| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 26D0438716 | 04/09/2024 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Endocrine Clinical Lab / Washington University | 4444 Forest Park Ave Suite 3100, Saint Louis, MO | |

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 |
|---|---|
| **D5469** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(10)(g)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the Roche e411 chemistry analyzer quality control (QC) records and interview with the general supervisor (GS), the laboratory failed to document how criteria was established for acceptability of control material providing quantitative results for 3 of 10 analytes for 3 levels of QC. Findings: 1. Review of Roche e411 QC records showed the laboratory used assayed Bio-Rad Immunoassayed QC. The laboratory could not show how they established, documented, and defined statistical parameter criteria (mean and standard deviations) for acceptability of quantitative chemistry QC when they had to change the ranges from the manufacturer's established ranges for the following: follicle stimulating hormone (FSH), human chorionic gonadotropin (HCG), and free thyroxine (FT4). 2. Review of the Roche e411 chemistry analyzer revealed the mean listed on the analyzer as the following: Level 1 FSH mean of 7.73 mIU/ML HCG mean of 5.07 IU/L FT4 mean of 1.19 ng/dL Level 2 FSH mean of 20.93 mIU/ML HCG mean of 20.68 IU/L FT4 mean of 3.04 ng/dL |

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| | Level 3 FSH mean of 40.59 mIU/ML HCG mean of 231.5 IU/L FT4 mean of 5.03 ng /dL 3. Review of the Bio-Rad Immunoassay QC manufacturer's package insert revealed the mean as the following: Level 1 FSH mean of 7.47 mIU/ML HCG mean of 4.92 IU/L FT4 mean of 1.14 ng/dL Level 2 FSH mean of 20.2 mIU/ML HCG mean of 20.1 IU/L FT4 mean of 2.99 ng/dL Level 3 FSH mean of 38.7 mIU/ML HCG mean of 223 IU/L FT4 mean of 4.92 ng/dL 4. Interview with the GS on April 9, 2024 at 10: 00 AM, confirmed the laboratory failed to document how criteria was established for acceptability of control material providing quantitative results. |
| **D6127** | TECHNICAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1451(b)(9)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of personnel records and interview with the general supervisor (GS), the technical supervisor (TS) failed to evaluate and document the performance of one of three testing personnel (TP) at least semiannually during the first year the individual tests patient specimens. Findings: 1. Review of 2023 performance evaluations showed the TS failed to perform the semiannual competency evaluation for TP #3. 2. Interview with the GS on April 9, 2024 at 10:00 AM, confirmed the TS failed to evaluate and document the performance of one of three TP at least semiannually during the first year the individual tests patient specimens. |