

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D0030383	(X3) Date Survey Completed 11/15/2023
Name of Provider or Supplier Longest Student Health Center Lab	Street Address, City, State 360 Hardy Road, Mississippi State, MS	
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of quality control (QC) records for Neisseria gonorrhoeae (NG) and Chlamydia trachomatis (CT) testing on the Cepheid GeneXpert test system from 4/4/2022 through 10/9/2023, patient test count reports, interview with the technical consultant on 11/15/2023 at 2:15 p.m., and the laboratory's written Individualized Quality Control Plan (IQCP), the laboratory failed to follow its written IQCP for performing external quality control each month of patient testing for two of eighteen months, when a total of 158 patient NG and CT results were reported. Findings include: 1. The laboratory's IQCP for NG and CT testing on the Cepheid GeneXpert test system states that one external positive and one external negative control will be performed on the first Monday of every month. 2. Review of QC records for NG and CT testing on the Cepheid GeneXpert test system from 4/4/2022 through 10/9/2023 revealed no documentation of performance of positive and negative controls for May and June 2023, two months of the eighteen-month time frame reviewed. There was no documentation of performance of external positive and negative controls from 4/3/2023 until 7/5/2023. 3. Review of patient test count reports for May and June 2023 revealed a total of 158 patient NG and CT results were reported during these two months. 4. In an interview on 11/15/2023 at 2:15 p.m., the technical consultant confirmed the external positive and negative controls for NG and CT testing were not performed in May and June 2023.</p>
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE

CFR(s): 493.1253(b)(1)

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.

This STANDARD is not met as evidenced by:

Based on review of quality control logs for the Streck Sickledex qualitative solubility test for sickling hemoglobins from 1/13/2023 through 9/1/2023, monthly patient test count reports, interview with the technical consultant on 11/15/2023 at 12:45 p.m., and lack of documentation of verification of performance specifications, the laboratory failed to verify the manufacturer's performance specifications for qualitative testing, to include accuracy and precision, for the Streck Sickledex qualitative solubility test before patient testing (167 samples tested) began on 1/13/2023. Findings include: 1. Review of quality control logs from 1/13/2023 through 9/1/2023 and confirmation by the technical consultant revealed patient testing with the Streck Sickledex solubility test began on 1/13/2023. 2. There was no documentation of verification of performance specifications, to include accuracy and precision, for the Streck Sickledex test available for review on the day of the survey, 11/15/2023. 3. In an interview on 11/15/2023 at 12:45 p.m., the technical consultant confirmed verification of performance specifications for the Streck Sickledex test was not performed before patient testing began on 1/13/2023. 4. Review of Streck Sickledex quality control logs from 1/13/2023 through 9/1/2023 and monthly patient test count reports revealed Streck Sickledex testing was performed for five months during this time frame - January, May, June, July, August 2023 - and on 9/1/2023, with a total of 167 patient specimens tested.