

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  14D0669515	<b>(X3) Date Survey Completed</b>  09/10/2019
<b>Name of Provider or Supplier</b>  Illinois State University Student Health Service	<b>Street Address, City, State</b>  201 N University Street, Normal, IL	
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>D5421</b>	<p><b>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE</b> CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory records, and interview with technical supervisor (TS) #2; the laboratory failed to perform verification studies for new specimens types (rectal and throat) performed on the Cepheid GeneXpert prior to reporting patient test results. Findings Include: 1. Direct observation of laboratory testing equipment on 9-10-2019, at 9:50 am, identified a Cepheid GeneXpert (Serial Number: 820963) used for bacteriology testing. 2. Review of Cepheid GeneXpert verification of performance documentation revealed the laboratory failed to perform verification studies for rectal and throat specimens used to test for Neisseria gonorrhoeae and Chlamydia. 3. Review of patient testing records for the Cepheid GeneXpert revealed the laboratory performed 4 rectal and 10 throat specimens for Neisseria gonorrhoeae and Chlamydia testing without performing verification studies for the new specimen types. 4. On survey date 9-10-2019, at 4:05 pm, the above findings were confirmed by TS#2.</p>