



# DIAGNOSTICS

## ADOPTION FORUM

### Final Report

Melbourne, 6-7 August 2008

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Report prepared by Jo Edmondston, December 2008

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## Executive Summary

The *Diagnostics Adoption Forum* held in Melbourne on 6-7 August 2008 brought together over 50 researchers and end-users to review diagnostic research projects funded by the Australian Biosecurity Cooperative Research Centre for Emerging Infectious Disease (AB-CRC). The delegates explored possible pathways to adoption of this research and identified a number of knowledge and research gaps. Consideration was given to how the AB-CRC and the proposed Biosecurity CRC Mark II could contribute to filling these gaps and prioritise future research.

On Day 1 of the forum, maturing projects in the AB-CRC's *Technologies for Enhanced Detection* Research Program were reviewed. Over four sessions, with topics ranging from test development through to building capacity, researchers presented the outcomes of 14 projects. Each session included a panel discussion which posed specific questions relating to the design and implementation of diagnostic tests. A number of the inherent difficulties posed by testing were raised in discussion, including test validation, cost, and the development of a 'perfect test'. There was consensus that 'fitness for purpose' should be the prime driver for the design and development of a test, and common agreement that shared reagents and common platforms offer significant benefits.

Day 1 concluded with a workshop in which a number of key outcomes, opportunities and gaps in research were discussed. Several opportunities for the AB-CRC were identified, including the development of new training programs, ongoing development and technology transfer of diagnostic tests for pathogen detection, strengthening of 'One Health', and further capacity building in the region. Validation was noted as an area with key knowledge gaps and a significant area of opportunity for the AB-CRC. It was suggested that researchers put themselves 'in the shoes' of diagnosticians and build validation into the early stages of their projects. It was also suggested that the scope of AB-CRC research could be broadened (particularly in the health sector) and that the legacy of the AB-CRC should be considered.

The second day of the forum aimed to inform delegates of future technologies for disease characterisation and assist the CRC Mark II Program Development Team in the development of the CRC Mark II research portfolio based on delegates' views of these new technologies. Over two sessions, 12 representatives from animal and public health sectors presented their views on new horizon technologies and their potential for improving early warning capability. The presentations reiterated a number of the issues raised on Day 1, including end-user engagement in diagnostic test development, incorporation of validation into research, and 'fitness for purpose'. Point-of-care (POC) tests were discussed in detail, and it was noted that

there needs to be a systematic analysis of these tests for use in Australia and the region. The need for improved and common understanding of public health and animal health systems, better coordination of the national system, and better links between these systems were also noted. The final session of Day 2 was a panel discussion, which considered the cost of implementing and trialing new technologies and the benefits they offer.

Feedback from the delegates indicated that the forum was very productive and contributed significantly to knowledge exchange amongst AB-CRC researchers and end-users. There was strong support for the uptake and adoption of AB-CRC funded research, and acknowledgement that taking research into practice or policy offers significant national benefits and is critical to the success of the Centre. The AB-CRC's PhD program was commended for its role in promoting a skilled biosecurity workforce. The Centre's role in improving national and regional preparedness and response capacity through diagnostic test development and capacity building was also commended.

A number of recommendations for the AB-CRC have been developed based on the forum outcomes and feedback provided by delegates. These recommendations will drive the Ab-CRCs planning of future research and knowledge exchange activities.

***Recommendation 1: The AB-CRC continue to update and inform industry representatives and state and commonwealth agencies of activities and outcomes from its diagnostic research portfolio, and promote interaction and linkage between AB-CRC researchers and these stakeholders.*** The benefits of information exchange about diagnostic technologies and research was highlighted in the forum. The AB-CRC will continue to promote information flow in this area through its established knowledge exchange mechanisms. It will also consider holding another diagnostics adoption forum in the future, contingent on funding. Future forums could provide a brief update of projects and allow greater time to be allocated to technology updates, group discussions and workshops. Consideration will be also be given to promoting national capacity by increasing cross-sector sharing and broadening sector representation to include delegates from the plant biosecurity and aquatic animal health.

***Recommendation 2: The AB-CRC continues to advance diagnostics research through its existing research program.*** The AB-CRC will follow-up with project leaders, researchers and end-users to consider the relevant issues that were raised in the forum. The AB-CRC acknowledges its role in funding research that addresses gaps in knowledge and ways these gaps may be filled by ongoing research, and will consider supporting new and ongoing projects that fit within Centre's remit and budget allocation.

**Recommendation 3: The AB-CRC consider future priority areas in diagnostics research for inclusion in the Biosecurity CRC Mark II.** Proposed or commissioned diagnostics-related research projects that continue on from current projects should be reviewed in light of the responses provided by the forum.

**Recommendation 4: The AB-CRC disseminates the outcomes of the Diagnostics Forum.** In addition to producing a forum report, the AB-CRC will highlight a number of the forum outcomes to specific end-users of AB-CRC research. In particular, comments regarding validation, POC tests and new test development will be forwarded to SCAHLS in a briefing note accompanying the report and the Centre will continue to work with SCAHLS to promote researcher understanding of these issues. Opportunities for reagent sharing will be followed up with specific laboratories and where appropriate, policy-related issues will be raised with the responsible state or federal agency.

## Abbreviations & Acronyms

A&L	Application & Linkage
AB-CRC	Australian Biosecurity CRC for Emerging Infectious Disease
ABIN	Australian Biosecurity Intelligence Network
AI	Avian influenza
AHA	Animal Health Australia
AWHN	Australian Wildlife Health Network
BTV	Bluetongue virus
cDNA	Complementary DNA
cELISA	Competition ELISA
CRC	Cooperative Research Centre
CSIRO	Commonwealth Scientific and Industrial Research Organisation
CSIRO-AAHL	CSIRO's Australian Animal Health Laboratory
DAFWA	Department of Agriculture & Food, Western Australia
DoHA	Department of Health & Ageing
DIVA	Differentiate infected from vaccinated animals
DNA	Deoxyribonucleic acid
EAD	Emergency animal disease
EI	Equine influenza
EID	Emerging infectious disease
ELISA	Enzyme-Linked Immunosorbent Assay
FMD	Foot-and-mouth disease
NAHLS	National Animal Health Laboratory Strategy
MU	Murdoch University
NAMP	National Arbovirus Monitoring Program
NCRIS	National Collaborative Research Infrastructure Strategy
NSW DPI	New South Wales Department of Primary Industries
NT DPIFM	Northern Territory Department of Primary Industry, Fisheries & Mines (DPIFM)
OIE	World Organization for Animal Health ( <i>Office International des Epizooties</i> )
PCR	Polymerase chain reaction
POC	Point-of-care
QA	Quality assurance
QC	Quality control
QDPIF	Queensland Department of Primary Industries and Fisheries
QHFSS	Queensland Health Forensic and Scientific Services (QHFSS)
RT-PCR	Real-time PCR
PCV2	Porcine circovirus type 2
SARS	Severe acute respiratory syndrome
SCAHLs	Sub-Committee on Animal Health Laboratory Standards
TGA	Therapeutic Goods Administration

## Background

Speedy characterisation and detection of emerging or known pathogens is essential for Australia's capacity to rapidly diagnose and manage emerging disease threats. As highlighted by the recent outbreaks of equine influenza and Hendra virus, accurate and timely detection of pathogens can have a major impact on the success of strategies for zoning, control and/or eradication of emerging infectious diseases (EIDs).

The Australian Biosecurity Cooperative Research Centre for Emerging Infectious Disease (AB-CRC) oversees research targeted at enhancing the early detection and management of emerging infectious diseases in Australia and the region. It also promotes capacity building through its Education & Training Program, and knowledge exchange and adoption through its Application & Linkage (A&L) Program.

The AB-CRC has a strong commitment to diagnostic test development through its *Technologies to Enhance Detection* Research Program, dedicated to developing new and improved detection methods for significant infectious disease threats. Coordinated by Dr David Boyle of CSIRO's Australian Animal Health Laboratory (CSIRO-AAHL), the program has funded over 10 research projects and supported over 20 postgraduate scholarships. Research in this program has focussed on diagnostic technologies for avian influenza (AI), severe acute respiratory syndrome (SARS), henipaviruses, foot and mouth disease (FMD), and a range of other emerging infectious diseases in the biosecurity arena.

The research outcomes of the *Technologies to Enhance Detection* Program have important implications for state, national & regional biosecurity policy and practice. To date, these outcomes have included the evaluation of new technologies, characterisation of new viruses, and development of new diagnostic reagents and tests. A number of these tests have been transferred to the animal and public health sectors, nationally and internationally.

## Rationale

The AB-CRC seeks to be responsive to emerging disease issues, consulting with scientific experts in Australia and interested stakeholders to facilitate knowledge exchange and develop an understanding of any potential research that would be of benefit to Australia and the region. The AB-CRC is also preparing for a rebid for funding for the Biosecurity CRC Mark II (2010-2017) and one of the proposed outcomes is 'increased capacity for mitigating emerging infectious disease risks to Australia and the region'. If successful in the rebid, the CRC Mark II will improve measures to prevent disease incursions, establishment and spread through 'early

warning' systems which are essential for mitigating the social, environmental and economic impacts of disease outbreaks. Included in these early warning systems will be tools to increase the likelihood of early detection of emerging infectious disease outbreaks and improve the cost-effectiveness of disease prevention, eradication and control interventions.

With the maturation of AB-CRC diagnostics-related research projects within the *Technologies to Enhance Detection* Program and consideration of projects for inclusion within the CRC Mark II research portfolio, it was considered timely to consider the future direction of diagnostics research in Australia in consultation with the end-users of AB-CRC research and other interested stakeholders. A two day forum (similar in format to the five adoption forums run previously by the AB-CRC) was considered the most effective means of discussing the Centre's research role in supporting diagnostics in Australia. The first day of the forum would review AB-CRC supported maturing diagnostic research projects, focussing on the adoption of this research in the national and international context. The second day of the forum would focus on future technologies for disease characterisation and detection, and assist the AB-CRC in shaping the CRC Mark II research portfolio.

## **Date, Location, & Funding**

The *Diagnostics Adoption Forum* was convened by the AB-CRC at the Melbourne Hilton Airport Hotel on 6-7 August 2008. The forum ran over two days, from 8.30am-5pm on Day 1, followed by a dinner for the delegates in the hotel from 6.30pm onwards. Day 2 ran from 8.15am-2pm for general delegates.

The forum was by invitation only and there was no attendance fee. The AB-CRC covered the catering costs for the event (including dinner on Day 1), and the flight and accommodation costs of the invited speakers. Where delegates were not supported by their organisation, the AB-CRC also covered the travel and accommodation costs of interstate and international delegates.

## **Delegates**

The forum was attended by a total of 55 delegates; 43 on Day 1 and 53 on Day 2. These delegates included scientific experts and stakeholders from the State and Commonwealth health and agriculture departments, a number of Australian universities, livestock industry representatives, Animal Health Australia, CSIRO, AusVet Animal Health Services and the AB-CRC. Representation covered the animal, public and wildlife health sectors.

## Objectives & Proposed Outcomes – Day 1

### The specific objectives of Day 1 were to:

- Update and inform researchers, industry representatives, and state & Commonwealth agencies of the diagnostic tests developed by the AB-CRC, including any associated validation and/or technology transfer completed to date;
- Profile AB-CRC researchers to these end-users;
- Review diagnostic project outcomes, considering potential for uptake and adoption across wildlife, animal & public health sectors, and how these can be implemented;
- Determine significant gaps in knowledge and research priorities for current projects that could be incorporated into Biosecurity CRC Mark II; and
- Develop an inventory of key information and/or actions that are needed to shape changes to practice and/or policy.

### The desired outcomes of Day 1 were to:

- Increase researcher and end-user awareness of the outcomes of the AB-CRC's *Technologies to Enhance Detection* Program and the Centre's efforts to enhance the uptake of technologies arising from this program;
- Identify end-user views of the most significant outcomes arising from the research program;
- Identify key knowledge gaps in diagnostics research;
- Identify adoption opportunities and barriers (and possible solutions);
- Identify the information and/or actions required for the AB-CRC Application & Linkage Program to promote adoption of the research;
- Promote stronger cross-sector networks and enhanced knowledge exchange between end-users & researchers, animal health, public health & wildlife health sectors;
- Develop a list of potential diagnostic research projects to be considered for inclusion in the proposed Biosecurity Mark II CRC research portfolio; and
- Produce a final report that includes a summary of the keynote presentations, panel discussions and workshop outcomes.

## Day 1 Program

8.30am	Registration and coffee		20
8.50am	Welcome – introduction and housekeeping	Debby Cousins	10
<b>Session I – Stephen Prowse [Chair] – End-user perspectives / Moving from research to diagnostic</b>			
9.00am	AB-CRC Technologies to Enhance Detection Program: aims, scope and expected outcomes	Stephen Prowse	10
9.10am	End-user perspective – Animal Health	Mike Nunn	15
9.25am	Molecular detection systems for emergency diseases	Hans Heine	25
9.50am	I've developed and validated a new test: Now what?	Bruce Corney	15
10.05am	Development and validation of a TaqMan assay for the detection of T. evansi, the agent of Surra	Trevor Taylor	15
10.20am	Panel discussion – Case Study 1 – From research tool to diagnostic test	Mike Nunn, Martyn Jeggo Peter Kirkland & David Jordan	20
10.40am	Morning tea		30
<b>Session II – Deb Cousins [Chair] – Technologies in translation</b>			
11.10am	One-step C-ELISAs for SARS antibody detection	Linfa Wang	15
11.25am	Influenza real time RT-PCR – Assay development, technology transfer & update	Hans Heine	15
11.40am	Development and application of methods for detection of Porcine Circovirus 2	Mark O'Dea	15
11.55am	Panel Discussion – Case Study 2 – National roll out of a new test or method	William Wong, Hans Heine, Peter Kirkland & Bruce Corney	20
12.15pm	Lunch		60
<b>Session III – Lisa Adams [Chair] – Capacity building</b>			
1.15pm	Henipavirus serological assays	Jennifer McEachern	20
1.35pm	Evaluation of rapid molecular detection and characterisation systems for surveillance of arboviruses circulating in northern Australia	Chris Cowled	20
1.55pm	Panel Discussion – Case Study 3 – Capacity building	Lorna Melville, Martyn Jeggo, Linfa Wang & Greg Smith	15
2.10pm	Short Break		5
<b>Session IV – Peter Kirkland [Chair] – Tools for remote and regional surveillance</b>			
2.15pm	Application of new platform technologies for the development of protein-based detection tests: Reagents for FMD tests	Hans Heine	20
2.35pm	Improving bluetongue virus surveillance in remote areas	Lorna Melville	15
2.50pm	Changing Papers – new serological tools for improved surveillance of Surra	Celia Smuts	15
3.05pm	Panel Discussion – Case Study 4 – Tools for remote and regional surveillance	Lorna Melville, Hans Heine, Rupert Woods & Mike Nunn	15
3.20pm	Afternoon tea		30
<b>Session V – Deb Cousins [Chair] – Conclusions</b>			
3.50pm	Technologies to Enhance Detection Program: what we have achieved	Stephen Prowse	10
4.00pm	Workshop: Successes, opportunities and gaps	All	50
4.50pm	Summary – outcomes and recommendations and wrap up	Bill Hall, David Smith, Lisa Adams & Debby Cousins	10

## Day 1 Presentations

Day 1 of the forum reviewed maturing research projects from the *Technologies for Enhanced Detection* Program led by Dr David Boyle (CSIRO-AAHL). The aim was to gain consensus on the most important research aspects, identify knowledge gaps, and discuss the potential for adoption in the national and international context. Over four sessions, 11 researchers provided overviews of 14 different AB-CRC funded diagnostic or A&L projects, with topics including test development, capacity building and technology transfer. Day 1 ended with a workshop in which delegates discussed research and adoption successes, opportunities and gaps; followed by short summaries from four of the forum delegates of the major outcomes of the day.

### Introduction

Dr Debby Cousins (AB-CRC) opened the forum and welcomed delegates on behalf of the AB-CRC. After a brief overview of the AB-CRC and the proposed Biosecurity CRC Mark II, she invited delegates with any queries about the CRC Mark II to raise these issues with AB-CRC management at the forum. Debby described the role of the A&L Program in managing and promoting adoption of AB-CRC funded research and stressed that the AB-CRC were looking to the delegates to provide feedback on significant research outcomes, opportunities for adoption, and knowledge gaps. In conclusion, Debby noted the importance of diagnostic tests in emerging infectious disease (EID) control and the role of new tests in response, preparedness, and capacity building.

### Research Session I – End-user Perspectives: Moving from Research to Diagnostics

The first session included five presentations and a panel discussion, and was chaired by Dr Stephen Prowse (CEO, AB-CRC). The AB-CRC has funded 29 projects in the *Technologies to Enhance Detection* Program, with a total expenditure of ~\$4.5m over the life span of the AB-CRC. Uptake and adoption of this research into policy and practice is critical for the success of the Centre and offers significant national benefits for the management of emerging infectious diseases.

Dr Mike Nunn (DAFF) presented an overview of the uses and requirements for diagnostic tests in veterinary and public health laboratories. He compared future needs with the current reality – noting the complex nature of the ‘perfect’ diagnostic test - a test that is fast, cheap, reliable and accurate, and is amenable to automation, high throughput and validation. He suggested that the future may lie in the integration of PCR with new materials to provide rapid point of care (POC) pathogen detection. He noted that researchers developing diagnostic

tests do not always work in diagnostic environments and, as a consequence, may not have a clear understanding of the requirements of quality assurance, test validation and proficiency testing. Following a question from Debby Cousins about who should be responsible for developing research for a diagnostic format, Mike suggested that there is a need to educate both researchers and end-users about validation but acknowledged it is not always easy to explain the complexities of diagnostic test requirements or the significance of sensitivity and specificity.

Dr Hans Heine (CSIRO-AAHL) gave the first research presentation on behalf of Dr David Boyle; an overview of molecular platform technologies and their use in the development of new and improved tests for the detection of emerging infectious diseases. This was one of the first AB-CRC funded projects and began at a time when molecular diagnostic tests were not used routinely. Real-time PCR has since become a frontline tool for diagnostics, despite its multiplexing limitations. Hans noted the challenges involved in validating a RT-PCR test that incorporates multiplexing as this process affects the chemistry of the test, though some delegates commented that their laboratories routinely multiplex a small number of RT-PCR tests for diagnostic purposes. He also provided a brief overview of molecular tests developed for vesicular diseases, arboviruses and poultry diseases (which are at various stages of development) with some of the technology transferred to other laboratories nationally and internationally. Describing sensitivity issues in diagnostic test development and the value of having different assays for the same virus, Hans questioned if a test that detects 98% of strains is sufficient, or should extra effort be made to obtain 100% coverage?

Hans then described several DNA microarray projects being run in collaboration with Columbia University. He encouraged delegates to consider whether the assays they develop are suited to a high throughput diagnostic environment, taking into account the resource-intensive process required for validation. The volume and complexity of the data generated from microarrays requires significant statistical and bioinformatics analysis and, while this technology is rapidly developing, microarrays are unlikely to be used as a frontline test. In conclusion, Hans described the application of Combimatrix silicon chip technologies to the development of a diagnostic test for influenza.

Dr Bruce Corney's (QDPIF) presentation described the process of implementing a validated PCR test for routine diagnostic use. He described two ways to maximise return from a validated test: (i) refine the test, and (ii) transfer the technology to other laboratories. He used Queensland's experience using the influenza type-A TaqMan assay in the recent equine influenza (EI) outbreak as a case-in-point for test refinement. In the peak period of the EI response, 12,492 RT-PCRs were performed, which Bruce stressed would have been

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<sup>12</sup> mouse inoculation test (MIT) and microhaematocrit centrifugation test (MHCT)

impossible without the laboratory's magnetic high throughput systems – MagMax and Kingfisher. He described the lessons learnt from this outbreak, stressing the need for laboratories to be proactive rather than reactive, ensuring that automation is optimised *before* an emergency animal disease (EAD) event occurs. In question time, delegates commented that, in the case of an outbreak of pandemic influenza, supply of reagents would be critical, and stockpiling of reagents may be required. Bruce replied that delays in obtaining consumables and competing for consumables presented the largest obstacles in the EI outbreaks. He also indicated that while the initial cost of probe production is high, the perception that RT-PCR is costly is unwarranted.

A presentation on the development of a TaqMan assay for the detection of *Trypanosoma evansi*, the causative agent of Surra, was provided by Dr Trevor Taylor (CSIRO-AAHL). The objective of this project was to improve national capability to detect this disease, with the goal of developing an OIE-prescribed test. Using serum and DNA samples from buffalo, cattle and horses in the Philippines (where the disease is endemic), a newly-developed Taqman assay (amenable to remote sampling and storage) was compared to established tests based on antibody detection<sup>2</sup> and serology<sup>3</sup>. The PCR results highlighted the need to understand the biology of infection, as the very low numbers of organisms present during chronic infection presented a number of barriers to detection.

### **Panel Discussion 1 – From Research Tool to Diagnostic Test**

The panel consisted of Dr's Mike Nunn (DAFF), Martyn Jeggo (CSIRO-AAHL), Peter Kirkland (NSW DPI) and David Jordan (NSW DPI), and considered the factors influencing movement of tests from a research to diagnostic environment.

The chair of the panel Dr Stephen Prowse (AB-CRC) asked Peter to address what issues a researcher should consider when transferring test into the diagnostics environment. He replied that the sensitivity and specificity of the test and its 'fitness for purpose'<sup>4</sup> were critical, the end use of the test (including the platform it will require) needs to be considered, including collection of appropriate specimens and samples for validation. David suggested a shift in thinking is required, to see test development as an overlapping process between research and diagnostics. Martyn noted that CSIRO-AAHL has a formal structure designed to promote

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<sup>3</sup> Enzyme Linked Immunosorbent Assay (ELISA) and card agglutination test (CATT)

<sup>4</sup> *AB-CRC note*: 'Fitness for purpose' involves a decision on the *purpose* of the test and validation to ensure the test meets the criteria or is *fit* for that purpose. The AB-CRC has a number of mechanisms in place to promote 'fit-for-purpose' diagnostic research. In addition to the A&L Program activities, the AB-CRC stipulates mandatory end-user input into the project proposal, project specific reference groups which promote end-user input into projects at all stages of research, and six monthly reviews of progress which include an assessment of pathways to adoption and uptake.

transfer, which involves a diagnostic test management committee, noting that successful transfer requires more than 'handing over' a test<sup>5</sup>.

The panel were asked about validation and when it should happen. David acknowledged the importance of validation, noting that it is required at each stage of test development, and as a test develops and broadens in impact, the level of validation required increases. Martyn reiterated that the first and most important criterion for validation is 'fitness for purpose' once this criterion has been met, then the prescriptive World Organisation for Animal Health (OIE) guidelines should be followed<sup>6</sup>. Stephen asked what role the AB-CRC should play in test development and validation, given that this is not the conventional grounds of research. Martyn indicated that he felt there is little purpose in the AB-CRC supporting tests that will not be used in the field. Catherine Ainsworth commented that validation should be an essential step in the development of any diagnostic test and the AB-CRC should play a key role in validating new tests, but suggested that best practice validation should be separated from the research process. Rupert Woods expressed an interest in downstream models for test validation, and more efficient and effective priority setting by end-users.

In the final question to the panel, Stephen asked how much emphasis should be placed on validation of current tests versus research into new technologies. Mike commented that the current gaps in testing may be filled by new technologies, but noted that what tests will be chosen and how they will fill these gaps has yet to be determined, and should be answered on a case-by-case basis. He highlighted the differences between verified and validated tests, and OIE and SCAHLS validation. David indicated the need to establish common vocabulary regarding verification and validation, including reproducibility, reliability, and repeatability. He suggested that projects be reviewed in the early stages of test development to outline the validation process<sup>7</sup> required later on.

## **Research Session 2 – Technologies in Translation**

Session 2 began with Dr Linfa Wang (CSIRO-AAHL) presenting AB-CRC funded research that helped to identify the reservoir host of SARS. He described the development of a

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<sup>5</sup>*AB-CRC note:* Similar processes are in place in most state jurisdictions. There is general agreement that these processes could be improved.

<sup>6</sup>*AB-CRC note:* SCAHLS Guidelines for validating diagnostic assays can be found at [www.scahls.org.au/policyguidelines/policyguides.htm](http://www.scahls.org.au/policyguidelines/policyguides.htm). Australian and New Zealand Standard Diagnostic Procedures (ANZSDP) are consistent with the OIE Manual of Standards for Diagnostic Tests and Vaccines, but may exceed those requirements where special procedures and interpretation are necessary for Australian circumstances.

<sup>7</sup>*AB-CRC note:* The AB-CRC is working with end-user validation experts to develop and fund a project that would provide the first step toward a simple model for diagnostic test validation.

one-step competitive ELISA (cELISA) for detecting antibodies to SARS, noting that the test was able to overcome issues related to species differences, striking a balance between specificity and sensitivity. Linfa noted that international collaboration was the key to success of this project, and described the 'reverse' technology transfer process – despite efforts to transfer this technology to China, the volume of tests required resulted in laboratories sending samples to CSIRO-AAHL for testing. The SARS test is a classic example of development of a test that is 'fit-for-purpose', and Linfa commented that the reverse technology transfer process was a result of the laboratory proving its ability to use this test effectively.

Dr Hans Heine (CSIRO-AAHL) gave an overview of research into highly pathogenic avian influenza (AI) strain H5N1, detailing the progress of three AB-CRC projects to develop, transfer and refine a RT-PCR for rapid detection of all influenza type-A viruses. This assay was transferred to all Australian state veterinary laboratories, and laboratories in New Zealand and South East Asia. They were evaluated on different platforms in a two-phase trial proficiency testing program, with ongoing refinement to cover evolving strains. Hans stressed that no single assay can be expected to achieve 100% detection, and it is important to keep track of sequence variations and their impact on existing tests. Martyn Jeggo added that the AB-CRC added value in terms of direction and resources, and CSIRO-AAHL would have struggled to transfer these tests to the States without assistance. Moira McKinnon commented that recent outbreak responses have shown that research into appropriate testing platforms to use in an outbreak is required and the AI test collaboration highlighted the sort of collaborative processes required to build response capacity.

In the final presentation of Session 2, Mark O'Dea (DAFWA) described the development and application of methods for the detection of porcine circovirus type 2 (PCV2), including the development of PCR, RT-PCR and a recombinant antigen to reduce Australia's reliance on off-shore reagents. Using an ELISA to test samples from the 2001 National Pig Serum Bank, PCV2 was shown to be highly prevalent and common across Australia. A test based on immunohistochemistry was also developed to allow visualisation of the PCV2 antigen *in situ*. This allowed for retrospective investigations into PCV2 infections by the Department of Agriculture and Food WA (DAFWA). RT-PCR and PCV2 sequencing has now been established for diagnostic purposes at DAFWA.

### **Panel Discussion 2 – National Roll-Out of a New Test or Method**

A panel consisting of Drs William Wong (DAFF), Hans Heine (CSIRO-AAHL), Peter Kirkland (NSW DPI) and Bruce Corney (QDPIF) considered the factors influencing national rollout of a new test or method.

The chair of the panel, Debby Cousins (AB-CRC), asked Hans to discuss the key factors for the successful transfer of tests to state laboratories. Hans indicated it can be very difficult for laboratories to adopt new technologies as the process requires urgency, commitment, and a facilitator to communicate and educate. William noted that with AI, even though his laboratory had prior experience with the test and the platform, difficulties were encountered because of changes to the viral sequence. He stressed that ongoing communication between his laboratory and the source laboratory was very important. Peter stated that without the AB-CRC his laboratory may have been unprepared for EI testing, as the CRC project drove and resourced the transfer of the test.

In response to an emergency animal disease (EAD), private laboratories may be prepared to play a role in the response, and technology transfer to private laboratories should not be discounted. Debby indicated that technology transfer was offered to all laboratories through the SCAHLS network for the AI test, and Hans noted that Gribbles was involved. There was further comment about the need for Government policy regarding the role of private laboratories in an outbreak.

Lisa Adams then commented on the recommendations stemming from the O’Kane Report *Collaborating to a Purpose*<sup>8</sup> which evaluated CRCs as part of a broader examination of the National Innovation System. Acknowledging that CRCs are not great at commercialisation, Lisa noted that there are other spill-over benefits of research. She asked the panel to consider the benefits offered by the AB-CRC to individual laboratories and/or the national diagnostics system. Bruce added that the AB-CRC contributions to AI testing capability had spilled over into EI testing, which ultimately contributed to updating high throughput technologies.

The chair asked for comment on the importance of sharing common reagents and platforms. Peter noted that standard methods and reagents result in highly reproducible results, and the EI outbreak response illustrates the benefits of having similar platforms – with a high level of consistency between platforms, technicians can be drawn from other jurisdictions and/or sectors to increase the surge capacity of a laboratory. The EAD network in the US has been supplied with identical platforms for these reasons. The 98% agreement in EI testing was noted by Martyn Jeggo, who suggested that while the message was simple – standardisation is the way to go – he also acknowledged that standardising platforms presents a number of difficulties related to resources and purchasing in different jurisdictions.

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<sup>8</sup>For a copy of the O’Kane Report see [http://catalogue.nla.gov.au/Record/4469418/Details?lookfor=isbn%3A978\\*&max=65230&offset=65230&](http://catalogue.nla.gov.au/Record/4469418/Details?lookfor=isbn%3A978*&max=65230&offset=65230&)

### **Research Session 3 – Capacity Building**

Ms Jennifer McEachern (CSIRO-AAHL) provided an overview of henipaviruses and the AB-CRC funded development of Luminex assays to complement existing diagnostic tests (ELISA and the gold standard Serum Neutralisation Test). These multiplexed bead-based assays can simultaneously differentiate between Hendra and Nipah viruses, are rapid and highly sensitive, require only small volumes of sera, and don't require high containment facilities (as they don't use live virus). Cell lines and test protocols from the US are being established at CSIRO-AAHL to generate an ongoing supply of reagents, and the technology has been transferred to Dr Greg Smith's laboratory in Queensland and Dr Jane Cardosa's laboratory in Malaysia. The test is currently being transferred to the UK.

Dr Chris Cowled (CSIRO-AAHL) began his talk with the argument that preparedness can only be achieved through a pre-emptive approach to risk management of emerging viruses, including the characterisation of unidentified viruses circulating in the environment. He then described his research into the development of pan-pathogen microarrays how, using cDNA subtraction, he identified and characterised the Stretch Lagoon and Middle Point orbivirus isolates. Chris noted that little is currently known about disease potential of these viruses, although almost all viruses in this particular orbivirus family have been associated with disease. It is not yet known if wildlife is susceptible to infection or able to act as a reservoir for these viruses. The AB-CRC funded transfer of the RT-PCR tests for these orbiviruses from CSIRO-AAHL to the Northern Territory laboratory at Berrimah – building capacity to test for these viruses in both laboratories. Sequence information on these viruses has also been supplied to QDPIF for use in diagnosis. It was noted that the allocation of resources to identification of unknown viruses is crucial for EAD preparedness, and resources should be increased as the need arises, such as during outbreaks of unknown origin.

### **Panel Discussion 3 – Capacity Building**

A panel consisting of Drs Lorna Melville (NT DPIFM), Martyn Jeggo (CSIRO-AAHL), Linfa Wang (CSIRO-AAHL) and Greg Smith (QHFSS) considered the issue of capacity building. Lisa Adams, session chair, began by asking Greg to comment on the importance of the henipavirus Luminex test. Greg stated that, based on his experience, the Luminex assay appears to be more specific than the ELISA, which suffers from false positives. He noted that the 'Achilles heel' of the technology transfer process had been the availability of reagents, specifically antigen and suggested that AB-CRC projects involving diagnostic test development should consider the long term supply of reagents. Linfa acknowledged the AB-CRC's role in facilitating the US collaboration that resulted in reagent production in Australia. It was noted that the Luminex assay is 'as ready to go as possible' in humans,

although the Therapeutic Goods Administration (TGA) validation criteria cannot be met due to insufficient cases for testing.

Lorna, discussing the value of high throughput sequencing for pathogen detection and where the capacity for this sequencing should reside, noted the value of the collaboration between the Berrimah laboratory and CSIRO-AAHL, which resulted in a large number of unknown isolates being 'weeded out'. She noted that tools other than sequencers, such as microarrays and PCRs are not useful for analysing unknown isolates as they require sequencing information. Catherine Ainsworth commented on the significant costs presented by the data analysis of high throughput sequencing.

Lisa asked the panel to comment on the AB-CRC's role in capacity building in laboratories, specifically the importance of staff exchanges. While Catherine stated that the Department of Primary Industry Victoria have been able to build critical mass without the AB-CRC, however Peter noted that, in NSW, linking with other laboratories requires an external funding source. Martyn agreed that the AB-CRC plays an important capacity building role by funding the skills development of individual researchers, but cannot be expected to address national skills shortages, which require a 5-10 year plan and development of a national system.

#### **Research Session 4 – Tools for Remote & Regional Surveillance**

Dr Hans Heine (CSIRO-AAHL) gave the first talk of this session, describing the development of new platform technologies for detecting emerging infectious disease threats. He described the AB-CRC funded development of a one-step cELISA assay for FMD which is able to differentiate infected from vaccinated animals (DIVA). The challenges to further development of this test include validation, finding a commercial partner, and the application of the reagents to other platforms. Hans noted that the future of diagnostics lies in faster, more sensitive and more specific devices that are able to detect pathogens, including on-site detection. Peter Kirkland commented that building and maintaining expertise is a significant issue for national capability, noting the difficulty in obtaining sufficient samples to fulfil validation criteria. Chris Morrissy noted that FMD sera samples are available from South East Asia, but accessing overseas sera is difficult and associated infection data is incomplete.

In the next talk, Dr Lorna Melville (NT DPIFM) described the development of a PCR test for detection of Bluetongue virus (BTV) in *Culicoides* sp. This test was developed to fill a gap in the National Arbovirus Monitoring Program (NAMP) surveillance by providing early warning and detection system for new BTV serotypes/genotypes in remote and offshore areas. The shortage of people skilled in identifying and isolating *Culicoides* from collections for testing was noted. The BTV PCR test is sensitive and specific, but needs further field testing and

may need to be adapted to a RT-PCR platform to improve sensitivity and allow for quantification of the virus.

Ms Celia Smuts (MU) set the context for her talk by describing the threat of introduction of surra through Northern Australia via illegal fishing. A component of Celia's AB-CRC supported PhD project involved the development of a blood collection method<sup>9</sup>; by simply adding a preservative to filter paper she was able to increase the viability and shelf life of serum antibodies in a range of temperatures and humidity's. She suggested that this method may be a cheap and easy means of promoting year round sample collection and surveillance in remote areas that experience high temperatures and humidity.

#### **Panel Discussion 4 – Tools for Remote & Regional Surveillance**

The panel consisted of Dr's Lorna Melville (NT DPIFM), Hans Heine (CSIRO-AAHL), Rupert Woods (AWHN), and Mike Nunn (DAFF). Peter Kirkland (NSW DPI), chair, asked Mike to comment on the DIVA strategy and the opportunities it offers for Australia's EAD responsiveness. Mike replied that DIVA tests are very important as the UK outbreak showed that 'stamping out' is no longer acceptable. Mike noted that Australia needs FMD outbreak tools that allow for vaccination in and around an outbreak, to decrease the duration of an outbreak and return proof of freedom from disease for trade resumption. It was noted that there is a role for the AB-CRC in developing platform technologies for technology transfer to Thailand and other laboratories in the region.

Hans commented that the new FMD cELISA could be useful as a point-of-care test; new recombinant FMD test reagents could be applied to POC tests using any platform, but would need to be validated first. Asked if there was a role for POC tests for surveillance in remote areas, Martyn responded that using POC tools prior to the confirmation of index cases may be problematic because of concerns with the communication of results of unknown certainty. He noted that once an index case had been identified, however, POC tests had a clear role to play in an outbreak. David Smith noted that POC tests raise issues not only about the test itself but also the individual performing test, stressing that they need to be used appropriately.

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<sup>9</sup>*AB-CRC note:* This technique may promote opportunities for remote surveillance. Several opportunities for use of the filter paper collection method were identified, including use in veterinary and public health sentinel chicken sampling. Human sample collection (saliva and blood spots) from remote communities was also suggested. These samples could be stored in a central location for testing at a later date.

When asked to comment on the role of diagnostic technologies in wildlife, Rupert noted that the issues for wildlife do not lie with technical capacity, rather in the framework for integration of new technologies into the national biosecurity program. He raised the issue of 'hard-wiring' the research coordinated by the AB-CRC – moving from the fixed-term model to a more permanent funding arrangement.

### **Session 5: Workshop**

This session, facilitated by Dr Debby Cousins (AB-CRC), began with Dr Stephen Prowse (AB-CRC) summarising the major comments stemming from the research presentations, followed by a description of the proposed Biosecurity CRC Mark II, including details of how the forum outcomes will feed into the research portfolio planning.

The delegates split into five groups to discuss what they considered to be the major adoption outcomes of the AB-CRC research projects presented, the opportunities they offered, and the gaps that remain. The combined responses of all the groups are listed below, individual group responses can be found in the Appendix (p42).

There were five major adoption *outcomes* identified from the research presentations. These included:

1. A positive contribution to establishing and reinforcing national and regional collaboration and partnership (especially between state laboratories and universities), improving access to expertise, and providing platforms and funding to promote networking and linkages.
2. The ability to act as a springboard to drive outcomes, leverage more beneficial outcomes, and give momentum to selected emerging technologies; using 'proof of concept' to ease the adoption of new technologies.
3. Realistic perceptions regarding application, linkage and commercialisation.
4. Improved preparedness and response capacity, including capacity building beyond the AB-CRC.
5. Contributions to AI, EI, and henipavirus diagnostic test development.

The AB-CRC was also commended for its support of high quality PhD students and the implications this has for generating a skilled biosecurity workforce.

Eight categories of *opportunities* arising from the research were identified by the groups. These included:

1. Development of new, specific training programs for emerging methods and platforms, and ongoing training to develop intergenerational capacity for the management of new technologies.
2. Further technology development and transfer of pathogen detection tools, including recombinant and Luminex technologies, improved economies of scale and promotion of rapid adoption using 'proof of concept'.
3. Need to build networks and links across sectors to strengthen 'One Health'.
4. Capacity building in the region using the diagnostic methods developed.
5. Replacement of commercialisation plans with adoption plans.
6. Clarification of aspects of validation, including SCAHLS criteria.
7. Transfer of PCV2 reagents and confirmation of the value of the refined AI RT-PCR test for state laboratories.

Five categories of research *gaps* were identified. These included:

1. Validation, including the need for greater communication between researchers and end-users, monitoring of test development methods incorporating QA, increased access to SCAHLS guidelines & policy requirements, clarification of responsibilities for QA and communication, and improved access to samples for validation (including platform templates & standards).
2. Commitment, engagement and visibility in the health and conservation sectors.
3. Consideration of post-CRC legacy of projects.
4. Scope of the AB-CRC beyond viral biosecurity issues and cell mediated tests, including the need for increased sequence data analysis and sample input into high through put sequencing, and consideration of the role of serum banks.
5. Prioritisation of research.

Dr Cousins (AB-CRC) concluded Session 5 with a short summation of the day, briefly reviewing the AB-CRC's role as a developer of high quality and sustainable reagents, a trainer for the biosecurity workforce, and a catalyst for action with regard to the transfer of diagnostic tests. She noted that the AB-CRC has resources available to drive change, but the Centre needed to find its fit in the national biosecurity system – a process that requires end-user input. She noted that the diagnostics sector requires good communication networks and better integration between sectors, before calling on Lisa Adams (AB-CRC), Bill Hall (AHA), and David Smith (PathWest), to summarise their perceptions of the day.

Lisa thanked Debby for organising the program and commended the speakers for focusing on the adoption implications of their work. Bill Hall noted that Day 1 of the forum was enlightening and AHA was very interested in the outcomes of AB-CRC research. He raised

the issue of who should be responsible for managing and paying for test updates, and reinforced the need for continued effective communication.

David Smith gave the final summation, noting a number of issues the AB-CRC may encounter when moving into public health arena, such as competition and the scale of testing required, and indicated that consideration should be given to the time and money dedicated to projects, both at the commencement of projects and as the project develops. He commented on the challenge that the pace of change represents to diagnostic test development and the need to have a clear understanding of where the future of diagnostic testing should be heading.

## Objectives & Proposed Outcomes – Day 2

### The specific objectives of Day 2 were to:

- Provide animal (including wildlife) and public health end-user perspectives of priorities and opportunities for early warning system research for Biosecurity CRC Mark II;
- Provide animal (including wildlife) and public health service providers perspective of the current system and how it may change through the application of new technologies;
- Provide an overview of new technologies both present and on the horizon (including pros and cons and use/potential use for pathogen characterisation and disease detection) to inform future research opportunities;
- Determine significant gaps in knowledge and systems, and identify related research priorities that could flow into the proposed Biosecurity CRC Mark II to support a national approach to early warning and preparedness for emerging infectious disease and emergency animal disease; and
- Improve networking and collaboration/integration between animal (including wildlife) and public health sectors.

### The desired outcomes of Day 2 were to:

- Inform researchers and end-users of the risks of emerging infectious diseases and emerging animal diseases, and the benefits of early warning;
- Update researchers and end-users knowledge of current diagnostic systems, including their limitations and opportunities;
- Improve researchers and end-users awareness of new horizon diagnostic technologies and the opportunities they present to the national system;
- Consider, and gain consensus of, what systems and/or technologies will be useful going forward, including routine diagnostic test opportunities;
- Generate a shared understanding of how the Biosecurity CRC Mark II can contribute to improved diagnostic capacity and capability; and
- Produce a final report that includes a summary of the keynote presentations, panel discussions and workshop outcomes.

## Day 2 Program

8.15am	Registration and coffee		15
8.30am	Welcome – introduction and housekeeping	Debby Cousins	10
<b>Session I – Deb Cousins [Chair] – End-user perspectives</b>			
8.40am	End-user presentation – Animal and Wildlife Health	Mike Nunn	15
8.55am	End-user presentation – Public Health: Current and future priorities for the Office of Health Protection	Gary Lum	15
9.10am	Service providers – the animal health system	Peter Daniels	15
9.25am	Service providers – the public health laboratory system	David Smith	15
9.40am	High throughput opportunities for pathogen detection: Case study – Equine influenza	Peter Kirkland	30
10.10am	The journey to quality	James Watson	15
10.25am	Morning tea		25
<b>Session II – Greg Smith [Chair] – Horizon technologies</b>			
10.50am	Genome analysis for biological diagnostics: Technology platforms and applications	John Forster	30
11.20am	Nanomics OptoPlex Biosensors: The next generation in molecular reading	Bronwyn Battersby	10
11.30am	Luminex: Pros and cons	Linfa Wang	10
11.40am	MassTag PCR: a highly multiplexed system for pathogen detection	David Williams	10
11.50am	Rapid diagnostic tests – are the new technologies as good as they say?	Stuart Blacksell	20
12.10pm	Diagnostic tests – needs and opportunities	Stephen Prowse	15
12.25 pm	Lunch		55
<b>Session III – Stephen Prowse [Chair] – Discussion and conclusions</b>			
1.20pm	Panel discussion Pros and cons of systems and future potential, review and recommendations	Peter Kirkland, Gary Lum, Stuart Blacksell	30
1.50pm	Synopsis of Biosecurity Mark II Technologies for detection	Stephen Prowse	10
2.00 pm	End of forum		

## Day 2 Presentations

Day 2 of the forum focused on future technologies for disease characterisation and detection. Representatives from both the animal and public health sectors discussed new horizon technologies and their potential for improving our early warning capability for prioritised diseases. This was a larger meeting than Day 1, with an additional 10 delegates attending. Twelve researchers and end-users provided their perspectives of diagnostic technologies (Session 1) and horizon technologies (Session 2). The final session considered the pros and cons of various systems and their future potential.

### Session 1 – End-user Perspectives

Chair of Session 1, Debby Cousins (AB-CRC), began by contrasting the aims of Day 1 (an update of mature AB-CRC projects focussing on livestock health) with Day 2, which focussed on projects with livestock, public and wildlife health impacts. She stressed that the AB-CRC was looking for advice on opportunities for integration across sectors for the present CRC and CRC Mark II. She noted that the AB-CRC was using this adoption forum as the vehicle for end-users to feedback their views of the outcomes and the direction of CRC, highlighting that the forum program was directed towards end-user participation.

Dr Mike Nunn (DAFF) gave an overview of diagnostic technologies from the perspective of government as a wildlife and agriculture end-user. He profiled government departments as users of diagnostic technologies and described the role they play, from research and development through to standardisation and policy development. He summarised his understanding of what government is looking for in diagnostic tests, and outlined the major drivers, challenges and gaps in test use and development. He suggested that that, from a government perspective, many of the challenges of diagnostic testing and advances in new test technology relate to QA and information management. He noted that there is a need to ensure that tests are used by appropriately trained and experienced people who understand the performance characteristics of each test they use. He stressed that announcing a positive test result can jeopardise export trade and undermine consumer confidence so that it is essential that any unusual test result is properly investigated before it is reported. For example, any sample that tests positive on a screening test for an emergency animal disease (for example an exotic disease such as FMD or an endemic disease such as anthrax) needs to be promptly notified to the relevant authorities and confirmed by other tests at a reference laboratory before release of the test result. As more rapid POC tests become available for animal diseases, ensuring appropriate notification and investigation of unusual results will be a significant challenge for animal health authorities.

Dr Gary Lum (DoHA) then provided an overview of the federal government's role in health protection, focussing on communicable diseases, natural disasters and biosecurity initiatives. He reviewed the Office of Health Protection's divisions, areas of responsibility, and surveillance systems and tools – acknowledging the AB-CRC's input into the latter. Focussing on national biosecurity, he then provided an overview of performance indicators and future biosecurity requirements, including EID risk analysis, detection, and response.

Following Gary, Dr Peter Daniels (CSIRO-AAHL) gave a service provider's perspective of the animal health system. He started his talk with an overview of the current operating system noting the need for a common understanding of how the system works. He provided details of the chain of command and broad responsibilities, including details of the Animal Health Committee and SCAHLS. Peter noted that veterinary laboratories are a diverse group with respect to activities and clients, and could be better coordinated as a national system. Focusing on national operating principles for emergency animal disease diagnosis, he commented that there is a need to deploy capability to enhance national benefits. He noted the National Animal Health Laboratory Strategy (NAHLS) objectives and other associated initiatives, including National Collaborative Research Infrastructure Strategy (NCRIS), Australian Biosecurity Intelligence Network (ABIN), eResearch, and the AB-CRC.

Dr David Smith (PathWest), as public health service provider, began by noting how the AB-CRC could fit into the public health system. Highlighting the significant variation between the health and agriculture jurisdictions, he stressed that the public health system is not profit driven. While he could not anticipate whether AB-CRC research outcomes would be adopted into public health, he noted that developments that are 'fit-for-purpose' are generally adopted. Using a framework for pathogen detection he then presented a number of factors that feed into public health capacity at the border, pre-border, and post-border. He described the criteria used for adoption of a new diagnostic technology within the public health system, and noted the role that the AB-CRC can play in expanding the application of diagnostic tests. He stressed that diagnostic tests need to be flexible enough to be adapted to various specimen types and platforms. He also noted that consideration needs to be given to supporting capacity for new diagnostic tests in non-traditional public health roles, such as bioinformatics skills and database management<sup>10</sup>.

Following David, Peter Kirkland (NSW DPI) described his experience with high throughput testing for EI as an example of the opportunities this technology offers for pathogen detection.

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<sup>10</sup> *AB-CRC note:* The AB-CRC is responsive to biosecurity workplace needs and increases capacity in areas of need by funding research and supporting workplace skills through its training programs. The Centre currently funds a bioinformatics specialist involved in sequencing AI strains to identify sequence variations.

The background to the EI outbreak was provided, including a description of the outbreak, diagnostic capacity prior to the outbreak, the control strategies used, and the role and expectations of the NSW Department of Primary Industries. He then described the laboratory's high throughput technology refinements, aimed at minimising handling and reducing steps to avoid compromises in biosecurity. Peter noted that during the outbreak the number of accessions and specimens received increased at least 10-15 fold but the throughput was achieved on a daily basis whilst maintaining same-day turnaround and normal business. The cost of testing in high throughput format was also significantly reduced. The challenges presented by large scale testing were described and the key to a successful laboratory response – trained and dedicated laboratory staff coupled with appropriate assays and equipment – was highlighted.

The final talk in Session 1 of Day 2 was provided by James Watson (CSIRO-AAHL). Moving from research to diagnostics he noted the QA/QC requirements for each, highlighting the need to engage end-users throughout the process. James commented that research and diagnostics should be seen as a continuum rather than separate upstream and downstream processes, and stressed that technology transfer should not be considered an optional extra. He stressed that having confidence in tests across laboratories requires pooled and assayed control materials, noting that the EI outbreak has enabled laboratories to gain experience both in the provision of these samples and management of quality coordination during an outbreak.

At the conclusion of James' talk David Smith acknowledged the importance of end-user engagement. He stressed that the knowledge that researchers bring should not be underestimated, as they may have an understanding of technology that end-users do not. Using PCR as an example, he noted that researchers recognised the need to push ahead with this technology despite end-users' reticence for uptake in the routine setting. He suggested that there should be negotiation between researchers and end-users. James agreed, suggesting that salesmanship should also be added to the skill set required by researchers.

## **Session 2 – Horizon Technologies**

Session 2 of Day 2, Horizon Technologies, was chaired by Greg Smith (QHFSS) who opened the session by describing Taqman as the current cornerstone of diagnostic technology. Dr John Forster (DPI Victoria), first speaker in the session, gave an overview of a suite of high end technologies coming online. He stressed the utility of genome analysis technologies in allowing high throughput outcomes in research and diagnostics and commercial service deliveries. He described advances in DNA arrays, robotics, microbead-based SNP multiplexes, high throughput pyrosequencing and other sequencing technologies. He also

described the next generation technologies, including nanoscale sequencing with one molecule of DNA polymerase per well and nanoknives which 'feel' their way along DNA molecules. John then provided several case studies using advanced platforms, including sequencing of a herpes-like virus in Victorian abalone using the GSFLX platform and the subsequent development of a diagnostic test that has proved successful for the early detection and control of the disease.

Dr Linfa Wang (CSIRO-AAHL) then gave an overview of the pros and cons of the Luminex protein based assay. The major driver for this technology was the need to find a replacement technology for ELISA when multiplex tests will provide a significant advantage and when sample volume is a major limiting factor. In comparison to the ELISA, Luminex has similar reaction times but higher initial outlay costs. The key to the technology is the multiplicity of readings facilitated by the different carrier beads and its amenability to high throughput.

Following Linfa's talk, Dr Bronwyn Battersby (Nanomics) described the unique features and key advantages of the OptoPlex biosensors produced by Nanomics. These biosensors are currently being applied to a range of research projects from cancer to infectious diseases, including an AB-CRC funded project led by Dr Bruce Corney and Dr Andrew Geering. Using bead-based molecular reading technology, this system is able to perform organic synthesis on beads without disrupting their fluorescent code. This allows for oriented attachment of antibodies, antibody fragments (scFv's), proteins, peptides and oligonucleotides for increased assay sensitivity and specificity. Bronwyn noted the technology is able to run on virtually any flow cytometer and may possibly be applied to hand-held devices in the future.

Dr David Williams (AB-CRC) then described another multiplex technology – MassTag PCR. While this technology has the potential for multiplexing over 35 primer sets, to date only 22 primer sets have been successfully multiplexed. First reported for use in SNP typing, MassTag PCR has been adapted for pathogen detection. An overview of the chemistry, the PCR workflow, and advantages and disadvantages of this technology was provided. David then described his work involving the development of MassTag PCR for detection of agents causing encephalitis in collaboration with PathWest and Columbia University.

The final talk in Session 2 was provided by Dr Stuart Blacksell (Mahidol-Oxford Tropical Medicine Research Unit) who gave an overview of the promise of rapid POC tests. He noted that field diagnostics for medical and veterinary use in low technology environments are not designed for use in reference laboratories. Bed-side and pen-side POC test formats, their underlying technology, and their modification to lateral flow devices and portable laboratory equipment were then described. Stuart noted that in a large scale evaluation of POC tests, issues with the sensitivity (10-20%) and specificity of various tests on the market, particularly for acute infections, have been observed. Better results were obtained with convalescent

samples, and the sensitivity significantly increased when antigen and antibody tests were combined. Stuart then described the Loop Mediated Amplification (LAMP) method (which he sees as the future of rapid POC tests in low tech settings), PCR microfluid-based chip technologies, and antigen capture and detection using ion channel biosensors.

In the question time following Stuart's talk David Smith asked how closed POC systems, such as customised chips, can be modified to broaden their diagnostic application. Stuart replied that manufacturers need to get involved with the end-users of tests in developing these new technologies.

### **Session 3 – Panel Discussion: Pros, cons & potential of diagnostic systems**

In the final panel session of the forum, Stephen Prowse (AB-CRC) chaired a review of diagnostic systems and their future potential. Stephen began the session by providing an overview of his views of diagnostic systems. He stated that many of the tests have been around for a long period still remain useful, although a number have fallen by the wayside (such as agar gel precipitation). He noted that ELISA represented a major advance in diagnostic testing due to its low costs, simplicity, good levels of sensitivity and specificity, and its ability to be automated and semi-quantified, and detect antigen or antibody. Stephen suggested that ELISA will remain the mainstay workhorse for many medical and veterinary applications.

Stephen also noted that molecular techniques have changed the approach to diagnostic testing, particularly RT-PCR which is now a frontline diagnostic tool. He stressed that need to consider existing diagnostic technologies and new technologies for further research in the Biosecurity CRC Mark II, including high throughput sequencing, LAMP, and MassTag. Stephen also noted that although a number of technologies have been 'on the drawing board' for many years (such as multiplexing technologies using beads), it remains to be determined which of these technologies will develop into routine diagnostic tests. He also commented on the complexities inherent in POC testing.

Stephen highlighted the need to look at the cost of implementing and trialling technologies (including infrastructure costs) in the context of the benefits they offer. Do they offer significant benefits over current tests? Do they fill a gap? He noted it is important that technologies are evaluated to determine where resources should be invested in high cost infrastructures, stressing that the following questions that will be addressed in the selection of research projects for the Biosecurity CRC Mark II. Do we have the tools to respond to a new disease incursion? Is there a distinction between the tests required for detection, eradication, and/or outbreak response? Can this test be developed in the research environment and what are the impediments to transferring this test to a diagnostic environment? Using the influenza

virus as an example, Stephen posed the following questions. Given the range of diagnostic technologies used for this virus, do we need a new POC test? What should the performance criteria be? How would this test be used? Does the technology underlying the POC test meet the required criteria?

The panel consisted of Drs Peter Kirkland (NSW DPI), Gary Lum (DoHA), and Stuart Blacksell (Mahidol-Oxford Tropical Medicine Research Unit). Stephen asked these panel members to provide their views of the pros and cons of POC systems. Gary Lum noted that the context of POC testing in Australia contrasts with Stuart's regional context. He noted that Australia had significant strengths in the development of laboratory-based technologies, but needs to be aware that POC vendors may be touting business to individuals that do not have a laboratory background and the vendors may misrepresent QA/QC issues. Gary then asked what Australia needs from field detection tests? He suggested that the prime requirement is for high quality tests that give quick results and allow for a rapid response to biosecurity threats. While it is not envisaged that these tests will replace laboratory tests, they may be able to reduce the costs associated with laboratory infrastructure and facilities. However, taken too far these savings represent a false economy. If high quality tests are developed, there may be potential for de-specialisation of laboratory expertise, a reduction in incentive to resource laboratory infrastructure, with potential to reduce the scope of reference laboratories. An emphasis on trialling field detection tests may also result in a diversion of funds away from research and development in mainstream research laboratories around the country. POC tests may present issues in accreditation and regulation, and if test specifications are poor the consequences may be disastrous. In conclusion, Gary noted that POC tests are not a panacea but are worthy of further investigation, with the understanding that laboratory confirmation will be always be required in parallel.

Stephen then asked Vicky Krause and David Smith for their perspectives on POC tests. Vicky commented that there is a long way to go with POC tests, that they are underutilised, and there needs to be systematic analysis of how these tests will be used. As an example she noted that POC tests for tuberculosis may be very useful in the Torres Strait. David suggested that 'horses for courses' should apply to POC tests. He noted that antigen POC tests are poor in terms of sensitivity, but may be useful in some situations, such as application in remote locations or for the identification of outbreaks. He noted they are under-evaluated, recognising that manufacturers only undertake the minimal level of evaluation required to get their products onto the market.

It was also noted that POC tests for anthrax have been used by NSW DPI field veterinarians for the last 6-7 years, and the test has been submitted to SCAHLS for validation. Assessment of this test in the field presents a number of challenges because there are very few positives in the Australian context – a problem that is likely to be encountered when evaluating other

exotic diseases. Chris Morrissy commented that the true value of POC tests in public health may be related to their use for specific diseases and/or pathogens organisms and they should not be viewed in generalist terms.

Stuart Blacksell then provided his views of POC tests from a regional perspective. He noted that there are many different levels of care and capacity in the region. In his experience, 50% of patients have no definitive diagnosis (with the exception of Singapore), suggesting it is in Australia's interest to know the causes of these cases from an emerging infectious disease perspective. He highlighted the need for rapid and simple tests for accurate diagnosis of disease. As the major hurdle in the region is a limited capacity to pay, he questioned the incentives for diagnostic test development in a region where there is little capacity for return, although he noted that some companies are looking at a two-tiered pricing system. He also noted a number of practical issues in the region including lack of trained staff, poor equipment maintenance, difficult environmental conditions (low avail reagents, dust, humidity), and complications in evaluating test results from patients with residual antibodies to other endemic diseases. In the veterinary setting Stuart suggested that tests must be simple and low cost, and livestock officers must be able to collect the appropriate sample, perform the test, and interpret the results.

Peter Kirkland then provided his views on POC tests agreeing with David that 'fitness for purpose' needs to be the primary focus. He noted that in the early stages of research, test developers need to engage with end-users and consider these issues. Peter then questioned the evaluation of particular platforms. Are the reagents readily available? Is the platform robust, cost effective, user friendly, and amenable to high throughput? He suggested we need to develop a matrix or checklist for evaluation of some of the promising technologies. He then asked if we are as clever as we can be. He suggested there has been a lot of 'reinventing the wheel' and validation of assays for exotic diseases that are used commonly overseas, noting that careful enquiry may eliminate some of these duplications. He suggested the need to be more flexible in validating tests and identify roles for tests that may not pass all validation criteria. He stressed that an emphasis should be placed on validation during test development, and noted the need to make decisions on the required degree of validation prior to getting the 'vehicle on the road'. In conclusion, he reminded the delegates of the need to maintain existing assays.

Stephen then concluded the forum with discussion of the proposed CRC Mark II diagnostics portfolio. He noted that four questions had been framed to generate discussion in the closed workshop that would follow. These questions were: What new technologies, tools, and systems will be required for public laboratories? What new technologies, tools, and systems will significantly improve diagnostic capacity outside of the major laboratories? What are the

constraints to validation? Where are the gaps in diagnostic capability at a national level, and which of these gaps can be addressed by the AB-CRC?

## Outcomes

Throughout Day 1, a number of challenges in diagnostic testing were acknowledged, including the difficulties in developing a 'perfect test' – a test that is fast, cheap, reliable, accurate, amenable to automation & high throughput, and able to be validated. There was general consensus that 'fitness for purpose' should be of prime importance in the development of a diagnostic test where the end use of the test (including the platform it will require) and the collection of appropriate specimens and samples for validation are considered. A number of technical issues presented by outbreaks were raised, including consumable availability and competition, delays in obtaining samples, and maintaining the skills to perform tests in absence of an outbreak. The advantages of uniform or compatible platforms, methods, and reagents across laboratories was also noted, particularly in relation to the recent EI outbreak response.

Several opportunities for improving diagnostic testing were identified from the research presentations provided on Day 1. These included the development of new training programs for specific emerging technologies, and training aimed at maintaining the skills required for existing tests. Further development of pathogen detection tests and the transfer of these technologies from one laboratory to another, the strengthening of 'One Health' initiatives through cross-sector collaborations and links, and further capacity building in the region, were also identified as areas of opportunity. Two specific technology transfer opportunities were raised.

Validation was noted as a significant area of opportunity, as well as being identified a key knowledge gap. The question of whose responsibility it is to take research into diagnostic format was raised repeatedly. There was a strong indication both in the workshop feedback and from the talks earlier in the day that researchers need to put themselves 'in the shoes' of diagnosticians and build validation into their projects from the earliest stages. The need for researchers and end-users to establish a common vocabulary was also identified.

A number of the themes that recurred in Day 1 were also reiterated in the presentations and question time in Day 2. One of these themes was the need for researchers to engage end-users throughout the process of diagnostic test development, and incorporate validation into test development research. The themes of 'striving for a perfect test' and 'fitness for purpose' were also raised on Day 2.

The contrast between the need for POC tests in the region was compared to use of these tests in the Australian context, and there was suggestion that in Australia these tests would

be used predominantly as a rapid response to specific biosecurity threats. It was noted that there needs to be a systematic analysis of how these tests will be used and an evaluation of their efficacy. The need for manufacturers to be involved in this process was raised in relation to POC tests. The benefits of accessing pooled and assayed control materials for test development and validation was also raised, although it was acknowledged that testing for rare, exotic diseases will continue to present challenges in the Australian context due to the low number of positive samples for evaluation. In the Day 2 presentations it was also noted that there is a need for improved and common understanding of how the public health and animal health systems work, better coordination of the national system, and better links between these sectors.

In the panel discussion on Day 2, there was discussion of the cost of implementing and trialing new technologies and the need to be assess this against the benefits they offer, possibly using an evaluation matrix. In the closed workshop following the forum, it was noted that the AB-CRC may have a role to play in assessing the factors that lead to the progression of new technologies from research through to production, and the factors that contribute to the demise of 'promising' technologies that do not reach the market.

The formal feedback provided by the delegates at the end of each day of the forum indicated the forum was a success, achieving many of its objectives. In this feedback, the national benefits of taking diagnostics research into practice and policy was acknowledged, as was the AB-CRC's promotion of improved preparedness and response capacity through diagnostic test development and capacity building, the significant level of uptake and adoption of research from the AB-CRC, and the promotion of a skilled biosecurity workforce through the PhD program. It was clear that many of the delegates felt the AB-CRC is making a positive contribution to establishing & reinforcing collaborations and partnerships.

## Recommendations

A number of recommendations for the AB-CRC were identified during the forum and from the formal feedback provided by the delegates in their evaluation forms. These recommendations will be used by the AB-CRC for forward planning in research and knowledge exchange.

**Recommendation 1: The AB-CRC continue to update and inform industry representatives and state and commonwealth agencies of activities and outcomes from its diagnostic research portfolio, and promote interaction and linkage between AB-CRC researchers and these stakeholders.** The benefits of information exchange about diagnostic technologies and research was highlighted in the forum. The AB-CRC will continue to promote information flow in this area through its established knowledge exchange mechanisms. It will also consider holding another diagnostics adoption forum in the future contingent on funding. Future forums could provide a brief update of projects and allow greater time to be allocated to technology updates and groups discussions and workshops. Consideration will be also be given to promoting national capacity by increasing cross-sector sharing and broadening sector representation to include delegates from the plant biosecurity and aquatic animal health.

**Recommendation 2: The AB-CRC continues to advance diagnostics research through its existing research program.** The AB-CRC will follow-up with project leaders, researchers and end-users to consider the relevant issues that were raised in the forum. The AB-CRC acknowledges its role in funding research that addresses gaps in knowledge and ways these gaps may be filled by ongoing research, and will consider supporting new and ongoing projects that fit within Centre's remit and budget allocation.

**Recommendation 3: The AB-CRC consider future priority areas in diagnostics research for inclusion in the Biosecurity CRC Mark II.** Proposed or commissioned diagnostics-related research projects that continue on from current projects should be reviewed in light of the responses provided by the forum.

**Recommendation 4: The AB-CRC disseminates the outcomes of the Diagnostics Forum.** In addition to producing a forum report, the AB-CRC will highlight a number of the forum outcomes to specific end-users of AB-CRC research. In particular, comments regarding validation, POC tests and new test development will be forwarded to SCAHLS in a briefing note accompanying the report and the Centre will continue to work with SCAHLS to promote researcher understanding of these issues. Opportunities for reagent sharing will be followed up with specific laboratories and where appropriate, policy-related issues will be raised with the responsible state or federal agency.

## Evaluation

Delegates were provided with two evaluation sheets to complete at the end of both days of the forum. The delegates were asked to provide their views of their expectations of each day, how well these expectations were met, and how they felt the forum could have been improved. They were also asked to rate the success of each of the sessions and how they felt the forum had been in achieving its desired outcomes.

### Day 1 Responses

Feedback for Day 1 was obtained from 35 delegates (representing a 96% response rate, not including AB-CRC staff members). A summary of these responses are provided below.

*What was your main reason(s) for attending Day 1 of the forum?*

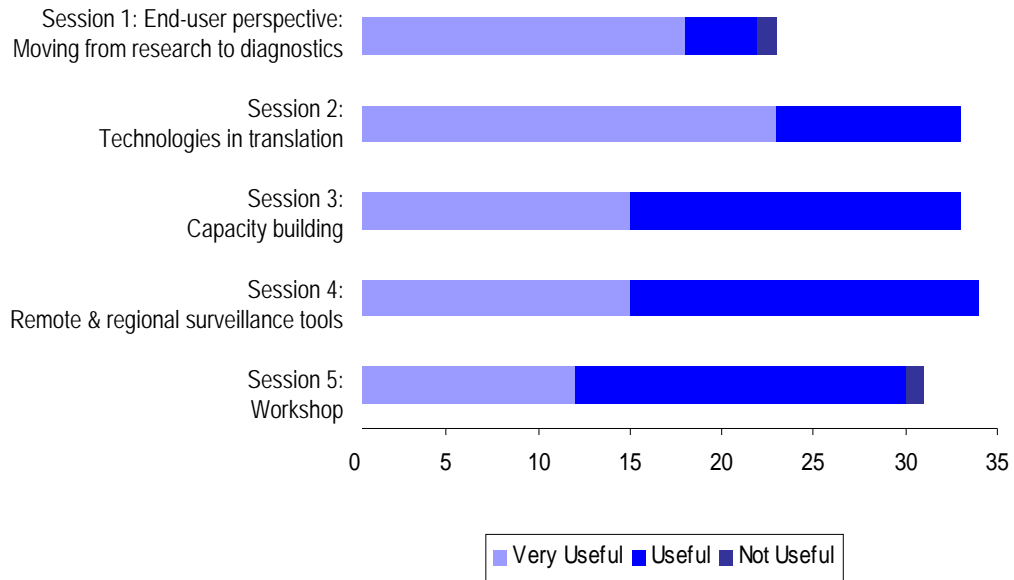
The majority of responses (n=27) to this question indicated the delegates were interested in updating their knowledge of diagnostic development and learning about new technologies, the future direction of diagnostic testing, the progress of the CRC (including major outcomes and technology transfer), and the planned Biosecurity CRC Mark II. Five delegates indicated they attended to provide their views of the future of diagnostic testing, adoption and end-user uptake of CRC outcomes, and future research in the CRC Mark II. Another five indicated they were interested in the networking and collaboration opportunities provided by the forum. Two delegates responded they attended because they were invited to attend, and another indicated they were a stakeholder and the forum was relevant to their position. One delegate did not respond to this question.

*Did this day fulfill your main reason(s) for attending?*

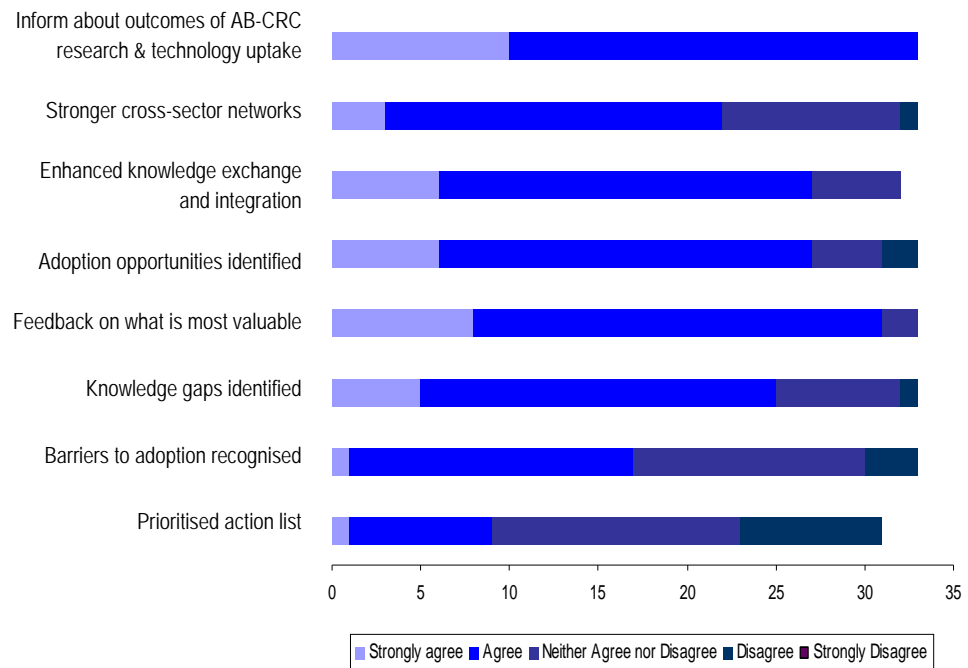
Thirty delegates indicated Day 1 fulfilled their main reasons for attending. One delegate felt they would have liked more detail on emerging technologies (these technologies were addressed in Day 2) another felt they were already very familiar with AB-CRC research outcomes. Three delegates did not answer this question.

*How useful do you feel the following sessions were in fulfilling your reason(s) for attendance?*

The majority of delegates who provided responses to this question indicated the forum sessions were useful or very useful. Only one delegate felt session 1 was not useful, another felt session 5 was not useful.



*Rate the extent to which the workshop achieved the desired outcomes of the meeting.*



*Do you have any suggestions for how Day 1 of the forum could be improved?*

Twelve delegates provided comments to this question. Four commented positively about Day 1 indicating it was excellent, well done, had a good mix of presenters, and kept to time. Two delegates felt more time could have been allocated to the day to allow for greater discussion of opportunities and gaps, although one of these individuals acknowledged the difficulties of combining workshops with research presentations. Two other delegates felt there could have been more end-user participation and interaction, and another felt the panel session could have benefited from questions initiated from the floor. One felt there was potential for the AB-CRC to capture its outcomes in a summary document for distribution to policy makers and other interested parties. Another felt that both days 1 and 2 were appropriate for public health end-users.

## **Day 2 Responses**

Feedback for Day 2 was obtained from 26 delegates (representing a 53% response rate, not including AB-CRC staff members). A summary of these responses are provided below.

*What was your main reason(s) for attending Day 2 of the forum?*

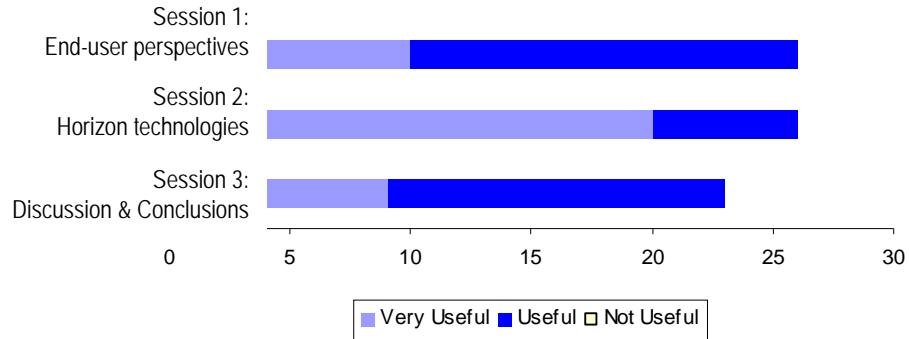
Similar to the responses provided in the evaluation of Day 1, many delegates also provided a number of responses to this question. The majority of these responses (n=24) indicated the delegates were interested in learning about new technologies, CRC outcomes, and the Biosecurity CRC Mark II. Six delegates indicated they were interested in the networking and collaboration opportunities provided by the forum. Four indicated they attended because they were invited speakers. One delegate did not respond to this question.

*Did this day fulfill your main reason(s) for attending?*

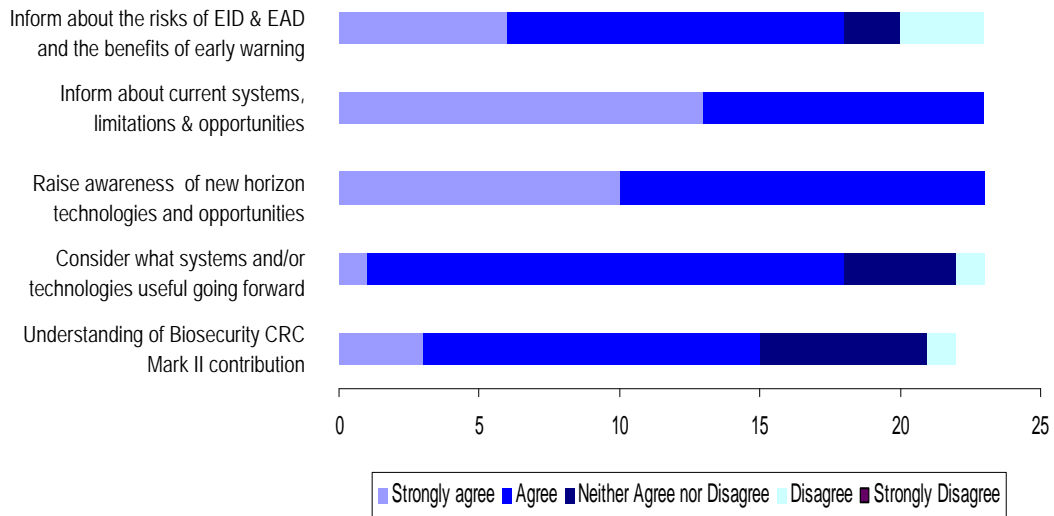
Twenty three delegates indicated Day 1 fulfilled their main reasons for attending. Four delegates indicated they found the talks on new technologies interesting and relevant. Three delegates did not answer this question.

*How useful do you feel the following sessions were in fulfilling your reason(s) for attendance?*

All delegates who provided responses to this question indicated the forum sessions were useful or very useful.



*Rate the extent to which the workshop achieved the desired outcomes of the meeting.*



*Do you have any suggestions for how Day 2 of the forum could be improved?*

Six delegates provided comments to this question. Three of these comments were positive, indicating that Day 2 was valuable, well organised, with good quality presentations that made the link between future trends and new test development more clear. One delegate felt there could have been a bigger emphasis on industry scenarios and forward problem solving addressing how the best end-user outcomes can be achieved using the range of diagnostic options available. One delegate felt more time could have been allocated to question time and 'open forum discussions', and another felt there was some redundancy in the presentations.

## Appendix

### PowerPoint Presentations Summary

The full powerpoint presentations for each of the presenters are available as an attachment to this report. See Diagnostics Forum PowerPoint Presentations.

#### Day 1

Molecular detection systems for emergency diseases	Hans Heine
I've developed and validated a new test: Now what?	Bruce Corney
Development and validation of a TaqMan assay for the detection of <i>T. evansi</i> , the agent of Surra	Trevor Taylor
Influenza real time RT-PCR – Assay development, technology transfer & update	Hans Heine
Development and application of methods for detection of Porcine Circovirus 2	Mark O'Dea
Application of new platform technologies for the development of protein-based detection tests: Reagents for FMD tests	Hans Heine
Improving bluetongue virus surveillance in remote areas	Lorna Melville
Changing Papers – new serological tools for improved surveillance of Surra	Celia Smuts
Genome analysis for biological diagnostics: Technology platforms and applications	John Forster
Rapid diagnostic tests – are the new technologies as good as they say?	Stuart Blacksell

#### Day 2

End-user presentation – animal and wildlife health	Mike Nunn
Service providers – the animal health system	Peter Daniels
Service providers – the public health laboratory system	David Smith
High throughput opportunities for pathogen detection: Case study – Equine influenza	Peter Kirkland
The journey to quality	James Watson
Improving bluetongue virus surveillance in remote areas	Lorna Melville
Genome analysis for biological diagnostics: Technology platforms and applications	John Forster
Nanomics OptoPlex Biosensors: The next generation in molecular reading	Bronwyn Battersby
Luminex: Pros and cons	Linfa Wang
MassTag PCR: a highly multiplexed system for pathogen detection	David Williams
Rapid diagnostic tests – are the new technologies as good as they say?	Stuart Blacksell

## Day 1 Group Responses

The following notes represent the responses provided by each of the groups during the workshop in Session 5, Day 1. The responses have been reproduced verbatim.

### Group 1 – Reported by Jane Oakey

#### Outcomes

1. Enhanced collaboration and communication between state laboratories, universities
2. Improved access to expertise
3. Proof of concept for ideas to allow ideas to be more easily adopted (i.e. Luminex)
4. Giving momentum to some emerging technologies

#### Opportunities

1. Proof of concept shows opportunities for rapid adoption
2. Specific training programs for science and processes of new methods
3. Capacity building in the region using surveillance methods developed by the AB-CRC

#### Gaps

1. Validation/ quality assurance. Gaps between researchers and end-users. Monitoring test development methods incorporating QA, increased access to SCAHLS guidelines & policy requirements, and greater communication between regulatory bodies including SCAHLS and researchers.

### Group 2 – Reported by Keith Walker

#### Outcomes

1. Molecular AI test adapted quickly and readily to EI
2. Provides platforms for networking, funds, linkages
3. positive contribution to establishing & reinforcing regional collaboration and partnership (e.g. CSIRO-AAHL's service to ongoing provision for SARS & multiple outcomes from one project)

#### Opportunities

1. Need to build networks across sectors to strengthen one health
2. Luminex technology presents opportunity to animal and public health
3. Ongoing training – intergenerational capacity and resourcing to manage new technologies

#### Gaps

1. Improved visibility in human health arena – could be incorporated into Biosecurity CRC Mark II
2. Consideration of legacy of projects post CRC
3. Samples for validation, catalysing needs analysis and gaps
4. CRC focus on cell mediated tests (antibody and antigen responses) may be enhanced by a different approaches (e.g. focusing on host genomic responses)
5. Expand scope of CRC beyond viral biosecurity issues, such as screw worm flies

### Group 3 – Reported by David Williams

#### Outcomes

1. Luminex assays
2. AI Taqman technology transfer

#### Opportunities

1. Transfer of PCV2 reagents
2. Pathogen detection technologies
3. AI RT-PCRs from QDPIF to state laboratories

#### Gaps

1. Increased sequence data
2. Increased sample input into high throughput systems

#### **Group 4 – Reported by Lisa Adams**

##### Outcomes

1. AB-CRC outcomes
2. High quality PhD students implications for biosecurity
3. Realistic perceptions regarding A&L and commercialisation

##### Opportunities

1. Commercialisation plans replaced with adoption plans
2. Validation aspects
3. Clarification from SCAHLS regarding validation criteria

##### Gaps

1. Capacity
2. Review of the role of serum banks

#### **Group 5 – Reported by Rupert Woods**

##### Positive outcomes

1. Collaboration –use of approaches to use as springboard and drive outcomes (e.g. AI)
2. Importantly has generated capacity outside of the CRC
3. Leverage for more beneficial outcomes
4. Improved preparedness and response capacity
5. Specific project outcomes – AI, H5N1, automation

##### Opportunities

1. Linkage – ‘One Health’ mechanism
2. Further technology development and technology transfer
3. Use of recombinant technology for production of Ab for other agents
4. Economies of scale

##### Gaps

1. Clarification of responsibility – QA and communication
2. Test validation – platform templates & standardisation
3. Prioritisation – knowns and unknowns
4. Lack commitment to health and conservation
5. Lack of engagement / benefit / opportunities to health outcomes

In addition to addressing outcomes, opportunities and gaps, Rupert Woods’ group also developed a list of project priority areas and risks.

##### Priority Project areas:

1. Process: criteria
2. Factors – in context of AusBIOSEC – Beale report, AB-CRC report
3. Same 3 elements – research, education& training, tech transfer

##### Risks

1. Knowledge retention
2. Lack of prioritisation
3. Lack of integration with other initiatives
4. Lack buy-in
5. Major outbreak required!
6. Solution – contingency plan for each built into CRC.

### **Molecular detection systems for emergency diseases**

Dr Hans Heine (*presenting on behalf of project leader, Dr David Boyle*)

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The aim of the project was to develop new and improved detection methods for significant emerging infectious disease threats and, specifically, DNA-based platform technologies to enhance the speed, sensitivity and specificity of pathogen detection. This project responded to the need for more rapid detection of pathogens, with enhanced specificity and sensitivity. The focus was on the detection of genetic materials by amplification and hybridisation detection systems. TaqMan real-time PCR based tests have been developed and implemented for high priority diseases identified in the Animal Health Australia cost-sharing agreement, the OIE listed diseases and other projects in the AB-CRC. A TaqMan-based differential diagnosis platform has been validated for vesicular and vesicular-like diseases, as well as other diseases. The capacity of real-time PCR for multiplexing is limited; at present up to four dyes can be identified simultaneously. DNA microarrays represent a potential solution to this problem as they have the ability for testing small quantities of sample for a large number of pathogens simultaneously. Global viral array differential diagnosis platforms have been developed and evaluated for vesicular disease testing and identification of novel isolates. The results indicate that with further development this microarray assay could be a valuable tool for the diagnosis of vesicular and vesicular-like diseases.

### **I've developed and validated a new test: Now what?**

Dr Bruce Corney

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Development and validation of new PCRs is an expensive and time-consuming process. Often, different laboratories develop and validate PCRs for the same pathogens, leading to unnecessary duplication of effort. Ways of maximising the return from test development and validation are discussed using as examples the Queensland experience with the influenza type A TaqMan assay and its use in the recent equine influenza response, and three TaqMan assays for avian respiratory diseases. All of these assays were outcomes of AB-CRC funded projects.

### **One-step C-ELISAs for SARS antibody detection**

Dr Linfa Wang

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Knowledge of the immunodominant regions in major viral antigens is important for rational design of effective vaccines and diagnostic tests. This is especially true for the SARS coronavirus (SARS-CoV) which is able to infect a wide range of hosts. In an AB-CRC funded study, we determined immunodominant regions of the spike (S) and nucleocapsid (N) proteins, which are recognized by sera from various animal species, including mouse, rat, rabbit, civet, pig and horse. Based on the epitope mapping data and mono-specific sera raised against immunodominant protein fragments, two one-step competition ELISAs (cELISAs) were established which could detect SARS-CoV antibodies from human and at least seven different animal species. Considering that a large number of animal species are known to be susceptible to SARS-CoV, these assays will be a useful tool for tracing the origin and transmission of SARS-CoV and minimising the risk of animal-to-human transmission. These tests are available to our collaborators in China and other countries for research as well as outbreak investigation.

## **Influenza real-time RT-PCR: Assay development, technology transfer & update**

Dr Hans Heine

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The aims of the projects were the development of diagnostic capabilities for highly pathogenic H5N1 influenza isolates, boosting capability for improved avian influenza diagnostics throughout Australia, and refining PCR assays for detecting changing H5N1 strains. TaqMan reverse transcriptase PCR assays were developed for rapid detection of all influenza type A viruses, and for identification of highly pathogenic H5N1 strains. The assays were highly sensitive and detected all of the tested viruses, allowing definitive confirmation of an avian influenza virus as H5 subtype within hours, which is crucial for rapid implementation of control measures in the event of an outbreak. The tests were evaluated on different platforms and transferred to all Australian state veterinary laboratories, New Zealand and some South East Asian countries. A proficiency testing program established that all laboratories could reliably identify influenza viruses.

The availability of the influenza type A assay paid off in the Equine influenza outbreak in Sydney, 2007, during which it was used as the primary molecular diagnostic test for index case diagnosis, surveillance and identification of infected properties. The challenge now is to update the H5 specific test so that newly evolving viruses can still be detected. Improved and updated assays will be transferred into state laboratories.

## **Development and application of methods for detection of Porcine Circovirus 2**

Mark O'Dea

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Development of methods for detection of both Porcine Circovirus 2 (PCV2) antigen and antibodies is important to reduce Australia's reliance on overseas produced reagents. A major focus of PCV2 research at Murdoch University was the development of diagnostic tests, and the application of these tests to samples obtained from Australian piggeries. This presentation will review the major diagnostic tests developed. These include a PCV2 specific ELISA, and its application to a national serological survey, and the development and transfer of a PCV2 specific immunohistochemical test.

## **Henipavirus serological assays**

Jennifer McEachern

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The henipaviruses – Hendra virus (HeV) and Nipah virus (NiV) – are highly pathogenic zoonotic viruses that have a broad species tropism and continue to re-emerge in human and animal populations in our region. As part of an AB-CRC funded project, novel multiplexed bead-based Luminex assays have been developed to improve serological diagnosis for the henipaviruses. The Luminex assays were designed specifically to replace/complement the current diagnostic serology tests which require live virus and can therefore only be performed in a Bio-security level 4 (BSL4) facilities. Compared with the current diagnostic assays available, the new Luminex assays are highly sensitive, rapid, require only small volumes of sera, can simultaneously differentiate between HeV and NiV, and don't require high biosecurity facilities for production. We are in the process of consolidating reagent supply at CSIRO's Australian Animal Health Laboratory and transferring the technology to collaborating laboratories in Australia, Asia and Europe to allow for a coordinated, rapid response to possible future henipavirus outbreaks in our region and beyond.

## **Evaluation of rapid molecular detection and characterisation systems for surveillance of arboviruses circulating in northern Australia**

Chris Cowled

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In recent years, several major international outbreaks of never-before-seen viruses have increased awareness of the threat posed by emerging viral diseases. The unpredictable nature of viral emergence necessitates a pre-emptive approach to risk management, and one such approach is the characterisation of unidentified viruses circulating in the environment.

This enables the development of tools for early detection of changes in viral activity, and for rapid diagnosis in the event of an outbreak.

Unidentified viruses are frequently isolated in northern Australia by the National Arbovirus Monitoring Program (NAMP). As an example, up to a third of the viruses isolated by NAMP in the Northern Territory in recent years have resisted identification by conventional diagnostic tests. We have used a range of molecular techniques to identify and characterise novel viruses from this collection. Microarray, cDNA subtraction and high throughput sequencing have proven to be valuable tools for obtaining genetic sequence data from viruses that resist identification by other methods. Using a combination of these approaches, a number of new viruses have been described including Middle Point orbivirus and Stretch Lagoon orbivirus. Diagnostic tests for these viruses have been adopted for routine use by the arbovirus surveillance program and hundreds of viral isolates have been identified as a result.

### **Application of new platform technologies for the development of protein-based detection tests: Reagents for FMD tests**

Dr Hans Heine

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The goal of this project was to develop new and improved detection methods for emerging infectious disease threats via devices that detect pathogens on-site, and the application of new platform technologies to enhance the speed, sensitivity and specificity. A major objective was to consolidate the available recombinant antibody technology for production of specific reagents used in various tests developed by the AB-CRC.

New immunological reagents and tests were developed for foot and mouth disease virus (FMDV), which will aid in the rapid detection of FMDV in Australia. Recombinant antibody libraries to FMDV were constructed in a bacteriophage expression system and screened with recombinant FMDV proteins. The recombinant antibodies were isolated from the library and characterised using existing assays to evaluate their potential as diagnostic reagents. The recombinant reagents were genetically engineered and optimised for a range of immunological assays, and a diagnostic test was developed to differentiate between infected and vaccinated animals (DIVA). The availability of quality diagnostic tests is crucial to prove freedom from disease and allow for the resumption of trade in livestock products should an outbreak occur in Australia.

### **Improving bluetongue virus surveillance in remote areas**

Dr Lorna Melville

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The National Arbovirus Monitoring Program (NAMP) carries out national surveillance of economically important insect-borne viruses of livestock and their vectors. This surveillance is carried out by testing blood samples from sentinel herds of cattle. Vector trapping and identification occurs at similar locations and time periods. Monitoring for arboviruses is also conducted both onshore and offshore by the Northern Australia Quarantine Strategy (NAQS) of the Australian Quarantine and Inspection Service (AQIS) to provide forewarning of incursion of new bluetongue virus (BTV) serotypes and genotypes into northern Australia and neighbouring countries, especially Timor Leste, Indonesia and Papua New Guinea. Surveillance using sentinel cattle is impossible in many remote areas, due to associated costs and access problems. Development of molecular techniques, in particular PCR, has provided a method by which surveillance for incursion of new BTV serotypes/genotypes may be carried out in such areas. Preliminary work using a BTV PCR on midges collected in alcohol indicated this technique could provide useful data on BTV activity in an area. A BTV PCR on alcohol-fixed midges was optimised and validated. The technique was compared to conventional monitoring at sites of known BTV activity and an assessment made of the cost effectiveness as a monitoring tool in remote locations. Other applications included assessing the vector potential of midge species for which data were not available.

## **Changing papers – new serological tools for improved surveillance of Surra**

Celia Smuts

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Surveillance programs for animal diseases in remote areas in Australia rely on data from serological surveys. Current methods of collection, transportation and storage of serum are cumbersome because they require careful processing of samples to avoid contamination and spoilage. In addition, serum has a limited shelf-life at room temperature, which restricts its collection in situations where electricity is not available. Blood is routinely collected on filter paper for surveillance of specific infant diseases in people. Attempts were made to improve on this system of sample collection so that it would be suitable for use in remote areas with humid climates, which significantly shorten the shelf-life of blood stored on plain filter paper. We found that adding a preservative to the paper increased the antibody shelf life of serum at higher humidity and temperatures. It did not appear to interfere with the ELISA results when compared to normal serum. This should increase the confidence in results obtained from paper samples stored for longer than 2 weeks at environmental temperatures.

## **Current and future priorities for the Office of Health Protection**

Dr Gary Lum

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The Office of Health Protection in the Department of Health and Ageing has a mission to protect the health of the Australian community through prevention, detection and effective response to national health emergencies, communicable disease outbreaks and natural disasters. This gives rise to the key areas of responsibility in communicable disease surveillance, pandemic preparedness, national biosecurity initiatives and health emergency management.

Technological developments will be important in providing early detection of communicable disease incidents and outbreaks and characterisation of emerging infectious disease agents. There is also a broad application for new technology for rapid screening at international borders and in response to disease outbreaks.

## **Genome analysis for biological diagnostics: Technology platforms and applications**

Dr John Forster

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The Biosciences Research Division (BRD) of the Victorian Department of Primary Industries (VDPI) has established a number of key technology platforms for genetic and genomic analysis at the Victorian AgriBiosciences Centre (VABC) located on the campus of La Trobe University. These platforms permit high-throughput analysis relevant to a number of agribiotechnology applications, including biological diagnostics. The platforms include: DNA array fabrication and analysis technology, for transcriptomics and chip-based genotyping; quantitative PCR, for real-time measurement of PCR amplification; biorobotics, for DNA extraction, sample rearraying and PCR reaction set-up; capillary electrophoresis, for low- to moderate- throughput DNA sequencing and genotyping; microbead-based reporter systems for digital genotyping and gene expression studies; and massively-parallel picolitre volume-based pyrosequencing (Roche GSFLX), for high-throughput DNA sequencing. These platforms have been used for a range of methodologies including simple sequence repeat (SSR) and single nucleotide polymorphism (SNP) genetic marker analysis, as well as both de novo sequence determination and targeted resequencing. Future developments in genomics analysis will be driven by next-generation sequencing methods using current short-read technology (Illumina Genome Analyser and ABI SoLiD), nanosequencing methods based on real-time outputs of single DNA polymerases (e.g. Pacific Biosciences, Visigen, Helicos), and direct physical examination of DNA structure (nanopores, nanoknives [Reveo], electron microscopy [ZS Genetics]).

Capacity will be demonstrated by reference to several case histories. Unusual large-scale mortalities were observed in both farmed and natural populations of Victorian abalone in 2005-2006. Electron microscopic studies revealed the presence of a herpes-like virus, which could not be cultured. A collaborative project was developed to develop diagnostic tests,

requiring determination of the genome sequence. Viral DNA was extracted from nerve tissue of infected animals, and was sequenced using the GSFLX platform. Bioinformatics analysis permitted identification of protein-encoding regions similar to those of the oyster herpes-like virus. Derived diagnostic tests are in the final stage of development, and will provide valuable tools for early detection and control of the disease.

Metagenomics is the use of DNA sequencing analysis to detect and dissect complex microbial communities. This approach is highly applicable for organisms that are recalcitrant to culture, and is hence potentially applicable to multiple infectious agents. For soil microbiome studies, samples were obtained from contrasting soil types in Victoria. The prevalences of different eubacterial, archaeal and fungal taxa were estimated, based on rDNA variation. Functional annotation has been initiated, and community diversity may be related to variability of environmental conditions. For rumen microbiome studies, samples were obtained from fistulated dairy cattles. Less than 0.1% of derived samples corresponded to previously characterised taxa. A total of 1% of records matched archaeal sources, allowing identification of multiple methanogen taxa. This study has provided a resource for manipulation of the rumen community. Reduced methanogenesis can lead to mitigation of methane release and contribute to reduced greenhouse gas effects.

The genetics of plant pathogens and mutualists also provides informative case histories. Temperate pasture grasses such as perennial ryegrass, which is a staple of the grazing industry for dairy production in southern Australia, are hosts to fungal endophyte species of the genus *Neotyphodium*. Endophytes produce diverse alkaloid secondary metabolites which produce both beneficial and detrimental effects (deterrence of insect feeding, and livestock toxicities, respectively). Development of SSR markers and a survey of global genetic diversity allowed validation of genetic diagnostics for toxin production, and is now routinely applied to quality control in commercial breeding programs. Genome survey sequencing (GSS) on the GSFLX has been applied to novel endophyte strains and revealed presence/absence variation for specific alkaloid biosynthesis genes, opening the way to new generations of diagnostic tests.

## **Nanomics OptoPlex biosensors: The next generation in molecular reading**

Dr Bronwyn Battersby

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The Nanomics OptoPlex system is the next generation in bead-based molecular reading technology. Differentiated from polymeric bead systems by their functionalised organosilica nature, tailored porosity and chemical robustness, the OptoPlex beads can be customised for a wide variety of multiplexed genomic, epigenetic and proteomic applications. Indeed, the ability to perform organic synthesis on the beads without disrupting their fluorescent code sets the OptoPlex system apart from all other bead systems. This advantage allows Nanomics to produce beads with a variety of unique polymer coatings which essentially eliminate non-specific protein binding. It also allows development of unique chemical methods for oriented attachment of antibodies, antibody fragments (scFv's), proteins, peptides and oligonucleotides for increased assay sensitivity and specificity. With the ability to run the OptoPlex assays on virtually any flow cytometer and potentially, future hand-held devices, the OptoPlex system is poised to become the next generation of biosensors for in-the-field diagnostic applications.

Through a QLD Smart State 'Biosecurity' project with collaborators, the AB-CRC, the CRC for National Plant Biosecurity and the QLD Department of Primary Industries and Fisheries, Nanomics is focussing on developing new tests for detection of pathogens which are highly significant biosecurity threats to public health and agriculture, including Influenza (e.g. human, equine, etc.), arboviruses and plant pathogens. Nanomics is aiming to implement the biosensors into the clinical research environment over the next 1-3 years with translation into diagnostic clinics within the next 3-5 years.

## **Luminex: Pros and cons**

Dr Linfa Wang

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As the first commercialised multiplex bead-based liquid array system, Luminex was considered to be one of the most promising platform technology to transform multiplex assay development for both protein- and nucleic acid-based analyte detection. One decade later, Luminex has been applied in many different applications and several commercial kits based on Luminex have been marketed for detection of virus, cytokines and other biological markers. A search of PubMed revealed more than 300 publications using Luminex. However, the full potential of Luminex is yet to be realised mainly due to the difficulty involved in the generation of high quality reagents and the optimisation of detection conditions for different analytes in one tube. The pros and cons of this technology and future development in relationship to AB-CRC activities will be discussed.

## **MassTag PCR: a highly multiplexed system for pathogen detection**

Dr David Williams

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MassTag PCR is a novel technology for the rapid, sensitive and simultaneous detection of multiple (>20) gene sequences. This technique, developed by the Lipkin Laboratory at Columbia University, utilises a library of unique Masscode tags, each differing in their molecular weight. MassTags are conjugated to oligonucleotide primers using a UV-cleavable linker that enables separation of primer and tag. Primers are labelled with a unique molecular weight tag and are used to amplify target nucleic acids in a multiplex RT-PCR. After removing unincorporated primers, tags are released by UV irradiation and analysed by mass spectrometry. Thus, amplification of the gene target produces a unique dual signal in mass spectrometry analysis that allows its identification. MassTag PCR offers an inexpensive and sensitive diagnostic platform suitable for high-throughput testing, and that can be adapted to suit diagnostic needs (e.g. syndrome-, vector-based). To date, MassTag PCR panels have been developed for the detection of respiratory pathogens and viruses that cause haemorrhagic fever. A third MassTag PCR assay is being developed to identify microbial agents that cause neurological disease in a North American diagnostic setting. In collaboration with the Lipkin group and PathWest Laboratory Medicine WA, we have recently begun developing and modifying this assay to address pathogens relevant to the Australasian region. Preliminary research experiences will be addressed in the accompanying presentation.

## **Rapid diagnostic tests – are the new technologies as good as they say?**

Dr Stuart Blacksell

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Rapid point-of-care tests (POCT) offer a great deal of promise to medical and veterinary practitioners, laboratory diagnosticians and disease control authorities to provide accurate disease diagnosis. Disease diagnosis is required for the treatment or management of patient or a disease outbreak, however many infections have similar clinical presentation with a broad differential diagnosis that necessitate laboratory diagnosis. POCT has the potential to provide a rapid and accurate diagnosis in a low-technology setting however there are still a number of issues that need to be addressed before POCT receive wide acceptance. The most familiar rapid POCT format is the lateral flow device or 'wick' style test however more recently, the advent of portable PCR machines and novel diagnostic approaches designed for use in the field have expanded the definition of POCT. Many of the POCT that are currently commercially available, especially lateral flow devices, have not been independently evaluated leading to inflated accuracy claims by manufacturers. There is a clear role for regulator agencies and international organisations such as WHO and OIE to evaluate new and existing POCT. The future of rapid POCT is most likely in the development and evaluation of microfluidic devices applying nanotechnology for miniaturised PCR for disease recognition and characterisation.

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