

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D0936918	(X3) Date Survey Completed 12/12/2019
Name of Provider or Supplier Cordant Health Solutions	Street Address, City, State 1760 E Route 66, Suite 1, Flagstaff, AZ	
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	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of established performance specification documentation for the LC /MS analyzer used for urine drug confirmation testing and interview with the facility personnel, the laboratory failed to document information regarding interfering substances that may effect the analytical specificity of the LC/MS test system. Findings include: 1. The laboratory began patient testing on two new LC/MS analyzers, identified by the laboratory as #12 and #13, in February 2019. The laboratory's approximate total annual test volume is 6,188,000. 2. The LC/MS performance specification documentation presented for review during the survey conducted on December 12, 2019 failed to include documentation regarding interfering substances which may effect and/or inhibit the analytical specificity of the test system, including but not limited to, information regarding the patients' clinical conditions, disease states, and any common medications. 3. The facility personnel acknowledged that there was no specific analysis performed that included the effects of the patients' clinical conditions, disease states and common medications as possible interfering substances that may effect analytical specificity of the test system.</p>