

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2048813	(X3) Date Survey Completed 03/09/2023
Name of Provider or Supplier Sysmex Inostics, Inc	Street Address, City, State 1812 Ashland Ave Suite 500, Baltimore, MD	
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
D2003	<p>ENROLLMENT CFR(s): 493.801(a)(2)(ii)</p> <p>For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1)</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the quality assurance manager (QAM), the laboratory failed to document the acceptance criteria for one of three alternative PT events performed for human papillomavirus (HPV) 16 and 18. Findings: 1. The laboratory performed testing to detect and quantify gene targets for HPV 16 and 18 which was not included in subpart I. 2. The first alternative PT event occurred in December 2021, the second in June 2022, and the third in December 2022. 3. The laboratory did not have an alternative PT procedure that was specific to HPV 16 and 18, therefore each event was written up as a nonconformance to the PT procedure. 4. The nonconformance report for the December 2022 event did not include a description of which samples were used and the acceptance criteria for evaluating the final PT results. 5. During the survey on 03/09/2023 at 11:45 AM, the QAM confirmed that the PT report for the December 2022 event did not include acceptance criteria for evaluating the results.</p>