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Australia and New Zealand Horizon Scanning Network

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National Horizon Scanning Unit
Horizon scanning prioritising summary

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Uni-Gold™ Recombigen® HIV test: To detect antibodies to HIV-1 in the plasma and whole blood of individuals at risk of HIV infection.

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Adelaide Health Technology Assessment

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PRIORITISING SUMMARY

REGISTER ID: **0000078**

NAME OF TECHNOLOGY: **UNI-GOLD™ RECOMBIGEN® HIV TEST**

PURPOSE AND TARGET GROUP: **TO DETECT ANTIBODIES TO HIV-1 IN THE PLASMA AND WHOLE BLOOD OF INDIVIDUALS AT RISK OF HIV INFECTION**

STAGE OF DEVELOPMENT (IN AUSTRALIA):

☒	Yet to emerge	☐	Established
☐	Experimental	☐	Established *but* changed indication or modification of technique
☐	Investigational	☐	Should be taken out of use
☐	Nearly established		

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

☐	Yes	ARTG number	
☒	No	☐	Not applicable

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
USA	✓		

IMPACT SUMMARY:

Trinity Biotech provides the Uni-Gold™ Recombigen® HIV test for the detection of antibodies to HIV-1 in plasma, serum and whole blood. The test was approved in the U.S.A. in December 2003. The technology has not yet emerged in Australia.

Alternate procedures to test for HIV-1 infection are to run assays for the various virus components or by tests that assess whether an individual's immune system has produced an HIV-1-specific response. Samples are screened with an ELISA and positives are confirmed with Western Blot or Immuno-fluorescence assay. The standard laboratory test algorithm may take 48 hours to one week whereas the Uni-Gold Recombigen HIV provides results in 10 minutes (Trinity Biotech 2003). The advantage of rapid HIV testing may be demonstrated in urgent medical circumstances and in settings where individuals do not return for HIV test results.

Uni-Gold™ Recombigen® HIV detects antibodies to HIV-1 using colloidal gold to give a result. Clinical studies (level 3b evidence, see Appendix A) of 1,032 HIV-1 positive samples undertaken by Trinity Biotech ascertained sensitivity at 100% [95% C.I. 99.5%, 100%]. 1,000 of the samples were collected from individuals known to be HIV-1 sero-positive, and previously confirmed by western blot. A further 32 samples were collected from individuals from high risk populations of unknown HIV serostatus who were subsequently found to be repeatedly reactive using ELISA and Western Blot. The Uni-Gold™ Recombigen® HIV test was reactive for all samples using serum, plasma and whole blood portions (Trinity Biotech 2003).

The specificity of the Uni-Gold™ Recombigen® HIV was evaluated using fresh serum, plasma and whole blood samples. A total of 1,968 HIV-1 ELISA negative individual samples were run as serum, plasma and whole blood on Uni-Gold™ Recombigen® HIV (level 3b diagnostic evidence). 1,000 were collected from individuals of unknown HIV status in a low risk population and subsequently confirmed as negative by ELISA. Of these samples, two were reactive in initial test by plasma and serum and three by whole blood when tested by Uni-Gold™ Recombigen® HIV. In a low risk population the specificity of Uni-Gold™ Recombigen® HIV in these studies was 99.8% [95% C.I. 99.3%, 100%]) for serum, 99.8% [95% C.I. 99.3%, 100%] for plasma and 99.7% [95% C.I. 99.0%, 100%] for whole blood (Trinity Biotech 2003).

In 968 samples from individuals of unknown HIV-1 status from a high risk population (level 3b evidence) who were subsequently found to be HIV-1 sero-negative by ELISA, two were reactive by plasma and whole blood and three by serum when tested with Uni-Gold™ Recombigen® HIV. Specificity in a high risk population was 99.7% [95% C.I. 99.0%, 99.9%] for serum, 99.8% [95% C.I. 99%, 100%] for plasma and 99.8% [95% C.I. 99 %, 100%] for whole blood (Trinity Biotech 2003).

In 2001 there were a total of 778 new cases of HIV infection in Australia (Communicable Diseases Network Australia - National Notifiable Diseases Surveillance System, 2004). Although the incidence rate in Australia is low the use of rapid of the test may be advantageous in hospital settings for quick assessment of emergency cases and in worker needle stick injuries.

CONCLUSION:

There is limited, level 2b evidence available from a single source (manufacturer). In addition, there is likely to be limited uptake of the Uni-Gold™ Recombigen® HIV test in Australia.

HEALTHPACT ACTION:

It is therefore recommended that this technology be monitored.

SOURCES OF FURTHER INFORMATION:

Constantine, N. T., Sill, A. M. et al (2003). 'Improved classification of recent HIV-1 infection by employing a two-stage sensitive/less-sensitive test strategy', *J Acquir Immune Defic Syndr*, 32 (1), 94-103.

Trinity Biotech *'Summary of Safety and Effectiveness'*. [Internet]. Available from: http://www.fda.gov/cber/pmasumm/P0300250S.pdf [Accessed 25th February 2004]

Phillips, B., Ball, C. et al (2001). *Oxford Centre for Evidence-Based Medicine Levels of Evidence (May 2001)* [Internet]. Centre for Evidence-Based Medicine, Oxford, UK. Available from: http://www.cebm.net/levels_of_evidence.asp [Accessed 28th January 2004].

SEARCH CRITERIA TO BE USED:

HIV Infections/ classification/ diagnosis
HIV Seropositivity/ diagnosis
Immunoenzyme Techniques
Sensitivity and Specificity