

## 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.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
11.1.1 Submission form is legible and contains the following: <ul style="list-style-type: none"> <li>• Complete signalment &amp; relevant history/indication for electrophoresis testing</li> <li>• Sample type (serum vs. plasma)</li> </ul>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
11.1.1.1 Sample and submission recommendations for cases with cryoglobulinemia are available in writing or by phone.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
11.1.2 Samples are stored appropriately prior to, during, and after testing.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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).	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
11.2.2, 11.2.3 Method validation and routine QA/QC are performed on instruments.	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	

<p>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.</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A</p>	
<p>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.</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A</p>	
<p>11.2.5.1.2 Control samples (commercial QCM, assayed pooled normal serum/plasma) are included in each electrophoresis run.</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A</p>	
<p>11.2.5 Employed techniques can be expected to resolve two beta peaks (high resolution electrophoresis).</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A</p>	
<p>11.3 Pathologist-generated reports are clear, concise, and employ nomenclature consistently.</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A</p>	
<p>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.</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A</p>	