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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 33D0669097 | (X3) Date Survey Completed 01/17/2024 |
| Name of Provider or Supplier Lab Of The Montefiore Institute For | Street Address, City, State 141 South Central Avenue Suite 201, Hartsdale, NY | |
| 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 | An announced CLIA exempt-state validation survey was conducted at the Lab of Montefiore Institute for Reproductive Medicine and Health on January 17, 2024, by a CMS New York CLIA Branch Location federal surveyor. The laboratory was surveyed under 42 CFR part 493 CLIA regulations. The laboratory is in compliance with condition-level CLIA requirements. The following standard-level deficiency were found during CLIA exempt-state validation survey performed on January 17, 2024. |
| D5209 | <p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of laboratory procedures, laboratory personnel competency assessment records and interview with the Technical Supervisor #2 (TS#2), the laboratory failed to establish a competency assessment policy that states how to assess laboratory personnel for competency 2022 and 2023. Findings: 1. On the day of survey, review of testing personnel (TP) competency assessment records revealed, TP#2 hired on 10/31/2022 was not assessed at least semiannually during the first year the individual tests Andrology and Endocrinology patient specimens in 2022 and 2023. 2. Review of laboratory procedures revealed, the laboratory did not establish a competency assessment policy that states the frequency of competency performed for laboratory personnel. 3. The LD and TS#2 confirmed the findings above on January 17, 2024 at 11:45 am.</p> |
| D5439 | <p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> |

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 review of the laboratory records and interview with the technical supervisor (TS) #2, the laboratory failed to perform calibration verification at least every six months for the Abbott Architect i1000 used for Endocrinology testing in 2022 and 2023. Findings: 1. Review of the Abbott Architect i1000 calibration verification records revealed, calibration verification was performed -09/29/2021, 11/11/2022, 02/09/2023, and 10/05/2023. 2. The laboratory was unable to provided Abbott Architect i1000 calibration verification records performed at least every six months in 2022 and 2023. 3. Approximately the laboratory performs 10,000 Endocrinology tests annually. 4. The LD and TS#2 confirmed the findings above on January 17, 2024 at 11:45 am.