Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0101344	06/23/2022
Name of Provider or Supplier	**Street Address, City, State**	
Children's Medical Group Of Greenwich	42 Sherwood Pl, Greenwich, 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
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review, surveyor observation and staff interview, the laboratory failed to check each new lot number and shipment of bacitracin discs for positive and negative reactivity in the subspecialty of bacteriology. Findings include: 1. Record review of the Bacitracin Disc Quality Control (QC) log sheets on 6/23/2022 revealed the following: a. The laboratory documents the Bacitracin Lot number and date received. b. S. pyogenes (positive control) and S. agalactiae (negative control) are the quality control organisms used. c. The last Bacitracin disc lot number documented was lot# 9156977 on 3/9/2020. d. Lack of QC documentation for shipments since April 2020. 2. Surveyor observation on 6/23/2022 at 1:30 PM of the laboratory area including the freezer and refrigerator revealed quality control organisms were not available in the laboratory. 3. Staff interview with the office manager on 6/23/2022 at 1:30 PM commented the former office manager said QC was not needed and therefore the laboratory stopped performing QC and he/she would need to order QC organisms. 4. The laboratory performs 1903 throat cultures annually in the subspecialty of bacteriology.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g)

	(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(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 laboratory director interview, the laboratory failed to check each lot number and shipment of Strep Select Agar (SSA) media for its ability to support growth, select or inhibit specific organisms, perform a visual inspection and check for sterility in the specialty of microbiology. Findings include: 1. Review of the Strep Select Agar Plates Quality Control log sheet on 6/23/2022 revealed the laboratory failed to document since April 2021 the following: a. The ability of the media to support growth, select or inhibit specific organisms for each lot number and shipment. b. A sterility test and visual physical characteristics of the SSA. 2. Staff interview with the laboratory director on June 23, 2022 at 12:00 PM confirmed the laboratory did not check each new lot number or shipment of SSA media for their ability to support growth, select or inhibit specific organisms, or check and document the sterility and physical characteristics. The LD commented the previous nurse manager stated that the laboratory does no longer need to perform the media QC. 3. The laboratory performs 1903 cultures annually in the specialty of microbiology.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director failed to ensure the laboratory reviewed, evaluated and if necessary, correct problems with Proficiency Testing (PT) Program results for 7 of 7 events for the regulated analyte of Bacteriology. Findings include: 1. Record review on 6/23/2022 of the American Academy of Family Physicians (AAFP) Proficiency Testing evaluation reports for Module: 776 Throat cultures revealed: a. Lack of documentation of the review and evaluation of PT results for Events: A-C 2020, Events: A-C 2021: and Event A: 2022. b. Event B: 2020 with a score of 80% with no evaluation/investigation or corrective action. c. Event A: 2021 with a score of 80% with no evaluation/investigation or corrective action. d. Event C:2021 with a score of 0% with no evaluation/investigation or corrective action. 2. Staff interview with the Laboratory Director (LD) on 6/23 /2022 at 1:05 PM confirmed the above findings. The LD stated "all the documents are in the manila envelope, had change in staffing and facing staff shortage to keep up with the review and evaluation of the PT results". 3. Staff interview with the Office

	Manager on 6/23/2022 at 11:00 AM commented that Event C 2021 shipment was not received by the laboratory and was told by AAFP it was okay for the laboratory to continue testing. 4. The laboratory performs 1903 throat cultures 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 testing personnel (TP) to ensure competency to perform and report accurate test results in the specialty of microbiology. Findings include: 1. Record review of competency assessment records on 6/23/2022 revealed the lack of documentation of assessments for 3 of 3 moderate complex testing personnel to perform and report throat cultures for the years 2020 and 2021. 2. Staff interview with the laboratory director on 6/23 /2022 at 1:05 PM confirmed the laboratory did not have a policy in place to assess the competency of moderate complexity TP and he/she was unaware of the regulatory requirement. 3. The laboratory performs 1903 throat cultures annually in the subspecialty of Bacteriology.