Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0664603	06/22/2023
Name of Provider or Supplier	**Street Address, City, State**	
Regence Health Network Ross	3113 Ross Street, Amarillo, 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
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 3. During interview of the lab coordinator conducted June 22, 2023 at 9:33 AM, he confirmed 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 22, 2023 at 11:29 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.