Laboratory Perspective: The Challenge of Standardisation in the Face of the Revolution in Biotechnology and Data Processing

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If the results of diagnostic tests are to be of value, it is essential that they are delivered to a uniform standard. This is critically important in regard to notifiable diseases, above all where the result may affect a country's official disease status, but also where the aim is to prevent the spread of infectious diseases, for example through international movements of animals or animal products, or in disease control operations. Even in more routine practice, such as tests for surveillance or to support clinical diagnoses, the customer of the laboratory has a right to expect that the results are meaningful, reliable, repeatable and reproducible.

This has been recognised by the World Organisation for Animal Health (OIE) for many years. During the 1980s the OIE adopted and published guidelines for laboratory tests as appendices to the International Zoosanitary Code (now the Terrestrial Animal Health Code), but from 1989 these were moved to a new publication, the OIE Manual of Recommended Diagnostic Techniques and Requirements for Biological Standards (now the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals and the Manual of Diagnostic Tests for Aquatic Animals). As the international organisation designated by the World Trade Organization for setting standards in the area of animal health, the OIE has, through the work of its specialist commissions, progressively enhanced its standards for diagnostic testing in laboratories, taking account of increasingly rigorous requirements for quality systems, biosafety and biosecurity, and validation criteria. In parallel with this a careful evaluation has to be made as new technologies impact on assay methods and opportunities for data manipulation.

All of this applies to diagnostic tests in general, not just the new technologies, however the latter bring specific challenges to the art of standardisation, which will be discussed during the presentation. High throughput sequencing methods, in particular, generate huge amounts of data requiring not just computational capacity, but the skill and understanding to transform the data into meaningful information for the diagnostician. The growing potential for point-of-care or pen-side tests, used outside the more controlled environment of a laboratory, adds to the complexities. The user of such a kit in the field inevitably has to rely on the manufacturer to have validated it in the first place, and to have instituted a robust system of quality control that ensures a consistent, standardised level of performance.

Much of the debate about deployment of the new technologies surrounds their high level of analytical sensitivity and how to interpret the results in a context of diagnostic relevance. This becomes even more challenging in the case of multiplex methods that may screen for evidence of hundreds of organisms in a single test run. There are no easy answers, but the issues will be aired.