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SCA·H·L·S

NEWSLETTER

SUB-COMMITTEE ON ANIMAL HEALTH LABORATORY STANDARDS

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New Test Development and Evaluation Policy

At its meeting in Adelaide in September 2006, SCAHLS members agreed on a new policy for New Test Development and Evaluation. The policy establishes mechanisms and guidelines for the development, evaluation and communication of new laboratory tests for infectious animal diseases for use in accredited veterinary laboratories in Australia and New Zealand. It is consistent with international (OIE) trends and will ensure a uniform understanding of the way in which new tests are appraised.

The policy includes information on the various levels of 'fitness for purpose', when a test should be submitted to SCAHLS for evaluation, when it is appropriate for a new test to be included into an ANZSDP and the priorities SCAHLS ascribes for its approval process. There are five stages in the validation process. The expectations of submitters are considered, along

with information on exclusions, legal implications and implementation.

Supporting documentation, which can also be found on the SCAHLS web site, includes standard operating procedure for managing new test approvals, validation templates for serological and nucleic acid detection tests and the ANZSDP Guide for Authors.

This policy replaces the 'Guidelines for New Diagnostic Tests' version 1.

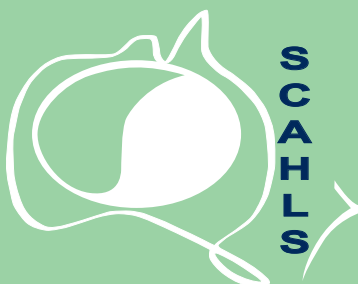
Key changes include the focus on fitness for purpose, the way the review is managed and the introduction of a charge for the review of validation data.

Suggested further reading on the evaluation and application of laboratory tests for screening, diagnosis and surveillance of animal diseases can be found on the SCAHLS website.

New Veterinary Laboratory Standards and Guidelines for Nucleic Acid Detection Techniques

Nucleic acid detection techniques are replacing or supplementing many conventional laboratory methods, such as cell and pathogen culture, immunoassays and protein biochemistry.

A document entitled Veterinary Laboratory Accreditation Standards & Guidelines for the Nucleic Acid Detection Technology has been finalised by SCAHLS. The aim of this publication is to provide consensus standards and guidelines for veterinary laboratories using nucleic acid detection techniques. These standards will be used in veterinary diagnostic laboratories undertaking disease diagnosis and for accreditation authorities such as the National Association of Testing Authorities (NATA), so that laboratories using nucleic acid detection techniques may be assessed for compliance. The document is available on the SCAHLS web site.



Avian Influenza Workshop

A National Workshop was held at the CSIRO Australian Animal Health Laboratory, Geelong in July 2006, to develop a plan for the standardisation of Real-Time PCR and Serological tests for avian influenza within Australia. The Workshop considered the current diagnostic “state-of-play” in Australia and overseas, discussed technical gaps in our national capability and developed an operational plan, with timelines, to achieve a national approach for AI testing. The program was split into two sections, with the first day devoted to molecular detection of AI, particularly the use of Real-Time PCR; the second day dealt with serological assays.

The action plan regarding real time PCR testing was to

- Harmonise Real-Time PCR by all labs using AAHL primer sets
- Complete a second round of inter-laboratory testing with a defined test panel by end of September, 2006
- Instigate a third round with a larger number of samples (>10), high and low RNA loads and unusual strains, to be completed by the end of 2006
- Complete a Ring Test for proficiency testing by the end of the current financial year
- Continue the commitment of the group to share information between labs

The action plan regarding serological tests was for

- AAHL to address issues regarding cELISA parameters, particularly low positive standards, and to undertake transfer of the optimised test to State labs
- AAHL to develop a strategy for obtaining validation data for selected wild bird species and to proceed with collecting data.

- Lobbying for replacement of the AGID test with the cELISA as a test for export
- Infrequently used tests to be maintained at AAHL and reagents available for States to take up test when needed.
- Proficiency testing for HAI and cELISA to be supported ANQAP
- Rapid (point of care) tests to be used only on sick and dead birds (additional samples for confirmatory diagnosis MUST be submitted to laboratories).
- Use of point of care tests should be restricted to remote areas within Australia and anyone issued with kits must be made aware of the limitations of the test, the shelf life and storage conditions, the need for additional samples, and restrictions on reporting of results to established channels. These tests also need to be validated for use in Australia, according to SCAHLS protocols.

Changes to the NATA Veterinary Testing program

As a result of recent NATA reviews, a new version of the Veterinary Testing Field Application Document (FAD) is due to be released by the end of the year. One significant change to be outlined in the FAD is the decision to cease granting signatory approval to individuals in veterinary pathology laboratories. This effectively shifts the responsibility for “approved signatories” from NATA to the laboratory management. However, all other requirements previously associated with “approved signatories” will remain.

Currently, accredited laboratories undergo a full on-site technical reassessment every two years. NATA’s surveillance model is not necessarily in keeping with international practice and as a result, most fields within NATA including Veterinary Testing will be moving to a new surveillance model in which an 18 month on-site visit will be conducted by a NATA staff officer to look at specific issues, followed by a full on-site technical reassessment every three years. Full details of the new surveillance model will be released in the near future. It is anticipated that implementation will be begin in July 2007.

Any enquiries in relation to the Veterinary Testing program can be directed to the Manager, Ms Nicole Bailey on (03) 9329 1633.

E-mail distribution lists on emergency animal diseases

The Australian Government Department of Agriculture, Fisheries and Forestry (DAFF) maintains a number of e-mail distribution lists on key emergency animal diseases. These lists circulate news, information and comment on specific diseases to interested staff in DAFF and to a range of external stakeholders (in other government departments, industry and others). Currently, these lists operate for avian influenza (EMPLAN AI), foot-and-mouth disease (EMPLAN FMD), and bovine spongiform encephalopathy (EMPLAN BSE) although the first of these is the most active. If you would like to have your name added to any of these lists, please contact Mike Nunn (mike.nunn@daff.gov.au).

Research Strategy

A Commonwealth-sponsored National Collaborative Research Infrastructure Strategy (NCRIS) has been proposed, with funding to be made available over the next five years. One capability area to be supported is biosecurity and considerable effort has been directed at determining how best to utilise resources that could be made available in the biosecurity domain. A priority target has been support for the development of a national biosecurity network built around existing veterinary and human health laboratories. This part of the plan has seen expenditure of \$25 million recently approved by the Minister for Education, Science and Training with \$8.5m destined for expansion of PC3 and PC4 facilities at AAHL. Approximately \$1m has been approved for a National Biosecurity Network scoping study and a further \$15.5m has been earmarked for State facilities, including Veterinary Laboratories.

ANQAP

After a recent review of ANQAP, the following changes to the program will be implemented in 2007:

- The fee structure will be changed to a charge-per-test basis. These changes will see significant reductions in costs for smaller participating laboratories.
- Samples will be dispatched to participating laboratories in batches rather than monthly.
- Laboratory identification codes will continue to be changed annually.
- The statistics used by the program will continue as before, but the acceptable variation range will be calculated from the median rather than the mean value.
- A limited number of molecular tests will be included in the program, depending on the importance of the tests and sufficient participants.
- ANQAP will continue to supply sera panels to participants at no extra cost. Laboratories are encouraged to assist ANQAP with collection and supply of sera for use in the program.

ANQAP currently requires positive serum for the following tests:

- EBL serum and milk - ELISA or AGID positive
- Lepto hardjo, pomona and tarassovi MAT positive
- *Ovine brucellosis* - CFT or ELISA positive
- Q Fever CFT positive (ovine or bovine)
- BVD Ag whole blood ELISA positive
- Chlamydia CFT positive (ovine or bovine)
- EAV VNT positive

ANQAP participants will be provided with further details on the changes to the program in the next ANQAP Bulletin. Contact Petrina Young (petrina.young@dpi.vic.gov.au)

World Association of Veterinary Laboratory Diagnosticians

The newly formed Australian Association of Veterinary Laboratory Diagnosticians will be hosting the international meeting of the WAVLD from the 11 – 14 November 2007. To be held in conjunction with a one day OIE (World Animal Health Organisation) meeting, this will provide an opportunity to discuss a range of issues concerning the activities of veterinary laboratories in Australia and elsewhere.

Up to 450 delegates are expected at the meeting, which will provide an exciting opportunity to showcase Australia, and for Australians to meet with similar professionals from around the world. On day one of the meeting, the topic will be “Global Risks and Challenges”, focussing on new and emerging diseases, zoonotic diseases, diseases of wildlife and trans-boundary animal diseases.

Day two will be for the OIE and there will be a number of invited speakers. This will provide a real chance for delegates to get to know more about the OIE. Day three will focus on “Preparing for the Future”, including issues of biosecurity and bio-safety, quality assurance and new technologies and diagnostic platforms. A call for papers has been made and full details can be found on the meeting website at [“http://www.wavld2007.com/melbourne.php”](http://www.wavld2007.com/melbourne.php)