Checklist for ASVCP Quality Assurance Guideline Section 6, Hemostasis Testing (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
6.1 The laboratory provides written guidance to offsite clients and is prepared to answer questions regarding sample collection and handling.	☐ Yes ☐ No ☐ N/A	
6.1.1.1 The laboratory either specifies one trisodium citrate concentration or has investigated the effect of trisodium citrate concentration on their analyzer and reagent, and as necessary has generated a separate reference intervals for 3.2% and 3.8% trisodium citrate.	☐ Yes ☐ No ☐ N/A	
6.1.1.2 Results from blood tubes filled to <90% of the desired fill volume are released with a warning that underfilling can cause false prolongations.	☐ Yes ☐ No ☐ N/A	
6.1.2 Samples should be checked for clots and clotted samples rejected.	☐ Yes ☐ No ☐ N/A	
6.1.2.1 For plasma-based assays, citrated plasma is separated from whole blood within 6 hours of collection for PT/aPTT, unless aPTT is being used for monitoring of unfractionated heparin, in which case plasma should be separated within one hour.	☐ Yes ☐ No ☐ N/A	
6.1.2.1 Plasma is separated before shipping to a remote laboratory for testing.	☐ Yes ☐ No ☐ N/A	

6.1.2.2 Plasma is separated by centrifugation at 1,500 x g for 15 minutes.	☐ Yes ☐ No ☐ N/A	
6.1.2.2 Centrifuge conditions, including temperature and use of the centrifuge brake, are consistent for all samples.	☐ Yes ☐ No ☐ N/A	
6.1.2.2 Plasma is transferred using a plastic pipette to a plastic, additive-free secondary tube, which is clearly identifiable as containing citrated plasma.	☐ Yes ☐ No ☐ N/A	
6.1.2.3 Whenever possible, plasma is analyzed within 1 hour of separation. If this is not achievable, the laboratory may follow storage recommendations established by in-house investigation or the recommendations herein. These allow plasma storage for up to 24 hours at room temperature or 4^{o}C for in-house specimens; storage at 4^{o}C and shipping same-day/overnight on ice for mail-in specimens that will be analyzed within 24 hours of patient collection; or, freezing followed by shipping overnight on ice for mail-in specimens that will not be analyzed within 24 hours of patient collection.	☐ Yes ☐ No ☐ N/A	
6.1.2.3 If frozen specimens are accepted, plasma is thawed for 5 minutes (or until full thaw) in a 37^{o}C water bath before analysis.	☐ Yes ☐ No ☐ N/A	
6.2.1 If aPTT is used for unfractionated heparin monitoring, the therapeutic range should be established using at least 20 samples from patients receiving unfractionated heparin. If this cannot be achieved, users requesting aPTT are advised that fold changes in aPTT do not	☐ Yes ☐ No ☐ N/A	

necessarily predict achievement of therapeutic targets.		
6.2.1 International Normalized Ratio (INR) is not provided (not validated in veterinary species).	☐ Yes ☐ No ☐ N/A	
6.2.2 The laboratory has a written policy defining the responses to out-of-range results and samples with interferences, including the triggers for use of confirmatory or alternative methods.	☐ Yes ☐ No ☐ N/A	
6.2.2 Water baths are regularly checked to ensure the desired temperature is achieved.	☐ Yes ☐ No ☐ N/A	
6.2.3 Personnel are aware of the potential urgency of coagulation test requests and the requirement to inform clinical staff as soon as possible if a redraw is required.	☐ Yes ☐ No ☐ N/A	
6.2.3 Personnel can provide information about the extent to which methods have been validated for commonly used therapeutics; likely magnitude of effect of common pre-analytical errors; likely causes of abnormalities; and, can provide recommendations for follow up testing.	☐ Yes ☐ No ☐ N/A	
6.2.4 For reference instruments, a minimum of 1 level of control material is assayed in each shift during which a coagulation test is requested. Ideally, two levels of control are assayed in every shift.	☐ Yes ☐ No ☐ N/A	
6.2.4 If manual (i.e. tilt tube) testing is performed, a minimum of one normal control is assayed at the same time as the patient sample. Control(s) and patient samples are assayed in duplicate, and criteria are defined for the acceptable difference between duplicates.	☐ Yes ☐ No ☐ N/A	

6.2.4 If laboratories are reporting assays as a percentage of normal pooled samples, procedures are in place to confirm that new pools generate acceptable results. Stability and handling conditions for pooled plasma are established by in-house experimentation.	☐ Yes ☐ No ☐ N/A	
6.2.5 Users are provided with advice, and where feasible, assistance to ensure correct sample collection and handling for outsourced tests.	☐ Yes ☐ No ☐ N/A	
6.3 If batched analysis is performed, the timing of analysis is available to users.	☐ Yes ☐ No ☐ N/A	
6.3 Wording for results reporting is clearly specified, including reporting of out-of-reportable range results and as applicable, the clear differentiation of patient results from simultaneously assayed control samples.	☐ Yes ☐ No ☐ N/A	
6.3 If multiple coagulation instruments are available within one institution, client education and written guidance are available regarding the variability in coagulation results generated by different instrument/reagent combinations.	☐ Yes ☐ No ☐ N/A	