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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 45D0506643 | (X3) Date Survey Completed 06/22/2023 |
| Name of Provider or Supplier Regence Health Network, Inc | Street Address, City, State 125 West Park Ave, Hereford, 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 |
|---------------------------|--|
| D2006 | <p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by: Based upon review of laboratory policies and procedures, review of proficiency testing (PT) records for the years 2022 and 2023 (three events per year), review of instrument printouts and interview of facility personnel, the laboratory failed to test proficiency specimens in the same manner as patient specimens in three of five proficiency events for Hematology. The findings included: 1. Review of the laboratory policy titled Critical Tests and Critical Results found under the heading Definition: "The organization defines critical tests and critical results and values: "WBC less than 3.0 or greater than 18.0 RBC less than 2.5 or greater than 6.5 Hemoglobin less than 7 or greater than 20 Hematocrit less than 30 or greater than 55 Platelet count less than 80 or greater than 600" Continued review found under the heading Procedure: "Repeat the test and enter both on the report on all critical values..." 2. Review of the policy titled Lab Quality Assurance Policy found on page 4 under Proficiency Testing (PT): "Verify PT is performed in accordance with CLIA guidelines. Ensure PT is performed in the same manner as patient testing. Ensure a review of graded results is conducted and documented. Verify unsuccessful or unsatisfactory PT events are investigated and corrective actions taken. Document findings and actions." 3. Review of the American Proficiency Institute (API)</p> |

Proficiency testing records between 2021 testing event 3 and 2023 testing event 1 (three testing events per year), found the laboratory failed to repeat the proficiency specimens that met their defined critical results criterion as follows: 2021 Hematology /Coagulation 3rd event: Specimen 11 - The laboratory obtained critical results for the analytes as follows: Red Blood Cell (RBC) 2.07×10^6 /uL Hemoglobin (HGB) 5.5 g/dL Hematocrit (HCT) 15.5% Platelet (PLT) 74×10^3 /uL Specimen 13 - The laboratory obtained critical results for the analytes as follows: White blood Cell (WBC) 21.9×10^3 /uL Platelet (PLT) 602×10^3 /uL Specimen 15 - The laboratory obtained critical results for the analytes as follows: White Blood Cell (WBC) 21.5×10^3 /uL Hematocrit (HCT) 26.4% 2022 Hematology /Coagulation 1st event: Specimen 1 - The laboratory obtained critical results for the analytes as follows: White blood Cell (WBC) 2.2×10^3 /uL Red Blood Cell (RBC) 2.22×10^6 /uL Hemoglobin (HGB) 5.2 g/dL Hematocrit (HCT) 15.4% Platelet (PLT) 74×10^3 /uL Specimen 3 - The laboratory obtained critical results for the analytes as follows: White blood Cell (WBC) 20.2×10^3 /uL Specimen 5 - The laboratory obtained critical results for the analytes as follows: White Blood Cell (WBC) 19.9×10^3 /uL Hematocrit (HCT) 25.6 % 2022 Hematology/ Coagulation 3rd event Specimen 13 - The laboratory obtained critical results for the analytes as follows: White Blood Cell (WBC) 19.6×10^3 /uL Specimen 14 - The laboratory obtained critical results for the analytes as follows: White blood Cell (WBC) 2.1×10^3 /uL Red Blood Cell (RBC) 2.17×10^6 /uL Hemoglobin (HGB) 5.2 g/dL Hematocrit (HCT) 15.6% During interview of the lab coordinator conducted June 20, 2023 at 11:25 AM, he confirmed that the laboratory did not repeat critical values obtained on proficiency testing results using the critical results as defined in the Critical Tests and Critical Results policy.

D2098

ENDOCRINOLOGY
CFR(s): 493.843(a)

Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

This STANDARD is not met as evidenced by:
Review of proficiency testing records and interview of facility personnel found the laboratory failed to attain satisfactory performance for serum HCG in one of five Chemistry Core proficiency testing events between 2021 and 2023 (three testing events per year). The findings included: 1. Review of the American Proficiency Institute (API) proficiency testing records for kit 42030 found the laboratory submitted unacceptable responses for two of five proficiency specimens in the 2022 Chemistry Core 1st Event as follows: Sample HCG-02 - was reported as positive with an expected result of negative. Sample HCG-05 - was reported as positive with an expected result of negative. Review of the attestation statement found specimens 01 and 02 were tested by testing person 7, and specimens 03, 04, and 05 were tested by testing person 1 on the CMS Report 209 Laboratory Personnel report. Review of the original submission forms found results documented for each of the five specimens as follows: HCG-01 Positive HCG-02 Negative HCG-03 Positive HCG-04 Positive HCG-05 Negative A second copy of the original submission forms found results documented for each of the five specimens as follows: HCG-01 Positive HCG-02 Positive (Negative result also colored in with X through the result) HCG-03 Positive HCG-04 Positive HCG-05 Positive (Negative result also colored in with X through the result) 3. During interview of the lab coordinator conducted June 20, 2023 at 11:

25 AM, he confirmed that he did not know what the second original submission form (marked all positive) was and that he entered all proficiency results tested at each of the three locations for which he was responsible.

D5469

CONTROL PROCEDURES

CFR(s): 493.1256(d)(10)(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-- 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.

This STANDARD is not met as evidenced by:

Based upon review of manufacturer instructions, quality control records and interview of the Lab Coordinator, the laboratory failed to verify Hematology quality control material met the manufacturer's acceptable limits prior to putting it into use for three of three lots or Minotrol-16 used in 2022 and 2023. The findings included: 1. Review of the Horiba Minotrol 16 instructions for use found under the heading Performance characteristics: "Assay values on a new lot of control should be confirmed before it is put into routine use. Test the new lot when the instrument is in good working order and quality control results on the previous lot are acceptable. The laboratory recovered mean should be within the assay range." 2. Review of quality control records found no documentation of the verification of each new lot of quality control material before putting it into use for the following lots: MX 433 in use 12/20/2021 MX 438 in use 10/20/2022 MX 441 in use 04/25/2023 3. During interview of the lab coordinator conducted June 20, 2023 at 1:30 PM, he confirmed that the laboratory did not verify each new lot of Hematology quality control material met the manufacturer's specifications prior to putting it into use as the sole source of quality control.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(i)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based upon review of laboratory policies and procedures, review of proficiency testing (PT) records for the years 2022 and 2023 (three events per year), review of instrument printouts and interview of facility personnel, the laboratory director failed

to ensure that proficiency specimens were tested in the same manner as patient specimens in three of five proficiency events for Hematology. (see D 2006)