Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D2224298	05/28/2025
Name of Provider or Supplier	**Street Address, City, State**	
Quest Diagnostics - Springfield Rrl	3231 S National Ave, Basement, Springfield, 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 CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(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. (d)(10)(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. (d)(10)(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. This STANDARD is not met as evidenced by: Based on interview with the technical consultant, review of Beckman Coulter DxC 700AU chemistry analyzer quality control (QC) for 4 of 32 analytes, review of Advia Centaur XP chemistry analyzer QC for 1 of 3 analytes, and interview with laboratory director (LD) the laboratory failed to provide criteria for acceptability of chemistry controls. Findings: 1. Interview with the technical consultant revealed the laboratory used assayed controls for chemistry but established their own ranges. 2. Review of Beckman Coulter DxC 700AU chemistry analyzer QC for alkaline phosphatase revealed QC lot # 77951 level 1 was in use. The laboratory could not provide documentation to acceptable mean and standard deviation for alkaline phosphatase for the lot #77951 currently in use. 3. Review of Advia Centaur XP chemistry analyzer for estradiol revealed QC lot # 88611 level 1, lot #88612 level 2, lot #88613 level 3 were in use. The laboratory could not provide documentation to acceptable mean and standard deviation for estradiol for the lot #88611, lot #88612, and lot #88613 currently in use. 4. Interview with the laboratory director on May 28, 2025 at 12:00 PM confirmed the laboratory failed to provide criteria for acceptability of chemistry controls.

D5807	TEST REPORT CFR(s): 493.1291(d) (d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of "Sysmex XN Series Operation for CBC" procedure, review of 2 of 2 patient reports, and interview with the laboratory director (LD) the laboratory failed to ensure the reference intervals or normal values on the patient report matched the procedure. Findings: 1. Review of "Sysmex XN Operation for CBC" procedure revealed: male complete blood count (CBC) Hematocrit (HCT) 39.4-51.1 MCV 81.4-101.7 MCHC 31.6-35.4 female CBC HCT 35.9-46.0 MCV 81.4-101.7 2. Review of male CBC patient report revealed: HCT 38.5-50.0 MCV 80.0-100.0 MCHC 32.0-36.0 3. Review of female CBC patient report revealed: HCT 35.0-45.0 MCV 80.0-100.0 4. Interview with the laboratory director on May 28, 2025 at 12:00 PM confirmed the normal values on the patient report did not match the procedure.