Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0195442	12/06/2019
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 procedure manuals and interview with testing personnel (TP) #1, the laboratory failed to establish a procedure to assess the competency of 3 of 3 technical supervisors (TS) 3 of 3 technical consultants (TC) and 5 of 5 general supervisors (GS) in 2018 and 2019. Findings Include: 1. On the day of survey, 12/06/2019, the laboratory failed to provide a written policy to assess the competency of 3 of 3 TS's, 3 of 3 TC's, and 5 of 5 GS's in 2018 and 2019: 2. TP #1 confirmed the finding above on 12/06/2019 around 09:00 am.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of laboratory temperature records and interview technical

	supervisors (TS) #1 and testing personnel (TP) #1, the laboratory failed to document 1 of 1 room temperature, 9 of 9 refrigerator temperatures and 5 of 5 freezer temperatures each day of testing from 2018 to the day of survey. Findings Include: 1. On the day of survey, 12/06/2019, review of the laboratory's temperature records revealed, the laboratory did not document, 1 of 1 room temperature, 9 of 9 refrigerator temperatures and 5 of 5 freezer temperatures on Saturdays and Sundays when patient testing was performed from 01/17/2018 to 12/06/2019. 2. The laboratory room, 9 refrigerators and 5 freezers house reagents, quality control and calibration materials for all departments in the laboratory, (Routine chemistry, hematology, bacteriology, serology and toxicology). 3. In 2018 - 951,717 patient tests were performed in the laboratory. 4. TS#1 and TP#1 confirmed on 12/06/2019 around 9:45 am that, daily room, refrigerator and freezer temperatures were not documented on the weekends when testing was performed.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of urine sediment microscopic examination quality control (QC) records and interview with the testing personnel (TP) #1, the laboratory failed to document urine sediment microscopic examination QC each day of patient testing for 3 of 12 months in 2018. Findings Include: 1. On the date of survey, 12/06/2019, review of the urine sediment microscopic examination QC records revealed, the laboratory did not document QC each day of patient testing for 3 of 12 months in 2018 (October, November and December). 2. The TP #1 confirmed the finding above on 12/06/2019 around 11:00 am.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure 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 the review of American Association of Bioanalysts (AAB) 2018 and 2019 proficiency testing (PT) scores and interview with the technical supervisor (TS) #3, the laboratory director (LD) failed to identify problems that required a corrective action for General Immunology PT scores for 1 of 3 events in 2018 and for 1 of 3 events in 2019. Findings Include: 1. On the day of survey, 12/06/2019, review of ABB PT records revealed, the laboratory did not document corrective actions for the following general immunology PT scores that were less than 100% for 1 of 3 events in 2018 and for 1 of 3 events in 2019 for: - AAB 2018, Event #3, HBS AG - 80% -

	AAB 2018, Event #3, Anti HBC - 80% - AAB 2019, Event #1, RA/RF - 0% - AAB 2019, Event #1, INF Mono - 0% 2. TS #3 confirmed the findings above at 12/06/2019 around 9:48 am.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (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 review of testing personnel competency assessment records and interview with the technical supervisor (TS) #1, #3 and testing personnel (TP) #1, the technical supervisors failed to assess the competency of 19 of 19 testing personnel (TP) for each methodology of non-waived tests performed from 2018 to the day of survey. Findings Include: 1. On the day of survey, 12/06/2019, review of competency assessment records revealed, 19 of 19 TP were not assessed for competency on each methodology of non-waived tests performed on from 01/17/2018 to 12/06/2019. 2. TS #1, #3 and TP #1 confirmed the finding on 12/06/2019 around 8:45 am.
D6125	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) records, review of the American Association of Bioanalysts (AAB) 2018 and 2019 proficiency testing (PT) attestation sheets, and interview with the technical supervisor (TS) #3, the TS failed to assess the competency of 6 of 7 TP through external immunology PT or internal blind testing samples in 2018 and 2019. Findings Include: 1. On the day of survey, 12/06/2019, review of TP records and ABB PT attestation sheets revealed, the laboratory did not assess the test performance of 6 of 7 TP (on the CMS 209 Testing Personnel Form - TP #5, 6, 7, 13, 16 and 17) thorough immunology PT samples or internal blind testing samples in 2018 and 2019. 2. TS#3 confirmed the finding above on 12/06/2019 around 10:00 am.