**USA COMMENTS IN RED FONT**

***Aquatic Manual* disease chapters Table 4.1. *OIE recommended diagnostic methods and their level of validation for surveillance of apparently healthy animals and investigation of clinically affected animals:* current Key for Table 4.1 with suggested edits tracked)**

4. Diagnostic methods

The methods currently available for ~~identifying~~ determining infection that ~~can~~ may be used in i) surveillance of apparently healthy ~~populations~~ animals, ii) presumptive diagnosis in clinically affected animals and iii) confirmatory diagnostic purposes are listed in Table 4.1. by animal life stage.

~~The designations used in the Table indicate:~~

**Ratings ~~against~~ aligned with purposes of use.** For each recommended assay, a qualitative rating ~~against~~ aligned with the purpose of use is provided. The ratings are determined based on multiple performance and operational factors relevant to application of an assay for a defined purpose. These factors include appropriate diagnostic performance characteristics, level of assay validation, successful application by diagnostic laboratories, cost, timeliness, and sample throughput. For a specific purpose of use, assays are rated as:

~~Key:~~

+++ = Method(s) have desirable performance and operational characteristics.

++ = ~~Suitable m~~Method(s) have acceptable performance and operational characteristics under most

circumstances.

+ = ~~Less suitable m~~Method(s) performance or operational characteristics may significantly limit application and results should be carefully evaluated.

Shaded boxes = Not appropriate for this purpose.

**RATIONALE:** The system/criteria used in this rating/scoring section should be described to ensure the process of evaluating assays is comparable. As written, the guidance is so vague that it is hard to imagine how this language could be used to evaluate different assays in the same way. Specifically,

1. Benchmarks are needed so that it is clear for each rating (i.e., +/++/+++) what the expectation is for a given factor. For example, for a (+++) rating (desirable performance and operational characteristics), the OIE should provide an example of a “desirable” assay result for each performance and operational factor. The same should be provided for assays with “acceptable” (++) performance and operational characteristics. The same should be provided for assays (+) with performance or operational characteristics that may significantly limit application. Without benchmarks, it is not clear how the rating of an assay relates to each of the performance and operational factors.
2. Within the ratings against purposes of use assessment, the inclusion of performance factors (e.g., appropriate diagnostic performance characteristics, level of assay validation) would appear to overlap with the separate level of validation assessment. The ratings against purposes of use assessments and level of validation assessments should be independent. One solution would be to include only the operational factors (e.g., successful application by diagnostic laboratories, cost, timeliness, and sample throughput) in the ratings against purposes of use assessment.

~~The selection of a test for a given purpose depends on the analytical and diagnostic sensitivities and specificities repeatability and reproducibility. OIE Reference Laboratories welcome feedback on diagnostic performance for assays, in particular PCR methods, for factors affecting assay analytical sensitivity or analytical specificity, such as tissue components inhibiting amplification, presence of nonspecific or uncertain bands, etc., and any assays that are in the +++ category.~~

**Validation stage**. The validation stage corresponds to the assay development and validation pathway in chapter 1.1.2. The validation stage is specific to each purpose of use. Where available, information on the diagnostic performance of recommended assays is provided in Section 6.3.

OIE Reference Laboratories welcome feedback on diagnostic performance of recommended assays, in particular PCR methods. Of particular interest are any factors affecting expected assay sensitivity (e.g. tissue components inhibiting amplification) or expected specificity (e.g. failure to detect particular genotypes). These issues should be communicated to the OIE Reference Laboratories so that advice can be provided to diagnostic laboratories and the standards amended if necessary.

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