

| | | |
|--|--|---|
| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 19D1064020 | (X3) Date Survey Completed 05/26/2022 |
| Name of Provider or Supplier Fertility Institute Of New Orleans, Apc | Street Address, City, State 8585 Picardy Ave, Ste 418, Baton Rouge, LA | |
| 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 | A Recertification survey was performed on May 26, 2022 at Fertility Institute of New Orleans, CLIA ID # 19D1064020. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited. |
| D5543 | <p>HEMATOLOGY CFR(s): 493.1269(a)(d)</p> <p>(a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy and procedure, quality control records, patient test reports and interview with personnel, the laboratory failed to perform and document quality control (QC) for each day of patient testing for manual sperm counts. Findings: 1. Review of the laboratory's policy for "Performing Daily QC for Sperm Counting" revealed "Perform QC on any day that sperm counting is performed" along with the following steps: a. Vortex Low and High level Accubeads to insure a uniform suspension b. With the micropipetter, pipette 2.5 uL of Low Level beads into the first chamber on the Cell Vision slide. Repeat with the High Level Accubeads in the second chamber. c. Allow the beads to settle for 5 minutes d. Count beads in two separate areas in each Cell Vision chamber for Low and High level beads, along the midline e. Record average results of replicate counts for each bead level on the Accubead QC chart 2. Review of the laboratory's quality control (QC) and patient test records during July 2021, December 2021 and March 2022 revealed the laboratory did not perform or document two (2) levels of QC for the following one (1) of six (6) patients reviewed: a) Patient 10497: Reported March 11, 2022 at 12:15 pm 3. In interview on May 26, 2022 at 4:40 pm, Personnel 3 stated she possibly</p> |

documented the QC on March 10, 2022 instead of March 11, 2022 but has no documentation to support. Personnel 3 confirmed that QC was not documented for the above identified patient.

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 review of the laboratory's policy and procedure, quality control and patient test records as well as interview with personnel, the Laboratory Director failed to ensure that a quality control program was established to assure the quality of laboratory testing. Refer to D5543.

D6117

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(4)

The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policy and procedure manual, quality control records and patient test reports as well as interview with personnel, the Technical Supervisor failed to ensure that a quality control program was maintained to assure the quality of manual sperm counting. Refer to D5543.