Checklist for ASVCP Quality Assurance Guideline Section 11, Protein electrophoresis and Electrophoresis-based Immunotyping (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
11.1.1 Submission guidelines are provided to client, to include preferred sample type and handling instructions.	☐ Yes ☐ No ☐ N/A	
11.1.1 Submission form is legible and contains the following: ● Complete signalment & relevant history/indication for electrophoresis testing ● Sample type (serum vs. plasma)	☐ Yes ☐ No ☐ N/A	
11.1.1.1 Sample and submission recommendations for cases with cryoglobulinemia are available in writing or by phone.	☐ Yes ☐ No ☐ N/A	
11.1.2 Samples are stored appropriately prior to, during, and after testing.	☐ Yes ☐ No ☐ N/A	
11.2.1, 11.2.5 Manufacturers' instructions are followed for all equipment; instrument performance and maintenance logs are kept (to include refractometers, biochemistry analyzers, electrophoresis units, stainers, and scanner/detection equipment).	☐ Yes ☐ No ☐ N/A	
11.2.2, 11.2.3 Method validation and routine QA/QC are performed on instruments.	☐ Yes ☐ No ☐ N/A	

11.2.4 Laboratory personnel are knowledgeable regarding the pre-analytical concerns, species and age differences, principles of method performance and operation, and the potential errors associated with these measurements, including appropriate retest/confirmatory test policies.	☐ Yes ☐ No ☐ N/A	
11.2.5, 11.1.3 Non-statistical QA practices occur for immunotyping procedures, including performance of the assay by well-qualified individuals and confirmation of results by a pathologist.	☐ Yes ☐ No ☐ N/A	
11.2.5.1.2 Control samples (commercial QCM, assayed pooled normal serum/plasma) are included in each electrophoresis run.	☐ Yes ☐ No ☐ N/A	
11.2.5 Employed techniques can be expected to resolve two beta peaks (high resolution electrophoresis).	☐ Yes ☐ No ☐ N/A	
11.3 Pathologist-generated reports are clear, concise, and employ nomenclature consistently.	☐ Yes ☐ No ☐ N/A	
11.3 Client reports include appropriate data, including an image of the gel (if gel-based methods are used), electrophoretogram and immunotyping (if performed), any derived quantitative data, and any appropriate comments.	☐ Yes ☐ No ☐ N/A	