

**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.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
4.2.1 Automated balances, pipettes, microscopes, and centrifuges are cleaned/calibrated annually.	<input type="checkbox"/> Yes <input type="checkbox"/> 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.	<input type="checkbox"/> Yes <input type="checkbox"/> 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.	<input type="checkbox"/> Yes <input type="checkbox"/> 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.	<input type="checkbox"/> Yes <input type="checkbox"/> No	

4.3.1 A reportable range/linearity study is performed for each species to be assayed, if recommended/applicable.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
4.3.5 An interference study is performed to assess systematic error caused by potential interfering substances, if recommended/applicable.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
4.3.8 A detection limit study is performed to determine the lowest concentration that can be measured, if recommended/applicable.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
4.5 Instrument function checks are performed each day of test use, with identification of possible interferences. Calibration should be	<input type="checkbox"/> Yes <input type="checkbox"/> 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).	<input type="checkbox"/> Yes <input type="checkbox"/> 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).	<input type="checkbox"/> Yes <input type="checkbox"/> No	
4.7.2 There is proper storage and handling of QC reagents and calibrators.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
4.7.1 Purchased quality control materials should have low, normal, and high levels that are medically relevant for veterinary species.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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 $P_{ed} \geq 90\%$ ), a low probability of false rejection (recommended $P_{fr} \leq 5\%$ ), 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).	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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,	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	

<p>in order to aid determination of which tests require more stringent statistical and non-statistical QC.</p>		
<p>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.</p>	<p><input type="checkbox"/> Yes   <input type="checkbox"/> No  <input type="checkbox"/> N/A</p>	
<p>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.</p>	<p><input type="checkbox"/> Yes   <input type="checkbox"/> No</p>	
<p>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”.</p>	<p><input type="checkbox"/> Yes   <input type="checkbox"/> No</p>	