

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0681336	(X3) Date Survey Completed 01/19/2022
Name of Provider or Supplier Kettering Health Huber Laboratory	Street Address, City, State 8701 Old Troy Pike, Huber Heights, OH	
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
D5485	<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 Technical Consultant (TC) #2, 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 5,596 patients tested in the subspecialties of bacteriology and parasitology. Findings Include: 1. Review of the laboratory's "Wet Prep Procedure", approved, signed and dated by the Laboratory Director on 10/06/2020, found the following statement: "QUALITY CONTROL: Illustration chart Form MB.10.025.FA Wet Prep QC Chart with pictures of Trichomonas, Yeast, and Positive and Negative Clue Cells. This is to be checked and compared with each specimen tested. Document this in LIS." 2. The Inspector requested the laboratory's wet mount preparation testing quality control documentation from the TC#2. The TC#2 confirmed the laboratory did not document wet mount preparation testing quality control procedures and was unable to provide the requested documentation on the date of the inspection. The interview occurred 01/19/2022 at 12:15 PM.</p>