

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D1019319	(X3) Date Survey Completed 06/18/2025
Name of Provider or Supplier Microbiology Research Laboratory	Street Address, City, State 1300 Badger St Rm 5032, La Crosse, WI	
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
D3029	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(2)</p> <p>Test procedures. Retain a copy of each test procedure for at least 2 years after a procedure has been discontinued. Each test procedure must include the dates of initial use and discontinuance.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of procedures and laboratory records and interview with the General Supervisor, the laboratory did not retain copies of the initial versions of two of two new test procedures reviewed and could not show the procedures were in place prior to the start of patient testing for Herpes Simplex Virus (HSV) and Bordetella (BP) with the Liaison MDX instrument. Findings include: 1. Review of procedures for two new Diasorin Simplexa assays performed on the Liaison MDX instrument showed the Laboratory Director signed the current procedure for HSV 1,2 Direct assay on February 19, 2025. The Laboratory Director signed the current procedure for the Bordetella Direct assay on March 26, 2025. 2. Review of laboratory records showed the laboratory began patient testing with the HSV 1,2 Direct assay on February 26, 2024, and began Bordetella Direct patient testing in March 2024. 3. Interview with the General Supervisor on June 18, 2025, at 1:45 PM revealed the laboratory did not retain the initial procedures for the Diasorin Simplexa assays for HSV 1,2 and Bordetella after they made revisions and confirmed the laboratory could not show the Laboratory Director had approved the procedures prior to use for patient testing.</p>
D5423	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2)</p> <p>(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</p>

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: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

Based on surveyor review of laboratory records and interview with the General Supervisor, the laboratory could not show the Laboratory Director approved the performance specifications for each new test system or modification to test systems prior to reporting patient results for eleven of twelve studies reviewed. Findings include: 1. Review of twelve studies showed no evidence of the date the reviewers approved eleven of the twelve studies. The studies included changes in control sets (Simplexa vs. Lumina), validation of additional primers for *Babesia duncani* and *Rickettsia* spp., fluorochrome changes, verification studies and several comparison studies between three Liaison MDX instruments, and comparisons with manual extraction and the EX2 automated extraction platform. The laboratory director signed and dated one study, the comparison between two MDX analyzers, SN1D1029 and 1D0744, for cytomegalovirus (CMV), Herpes Simplex Virus (HSV), Enterovirus (EV) and *Bordetella pertussis* (BP), on March 13, 2024. 2. Interview with the General Supervisor on June 18, 2025, at 1:45 PM confirmed the Laboratory Director had not dated the studies and confirmed the laboratory could not show completion of the evaluation and approval of the test systems prior to performance of patient testing.