Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0195442	01/17/2018
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
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on, the review of the laboratory's quality control logs and an interview with the Technical Supervisor, the laboratory failed to document the testing of the reactivity of staining materials used for manual differential analysis from 2016 to the date of survey. Findings include: 1. On the date of survey 01/17/2018 at 12:22 pm, the surveyor reviewed the Hematology departments quality control logs and discovered there was no documentation for the testing of the reactivity of the staining material used for manual differential analysis. 2. On 01/17/2018 at 12:22 pm an interview with the Technical Supervisor revealed that no documentation was availble for the manual differantial stain quality.
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, the review of the laboratory's quality control records and an interview with the Technical Supervisor, the laboratory failed to document all control procedures performed for for each batch or shipment of media used for microbiology testing from 2016 to the date of survey. Findings: 1) On the date of survey 01/17/2018 at 11:49 am, the surveyor reviewed the microbiology quality control logs and discovered that the department did not document each batch of media for sterility, it's ability to support growth, its ability to produce a biochemical response and its physical characteristics. 2) 10,250 patient samples were tested. 3) On the date of survey 01/17 /2018 at 11:49 am an interview with the Technical Supervisor confirmed the findings above
D5485	CONTROL PROCEDURES CFR(s): 493.1256(h) If control materials are not available, the laboratory must have an alternative mechanism to detect immediate errors and monitor test system performance over time. The performance of alternative control procedures must be documented. This STANDARD is not met as evidenced by: Based on, the review of laboratory quality control records and interview with Laboratory Supervisor, the laboratory failed to have an alternative mechanism to detect immediate errors for microscopic urinalysis performed from 2016 to the date of survey. Findings: 1) On the day of survey 01/17/2018 at 01:13 pm the surveyor reviewed the Urinalysis departments quality control logs and discovered no alternative control mechnism for microscopic urinalysis were performed and documented. 2) On 01/17/2018 at 01:13 pm an interview with the Laboratory Supervisor confirmed the findings above.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of competency assessment records and interview with the Technical Supervisor (TS), the Technical Supervisor failed to evaluate and document the performance of the testing personnel # 6 at least semi-annually during the first year in 2016. Findings include: 1. At the time of survey, the laboratory was unable to provide a six month competency assessment record for testing personnel #6. 2. The TS confirmed the finding above on 1/17/2018 around 10:30 am.