

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0185014	(X3) Date Survey Completed 07/13/2021
Name of Provider or Supplier Geisinger Health System	Street Address, City, State 200 Scenery Drive, State College, PA	
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
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory and interview with the laboratory supervisor, Tech II and GCL team leader, the laboratory failed to establish a maintenance policy to assess the maintenance/function of 2 of 2 Temp Chex Red Spirit thermometers and 1 of 1 Market Laboratory thermometer used to monitor the laboratory and refrigerator temperatures from 2019 to the day of survey. Findings Include: 1. On the day of survey, 07/13/2021, the surveyor observed thermometers use to monitor the temperatures of reagents in the laboratory from 07/13/2019 to 07/13/2021: 3 of 3 Temp Chex Red Spirit thermometers- Refrigerator #1 and #2. 1 of 1 Market Laboratory thermometer - Room Temperature. - S/N: 122439964. - Due for maintenance: 07/31/2014. 2. The laboratory could not provide a maintenance policy for the thermometers. 3. The laboratory could not provide documentation of maintenance/function checks performed on the thermometers. 4. The laboratory supervisor, Tech II and GCL team leader confirmed the findings above on 07/13/2021 around 11:50 am.</p>
D6021	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p>

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on review of quality control (QC) records and interview with the laboratory supervisor, Tech II and GCL team leader, the laboratory director failed to ensure quality assessment activities were maintained to assure the quality of laboratory services provided in 2020 and 2021. Findings include: 1. On the day of survey, 07/13/2021, the following QC records were not reviewed and signed by the LD or designee for Potassium hydroxide (KOH), Scabies, urine sediment and manual differential microscopic examination analyzed in 2020 and 2021: KOH and scabies examinations - 6 of 7 months in 2021 (January, February, March, April, May and June). Urine sediment examinations - 4 of 12 months in 2020 (September, October, November and December). Manual differential examination 3 of 12 months in 2020 (September, October and November). 2. The laboratory supervisor, Tech II and GCL team leader confirmed the finding above on 07/13/2021 around 11:30 am.