Checklist for ASVCP Quality Assurance Guideline Section 4, Analytical factors Important in Veterinary Clinical Pathology (v.3, 2019)

The purpose of these checklists is to facilitate guideline implementation/practical application and may be further detailed in laboratory-specific standard operating procedures (SOPs). The numbers in the first column correspond to the section numbers in the guideline. The N/A option (listed here only for applicable items) should only be employed for items not pertaining to the laboratory, with an explanation in the additional comment box.

Guideline Recommendation	Compliant?	Additional Comment(s) by Auditor
4.2.1 Laboratory water quality electrical power stability, and temperature (to include refrigerator/freezer)/humidity conditions are monitored on a regular schedule.	☐ Yes ☐ No	
4.2.1 Automated balances, pipettes, microscopes, and centrifuges are cleaned/calibrated annually.	☐ Yes ☐ No	
4.2.1 An Instrument Performance Log is created and maintained for each instrument, recording routine and special maintenance/repairs and any other corrective actions taken.	☐ Yes ☐ No	
4.2.2 The laboratory participates in an external quality assessment/proficiency testing program, with results distributed and discussed among laboratory personnel. Inquiry/internal audit is performed if there is an unacceptable deviation from the peer group mean.	☐ Yes ☐ No	
4.3/4.3.9 Appropriate method validation or method verification/transfer studies are performed prior to adopting a new test procedure and/or bringing a new instrument on-line; the choice between full validation and verification matches the specific laboratory situation.	☐ Yes ☐ No	

4.3.1 A reportable range/linearity study is performed for each species to be assayed, if recommended/applicable.	☐ Yes ☐ No ☐ N/A	
4.3.2, 4.3.3 Short-term and long-term replication studies are performed to assess assay imprecision/random error, if recommended/applicable.	☐ Yes ☐ No ☐ N/A	
4.3.4 A comparison of methods study is performed to assess systematic error of the new method compared to the comparison method, if recommended/applicable.	☐ Yes ☐ No ☐ N/A	
4.3.5 An interference study is performed to assess systematic error caused by potential interfering substances, if recommended/applicable.	☐ Yes ☐ No ☐ N/A	
4.3.6 A recovery study is performed to assess potential systematic error caused by substances within the sample matrix, if recommended/applicable.	☐ Yes ☐ No ☐ N/A	
4.3.7 A reference interval study is performed for creation of reference intervals for each species to be assayed, if recommended/applicable.	☐ Yes ☐ No ☐ N/A	
4.3.8 A detection limit study is performed to determine the lowest concentration that can be measured, if recommended/applicable.	☐ Yes ☐ No ☐ N/A	
4.4 Multisite/multi-instrument laboratories should compare test results among various methods, instruments, and/or laboratories to monitor performance and identify deficiencies.	☐ Yes ☐ No ☐ N/A	
4.5 Instrument function checks are performed each day of test use, with identification of possible interferences. Calibration should be	☐ Yes ☐ No	

performed at least every six months and more frequently if indicated.		
4.6 Laboratory personnel have thorough working knowledge of instruments and their use/maintenance and can perform basic troubleshooting/can take appropriate steps with various error messages/flags (see also section 2 for more information on personnel knowledge/training).	☐ Yes ☐ No	
4.7, Appendix 1 A routine quality control (QC) plan is in place (see also following detailed items) to monitor method/instrument performance, with rules and policies established for analysis of QC measurement tools (e.g. Levey-Jennings plots).	☐ Yes ☐ No	
4.7.2 There is proper storage and handling of QC reagents and calibrators.	☐ Yes ☐ No	
4.7.1 Purchased quality control materials should have low, normal, and high levels that are medically relevant for veterinary species.	☐ Yes ☐ No ☐ N/A	
4.7.1, 4.7.3, 4.7.4, Appendix 1, Figures 2 and 3, Table 4 Statistical QC rules, number of control levels analyzed, and QC frequency are chosen to ensure a high probability of error detection (recommended Ped $\geq$ 90%), a low probability of false rejection (recommended Pfr $\leq$5%), and hence a low risk of reporting unreliable final patient results (i.e. results are within quality goals as may be defined by allowable total error/TEa, clinical decision limits, and/or expected biologic variation).	☐ Yes ☐ No ☐ N/A	
4.7.1, 4.7.4, Appendices 1 and 2, Tables 2 and 4 Sigma metrics are calculated for each test from TEa, bias, and coefficient of variation (CV) data,	☐ Yes ☐ No ☐ N/A	

in order to aid determination of which tests require more stringent statistical and non-statistical QC.		
4.7.1, 4.7.4, Appendix 1, Figure 3, Table 4 The potential need for multi-level control rules for individual measurands (with lower sigma), as well as the potential need for multistage QC during a run are assessed.	☐ Yes ☐ No ☐ N/A	
4.7.1, 4.7.4, Appendix 1, Table 2, Figure 2 Non-statistical QC items are employed as applicable for lower throughput labs and/or for any measurands with low sigma performance.	☐ Yes ☐ No	
4.2.1 Accumulated QC data is systematically reviewed on a determined regular schedule (e.g. Levey Jennings plot analysis), and appropriate corrective actions are taken when there are undesirable trends/results outside of control rule parameters. Patient samples are not run/reported until quality control materials are assayed as back “in control”.	☐ Yes ☐ No	