Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0195442	06/14/2022
Name of Provider or Supplier	**Street Address, City, State**	
Brookside Clinical Lab Inc	2901 W Duttons Mill Road, Suite 100, Aston, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of laboratory's competency policy and interview with the Laboratory Director (LD), the laboratory failed to establish a procedure to assess the competency of 1 of 1 Clinical Consultant (CC) (on the CMS 209 form, listed as personnel #2) for their Consultant responsibilities in 2020 and 2021. Findings include: 1. On the day of survey 06/14/2022 at 09:05 am, the laboratory could not provide a policy that stated how to assess the competency for 1 of 1 CC their consultant responsibilities in 2020 and 2021. 2. The LD could not provide competency assessment records for 1 of 1 CC in 2020 and 2021 3. The LD confirmed the findings above on 06/14/2022 around 01: 15 pm.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on the lack of documentation, observation of the lab and interview with the testing personnel (TP) #4, the laboratory failed to calibrate and document the expiration date on 6 of the 6 thermometers being used for monitoring reagent storage

	temperature and 2 of 2 timer being used for chemistry and microbiology testing as defined by manufacturers. Findings include: 1.Observation of the lab on 06/14/2022 at 10:20 AM revealed that following thermometers did not have expiration date on them. Lot 90530268-Chemistry 1 refrigerator Lot 71170268-Chemistry 2 refrigerator Lot 71870551-Toxicology 2 refrigerator Lot 91300551- -20 freezer Lot 70890269-Room temperature Lot 02530268-Microbiology refrigerator 2.The following timers did not have expiration date Timer 1-Chemistry department Timer 2-Microbiology department 3.Calibration record review revealed that no calibration was performed on these thermometers and timers. 4. TP #7 confirmed the above findings on 06/14/2022 at 01:22 PM.
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 review of quality control records for microbiology media and interview with Technical Supervisor (TS) #3, the laboratory failed to check and document each batch or shipment of microbiology media, for physical characteristics, its ability to support growth, select or inhibit specific organisms or produce a biochemical response from 06/14/2020 to 06/14/2022. Findings Include: 1. On the day of survey 06/14/2022 at 10:00 am, review of microbiology quality control records revealed, the laboratory did not document the visual checks for each batch or shipment for microbiology media from 06/14/2020 to 06/14/2022 2. Review of the microbiology quality control records revealed, the laboratory failed to use at least one organism to confirm the following media for its inhibitory and biochemical characteristics from 06/14/2020 to the day of survey: - Thayer Martin - Bile Esculin Azide Slant BE - Hecktoen Enteric 3. The TS#3 confirmed the findings above on 06/14/2022 around 01:15 pm
D5507	BACTERIOLOGY CFR(s): 493.1261(b)(c) (b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the Antimicrobial Susceptibility test Quality Control (QC) Records, and interview with the Technical Supervisor (TS) #3, the laboratory failed to

	check QC for Carbapenem-resistant Enterobacteriaceae (CRE) and the Extended Spectrum Beta-lactamase (ESBL) confirmation susceptibilities each day of patient testing from 06/14/2020 to the date of survey. Findings Include: 1. On the day of survey 06/14/2022 at 12:07 pm, review of the CRE and ESBL confirmation test Quality Control (QC) Records revealed, the laboratory performed QC on a weekly bases from 06/14/2020 to 06/14/2022 2. TS #3 confirmed the findings above on 06/14 /2022 around 01:15 pm.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the Testing personnel (TP) #17, the laboratory failed to evaluate twice a year the accuracy of test results between 3 of 3 ThermoFisher Quant studio 3 Polymerase Chain Reaction (PCR) systems for Virology and Bacteriology testing in 2021. Findings include: 1. On the day of survey 06/14/2022 at 12:45 pm, review the laboratory could not provide comparison study records of patient test results between 3 of 3 Quant studio 3 PCR systems for Virology and Bacteriology testing from January 2021 to December 2021. 2. TP #17 confirmed the above finding on 06/14/2022 at 01:22 PM.