

### 14.0 PBGM Guideline Compliance Checklist

Compliance with ASVCP guidelines is voluntary. Purpose of this checklist is to facilitate guideline implementation and practical application.

(The numbers in the first column correspond to the item numbers in the PBGM Guideline.)

<b>Guideline Recommendation</b>	<b>Compliant?</b>	<b>Auditor Comment(s)</b>
4.0 PBGM operators are knowledgeable regarding the operation, principle of measurement, and potential errors associated with the methodology used on the instrument.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
5.1.1 PBGM operators have received adequate initial and ongoing training, which is documented.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
5.1.2, 5.1.3 PBGM operators understand patient preparation requirements for the desired application of the test.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
5.1.3 PBGM operators are aware of the sample collection vacutainer and volume requirements needed for the instrument.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
5.1.3 PBGM operators understand the importance of standardization of the sample type and collection site to minimize variation due to these pre-analytical variables.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
5.1.4 Operators of PBGM are aware of the potential of erroneous results due to different animal sample rheological properties if meters have not been validated for veterinary use.	<input type="checkbox"/> Yes <input type="checkbox"/> No	

5.2.1 Operators of PBGM know and understand the importance of the sample type the PBGM reports i.e. whole blood, plasma or calculated plasma equivalent.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
5.2.1 Operators of PBGMs know when and how to apply glucose meter conversion equations.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
5.2.2.1 Test strips are stored according to manufacturer's recommendations and are in date.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
5.2.2.1 Key code or other instructions regarding batches of test strips are followed.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
5.2.2.1 Correct species codes are used, if applicable.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
5.2.2.1 Manufacturer's recommendations for temperature equilibration of test strips are followed.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
5.2.2.1 Manufacturer's instructions for timing of reactions (if applicable) are followed.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
5.2.2.2 Manufacturer's instructions regarding environmental temperature, humidity and altitude are followed.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
5.2.2.3 Operators of PBGMs are aware that the performance (accuracy) of PBGMs may vary at different glucose concentrations.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
5.2.2.3 Operators of PBGMs know whether HCT is concurrently measured, whether the instrument is HCT independent, or if this needs to be done as a separate procedure. Operators understand the effect of ranges of HCT on glucometer results and actions that should be taken.	<input type="checkbox"/> Yes <input type="checkbox"/> No	

5.2.2.3, 5.2.2.4 Procedures are in place to indicate possible test interference from substances such as lipids, bilirubin, changes in pO <sub>2</sub> or pH, drugs, if known and applicable at time of testing.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
5.3.1 PBGM operators should be aware of units in which the glucose result is reported to avoid possible inadvertent change and misinterpretation of results in a different unit.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
5.3.2 Records regarding instrument performance, maintenance, battery change dates and QC are present and maintained.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
6.1 ASVCP-recommended guidelines for Total Allowable Error (TEa) are used to evaluation instrument performance at hypo/normo & hyperglycemic ranges prior to clinical use.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
6.2 Choice of quality control materials and rules has been tailored for the specific instrument.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
6.2 Periodic QC is performed and frequency justified.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
6.2 QC is performed and documented following battery change, new lot/vial/batch of test strips, instrument damage (e.g. dropped), or if there is any concern regarding result accuracy.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
6.3 The laboratory participates in an External Quality Assurance program for all PBGMs or does comparative testing with a reference laboratory.	<input type="checkbox"/> Yes <input type="checkbox"/> No	

6.3. EQA or comparative testing performance is documented along with appropriate actions if a problem is identified.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
6.4 If multiple PBGMs are used, these should be of the same type (manufacturer) or use the same methodology.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
6.4 If multiple PBGMs are used at one site, the PBGM identification is recorded with the patient result and serial evaluations conducted with the same PBGM (if possible).	<input type="checkbox"/> Yes <input type="checkbox"/> No	
6.4. If multiple PBGMs are used at one site, they should all be included in EQA or comparative testing or harmonized to ensure comparable results.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
6.5 Appropriate non-statistical QC/QA procedures are used and documented, such as repeat testing, critical medical decision limit notification, and/or verification testing.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
6.6 Pet owners operating PBGMs for their diabetic pets should be trained to operate PBGMs for daily use and application of quality control measures.	<input type="checkbox"/> Yes <input type="checkbox"/> No	
6.6 Performance of PBGMs used by pet owners should be evaluated prior to home use and periodically in an EQA or comparative test program.	<input type="checkbox"/> Yes <input type="checkbox"/> No	