Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 06D2169671	(X3) Date Survey Completed 11/23/2021
Name of Provider or Supplier Quality Urgent Care, Llc	**Street Address, City, State** 1335 E South Boulder Rd, Unit C, Louisville, CO	

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
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of general laboratory systems quality assessment (QA) documentation and staff confirmation, the laboratory (a) failed review the effectiveness of corrective actions taken to resolve problems, (b) failed to document all QA activities, (c) the laboratory director failed to sign the quality assessment plan.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the procedure manual and staff confirmation, the laboratory director failed to review, sign and date the approval of the procedure for the Medonics M Series Hematology Analyzer.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)

	Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the validation documentation and staff confirmation, the laboratory director failed to review, sign and date the approval of the validation for the Medonics M Series Hematology Analyzer.