

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D2130541	<b>(X3) Date Survey Completed</b>  06/27/2024
<b>Name of Provider or Supplier</b>  Cirrus Dx Inc	<b>Street Address, City, State</b>  77 Upper Rock Circle 4th Flr, Rockville, MD	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5219</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on review of the procedure, review of the proficiency testing (PT) records, and interview with the technical supervisor (TS), the laboratory failed to ensure that all organisms from the molecular urinary tract infection (UTI) panel were verified for accuracy at least twice annually. Findings: 1. The laboratory was enrolled in PT with American Proficiency Institute (API) and tested their molecular UTI panel with the API Urine Identification PT module. 2. The following organisms from the laboratory's molecular UTI panel were not included in API's Urine Identification PT module and were not verified at least twice in 2023: Ureaplasma species, Actinotignum schaalii, Candida krusei, C. tropicalis, C. albicans, C. glabrata, and C. parapsilosis. 3. During the exit interview on 06/27/2024 at 4:10 PM, the TS confirmed that not all organisms from the molecular UTI panel were included in the API Urine Identification module and were not verified for accuracy at least twice in 2023.</p>