Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D1085540	(X3) Date Survey Completed 03/15/2022
Name of Provider or Supplier Cleveland Clinic Avon Andrology Laboratory	**Street Address, City, State** 33100 Cleveland Clinic Boulevard, Avon, OH	
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
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 record review and interviews with the Laboratory Director (LD), Technical Supervisor (TS) and Testing Personnel (TP) #2, the laboratory failed to define humidity criteria consistent with the manufacturer's instrument instructions and monitor and document humidity conditions for reliable testing procedures on semen specimens. This deficient practice had the potential to affect 212 out of 212 patient semen specimens tested from 03/15/2021 to 03/15/2022. Findings Include: 1. Review of the "Olympus CX43 Biological Microscope" manufacturer's operating instructions, provided on the date of the inspection, found the following operating environment instructions: "Humidity: Max. 80% (31C or less) (without condensation)" 2. Review of the laboratory's policies and procedures provided on the date of the inspection, did not find any instructions to monitor and document humidity conditions. 3. The Inspector requested the laboratory's humidity documentation from 03/15/2021 through 03/15/2022 from the LD, TS and TP#1. The TS confirmed the laboratory did not establish a policy and procedure to monitor and document humidity conditions consistent with manufacturer's instructions for semen testing procedures, did not monitor and document humidity conditions from 03/15/2021 through 03/15/2022 and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 03/15/2022 at 10:28 AM. %; percent C; degrees Celsius

D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interviews with the Laboratory Director (LD), Technical Supervisor (TS) and Testing Personnel (TP) #2, the laboratory failed to perform and document any quality control (QC) procedures for the MiOXSYS sORP test system. This deficient practice had the potential to affect 60 out of 60 patient semen specimens tested for oxidation reduction potential (ORP) from 03/15/2021 to 03/15/2022. Findings Include: 1. Review of the laboratory's "MiOXSYS sORP" manufacturer's instructions, provided on the date of the validation inspection, found the following statements: "1. Good laboratory practice recommends the use of the control materials. Users should follow the appropriate federal, state, and local guidelines concerning the running of external controls. 2. ...It is recommended that each new lot or shipment of MiOXSYS Sensors should be verified upon receipt and before use. External control tests should be performed thereafter in accordance with appropriate Federal, State, and local guidelines. A separate sensor must be used for each external control test. 3. MiOXSYS System should not be used in patient testing if the external controls do not produce the correct results." 2. Review of the laboratory's "Oxidation Reduction Potential Measurement SOP" did not find any instructions for the type, number and frequency of QC testing of the MiOXSYS System; however, revealed the following statements: "1. Good laboratory practice recommends the use of the validation materials. 2. Users will follow the appropriate federal, state, and local guidelines concerning the quality control. 3. Calibration Verification Key testing will be performed daily." 3. The Inspector requested the laboratory's 2020, 2021 and 2022 ORP QC documentation from the LD, TS and TP#2. The TS stated that the laboratory conducted calibration every day of patient testing, while interchanging calibration and QC verbiage. The TS confirmed the laboratory was not conducting external QC on the MiOXSYS System as required. The interview occurred on 03/15/2022 at 11:50 AM.
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 record review and interviews with the Laboratory Director (LD), Technical

	Supervisor (TS) and Testing Personnel (TP) #2, the laboratory failed to perform and document stain quality control (QC) for the intended reactivity to ensure predictable staining characteristics each day of use. This deficient practice had the potential to affect 212 out of 212 patient semen specimens tested from 03/15/2021 to 03/15/2022. Findings Include: 1. Review of the laboratory's "Quality Control for Andrology Tests SOP" found the following statements: "Staining Quality of Diff-Quick Reagents Slides are made using a reagent donor for use in checking the staining quality of Diff-Quick reagents. The slides are allowed to air-dry and are fixed using the Diff-Quick Fixative. These slides are then stored at room temperature until used. The working solution of Diff-Quick stains is changed weekly. A QC slide is dipped into the fresh reagents and checked for stain quality...If there is poor staining quality on the QC slides, then repeat the staining using another QC slide." "Eosin-Nigrosin Staining When new stain is prepared, a fresh seminal smear from a donor is stained within 20-30 minutes of collection..." 2. The Inspector requested the laboratory's Diff-Quick and Eosin-Nigrosin stain QC documentation for each day of stain use in 2020, 2021 and 2022 from the LD, TS and TP#2. The TS stated that the stain QC was performed weekly after the stain was changed or prepared and confirmed the laboratory did not perform Diff-Quick stain QC each day of use. The interviews occurred 03/15/2022 at 9:20 AM.
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 record review and interviews with the Laboratory Director (LD), Technical Supervisor (TS) and Testing Personnel (TP) #2, the laboratory failed to follow their corrective action protocols for documented ambient/room temperatures that were out of acceptable range to maintain the laboratory's operation for testing patient semen specimens in a manner that ensured accurate and reliable patient semen tests performed. This deficient practice had the potential to affect all patient semen specimens tested 43 out of 366 days in 2020. Findings Include: 1. Review of the laboratory's "Quality Control for Andrology Tests SOP" policy and procedure, provided on the date of the inspection, revealed the following instructions: "If the temperature is out of range, consult the Supervisor and file an Instrument Maintenance Report Form. In case of a problem with the temperature readings, notify Cleveland Clinic Clinical Engineering...When Quality Control criteria are not met, the Supervisor or the Director must be informed immediately and corrective responses initiated." 2. Review of the laboratory's 2020, 2021 and 2022 "Ambient Air Temperature" graphs, provided on the date of inspection, revealed the acceptable ambient air temperature to be 21-25C with out of acceptable range temperatures recorded in 2020 without any documentation indicating the corrective action taken for the months/dates listed below. Recorded Temperatures Below 21C January - 29, 31 February - 5, 14 March - 11, 24, 25, 26, 27 May - 6, 8, 27, 28, 29 June - 5, 10, 11, 12, 23, 24 July - 14, 15, 16, 17, 20, 21, 22, 23, 24, 28, 29, 30 August - 4, 5, 11, 12, 13, 14, 25, 26, 27, 28 September - 18 3. The Inspector requested the laboratory's corrective action documentation for the documented out of range room temperatures listed above from the LD, TS and TP#2. The TS provided the Clinical Engineering work request the laboratory submitted, however the out of range room temperature documentation

	continued with no corrective action. The TS confirmed the laboratory did not document any corrective action each day the temperature was unacceptable, the laboratory's corrective action policy and procedure was not followed and therefore no corrective action was documented. The interview occurred on 03/15/2022 at 9:50 AM. C; degrees Celsius