

## Society for Applied Microbiology response to the Draft Laboratory Guidelines for the Diagnosis of *Mycobacterium tuberculosis* Infection

The Society for Applied Microbiology (SfAM) welcomes this opportunity to respond to the Draft Laboratory Guidelines for the Diagnosis of *Mycobacterium tuberculosis* (*M. tuberculosis*) Infection. Since the early 1990's there has been a year-on-year increase in the number of notifications of tuberculosis (TB) infection in the UK with an overall increase of 25 per cent over the last 10 years. Regaining control of TB infection requires concerted action on a number of fronts as noted in the Chief Medical Officer's National Action on TB ("Stopping Tuberculosis in England – an Action Plan from the Chief Medical Officer", October 2004).

First class laboratory services are fundamental to the accurate diagnosis of TB infection, therefore the standardisation of laboratory procedures through the introduction of agreed standard operating procedures (SOPs), quality assurance and performance monitoring programs is essential. National SOPs should encompass both routine diagnostic testing, such as microscopy and culture, as well as specialist reference services including drug susceptibility and molecular diagnostic testing. In addition, the requirements for regional and reference laboratory services should be agreed and systems put into place to ensure all isolates are referred to the regional centres for mycobacteriology for identification, drug susceptibility testing and molecular fingerprinting.

The guidelines recommend that basic culture and microscopy services must be provided as a six-day service, which may be problematic for smaller clinical microbiology laboratories that may not have sufficient numbers of staff to provide such a service. Additionally the guidelines also recommend that all samples should be processed using automated liquid culture. However, this may not be cost effective for smaller microbiology laboratories that do not process sufficient numbers of samples to justify the investment in capital equipment. The authors themselves note that adoption of the guidelines "would not be met at present in many parts of the country". Therefore to achieve the highest class of laboratory services (in the absence of additional national funding) will require local and regional cooperation between clinical microbiology laboratories. In particular, the cost effectiveness of performing TB diagnostic work in smaller hospital microbiology laboratories needs to be objectively reviewed and services rationalised. Adoption of these guidelines may require reorganisation of the

services to become centralised within regions with significant numbers of laboratories ceasing the processing of TB specimens altogether. The benefits of implementing these guidelines nationally will far outweigh the initial difficulties of service reorganisation and will hopefully lead to a first class laboratory service, available to all patients in all regions.

We endorse the adoption of molecular fingerprinting of all new isolates of *M. tuberculosis* which will be performed at the regional centres for mycobacteriology using standardised methods. Fingerprinting of all new isolates of *M. tuberculosis* will provide a clearer understanding of the molecular epidemiology of the organism. In addition, this data will aim to improve our understanding of the epidemiology and transmission of tuberculosis infection at both the local and national levels.

Thank you for this opportunity to contribute to this extremely important consultation and SfAM will be willing to provide any further information you may require.