Response from the Institute of Biomedical Science

The Institute of Biomedical Science (IBMS) is the UK professional body for biomedical science. It represents approximately 20,000 members employed mainly in NHS laboratories, NHS Blood and Transplant, Public Health services, private laboratories, research, industry and higher education. In its capacity as a standard setting organisation, and also an HCPC approved education provider, the Institute welcomes the opportunity to contribute to the consultation on the UK SMI Matrix-Assisted Laser Desorption/Ionisation - Time of Flight Mass Spectrometry (TP 40).

The comments below have been compiled from those made by the members of the IBMS' Specialist Advisory Panel for Medical Microbiology:

Section: Introduction

- “users do not even need to know whether a bacterium or yeast is being tested”.

  It is felt that this is an unhelpful statement, in reality you should have some idea of what the organism is and you have to be 100% confident that your database is complete (which none are) and you have not got a mixture of organisms. MALDI ID should always be backed up with supplementary tests.

- “may prove the most cost-effective means of identification dependent only on how comprehensive the databases are.”

  It was noted that it is only cost effective if you have the through-put of samples to warrant the initial substantial capital outlay. The relationship of volume to cost-effectiveness should be stated.

Section: Technical Information/Limitations

- Differentiation between organisms

  Problems related to differentiation between genera is documented, however there is not a section for species level limitations. References (7) and (8) cited in the draft document both discuss many problematic areas. The following organisms should be highlighted in the narrative:

  Mycobacteria
  Burkholderia
Acinetobacter
Corynebacteria
Beta haemolytic streptococci

- **Difficulty in lysis cell wall structures**
  This section states that if testing in duplicate is used, the user needs to have a ‘reconciliation strategy’. References (7) and (8) are provided as evidence of this statement. There is no mention of a reconciliation strategy or what it entails in either of the references given. There needs to be further clarification of this point.

- **Identification of antimicrobial resistance**
  Reference (8) by Clark et al provides details related to the current limitations for detecting specific resistance mechanisms. It would be useful if a small section discussing the points raised by Clark and his team could be inserted into the narrative. The policy currently only mentions detection of methicillin; it is suggested that there should be scope to add details of beta lactamase testing at least. The SMI authors have made it clear that further improvements are required in specimen processing prior to implementation of direct testing of clinical samples however they have not considered that further improvements are required before antibiotic testing becomes routine practice.

**Section: Procedure and Results**
- **First Point**
  A bacterial or fungal colony (typically single) is picked from a culture plate to a spot on a MALDI-TOF MS target plate using a wooden or plastic stick, pipette tip, or loop

  **Note:** Direct on-plate testing must be avoided with organisms hazardous to laboratory staff (for example, Brucella species and Bacillus anthracis). This must be extracted with formic acid overlay as it kills most bacteria. This is done so as to avoid the risk of causing infection in staff handling these organisms.

  It was noted that this point could be confusing as all HG3 organisms should be deactivated at CL3 before being put on to the target plate. It was also felt that it would be useful to document here that neither culture medium, incubation temperature, incubation conditions, nor length of incubation affect the accuracy of identification (also stated in reference (7) by van Veen et al).

- **Second Point**
  The spot on the target plate is then overlaid with matrix……

  It would be helpful to the user to specify that matrix has to been applied within a short time frame to prevent oxidisation of the sample on the target plate.