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Paper Poster Session
Emerging and pre-emerging viruses

Ebola preparedness in Australia: a rapid approach for proficiency testing

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Background: The recent unprecedented outbreak of Ebola virus (EBOV) was declared a public health emergency of international concern, making testing quality a major global issue. While there have been no cases of the disease in Australia to date, the threat of imported cases remains with the need for ensuring Ebola preparedness through test availability and proficiency. The Royal College of Australasia Quality Assurance Program (RCPAQAP) in Biosecurity rapidly developed a proficiency testing (PT) strategy to enhance the technical capability of Australian, and subsequently international laboratories diagnostic capacity. The use of appropriate survey specimens for PT is a challenge in the absence of readily available clinical samples, which have biocontainment and importation restrictions. Therefore we produced a well-characterised, simulated Ebola specimen consisting of molecular targets, in order to evaluate the performance of the laboratories in using PCR-based nucleic acid testing (NAT) assays to detect the presence of EBOV.

Material/methods: A summary was made of the EBOV-specific gene targets, including the most frequently tested gene regions, based on previously published studies. The *in vitro* RNA transcripts included in the simulated specimen were then designed based on this information. This simulated specimen used in the PT panel consisted of RNA transcripts generated using *in vitro* T7 transcription of plasmids harbouring parts of EBOV nucleoprotein (NP), glycoprotein (GP) and RNA-dependent RNA polymerase (L) genes. Prior to the dispatch to the laboratories, the simulated specimen was tested for its specificity (possible cross-reactivity when tested with NAT assays specific for Sudan strain of EBOV, and another Filovirus – Marburg virus); stability (short-term and long-term storage) and homogeneity (consistency across replicates of specimen).

Results: The simulated specimens showed no cross-reactivity when tested with Sudan virus and Marburg virus-specific NAT assay; were stable on short-term (2-week) and long-term (1-year) storage at –80°C, and were homogeneous. These simulated specimens were used in two separate PT panels that were offered to Australian laboratories in April 2014 and November 2014. All laboratories (3/3) in the first survey correctly identified specimens containing EBOV RNA transcripts. In the second survey, 5/6 laboratories correctly confirmed the presence of EBOV while one laboratory reported false negative and false positive results for EBOV in specimens containing EBOV RNA transcripts and negative samples, respectively.

Conclusions: The EBOV PT panel is useful for ensuring the competency of laboratories in detecting virus. It also demonstrated the value of the simulated Ebola specimen as a control in the development of PCR assays by laboratories which initially did not have the capacity for Ebola detection. The simulated specimen was stable, reliable and will be used for future EBOV PT panels to be offered in March 2016.