Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D2153452	05/03/2019
Name of Provider or Supplier	**Street Address, City, State**	
Intelligene Cg Llc	10900 S Clay Blair Blvd, Rooms 372/373, Olathe, KS	

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
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of the performance verification procedures for the qTower G analyzer for urinary tract infections (UTI) and interview with the technical supervisor, the laboratory failed to verify specificity and reference intervals (normal values). Findings: 1. Review of the verification procedures for the qTower G analyzer for pathogens in UTI showed no verification of normal values or specificity which includes interfering substances. 2. Interview with the technical supervisor on May 3, 2019 at 11:30 a.m. confirmed the laboratory failed to ensure that specificity and normal values for the qTower G analyzer was appropriate for the laboratory's patient population.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)

	(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control documentation for bacteriology and interview with the technical supervisor, the laboratory failed to check and document each batch of chocolate and MacConkey agar for sterility, its ability to support growth, and document physical characteristics. Findings: 1. Review of the quality control documentation showed the laboratory failed to check and document each batch of chocolate and MacConkey agar for sterility, its ability to support growth, and document physical characteristics. 2. Interview with the technical supervisor on May 3, 2019 at 11:30 a.m. confirmed the laboratory failed to check each batch of media.