Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0940439	09/05/2024
Name of Provider or Supplier	**Street Address, City, State**	
Cooper Institute Reproductive Laboratory	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	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.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on the review of the Certification and Survey Provider Enhanced Reporting (CASPER) 155 report from 2023 to 2024, the AAB-MLE proficiency testing policy, the proficiency testing results in 2023, and confirmed in an interview, the laboratory failed to self-evaluate missing proficiency testing event for 6 of 6 analytes. The findings were: 1. Review of the Certification and Survey Provider Enhanced Reporting (CASPER) 155 report from 2023 to 2024 revealed the laboratory did not receive grades from 2nd event in 2023. 2. Review of the AAB-MLE proficiency testing policy titled AAB-MLE Proficiency Testing Service Evaluating Your Proficiency Testing Results revealed "II. If PT results for any analytes are unsatisfactory:...C. If any of the above appear to be the reason for the PT problems: 1. Document the cause and the corrective action taken to prevent them from happening in the future." 3. Review of the laboratory's AAB/MLE proficiency testing Chemistry M2 2023 revealed no documentation of self-evaluation for the 6 of 6 analytes included in the proficiency testing. Chemistry M2 2023 -Estradiol -FSH (follicular stimulating hormone) -Progesterone -HCG (human chorionic gonadotropin) -TSH (thyroid stimulating hormone) -Free T4 (Free Thyroxine) 4. In an interview at 9:58 am on 09/05/2024 in a break room, the laboratory director confirmed the above findings. Key: AAB=American Association of Bioanalysts MLE=Medical Laboratory Evaluation

D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on the review of the laboratory's proficiency testing policies, the proficiency testing events from 2023 to 2024, and confirmed in an interview, the laboratory failed to have documentation of performing corrective actions for 4 of 6 proficiency testing events from 2023 to 2024 with unsatisfactory scores. The findings were: 1. Review of the laboratory's policy titled PROFICIENCY TESTING revealed "Any unacceptable of unsatisfactory results must be documented on the review and corrective action must be initiated." 2. Review of the laboratory's another policy titled LABORATORY PROFICIENCY TESTING (PT) revealed "(9) Document remedial actions for unsatisfactory performance." 3. Review of the laboratory's AAB-MLE proficiency testing events from 2023 to 2024 revealed 4 of 6 proficiency testing events included unsatisfactory scores, Embryology, Andrology $ Fetal S2 2023 984-Embrology Grading Day3-Embryo Grade 50% Spec 7 Reported Value Poor Mean/Intended Fair Chemistry M3 2023 Follicle Stimulating Hormone (FSH), mIU/mL 0% Spec 11 Reported Value 18.2 Grading Range 20.1-29.0 Spec 12 Reported Value 31.1 Grading Range 34.4-39.6 Embryology, Andrology $ Fetal S1 2024 -984-Embrology Grading Day3-Embryo Grade, Digital image 50% Spec 1 Reported Value Fair Mean/Intended Poor Chemistry M1 2024 Follicle Stimulating Hormone (FSH), mIU/mL 0% Spec 1 Reported Value 15.0 Grading Range 15.5-22.4 Spec 2 Reported Value 25.8 Grading Range 26.7-38.5 4. Review of the laboratory's records revealed no documentation of the laboratory performing corrective actions for the unsatisfactory scores from above.. 5. In an interview at 9:58 am on 09/05/2024 in a break room, the laboratory director confirmed the above findings. Key: AAB=American Association of Bioanalysts MLE=Medical Laboratory Evaluation
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a review of the manufacturer's instructions for the QC-Beads quality control material, surveyor observation, a review of patient test records, and staff interview, the laboratory failed to ensure the two levels of QC-Beads control material had not exceeded the expiration date for 13 of 13 months from July 2023 to August 2024. Findings include: 1. A review of the manufacturer's instructions for the QC-Beads quality control material revealed the following: "Storage and Stability: Store the reagents at room temperature. They can be used until the expiration date on each label. The expiration date is two years from the date of manufacture." 2. During a tour on 9/5/24 at 9:20 a.m. in the laboratory, the surveyor noticed the box of QC-Beads in use- lot number: R01-200 expiration date: 7/5/23. 3. A random review of patient test records revealed the following patient specimens were run in the 13 months since the QC-Beads had exceeded their expiration date on 7/5/23: Date: 7/7/23 Patient ID: A1488 Date: 8/18/23 Patient ID: A1501 Date: 9/22/23 Patient ID: 1522 Date: 10/13

	/23 Patient ID: 1528 Date: 11/17/23 Patient ID: 1542 Date: 12/1/23 Patient ID: 1549 Date: 1/12/24 Patient ID: 1559 Date: 2/16/24 Patient ID: 1576 Date: 3/29/24 Patient ID: 1594 Date: 4/26/24 Patient ID: 1609 Date: 5/10/24 Patient ID: 1616 Date: 6/7/24 Patient ID: 1633 Date: 7/19/24 Patient ID: 1651 Date: 8/23/24 Patient ID: 1662 4. In an interview on 9/5/24 at 3:00 p.m. in the break room, after review of the records, the laboratory director confirmed the above findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on the surveyor's direct observation, the laboratory's CMS 116 application form, the laboratory's calibration verification records for 2022 to 2023, and confirmed in an interview, the laboratory failed to have 4 of 4 documentation of calibration verification every 6 months for 1 of 1 Roche Cobas e411 chemistry instrument. The findings were: 1. Review of the laboratory's CMS 116 application form, signed by the laboratory director on 08/26/2024 revealed the Roche Cobas e411 (SN: 6642-55) performed the following tests: Estradiol FSH (follicular stimulating hormone) Progesterone HCG (human chorionic gonadotropin) TSH (thyroid stimulating hormone) Free T4 (Free Thyroxine) 2. In a tour of the laboratory at 9:30 am on 09/05 /2024, the laboratory director confirmed the facility started using Roche Cobas e411 in 2020. 3. In an interview at 11:40 am on 09/05/2024 in a break room, the testing personnel #2 confirmed the Cobas e411 calibrated with 2 levels of calibrators. 4. The surveyor's direct observation at 1:30 pm on 09/05/2024 in the laboratory refrigerator, the surveyor observed 2 levels of calibrators for the analytes above. 5. Review of the laboratory's calibration verification records for 2022 to 2023 revealed no documentation for 4 of 4 calibration verification records every 6 months. 4. In an interview at 3:15 pm on 09/05/2024 in a break room, the laboratory director confirmed the above findings.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g)

	(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test 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 quality control material, a random review of the Andrology/Blood Lab QC forms, patient test records, and staff interview, the laboratory failed to ensure the duplicate bead counts for each level of control were within 10% of each other prior to testing patients for five of ten days reviewed between June 2023 and June 2024. Findings include: 1. A review of the manufacturer's instructions for the QC-Beads quality control (QC) material revealed the following steps for performing quality control testing: "Procedure for Manual Counting of QC Beads: - Invert the bottle several times to resuspend the Hi QC-BeadsTM. - Using a pipette, remove the volume recommended for the counting chamber you are using. (If using a hemacytometer, dilute the Hi QC-BeadsTM before counting.) - Pipette the bead suspension into the counting chamber. - Immediately recap the bottle. - Wait about 5 minutes to allow the beads to stop moving and then observe using a microscope. - Count at least 200 beads. - Calculate the concentration of beads according to the counting chamber manufacturer's instructions. - Repeat steps 1- 7 using a fresh aliquot of beads. - Compare the two results. If the results are within 10% of each other, then average the two counts. - 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. - Repeat steps 1-10 using the Lo QC-BeadsTM." 2. A random review of the Andrology/Blood Lab QC forms and patient test records from June 2023 to June 2024 revealed the following 5 days when the duplicate bead counts for the QC material were not within 10% of each other and patient's samples were reported: Date: 6/22/23 High QC counts: 55 and 62 Percent difference: 12% Patients reported: A1471 Date: 7/19/23 Low QC counts: 29 and 25 Percent difference: 15% Patients reported: A1490 Date: 8/23/23 High QC counts: 54 and 65 Percent difference: 18% Patients reported: A1504 Date: 2/2/24 Low QC counts: 29 and 33 Percent difference: 13% Patients reported: A1567 Date: 6/22/24 Low QC counts: 29 and 25 Percent difference: 15% Patients reported: A1641 3. In an interview on 9/5/24 at 3:00 p.m. in the break room, after review of the records, the laboratory director confirmed the above findings.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, the laboratory's Andrology/Blood Lab

	QC forms, patient test records, and staff interview, the laboratory failed to have documentation of performing corrective actions when the room temperature was documented outside the laboratory's acceptable range for ten of ten days reviewed from August 2023 to August 2024. Findings include: 1. A review of the laboratory's policy titled 'Quality Indicators for Cooper Institute for ARM Laboratory Equipment' revealed the following: "When equipment is checked, the responsible person is to document that it has been checked and/or records the levels on the appropriate log sheet. If any readings are out of the allowable tolerance levels, document the actions taken to correct the levels." 2. A review of the laboratory's Andrology/Blood Lab QC forms revealed the following allowable tolerance levels for the room temperature: 21 - 27C. 3. A random review of the laboratory's Andrology/Blood Lab QC forms from August 2023 to August 2024 revealed the following 10 days where the room temperature was outside the laboratory's allowable range, no corrective action was documented, and patients were tested: Date: 8/25/23 Room Temperature: 20.1C Patients tested: A1505, A1506, A1507, A1508, A1509, A1510 Date: 9/15/23 Room Temperature: 20.1C Patients tested: A1516, A1517 Date: 9/22/23 Room Temperature: 19.7C Patients tested: A1519, A1520, A1521, A1522 Date: 10/6/23 Room Temperature: 19.0C Patients tested: A1527 Date: 11/3/23 Room Temperature: 18.6C Patients tested: A1534, A1535. A1536, A1537 Date: 1/19/24 Room Temperature: 18.9 C Patients tested: A1562, A1563 Date: 4/26/24 Room Temperature: 20.6C Patients tested: A1606, A1607, A1608, A1609, A1610 Date: 6/7/24 Room Temperature: 20.4 C Patients tested: A1631, A1632, A1633 Date: 7/26/24 Room Temperature: 20.0C Patients tested: A1652, A1653 Date: 8/30/24 Room Temperature: 19.5C Patients tested: A1666, A1667 4. In an interview on 9/5/24 at 3:05 p.m. in the break room, after review of the records, the laboratory director confirmed the above findings. Key: C = Degrees Celsius
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on the review of the laboratory's CMS 209 Laboratory Personnel Report, the laboratory's personnel competency records from 2021 to 2024, and confirmed in an interview, the Technical Supervisor failed to have documentation of testing personnel initial training record and 6-month competency assessment during the 1st year for 1 of 1 testing personnel performing high complexity testing. The findings were: 1. Review of CMS 209 form Laboratory Personnel Report (CLIA) revealed the laboratory identified 1 testing personnel performing high complexity tests. 2. Review of the laboratory's personnel competency from 2021 to 2024 records revealed the technical supervisor failed to have documentation of initial training record and 6-month competency assessment documentation during the 1st year for 1 of 1 testing personnel performing high complexity testing. Testing personnel #1 Hired date: 08/05/2022 3. In an interview at 12:10 pm on 09/05/2024 in the break room, the laboratory director confirmed the above findings. Key: CMS=Center of Medicare and Medicaid Services
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)

	The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on the review of the laboratory's CMS 209 Laboratory Personnel Report, the laboratory's personnel competency records, and confirmed in an interview, the Technical Supervisor failed to have documentation of testing personnel annual competency assessment for 2024 for 1 of 1 testing personnel performing high complexity testing. The findings were: 1. Review of CMS 209 form Laboratory Personnel Report (CLIA) revealed the laboratory identified 1 testing personnel performing high complexity tests. 2. Review of the laboratory's personnel competency records revealed the technical supervisor failed to have documentation of annual competency assessment documentation for 2024 for 1 of 1 testing personnel performing high complexity testing. Testing personnel #1 Hired date: 08/05/2022 3. In an interview at 12:10 pm on 09/05/2024 in the break room, the laboratory director confirmed the above findings. Key: CMS=Center of Medicare and Medicaid Services