## CHECKLIST 17. HORMONE AND TUMOUR MARKERS

| No. | Component | LC | Example of result / type of evidence |
|---|---|---|---|
| | *Good laboratory practices* | | |
| 17.1 | Does the radioimmunoassay service have formal authorization from a recognized national authority? | | Check written authorization from the national authority |
| 17.2 | Is there a clear written protocol for using all radioimmunoassay, IRMA (immunoradiometric assay), ELISA (enzyme linked immunosorbent assay) analytes used in the laboratory? | | Check the written protocol |
| 17.3 | Is there a clear protocol stating the action required in a follow-up of suspected result errors in the laboratory? | | Check the protocol |
| 17.4 | Is there a mechanism to check why its recent results are 20% lower, while all previous results have all been within 10% of the target? | | Check the mechanism |
| 17.5 | Is there a mechanism to follow-up random errors, e.g. wrong sample on analyser, wrong specimen assayed, wrong result reported by accident? | | Check the mechanism |
| 17.6 | Is there a mechanism to double check records of reported ‘undetectables’ when the expected result would have been clinically significant? | | Check the mechanism |
| | *Pre-analytical phase* | | |
| 17.7 | Is there a procedure to follow when the clinical user does not provide the necessary information or the correct specimen? | | Check the procedure |

CHECKLIST 17. HORMONE AND TUMOUR MARKERS (cont.)

| No. | Component | LC | Example of result / type of evidence |
|---|---|---|---|
| 17.8 | Is there a periodic review to prevent pre-analytical errors, e.g. use of inappropriate specimen collection tubes, specimen mix-ups, incorrectly labelled or mixed up requests from the requesting unit or laboratory? | | Check records |
| 17.9 | Is there a periodic review of the appropriateness and integrity of the sample transport system? | | Check records |
| 17.10 | Is there a periodic review to ensure that the confidentiality of patient results is guaranteed? | | Check records |
| 17.11 | Is there a periodic review to ensure biological safety? | | Check records |
| | *Analytical phase* | | |
| 17.12 | Are there records of regression line analyses with a known amount of the international standard in serum? | | Check records |
| 17.13 | Are there records of recovery experiments to validate a new method? | | Check records |
| 17.14 | For each type of assay and/or each type of data set, is there a record of calculated mean, standard deviations and coefficient of variation? | | Check records |
| 17.15 | Is there a Levey-Jennings plot, including controls and standards for each assay? | | Check records |

CHECKLIST 17. HORMONE AND TUMOUR MARKERS (cont.)

| No. | Component | LC | Example of result / type of evidence |
|---|---|---|---|
| 17.16 | Is there a clear written protocol when points are outside the 2 standard deviation limits? | | Check the written protocol |
| 17.17 | Is there a system in place to guarantee safe disposal of samples and are samples treated as infectious waste? | | Observation on-site |
| | *Post-analytical phase* | | |
| 17.18 | Is there a standard format for reporting laboratory results that includes the laboratory's name, patient details, requesting person, test description, sample type (serum, urine, etc.), results (plus reference values), interpretative comments (if any) and signature of authorized professional? | | Check procedures / check reports |
| 17.19 | Is there a list of authorized staff members who are designated to amend patient notes or reports and for communicating results? | | Check procedures / check reports |
| 17.20 | Are reference values based on national or regional findings available for each assay type? | | Check written procedures |
| 17.21 | Is feedback from clinical interpretative services documented? | | Check records |

**Note:** LC: level of conformance (range 0–4). 0: absent or inappropriate; 1: planned or approximate; 2: partial conformance or partial implementation; 3: near full conformance or near full implementation; 4: full conformance or full implementation.