

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 07D0093029	(X3) Date Survey Completed 11/14/2024
Name of Provider or Supplier New Britain Pediatric Group	Street Address, City, State 1095 West Main St, New Britain, CT	
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 surveyor observation, record review and staff interview, the laboratory failed to establish policy and procedures for proper function checks of ancillary equipment to ensure accurate and reliable test results are obtained in the subspecialty of bacteriology. Findings include: 1. Surveyor observation on 11/14/2024 at 10:00 AM of the bacteriology laboratory area revealed three thermometers in use lacking calibration date documentation. 2. Record review on 11/14/2024 of the laboratory's quality binders revealed: a.Lack of documentation of calibration being performed for 3 of 3 thermometers in use. b.Lack of documentation of an established policy and procedure for the proper function check of ancillary equipment. 3. Staff interview at 11/14/2024 at 10:30 AM with the Laboratory Director (LD) confirmed the above findings. The LD further commented that he/she was not aware that the thermometers needed to be calibrated. 4. The laboratory performs 2,000 tests annually in the subspecialty of bacteriology.</p>
D5477	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e)</p>

(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to check each new lot number and shipment of media for sterility and the ability to support growth and, as appropriate, select for or inhibit specific organisms prior to patient testing in the subspecialty of bacteriology. Findings include: 1. Record review of the 'Uricult Testing' and 'Uricult Quality Control Log' on 11/14/2024 revealed the laboratory failed to check each new lot number and shipment for sterility and the ability to support growth, select or inhibit specific organisms prior to patient testing for 3 of 8 new reagent lots from 01/09/2023 to 11/12/2024. 2. Record review of the 'Bacteriology Media Control log' and 'Selective Strep Agar (SSA) Quality Control Log' on 11/14/2024 revealed the laboratory failed to check each new lot number and shipment for sterility and the ability to support growth, select or inhibit specific organisms prior to patient testing for 9 of 12 reagent lots from 05/09/2023 to 10/15/2024. 3. Staff interview with the laboratory director on 11/14/2024 at 11:00 AM confirmed the laboratory did not check each new lot number or shipment of SSA or Uricult media prior to patient testing. 4. The laboratory performs 2,000 tests annually in the subspecialty of bacteriology.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to evaluate the competency assessment (CA) of testing personnel (TP) using the six required elements to perform and report accurate test results in the subspecialty of bacteriology. Findings include: 1. Record review on 11/14/2024 of the laboratory's CMS 209 form "Laboratory Personnel Report (CLIA)" revealed 6 of 6 TP performing moderate complexity testing. 2. Record review on 11/14/2024 of the laboratory's annual competency evaluation forms for the year 2023 and 2024 revealed lack of documentation for the six required CA criteria for 6 of 6 TP. 3. Staff interview on 11/14/2024 at 11:30 AM with the technical consultant confirmed the above findings. 4. The laboratory performs 2000 tests annually in the subspecialty of bacteriology.