IVD AUSTRALIA

8 May 2015

Dr Cheryl McRae
Branch Head
Devices Authorisation Branch
Therapeutic Goods Administration
Department of Health
PO Box 100
Woden ACT 2606

Dear Cheryl

Re: Consultation - Classification of IVDs to Detect Pathogens on NNDSS List

Overall, the IVD Australia believes that the TGA has presented solid cases, well-based on logic and evidence in the *Classification of IVDs to Detect Pathogens Included in the Australian National Notifiable Diseases Surveillance System*. We submit the comments below in three categories *General*, *Classifications* and *Security Sensitive Biological Agents*.

Please contact me if there are further questions regarding the IVD Australia response.

Yours Sincerely

Dr Wendy-Jane Morrow
Chief Executive Officer

Attachments:
Track-changes word version of the *Classification of IVDs to Detect Pathogens Included in the Australian National Notifiable Diseases Surveillance System*

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IVD Australia Comments

General

We have attached a track-changes word version of the *Classification of IVDs to Detect Pathogens Included in the Australian National Notifiable Diseases Surveillance System* with some minor edits.

There is concern in industry as to the apparent lack of a clear definition of the levels of public health risk as defined by the TGA. The source of the classifications used does not appear to be from GHTF papers, Therapeutic Goods Legislation, World Health Organisation or documents from other health jurisdictions within Australia. [1] For example: the "serious public health risk" definition of the GHTF is "Any event type, which results in imminent risk of death, serious injury, or serious illness that requires prompt remedial action."[2]

Classifications

We agree with the classifications the TGA have made, with the following comments:

Hepatitis A and Salmonella

Hepatitis A and Salmonella assays fall into the category of low personal risk/low public health risk and therefore belong in Class 2 as determined by the TGA. While the vector for the spread of disease is the food chain and an incorrect diagnosis may lead to continued spread, the likelihood of death or serious deterioration in health of those affected is low.

Varicella Zoster Virus

IVD Australia agrees with the TGA assessment that an erroneous result with an Varicella Zoster Virus IVD used to detect VZV is unlikely to cause death or severe disability or lead to a patient management decision resulting in a life threatening situation. Therefore it should be Class 2.

In addition, as stated, where the intended purpose is for pre-natal testing the assay will be Class 3 as it will be captured under rule 1.3(1)(d)".

Influenza

Whilst a pandemic is still in the diagnostic phase, it would not be possible for a sponsor to complete a Class 4 application in time. This is a difficult classification. Many screening assays including PoCT will detect all influenza A. Only after performing another specific assay in the diagnostic algorithm will the organism be identified as a pandemic strain. So are both assays Class 4 or is only the second assay? Additionally, when does a pandemic strain cease to become a pandemic strain?

On this basis, Influenza should be classified as Class 3.

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1 Environmental Health Directorate/Health Impact Assessment, *Health Risk Assessment (Scoping) Guidelines* WA Department of Health, 2010.

2 GHTF, *Medical Devices: Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices – GHTF/SG2/N54R8:2006*.

E.coli

The current NNDSS definition of STEC or VTEC is relatively straightforward, but it appears that IVDs that are related to this more broadly have been reviewed. For example: IVD test kits for some E.coli (such as O157:H7) have been classified as Class 3, but tests for E.coli O111, O26 and others have been classified as Class 2. The rationale for this is unclear.

There is a clear need to recognise and understand the difference between serovar identification and enterotoxin production tests. The serovar alone does not determine if a strain is toxin-producing, only the potential to be a toxin-producer. It is appropriate that the tests that determine the production of entertoxin from E.coli strains, or the presence of Shiga toxin or verotoxin in clinical samples be classified as Class 3.

A consistent approach for the determination of E.coli serovars would be that these tests, including O157:H7, be classified as Class 2. Supporting this classification are the:

- *Surveillance Case Definitions for the Australian National Notifiable Diseases Surveillance System* (p. 81, hyperlink to document); and
- *Shiga-Like Toxigenic Escherichia coli Laboratory Case Definition (LCD)*, the Public Health Laboratory Network (PHLN) document (hyperlink to page) on which the surveillance case definition is based.

The PHLN document identifies the actual types of tests that are toxin tests. These are the ones that should be classified as Class 3. Serovar tests should be consistently classified as Class 2.

Security Sensitive Biological Agents

An area of the document that could be more explicit is underlining the other considerations pertaining to some of these organisms, as affected by Department of Health, namely, Security Sensitive Biological Agents (SSBA). Guidance could include, for example: Vibrio cholerae, Salmonella Typhi… include a sentence along the lines of, 'These are also subject to the requirements of the security sensitive biological agents (SSBA) legislation and all relevant parameters pertaining to this legislation also needs to be considered', or similar.