentation of monitoring and assessing, and when indicated, correcting problems identified in the analytic systems. Findings include: 1. A review of the laboratory's Quality Assurance Plan revealed the laboratory will perform the following quarterly reviews: "Maintenance/Function Check Records - Maintenance tasks performed according to manufacturer's recommendations. Procedure Reviews - Each procedure reviewed and signed by Lab Director within 12 months." 2. A review of the laboratory's records from April 12, 2019 (effective date) to April 21, 2021 (the day of the survey) revealed the laboratory failed to have documentation of monitoring, assessing, and correcting problems for the quality indicators specified in its policy. 3. An interview with the laboratory director on 4/22/21 at 12:30 p.m. in the break room, after review of the records, confirmed the above findings.

D6007

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(1)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (E) The laboratory director must-- (E)(1) 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 manufacturer's instructions, a review of patient test records, and staff interview, it was revealed that the laboratory director failed to ensure the test system provided quality laboratory results (refer to D5311).

D6102

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory's submitted CMS 209 form, a review of the laboratory's personnel files, a review of patient test records, and staff interview, it was revealed the laboratory director failed to ensure documentation of site-specific training for 1 of 1 testing personnel performing high complexity testing- Embryology and Andrology. Findings include: 1. A review of the laboratory's submitted CMS 209 form revealed the the laboratory identified 1 testing person performing high complexity testing- Embryology and Andrology. 2. A review of the laboratory's personnel records revealed testing person #1 had no documentation of site-specific training (demonstrating that they can perform all testing operations for this laboratory)

to perform high complexity testing. 3. An interview with the laboratory director on 4/22/21 at 10:30 a.m. in the break room, after review of the records, stated that no on-site training was documented. This confirmed the above findings.

D6174

TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1495(a)

Each individual performs only those high complexity tests that are authorized by the laboratory director and require a degree of skill commensurate with the individual's education, training or experience, and technical abilities.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's policies, a review of the submitted CMS 209 form, a review of the laboratory's personnel records, a review of the laboratory's testing records, and staff interview, it was revealed that the laboratory failed to ensure that 1 of 1 testing personnel performed high complexity tests authorized by the laboratory director. Findings include: 1. A review of the laboratory's policy titled 'Training policies for new procedure or new personnel' revealed the following: "When both the director and the employee are confident that the employee can perform procedure unassisted, then written certification to perform procedure unassisted is granted by the director." 2. Further review of the laboratory's policy titled 'Training policies for new procedure or new personnel' found the following form attached to the back of the policy, 'Training/Credentialing Document and Authorization Form'. 3. A review of the submitted CMS 209 form revealed the laboratory employed 1 testing person to perform high complexity testing. 4. A review of the laboratory's personnel records revealed no documentation of the laboratory director's authorization to test or documentation of the 'Training/Credentialing Document and Authorization Form' for testing person #1. 5. An interview with the laboratory director on 4/22/21 at 10:00 a. m. in the break room, after review of the records, confirmed the above findings.