

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0195442	(X3) Date Survey Completed 03/27/2024
Name of Provider or Supplier Brookside Clinical Lab Inc	Street Address, City, State 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
D3009	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory director (LD), the laboratory director (LD) failed to be present for a reasonable period of each working day in each laboratory for which he is director from 06/14/2022 to the day of survey as required by PA State regulations. Findings include: 1. The PA State regulation 5.22 (g) states: "A director shall be present for a reasonable period of each working day in each laboratory for which he is director." 2. According to the laboratory's "Responsibilities and Functions of the Clinical Laboratory Director" procedure, the LD should visit the laboratory monthly or as often as deemed necessary, communicate with the laboratory daily to cover any laboratory issues utilizing face time or skype to interact with employees or clients if necessary. 3. On the day of survey, 03/27/2024 at 12:34 pm, an interview with the LD revealed that he visited the laboratory 7 of 22 months from June 2022 to 03/27/2024. 4. The LD confirmed the findings above on 03/27/2024 at 1:30 pm.</p>
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p>

This STANDARD is not met as evidenced by:
 Based on review of the American Proficiency Institute (API) and College of American Pathologists (CAP) proficiency testing (PT) records and interview with technical supervisor (TS) #2 and technical supervisor (TS) #3, the laboratory failed to verify the accuracy of the PT results obtained for 5 of 5 CAP Chemistry and 1 of 6 API Microbiology testing events in 2022, 2023, and 2024. Findings Include: 1. On the day of survey, 03/27/2024 at 10:06 am., review of the laboratory's CAP and API PT records revealed that the laboratory did not verify the accuracy for the following analytes that were not scored by the PT agencies in 2022, 2023, and 2024: - CAP General Chemistry/Therapeutic Drugs- T3 Uptake/ Related Test 2022 CAP C-C, 2023 CAP C-A, C-B, C-C 2024 CAP C-A 2024 - 2024 API Microbiology 1st event UTI Panel 2. The API Proficiency Testing performance Evaluation form states " Laboratories are responsible for documenting and performing corrective action for failures and must perform a self-evaluation using statistics presented in the Participant Data Summary for samples that have not been graded." 3. The CAP's actions laboratories should take when a PT result is not graded document states, "the laboratory is required to review participant summary for comparative results and document performance accordingly. Evaluation criteria is not established for educational challenges. Laboratories should determine their own evaluation criteria approved by their laboratory director for self-evaluation." 3. TS #2 and TS #3 confirmed the findings above on 03/27/2024 at 1:30 pm.

D5221

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
 CFR(s): 493.1236(d)

All proficiency testing evaluation and verification activities must be documented.

This STANDARD is not met as evidenced by:
 Based on review of laboratory's College of American Pathologists (CAP) proficiency testing (PT) records and interview with technical supervisor (TS) #2 (CMS 209 personnel #4), the laboratory failed to document the evaluation and verification activities for 2 of 6 PT testing events in chemistry in 2023. Findings include: 1. On the day of survey, 03/27/2024 at 11:40 am, a review of laboratory's CAP PT records revealed that the laboratory did not document the review and corrective action taken for the following 2 of 6 CAP PT testing events in 2023 that received unacceptable scores: - C-B 2023 General Chemistry/ Therapeutic Drugs Vancomycin- CMM 07 - K-B 2023 Ligand General Cortisol serum- K 07 2. TS #2 confirmed the findings above on 03/27/2024 at 01:30 pm.

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 document review, observation of the laboratory and interview with the technical supervisor (TS) #3 (CMS 209 personnel #5), the laboratory failed to maintain storage temperature conditions consistent with the manufacturer's instructions for microbiology reagents in 2022 and 2023. Findings include: 1. On the day of survey, 03/27/2024 at 12:18 pm, during observation of the laboratory the following microbiology reagents were found open/in use and stored in -20 to 0 degrees Celsius. 3 of 3 EN- Oxid Antimicrobial Susceptibility Test discs 2. According to manufacturer's instructions, Oxid Antimicrobial Susceptibility Test discs should be stored in 2 to 8 degrees Celsius once opened/in use. 3. TS#3 confirmed the findings above on 03/27/2024 at 1:30 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 technical supervisor (TS) #1, the laboratory failed to have a system in place that twice a year evaluates and defines the relationship between test results for automated white blood cell (WBC) differential and manual microscopic WBC differential performed in hematology from 06/14/2022 to the day of survey. Findings include: 1. On the day of survey, 03/27/2024, the laboratory could not provide documentation of the biannual comparison of test results for WBC differential performed on the Sysmex XN 1000 hematology analyzer (automated) and microscopic WBC differential (manual) from 06/14/2022 to 03/27/2024. 2. The laboratory reported an annual volume of 207,060 tests for hematology (CMS 116). 3. TS #1 confirmed the findings above on 03/27/2024 at 1:30 pm.

D5807

TEST REPORT
 CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:
 Based on record review and interview with the technical supervisor (TS) #3 (CMS 209 personnel #5), the laboratory failed to include pertinent reference intervals/normal values on patient test reports for 4 of 4 virology analytes tested in 2022. Findings Include: 1. On the day of the survey, 03/27/2024 at 10:00 am, review of patient reports revealed that the laboratory failed to include pertinent reference intervals /normal values on the final report for 4 of 4 virology analytes (HBSAG, ANTI-HAV IGM, ANTI- HBC IGM, Hepatitis C ANTI) tested on the following date -10/31/2022. 2. The TS #3 confirmed the findings above on 03/27/2024 at 01:30 pm.

D6103

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:

Based on lack of documentation and interview with technical supervisor (TS) #3, the Laboratory Director (LD) failed to ensure that a policy was established to monitor and maintain competency for 1 of 16 testing personnel (TP) who conducted preanalytical, analytical and postanalytical phases of testing in microbiology in 2023. Findings include: 1. On the day of survey, 03/27/2024, the laboratory could not provide documentation of the competency assessment for 1 of 16 TP (CMS 209 personnel #5) who performed microbiology testing in 2023. 2. TS #3 confirmed the above findings on 03/27/2024 at 1:30pm.