Appendix E
Compliance Checklists

Section 4 External Quality Assessment

Guideline Item	Compliant?	Additional Comment(s) by Auditor
4.4.2 Controls are run prior to testing, in accordance with laboratory policy	☐ Yes ☐ No	
4.4.1, 4.4.2 A quality monitoring plan is in place including an EQA program that meets laboratory needs	☐ Yes ☐ No	
4.4.4 EQA testing is performed quarterly or more often as needed	☐ Yes ☐ No	
4.3.1. Mechanisms are in place to detect potential pre- and post-analytic errors	☐ Yes ☐ No	
4.5.1,4.7.3 Quality of EQA test items is verified upon receipt and problematic findings are communicated to EQA provider	☐ Yes ☐ No	
4.5.2 EQA provider instructions are strictly followed	☐ Yes ☐ No	
4.5.3 EQA materials are processed identically to patient samples	☐ Yes ☐ No	
4.5.4 EQA testing is performed in a timely manner	☐ Yes ☐ No	
4.6.1 EQA data and interpretation are assessed upon receipt	☐ Yes ☐ No	
	☐ Yes ☐ No	
4.6.1, 4.7.1 EQA data, interpretation, and procedural and/or policy changes resulting from EQA analysis are archived on paper or electronically for 7+ years	☐ Yes ☐ No	
4.6.3, 4.7.5 EQA provided continuing education and other assistance are utilized, when necessary	☐ Yes ☐ No	
4.7.1 All laboratory personal are informed of EQA results	☐ Yes ☐ No	
4.7.1 Designated person(s) analyze, troubleshoot, and monitor EQA performance	☐ Yes ☐ No	
4.7.2 Problematic EQA results are categorized and root cause(s)	☐ Yes ☐ No	

identified and monitored		
4.7.4 Troubleshooting of problematic results is prioritized based on clinical significance	☐ Yes ☐ No	

Section 5 Comparative Testing

Guideline Item	Compliant?	Additional Comment(s) by Auditor
5.1.2 Have defined acceptance criteria for independent laboratory comparisons	☐ Yes ☐ No	
5.2.2.1 Use comparability testing to investigate unexpected test results and as designated in the quality management system	☐ Yes ☐ No	
5.2.2.3 Conduct comparison with external laboratories when EQA programs are not available for a specific test	☐ Yes ☐ No	
5.4.1.1, 5.4.2, Use good quality, appropriate samples and test materials for comparison within the stability timeframe of the measurands being evaluated	☐ Yes ☐ No	
5.4.1.2 Consult knowledgeable professional(s) prior to altering samples for comparison	☐ Yes ☐ No	
5.5 Use appropriate methods for determining result comparability (with expert consultation, as needed)	☐ Yes ☐ No	
5.6.2 Conduct further investigation if and when results are not comparable	☐ Yes ☐ No	