



SCAHLs

NEWSLETTER

ISSUE 18 (MAY 2013)

SUB-COMMITTEE ON ANIMAL HEALTH LABORATORY STANDARDS

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LEADDR Update

The last six months have been a busy time for the Laboratories for Emergency Animal Disease Diagnosis and Response (LEADDR) network. The network has continued to work towards increased network quality assurance and preparedness for emergency animal diseases (EADs). The network continues to hold monthly teleconference meetings and working group meetings as appropriate. It has also continued to provide laboratory support to the Consultative Committee on Emergency Animal Disease for managing EAD incidents as required.

Projects

The network has been involved in several Department of Agriculture, Fisheries and Forestry funded projects for advancing its testing capabilities and capacities.

1. Hendra Soluble G ELISA

The Hendra Soluble G serology ELISA project has reached its conclusion with the submission of a validation dossier to SCAHLS and the National Association of Testing Authorities. The Australian Animal Health Laboratory (AAHL) is working towards the production of manufactured test kits for participating LEADDR laboratories.

2. FMD

The network has been involved in phase two of the foot and mouth disease (FMD) project. This phase has seen the deployment of initial FMD testing capabilities to interested state and territory laboratories. The network will begin to incorporate FMD testing into its quality assurance scheme through ongoing proficiency testing. In addition, the network is participating in a specificity trial for the FMD 3ABC C-ELISA using serum from Australian animals.

3. Influenza A ELISA

The network is seeking to contract the production of a multispecies Influenza A ELISA kit which can be made available to participating laboratories. This will further improve the harmonization of influenza A serology testing across the network.

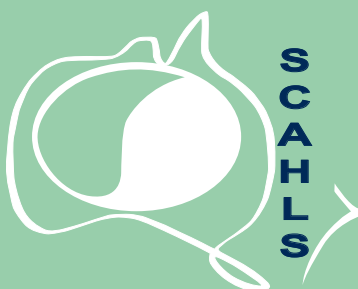
Transport of Specimens for Hendra Virus Testing

Hendra virus (HeV) infection in horses has continued to be seen sporadically in Queensland and New South Wales. However 2011 was an unprecedented year with a significant increase in the number of confirmed cases in these two states. As such, SCAHLS received a request to provide advice on the appropriate

transport classification for the transfer of samples from veterinary practices to laboratories for HeV testing.

There is no pathognomonic clinical presentation of HeV infection in horses. Clinical signs can be variable and initial presentation may be vague (e.g. colic). This limitation combined

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with the zoonotic potential, has led to a recommendation from the Queensland Government that laboratory testing is undertaken to definitively determine the HeV status of clinically ill horses, where HeV infection could be involved. This has led to a significant number of submissions for HeV testing, to exclude it as a differential diagnosis, being received by government laboratories. As the prevalence of HeV infection in horses is low, the likelihood of testing positive on a submission is also usually very low.

The attending veterinarian usually has access to the case history, clinical presentation and property information and is in the best position to determine the risk of HeV infection in their case assessment. In addition, a number of state and territory jurisdictions provide guidelines for veterinarians to assist them in assessing the risk of HeV infection and submitting samples for laboratory testing.

A SCAHLS Working Group has therefore concluded that:

- Samples for HeV testing from either clinically normal or clinically ill horses, for which the submitting veterinarian, in their professional opinion, considers it is reasonably unexpected that there would be a positive HeV test result, should be transported as UN3373 Biological Substances Category B.
- Samples for HeV testing from clinically normal or clinically ill horses for which the submitting veterinarian, in their professional opinion, considers it is reasonably expected that there would be a positive HeV test result should be transported as UN2814 Infectious Substance affecting Humans Category A.

For more information on transport categories see the current version of *Requirements for the Packaging and Transport of Pathology Specimens and Associated Materials* at the Australian Government Department of Health and Ageing website - <http://www.health.gov.au/>

New Test Approvals

In the last six months SCAHLS has approved a high throughput PCR for Johne's disease (HT-J). This test was developed by the University of Sydney and the Elizabeth Macarthur Agricultural Institute. There are a number of conditions of use for this new test and a working group has been established to decide how it will be used in national Johne's disease (JD) management programs. The test has already been used extensively in support of investigation of bovine JD cases by various jurisdictions

SCAHLS has also approved a new JD culture media to replace the BACTEC media which is no longer available commercially. Testing by the University of Sydney has shown the replacement media, 7H9C, to be a suitable alternative to BACTEC.

A writing group has been established to update both the JD ANZSDP and the JD Quality Plan to include these developments.



Adoption of the OIE Template for SCAHLS New Test Validation

At the 34th SCAHLS meeting in March 2013 members discussed the adoption of the World Organisation for Animal Health (OIE) template as the validation dossier for SCAHLS new test approvals. The OIE uses only one template to assess the validation of all test types while SCAHLS currently has three templates - nucleic acid detection, serological and an extension template. The information being gathered through SCAHLS and OIE templates is very similar as both bodies aim to address the same core criteria. Considering this, SCAHLS members agreed that the new OIE validation¹ template in conjunction with the OIE guidelines for use of the template² will replace the three existing SCAHLS templates for a trial period of two years.

The OIE validation process is supported by the validation chapter (1.1.4) in the OIE Manual and seven appendices or best practice

documents, which inform about assay specific requirements, i.e. for antibody, antigen and nucleic acid detection tests, statistical methods, method comparison or comparability or equivalence, measurement of uncertainty and composition of reference panels for different purposes. An overview of the OIE validation process is given in the chart below.

SCAHLS members recognise that the new validation approach is efficient and has the potential of global test certification rather than regional (Australia/New Zealand) recognition. Using the OIE template allows the submitter to apply directly to OIE for certification and have a peer reviewed and globally accepted registered test.

SCAHLS members emphasised that the development and validation of a diagnostic test needs to be driven by the purpose of the test, e.g.

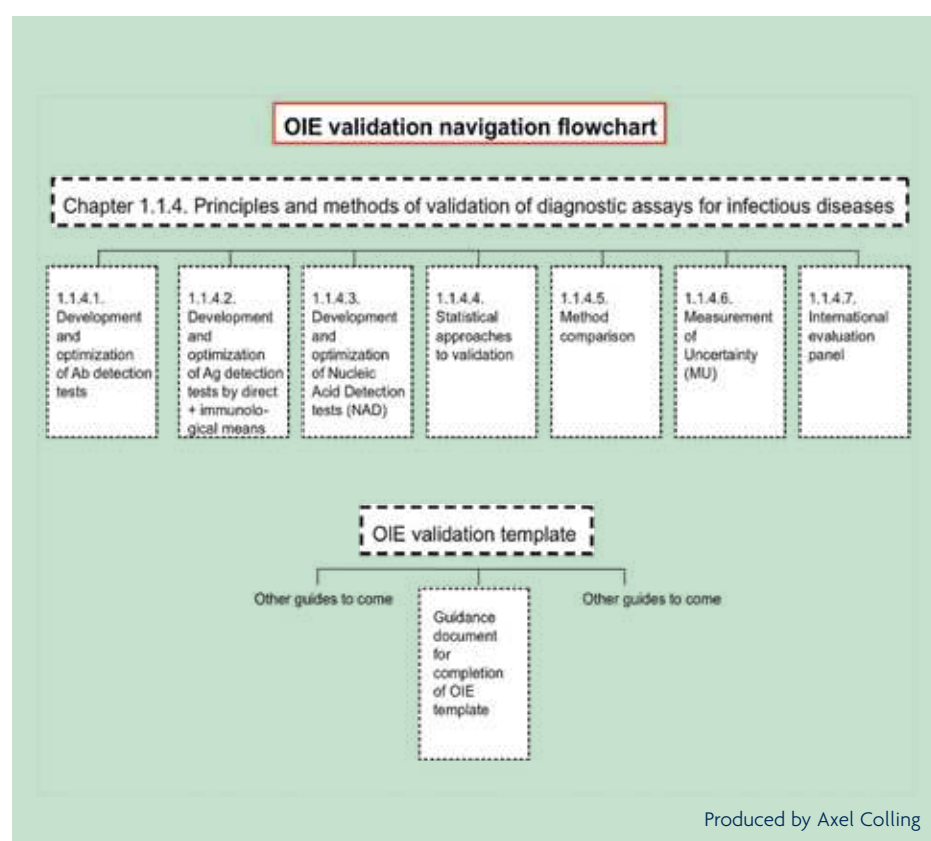
screening tests have an emphasis on the diagnostic sensitivity (DSe), confirmatory tests have an emphasis on the diagnostic specificity (DSp), Point of Care or field based tests have an emphasis on the intra- and inter-operator variation and include environmental factors and other contaminating factors. It is also recognised that next generation platforms such as multiplex PCR, Luminex, Maldi Toff and deep sequencing represent new specific challenges for science based test development and validation strategies and some of these must be regarded as a “work in progress”.

Nevertheless the aim of test validation should always be to address the following relevant validation parameters; 1) selection and determination of fitness for purpose; 2) analytical Sensitivity and Specificity; 3) repeatability; 4) cut-off; 5) DSe and DSp; 6) reproducibility; 7) technology transfer and ongoing monitoring of the assay. Other relevant factors include case definition, species of concern, nature, quality and quantity of samples, suitability, costs, technical skills, equipment, turn-around time, quality control/quality assurance and acceptance in stakeholder circles.

The SCAHLS New Test Evaluation working group will continue to further develop science based strategies or solutions for complex and multiplex modern test platforms and by doing so inform and influence regulatory policies and provide input into and receive stimuli from relevant research coming out of laboratories and academia.

¹[<http://www.oie.int/our-scientific-expertise/certification-of-diagnostic-tests/guidelines-on-fees/>]

²[http://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/A_SOP_2012_web.pdf]



Produced by Axel Colling

SENDING ANIMAL SAMPLES OVERSEAS

– What are the Risks and Procedures?

Terrestrial and aquatic animal industries, state and territory governments and the Australian Government invest considerably in surveillance, disease investigation and official reporting activities in order to demonstrate Australia's favourable animal health status to international trading partners. This investment is important for our industries to access international markets and for Australia to justify quarantine arrangements that aim to manage the risk of exotic diseases entering the country.

Suspicion of important exotic animal diseases in Australia is managed through arrangements that include:

- a legal requirement to report the suspicion of diseases listed on Australia's National Notifiable Disease List of Terrestrial Animals and National List of Reportable Diseases of Aquatic Animals in each state and territory
- all specimens to be tested for suspicion or possibility of a

disease not known to be present in Australia are referred to Australia's national laboratory, the CSIRO – AAHL for confirmatory testing

- consideration of diagnostic test results by the Consultative Committee on Emergency Animal Diseases.

These arrangements are supported by standards and quality systems that operate in Australian laboratories.

Based on past experiences, there is a real risk to Australia's aquatic animal trade and health status associated with the transfer of specimens overseas for infectious and parasitic disease testing. The risk can result in a loss of market access, leading to significant socio-economical impact on Australia's livestock, fisheries and aquaculture industries. Major issues of concern include:

1. The possibility of inappropriate overseas reporting of test results that suggests the presence of an infectious or parasitic agent not previously known to occur in

Australia.

2. The difficulty in refuting any questionable test results when the standard of testing and the provenance of samples (and so the validity of test results) are beyond Australian control.

Before any biological specimens are sent overseas for testing, the sender is required to ensure that the relevant State Chief Veterinary Officer (CVO) is satisfied with the reason(s) for having the testing conducted overseas rather than in Australia and has approved the transfer in writing. It is then the responsibility of the sender to notify the State CVO of any test result that identifies or suggests the presence of an infectious or parasitic disease or agent not known to occur in Australia. In the event that such a result is obtained, the release of the result by the sender is subject to approval by the State CVO.

State and territory governments have agreed on a policy to manage the risks associated with the transfer of specimens overseas for infectious and parasitic disease testing. The policy applies to all testing laboratories, research institutions and persons sending biological specimens from Australian animals to overseas laboratories or other agencies for laboratory or consultative procedures that may lead to or suggest a diagnosis of infectious or parasitic disease.

The Policy for the Transfer of Biological Specimens to Overseas Laboratories for Infectious and Parasitic Disease Testing is available on the SCAHLS website: http://www.scahls.org.au/procedures/other_procedures

Anyone intending to send terrestrial and aquatic animal specimens overseas for disease testing should consult this policy. For further information, contact your state or territory animal health officer.

Introducing the New SCAHLS Chair

– Dr Kurt Zuelke

Dr Kurt Zuelke commenced as Director of the CSIRO - AAHL and Chair of SCAHLS in January 2013 following the retirement of Dr Martyn Jeggo.

Dr Zuelke has had a long and distinguished career in the animal health/biosecurity area and is a Doctor of Veterinary Medicine with a PhD in animal physiology. His most recent role was Centre Director of the US National Animal Disease Centre (NADC). The NADC is the largest US federal animal health research facility focussed on high impact endemic diseases of livestock and wildlife species.

Dr Zuelke previously worked in Australia at the Victorian Institute of Animal Science, Attwood, Victoria from 1995 to 2001 where he co-developed a bovine dairy genomics research program employing high-throughput gene expression based strategies to identify and analyse novel genes in the mammary gland.

During the last six months there have been some other changes to the SCAHLS membership. We welcome Dr Mel Gabor as our New South Wales representative and Jim Taylor as our Tasmanian representative and we welcome back Lisa Bartlett, our NATA representative, who has returned from extended leave.



AgriBio – Centre for Agribiosciences

AgriBio, the Centre for AgriBioscience, is a A\$288 million world-class facility for agriculture biosciences research and development. The Centre is a joint initiative of the Victorian Government and La Trobe University and is located at La Trobe University's Melbourne campus in Bundoora. The Centre is the Victorian Government's main facility for the identification, control and prevention of animal and plant diseases and pests, and is Australia's only integrated systems biology agriculture biosciences research centre. The five star Green Star facility has a total size of 30,777m² which includes over 100 laboratories, 13 glasshouses, PC3 laboratories and glasshouse, and 78 controlled environment rooms.

The range of Department of Primary Industries Victoria laboratory functions previously performed at the Attwood, Knoxfield, Frankston and Bundoora sites have all been

moved to the new facility, there will be 400 people working at AgriBio when all the moves are complete in April 2013. Should you wish to contact staff previously at any of

the other sites, please call (03) 9032 7000 or use existing email as electronic contact details have not changed.

