

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  36D1087513	<b>(X3) Date Survey Completed</b>  01/11/2022
<b>Name of Provider or Supplier</b>  Cincinnati Children's Liberty Campus	<b>Street Address, City, State</b>  7777 Yankee Road Room 110, Liberty Township, OH	
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>D5485</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(h)</p> <p>If control materials are not available, the laboratory must have an alternative mechanism to detect immediate errors and monitor test system performance over time. The performance of alternative control procedures must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on record review and an interview with the General Supervisor (GS) #1, the laboratory failed to perform and document alternative quality control for the wet mount preparation testing procedures performed when commercial control materials were not available. This deficient practice had the potential to affect 102 patients tested in the subspecialty of parasitology. Findings Include: 1. Review of the laboratory's "Wet Prep Procedure for Trichomonas Vaginalis", electronically approved, signed and dated by the Laboratory Director on 11/09/2020, found no mention of quality control. 2. Review of the laboratory's October, November, and December 2021 "Microbiology Manual Testing Worksheet/Log", found no quality controls noted. 3. The Inspector requested the laboratory's wet mount preparation testing quality control documentation from the GS#1. The GS#1 confirmed the laboratory did not establish and document wet mount preparation testing quality control policies and procedures and was unable to provide the requested documentation on the date of the inspection. The interview occurred 01/11/2022 at 12:00 PM.</p>