Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D2326552	05/20/2026
Name of Provider or Supplier	**Street Address, City, State**	
Community Pathology Laboratory-Brookwood	2010 Brookwood Medical Center Drive, Homewood, AL	

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
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 a review of the Peer Review (PR) Proficiency Testing (PT) records and an interview with Testing Personnel 1 (TP1), the laboratory failed to document the accuracy verification performed by four of the seven TP for the high complexity testing from 01-01-2026. The findings include: 1. A review of the 2026 PR PT records revealed no documentation of the accuracy verification performed by TP1, TP2, TP5 and TP7. 2. TP1 confirmed the above findings during the exit conference on 05-20-2026 at 12:13 PM.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of the Policy and Procedure (P&P) Manual and an interview with the Testing Personnel 1 (TP1), the Laboratory Director (LD) failed to document review and approval of the laboratory's policies and procedures. The surveyor noted there was no evidence the LD reviewed and approved the P&P before patient testing began on 01-01-2026. The findings include: 1. A review of the P&P Manual revealed

	the laboratory had no documentation of the LD's review and approval (as indicated by his signature and date) before patient testing began on 01-01-2026. 2. During the exit conference on 05-20-2026 at 12:13 PM, TP1 confirmed the above findings.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) (e)(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on reviews of personnel records and an interview with the Testing Personnel 1 (TP1), the Laboratory Director (LD) failed to specify in writing the duties and responsibilities of TP. The surveyor noted no written documentation of the TP duties and responsibilities when the laboratory started testing on 01-01-2026. The findings include: 1. A review of personnel records revealed the LD had no documentation of the duties and responsibilities of TP in all phases of the laboratory testing process. 2. During the exit conference on 05-20-2026 at 12:13 PM, TP1 confirmed the above findings.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) (b)(9) 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 a review of the personnel records and interviews with the Testing Personnel 1 (TP1), the Technical Supervisor (TS) failed to ensure Testing Personnel (TP) listed on the CMS-209 (Laboratory Personnel Report), performing high complexity testing had competency assessments which included all six CLIA minimal regulatory requirements. The surveyor noted four of the six requirements were missing on the semi-annual and annual competencies. The findings include: 1. A review of the 2026 personnel records for TP listed on the CMS-209 (Laboratory Personnel Report) revealed competency assessments for the Pathology specialty had no documentation on four of the six CLIA minimal regulatory requirements, as follows: (1) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing, and testing. (2) Monitoring the recording and reporting of test results. (3) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. (4) Assessment of problem-solving skills. 2. TP1 confirmed the above findings during the exit conference on 05-20-2026 at 12:13 PM.