Checklist for ASVCP Quality Assurance Guideline Section 10, Endocrinology and Immunoassays (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
10.1.2.1 Clients are advised that a single hormone measurement is usually insufficient for a clinical endocrinopathy diagnosis.	☐ Yes ☐ No ☐ N/A	
10.1.2.2 Clients are advised to order endocrine tests with consideration to index of suspicion for an endocrinopathy and the presence of any other underlying disease(s); the endocrinology laboratory submission form has a dedicated section(s) for these items (i.e. brief, relevant history).	☐ Yes ☐ No ☐ N/A	
10.1.2.3 Clients are advised that drugs (such as medications and owner-hormone replacement therapy exposure) may impact test results/interpretation; the endocrinology laboratory submission form has a section asking for listing of current/recent treatment(s) (name, dose, frequency, duration) and potential exposure to topical human hormone replacement therapy.	☐ Yes ☐ No ☐ N/A	
10.1.3 The written/electronic laboratory test protocols for clients provide: • the test indication(s) (and desired timing, as applicable) • product dose/administration for each dynamic test	☐ Yes ☐ No ☐ N/A	

• sample requirements (serum v. other, minimal volume, etc.) • number of samples and timing, as applicable • submission modalities (tubes, handling, shipping)		
10.2.2 The client is informed, upon request, of the specific technique(s) employed for each immunoassay (e.g. competitive versus noncompetitive) and the signal involved (radioactivity, chemiluminescence, fluorescence, or enzymology).	☐ Yes ☐ No ☐ N/A	
10.2.2.2 For radioactive assays, all regulations are posted and followed regarding staff training, protective equipment, radioactivity monitoring, and proper waste disposal.	☐ Yes ☐ No ☐ N/A	
10.2.3 Each immunoassay (IA) used in the laboratory is properly validated in each species for which it is used.	☐ Yes ☐ No ☐ N/A	
10.2.4 The analytical performance goals, expressed separately for imprecision and bias, or as TEa, should be determined for each endocrine immunoassay.	☐ Yes ☐ No ☐ N/A	
10.2.5 Special issues related to IA such as prozone/postzone effects, antibody interference, and cross-reactivity should be investigated in case of a discordant result.	☐ Yes ☐ No ☐ N/A	
10.2.6.1 Each IA is properly calibrated, as needed, based on the assay method and QC results. Calibration materials are properly stored, and daily record of use are maintained for traceability.	☐ Yes ☐ No ☐ N/A	
10.2.6.2 Quality control materials (QCM) are selected/generated, properly stored, and used daily.	☐ Yes ☐ No ☐ N/A	

Records are kept for quality control measurements for each IA on a spreadsheet and a Levey-Jennings chart.		
10.2.6.2 A proper quality control strategy (QC rules) and QC Validation are determined and documented for each IA, with criteria for rejection.	☐ Yes ☐ No ☐ N/A	
10.2.6.2 Each failure of QCM for the chosen QC rules is recorded, and corrective and preventive actions are implemented and documented. QCM is re-evaluated following corrective actions before testing of patient specimens.	☐ Yes ☐ No ☐ N/A	
10.2.6.3 External quality assurance (EQA) is ideally performed at a minimum of four times per year, and records of results, as well as any necessary corrective and preventive actions, are kept for a predetermined period of time.	☐ Yes ☐ No ☐ N/A	
10.3.1 Results are communicated to the client in a timely manner, in a clear presentation, with units, reference intervals, and an optional report/interpretation chart.	☐ Yes ☐ No ☐ N/A	
10.3.2 Laboratory clients are advised that endocrinology results are interpreted in light of complete case data, potential medication interferences, and knowledge of hormone physiology/pathophysiology.	☐ Yes ☐ No ☐ N/A	