

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0913430	(X3) Date Survey Completed 05/18/2022
Name of Provider or Supplier Micro-Diagnostic Laboratories, Inc	Street Address, City, State 1200 Salem Road, Benton, AR	
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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Through a review of the Aptima Panther System instructions for use, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to perform contamination monitoring as required by the manufacturer. Survey findings include: A. The Aptima Panther System instructions for use were reviewed. The instructions for use state, "Intervals for contamination monitoring should be established based on each laboratory's practices and procedures." B. The surveyor requested the contamination monitoring protocol and documentation. None was provided. C. In an interview, at 1:20 p.m. on 5/18/2022, employee #7 (as listed on the Employee Identification Worksheet) stated that the laboratory did not have a contamination monitoring protocol and that the laboratory had not monitored for contamination.</p>