Australian Government

Department of Health

MEDICAL SERVICES ADVISORY COMMITTEE

Rapid point of care combined Antigen/Antibody HIV test to aid in the diagnosis of HIV infection

Application 1391

Final Protocol

January 2014

1) Title of Application

Rapid point of care combined Antigen/Antibody HIV test to aid in the diagnosis of HIV infection.

2) Purpose of application

Please indicate the rationale for the application and provide one abstract or systematic review that will provide background.

The purpose of this application is to increase HIV testing and early HIV diagnosis high-risk groups in Australia through Commonwealth funding of rapid point of care HIV testing.

The number of new HIV infections in Australia rose 10% in 2012, the highest rate of increase in 20 years (*Kirby Institute 2013 Annual Surveillance Report of HIV, viral hepatitis, STIs*).

The draft Seventh National HIV Strategy, 2014 – 2017 has a target of reducing sexual transmission of HIV by 50 per cent by 2015. A priority area for action of the Strategy is to make HIV testing accessible and promote its use. The Strategy calls for the continued expansion and development of existing testing methods such as rapid testing.

The Melbourne Declaration 2012 is an earlier HIV strategy document and has been endorsed by leading HIV community, professional and research organisations. A key action area of the Declaration is the widespread availability and Commonwealth funding of rapid point of care HIV tests.

A study by Eu *et. al.* 2014 provides an example of the proposed benefit of the service. Point of care HIV testing in a Victorian General Practice clinic detected three times as many new HIV infections in high-risk patients compared to traditional laboratory-based pathology testing. The authors concluded that the increased detection of HIV infections was due to patients at high risk of undiagnosed HIV infection being attracted to rapid testing i.e. the availability of rapid testing resulted in high-risk patients getting tested, or being tested more frequently, compared to traditional laboratory testing leading to increased detection of new HIV infections.

> *Eu B, Roth N, Stoové M, O'Reilly M, Clarke E. Rapid HIV testing increases the rate of HIV detection in men who have sex with men: using rapid HIV testing in a primary care clinic. Sex Health. 2014 Mar;11(1):89-90.*

Another example is recent data which shows that state government programs in QLD and NSW to increase availability of rapid point of care testing have contributed to an increased rate of testing which in turn is leading to earlier diagnosis of HIV infection. This has led to a 32% and 34% increase in HIV diagnoses in NSW and QLD respectively in early 2014 (*NSW HIV Strategy 2012 – 2015, Quarter 1 2014, Data Report* and *Queensland Health Statewide Weekly Communicable Diseases Surveillance Report, 19 May 2014*).

It is proposed that rapid 4th generation combined Antigen/Antibody HIV tests can be used to safely, accurately and cost-effectively aid in the early diagnosis of HIV infection. It is considered that Commonwealth funding of these tests will increase the accessibility of HIV tests, a priority area of the Seventh National HIV Strategy.

3) Population and medical condition eligible for the proposed medical services

Provide a description of the medical condition (or disease) relevant to the service.

HIV (Human Immunodeficiency Virus) is a virus that weakens the immune system. It infects immune cells and uses them to reproduce itself, destroying the cells in the process. AIDS (Acquired Immune Deficiency Syndrome) is a serious weakening of the body's immune system caused by HIV. When an HIV positive person's immune cells (CD4 cells) drop below a certain level, they can be vulnerable to infections that their body would normally fight off.

Early diagnosis of HIV infection is important as early treatment improves chances of maintaining good health. Early treatment and knowledge of HIV status can also reduce the risk of transmitting the virus. While there are effective treatments for HIV, there is currently no cure.

Define the proposed patient population that would benefit from the use of this service. This could include issues such as patient characteristics and /or specific circumstances that patients would have to satisfy in order to access the service.

The proposed patient population are patients where an HIV test is indicated and that are at a high-risk of HIV infection.

HIV testing is indicated in a number of contexts, including:

- clinical suspicion of HIV infection
- inclusion of HIV within the differential diagnosis
- diagnosis of a condition with shared transmission route
- reported high-risk exposure
- unprotected sexual intercourse with a partner whose HIV status is unknown
- reported reuse of equipment used for skin penetration
- in the setting of contact tracing

Adapted from the 2011 National HIV Testing Policy v1.3 – see Policy for complete details. The 2011 Testing Policy is currently under revision and a new version of the policy is expected in 2015.

In Australia, HIV infection is transmitted primarily through sexual contact between men, accounting for 70% of new HIV diagnoses in 2012, (*Kirby Institute 2013 Annual Surveillance Report of HIV, viral hepatitis, STIs*). The majority of other new HIV infections are attributed to injecting drug use, heterosexual contact in a person from a high prevalence country, and heterosexual contact with a partner with/at risk of HIV infection. Another risk-factor is needle-stick injury. Patients with one or more of these risk factors are considered at high-risk of HIV infection.

Point of care testing benefits people who might be otherwise reticent to access conventional testing. Such testing is of particular benefit for high-risk or hard-to-reach populations who may be resistant to conventional testing such men who have sex with men (MSM) who do not routinely access health services. These populations will benefit from a single point of contact and rapid results in the case of negative results and early notification of positive results.

Indicate if there is evidence for the population who would benefit from this service i.e. international evidence including inclusion / exclusion criteria. If appropriate provide a table summarising the population considered in the evidence.

The proposed inclusion criteria for the patient population who would benefit from the test are described above i.e. patients where an HIV test is indicated and that are at high-risk of HIV infection.

Point of care HIV testing would not be applicable to the majority of HIV testing that is currently performed in Australia. For example, the proposed service would not be applicable for HIV testing performed on blood donations, for other organ or tissue donations, or for routine microbiological serology during pregnancy.

Point of care HIV testing is not intended for the screening of patients and is only intended to be used where an HIV test is clinically indicated (see above).

Some documents refer to point of care tests as "screening" tests because a reactive point of care result must be confirmed using traditional laboratory testing. Reference to "screening" in this context refers to the place of the point of care test in the diagnostic algorithm for HIV infection and does not refer to a diagnostic test unrelated to the patient's medical condition. In the same manner the initial EIA test (or similar) used by a laboratory could be considered a "screening" test, where a reactive results is subject to additional confirmatory testing including the gold standard of Western blotting. In other words, "screening" in this context refers to screening of diagnostic results rather than screening an at-risk population.

Provide details on the expected utilisation, if the service is to be publicly funded.

The estimated overall utilisation would be approximately 45,000 tests per annum.

This estimate is an extrapolation based on the number of rapid HIV tests performed in NSW performed in the first quarter of 2014 (*NSW HIV Strategy 2012 – 2015, Quarter 1 2014, Data Report*) to the rest of Australia.

Where indicated, repeat-testing in high-risk patients is recommended every 12 months, and 3 – 6 monthly if they have had a larger number of partners or participated in certain types of sex (*Australian Sexually Transmitted Infection & HIV Testing Guidelines 2014*). The above estimate of overall utilisation includes such repeat testing.

Actual utilisation will depend on the extent of client preference for point of care tests, the number of clinics where the test is available, and potential out of pocket expenses for both point of care and pathology laboratory based HIV testing options.

4) Intervention – proposed medical service

Provide a description of the proposed medical service.

Provision of a rapid combined Antigen/Antibody HIV test at the point of care to aid in the diagnosis of HIV infection.

Reactive results from the point of care test and final diagnosis of HIV infection are subject to confirmatory laboratory testing.

The following MBS descriptor is proposed:

Category 6 – Pathology	Group P9 – Simple Basic Pathology Tests
MBS [item number] Point of care HIV antigen/antibody test by one or more immunochemical methods in a blood sample from a high-risk patient. Fee:	

An explanatory note would need to be included or accompany the proposed MBS descriptor explaining that the test must be performed at the point of care and that the MBS item cannot be claimed on laboratory testing.

If the service is for investigative purposes, describe the technical specification of the health technology and any reference or "evidentiary" standard that has been established.

The Advisory Committee on Medical Devices (ACMD) is a statutory committee which provides independent advice to the TGA and the Minister on safety, quality and performance of medical devices supplied in Australia. This committee recently released the following advice in relation to point of care testing devices used in the diagnosis of HIV infection:

"The ACMD recommends that, when compared to Western Blot testing of known HIV positive specimens (not including seroconversion specimens), the sensitivity of point of care testing devices should be 100% and the specificity at least 99%."

The Alere Determine™ HIV-1/2 Ag/Ab Combo (Determine HIV Combo) is currently the only HIV test registered by the TGA for point of care use (ARTG 203911) and meets this specification.

The Determine HIV Combo is a "4th generation" Antigen/Antibody test; it tests for the both circulating HIV virus itself by detecting p24 antigen (Antigen) and antibodies to the HIV virus (Antibody).

The test is a qualitative test; results are "reactive" or "non-reactive" on the basis of formation of coloured bars in the test window. This is in contrast to quantitative methods such as EIA where a quantitative result is obtained and a diagnostic cut-off is used. For the Determine HIV Combo qualitative, reactive or non-reactive, results are used to determine sensitivity and specificity.

According to the product insert, the sensitivity of the Determine HIV Combo is 100.00% across 1179 specimens positive for various types and subtypes of HIV. The specificity of the test is 99.61% for the antigen test line and the 99.21% for the antibody test line across 2343 HIV-negative specimens. Aside from the information provided in the product insert there are numerous published studies, including Australian studies, examining the diagnostic performance of the Determine HIV Combo.

Antigen detection is important in reducing the window period; the length of time between the time of HIV infection and when the infection can be detected using a particular HIV test. An evaluation by the US CDC found that the Determine HIV Combo detected HIV infection

approximately 10 days earlier than a range of antibody-only rapid tests (*Masciotra et al. Performance of the Alere Determine™ HIV-1/2 Ag/Ab Combo Rapid Test with specimens from HIV-1 seroconverters from the US and HIV-2 infected individuals from Ivory Coast. J Clin Virol. 2013 Dec;58 Suppl*).

The analytical cut-off for the p24 antigen is approximately 12.5 - 25 pg/mL (information provided by manufacturer). This cut-off is higher than laboratory-based systems but it is proposed that increased testing due to the convenience of rapid testing outweighs slightly decreased sensitivity for acute infections.

The risk of false-negative results is mitigated through information provided in the product's instructions for use and through training of health professionals performing the test. The product's instructions for use detail the limitations of the test, including the limitation of the test at early stages of infection. These limitations are explained to health professionals performing the test when they are trained in the use of the product.

In terms of the clinical perspective, if a patient presents with a recent history of an event with a high-risk HIV exposure or clinical signs and symptoms suggestive of acute HIV infection then (i) a laboratory-based HIV test is provided instead of or in addition to the rapid HIV test, and (ii) the patient is encouraged to return for a follow-up HIV test, typically 3 months later.

All tests have a risk of the false-negative results. However, it is proposed that the clinical performance of test combined with the above risk-mitigation measures are such that the benefits of testing outweigh the risk of false-negative results.

The safety and performance of any HIV test is extensively reviewed by the TGA prior to registration in Australia. As such, the assessment of this application should focus on reviewing the cost-effectiveness of 4th generation point of care HIV tests rather than repeating a review of their safety and effectiveness.

Indicate whether the service includes a registered trademark with characteristics that distinguish it from any other similar health technology.

It is proposed that any TGA registered rapid 4th generation combined Antigen/Antibody HIV test could be used to deliver the service.

A combination Antigen/Antibody test is important because Antigen detection reduces the window period. The window period is the length of time between the time of infection and when the infection can be detected using a particular HIV test.

Indicate the proposed setting in which the proposed medical service will be delivered and include detail for each of the following as relevant: inpatient private hospital, inpatient public hospital, outpatient clinic, emergency department, consulting rooms, day surgery centre, residential aged care facility, patient's home, laboratory. Where the proposed medical service will be provided in more than one setting, describe the rationale related to each.

The proposed service would be provided primarily in the consulting rooms of sexual health clinics and General Practitioners.

Based on Australian experience to date, uptake by General Practitioners has been limited to those whose patient mix includes a relatively high number of high-risk patients such as MSM.

It is expected that if point of care HIV testing is listed on the MBS then the number of GP clinics offering the service will increase with the increases mainly additional clinics that have a high number of high-risk patients. Although MBS funding would make it more economically viable there would still be significant hurdles for clinics to provide the service including the

paperwork required to comply with TGA conditions, QAP enrolment, and the time required for training to perform the test. Unless there is significant demand from high-risk patients it would not be worthwhile for a GP clinic to offer the service.

Point of care HIV testing provides the greatest health impact in high-risk populations and should be targeted to such groups. It is proposed that the regulatory hurdles to providing the service, even if it is MBS listed, are so significant that in practice it would only be provided by clinics serving high-risk populations.

It is noted that sites currently performing point of care HIV testing have a relationship with a NATA accredited laboratory but are not themselves NATA accredited. Therefore they would not normally be able to claim pathology services except for a limited number of simple basic pathology tests (P9) such as immunochemical pregnancy tests.

Describe how the service is delivered in the clinical setting. This could include details such as frequency of use (per year), duration of use, limitations or restrictions on the medical service or provider, referral arrangements, professional experience required (e.g.: qualifications, training, accreditation etc.), healthcare resources, access issues (e.g.: demographics, facilities, equipment, location etc.).

Summary of Service

Where an HIV test is indicated, the patient undergoes pre-test counselling and provides consent to the test. The patient would then be offered a traditional laboratory HIV test or, if available, a point of care HIV test.

The limitations of both testing methodologies would be explained, including:

- The window periods for both types of testing
- That a point of care HIV test functions as an initial diagnostic test rather than a definitive diagnostic test and that a reactive result needs to be confirmed by laboratory testing.

If the patient chooses a point of care HIV test then the test would be performed by a nurse or medical practitioner.

In brief, the test procedure for the Determine HIV Combo is as follows:

- A small amount of blood is collected by a fingerstick procedure
- The blood sample is added to the test, followed by a drop of buffer
- After 20 minutes, test results are interpreted by the presence/absence of Control, Antigen and Antibody test lines

If the result from the point of care test is negative then the patient is provided post-test counselling. In contrast to traditional laboratory-based testing, the entire service is provided in a single visit to the provider.

If the result from the point of care test is reactive then counselling is provided and confirmatory laboratory testing is requested through established Medicare pathways. The exact testing performed by the laboratory will depend on the diagnostic algorithm in use but would typically consist of full testing protocol i.e. initial and confirmatory testing.

Frequency of Use

It is recommended that members of high-risk groups have an HIV test at least once a year.

For asymptomatic MSM, the evidence-based Australian Sexually Transmitted Infection and HIV Testing Guidelines 2014 recommend an HIV test one or 4 times a year depending on risk behaviours.

Professional Experience Required

The requirements to use point of care HIV tests outside of clinical trials are dictated by the TGA registration conditions of the Determine HIV Combo. The test can only be used by health professionals and can only be supplied to sites that:

- Have been trained in the correct use and interpretation of the test
- Have an established relationship with a NATA accredited medical testing laboratory for the referral and testing of specimens
- Participate in an HIV point of care quality assurance program
- Provide an annual declaration that all health professionals using the test have been trained in accordance with the National HIV Testing policy

These registration conditions explicitly reference the National HIV Testing Policy and ensure that point of care testing is performed in accordance with the Policy. The registration conditions also address quality concerns by requiring all sites using the test to enrol in a quality assurance program.

In regard to the "relationship with a NATA accredited medical testing laboratory", this is intended to ensure that the site performing the point of care HIV testing has access to laboratory HIV testing in the case that there is a reactive point of care result. The minimum requirement is a routine relationship for sending samples to an accredited laboratory.

It is proposed that these conditions, or substantially similar conditions, apply to point of care HIV testing. Complete details on the conditions that have been imposed by the TGA can be found on the TGA's website: 'TGA Product specific conditions'

Resources Required

Resources required to perform the test are summarised as follows:

- The test itself
- Fingerstick blood sample collection equipment (alcohol wipe, lancet, gauze pad, bandaid, sharps bin)
- Facilities to collect or refer for venous blood draw for confirmatory testing in case of a reactive result
- Enrolment in an appropriate external Quality Assurance Program (QAP)

Clinical Setting

This application concerns rapid HIV tests performed at the point of care i.e. tests that are performed by health practitioners, at or near where the patient consultation is conducted, and not in a laboratory.

It is acknowledged that rapid HIV testing has been safely and effectively undertaken by peer educators in community outreach settings as part of clinical trial and other arrangements. Although such programs are effective, it is currently unclear how HIV testing performed by non-health practitioners could be funded through MBS and so such testing is outside the scope of this application.

Rapid HIV tests can also be used by medical testing laboratories as part of their HIV testing algorithms. However, such use of rapid HIV tests is already covered by existing MBS arrangements and is also outside the scope of this application.

5) Co-dependent information (if not a co-dependent application go to Section 6)

Please provide detail of the co-dependent nature of this service as applicable

This is not a co-dependent service.

6) Comparator – clinical claim for the proposed medical service

Please provide details of how the proposed service is expected to be used, for example is it to replace or substitute a current practice; in addition to, or to augment current practice.

It is intended that this service will provide an alternative option for laboratory-based HIV-testing.

Where appropriate, patients would be offered the choice of a traditional laboratory-based HIV test or a point of care HIV test. It is proposed that a point of care option will improve current practice by providing a more attractive testing option for high-risk groups:

- In the great majority of cases the point of care result will be negative and no laboratory testing would be required.
- In the rare case of a reactive point of care test result, a laboratory-based HIV test is required for confirmatory testing and diagnosis.

7) Expected health outcomes relating to the medical service

Identify the expected patient-relevant health outcomes if the service is recommended for public funding, including primary effectiveness (improvement in function, relief of pain) and secondary effectiveness (length of hospital stays, time to return to daily activities).

Primary Health Outcome

The primary health outcome is earlier diagnosis of HIV infection.

Early diagnosis of HIV leads to:

- Earlier treatment for the patient which improves length and quality of life
- A reduction in new HIV infections in the community because diagnosis of HIV infection reduces the chance of the infection being transmitted

It is likely that most patients with HIV infection will be diagnosed eventually. However, compared to early diagnosis, late diagnosis is associated with worse outcomes for the patient and increased likelihood of HIV transmission.

Preference for Rapid Testing Amongst High-Risk Patients

It is estimated that 20 to 30 per cent of Australians living with HIV have not been diagnosed and that up to 35 per cent of people living with HIV in Australia are diagnosed late (*Kirby Institute 2013 Annual Surveillance Report of HIV, viral hepatitis, STIs*).

In 2011, the Burnett Institute conducted a systematic review of community models of HIV testing for MSM. The review concluded that one of the key facilitators for MSM consumers to access testing was the provision of rapid testing (*Pedrana et. al. (2011). Community models of HIV testing for men who have sex with men (MSM): Systematic Review 2011*).

The PASH (Pleasure and Sexual Health) study in 2009 collected quantitative and qualitative data from mainly homosexual men in regard to a range of issues, including attitudes to HIV testing. The study concluded that the amount of time required for a HIV test (schedule an appointment with the doctor, attend blood collection centre and return for results) was the

main impediment accessing HIV tests. It was concluded that rapid HIV testing should be made available (*Prestage et. al. The PASH Study (2009). Monograph, National Centre in HIV Epidemiology and Clinical Research, Sydney Australia.*).

"I should get tested on a regular basis. However due to how busy I normally am, it is difficult to find time and make an appointment and organise" (Adelaide, 22, HIV status not known) – respondent in The PASH Study, 2009.

Lack of access to rapid HIV testing is not the only barrier to HIV testing. For example, another reason for high-risk groups not accessing HIV tests is the concern about the need to tell sexual partners if diagnosed with HIV. This reason had the greatest impact on the decision to get tested according to the MidSumma Testing Patterns Survey which was conducted in January 2010 to assess testing patterns and preferences for HIV tests among gay men (*Koelmeyer et. al. (2011)Motivations for and barriers to HIV testing in Australia, Australian Research Centre in Sex, Health and Society)*. Other major barriers to HIV testing identified by this survey were (i) having to return for test result, (ii) finding time to get tested, and (iii) worry that testing would become known to other people.

Prestage *et al.* conducted an online survey of 519 non-HIV-positive Australian gay men found that the most common reason for avoiding or delaying HIV testing was the belief that that they had not done anything risky (41.2%)(*Prestage et al. (2012) Barriers to HIV testing among Australian gay men. Sex Health*). However, the second most common reason (40.3%) was the need to return for a second clinic visit to receive results. Since this study was conducted some Australian sexual health clinics now offer negative HIV test results via SMS or telephone which in some cases removes the requirement for return clinic visits.

In other jurisdictions rapid HIV tests have been available for many years. Much of their use is in developing countries and therefore not informative for the Australian healthcare system. However, some studies have examined testing preferences in high-income countries where rapid testing is available. For example, Hoyos *et al*. surveyed clients attending a mobile rapid testing programme located on a central street in the gay district of Madrid, Spain. The survey found that according to the clients immediate results (84.8%) was the most important characteristic of HIV tests, much higher than other characteristics such as private testing (45.5%) or anonymous testing (48.7%) (*Hoyos et. al. (2013) Preferred HIV testing services and programme characteristics among clients of a rapid HIV testing programme. BMC Public Health*).

Overall, there are a number of structural and psychosocial reasons why high-risk groups do not access HIV testing and a comprehensive review of these reasons is beyond the scope of this Protocol. A common theme among studies looking at this issue is a preference for rapid tests compared to traditional laboratory-based testing. To access a laboratory-based HIV test up to three healthcare visits can be required: (i) an appointment with a GP where an HIV test is requested or recommended, (ii) a visit to a collection centre for a venous blood draw, and (iii) a return visit with the GP 2 – 8 days later to receive results. Although some aspects of this process have been somewhat simplified in recent years through initiatives such as co-location of GP clinics and pathology collection centres and the provision of negative test results by SMS or telephone in certain circumstances, there is an obvious appeal of rapid testing in terms of time and scheduling, where results can typically be provided on the spot.

An example of the potential impact of meeting the preference for rapid testing in high-risk populations is the study of Eu *et. al.* 2014 in a Melbourne GP clinic serving high-risk clients. Since it was introduced point of care HIV testing has been: well accepted, identified three

times as many new HIV infections due to increased testing and one in five patients completing a patient satisfaction questionnaire indicated that they would not have had an HIV test if the rapid, point of care test were not available.

It is proposed that the accessibility and acceptability of rapid point of care HIV testing will contribute to early diagnosis of HIV infection in high-risk patients.

Timing of Test Result Delivery

In the case of a negative point of care test, the result can be conveyed to the patient immediately removing the need for a follow-up appointment with their doctor to receive the test result.

This situation would apply in the great majority of cases and has the advantages of:

- Being preferred by some high-risk patient groups (see above)
- Eliminating the need for the patient to schedule an additional appointment to receive results saving the patient time, and the health system the expense

In the case of a reactive point of care test, a venous blood draw is performed and the sample sent for traditional laboratory analysis i.e. the timing of the final test result is the same as traditional laboratory testing.

Outcomes Following HIV Diagnosis

At the level of the individual, the clinical pathway following the diagnosis of HIV is expected to be the same whether diagnosis occurs through a reactive point of care HIV test followed by confirmatory laboratory testing or the diagnosis is made by traditional laboratory testing alone.

In both scenarios the patient would be counselled, additional testing performed e.g. CD4 count, contact tracing performed if appropriate and the patient entered into treatment. Once a diagnosis of HIV infection is made there would be no difference in the time taken to commence treatment and alter high-risk behaviour.

It is proposed that the availability of point of care testing will encourage high-risk patients to access an HIV test when such a test is indicated increasing the likelihood of an early diagnosis.

For the patient an early diagnosis leads to improved length and quality of life.

At the population level it is proposed that the availability of point of care testing would provide an additional avenue for HIV testing where indicated. This would result in increased testing where appropriate, a smaller number of the patients with undiagnosed HIV infection and a reduction in new HIV infections.

Describe any potential risks to the patient.

Potential risks are :

- The potential for false-negative results due to recent HIV infection is a potential safety concern.
- The potential for false-positive results leading to patient distress while confirmatory testing is performed

These risks should be included in the analysis of outcomes.

Specify the type of economic evaluation.

Cost-effectiveness analysis

8) Fee for the proposed medical service

Explain the type of funding proposed for this service.

Please indicate the direct cost of any equipment or resources that are used with the service relevant to this application, as appropriate.

The direct cost of the Determine HIV Combo in Australia is approximately $18.00 per test.

The other equipment or resources required to perform the test are consumables to perform the fingerstick blood sample collection (alcohol wipe, lancet, waste bin). The site performing the testing is also required to enrol in a quality assurance program (QAP) which costs approximately $400 – 500 annually. Finally, practitioners performing the testing must be trained in the use of the test which takes 1 to 1½ hours.

It is acknowledged that the Determine HIV Combo and other rapid HIV tests are available in other countries, particularly developing countries, at lower prices. However, high TGA registration fees (up to $84,200 + on-site audit fees every 5 years); the relatively low test volumes; and relatively higher import, staff, warehousing and distribution costs mean that comparable pricing is not feasible in Australia.

The stringent conditions imposed on the TGA registration of the Determine HIV Combo such as compiling training records, site declarations, site training, preparation of regulatory reports, etc. mean that supply of more product requires specialist regulatory resources and incurs additional regulatory expenses and larger testing volume does not necessarily generate economies of scale. Additional sites using the test will generate additional compliance, reporting, training and other support activities which must be covered by the direct cost of the test.

Provide details of the proposed fee.

The proposed fee is $30.00.

This covers the direct cost of the test plus the amount of time it takes the health professional to perform the test.

It is proposed that the item would be listed in Group P9 – Simple Basic Pathology Tests.

For any HIV test the treating doctor would typically provide pre-test counselling through a GP consultation, this consultation is not included in the proposed item listing and fee.

If an HIV test is indicted then the doctor would:

- order a laboratory HIV through established Medicare requesting pathways in which case standard pathology benefits would be paid, or
- conduct a rapid point of care HIV test in which case the proposed $30.00 fee would be paid. In the rare case (1-4%) of a reactive point of care HIV test result, confirmatory laboratory HIV testing would be requested through established Medicare pathways.

The proposed fee covers performing the Point of Care HIV test and interpreting the results. During the 20 min that the test develops the treating practitioner would typically conduct other activities, including potentially seeing other patients. This proposed cost is based on the out of pocket expense patients are currently being asked to pay in Australia when a point of care HIV test is performed privately. The proposed fee covers the direct cost of the test ($18.00 per test), the “hands-on” time required to perform and interpret the test (approximately 3 – 5 min), and the required enrolment in a point of care quality assurance

program (QAP) which costs $400 - $500 year (considering that a GP practice might perform 100 – 200 tests per year the requirement for QAP enrolment equates to $2 to $5 per test).

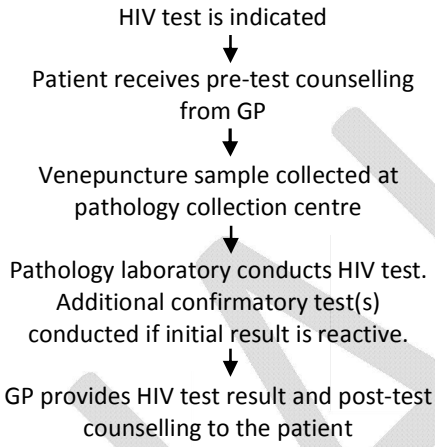
It is acknowledged that $30.00 is more than the $15.65 item fee (plus the PEI and other possible fees) that a laboratory-based HIV test attracts. However, the higher fee is considered justified because of the overall benefits of increased HIV testing in high-risk groups and earlier HIV diagnosis to the health system.

Also, negative point of care results (the great majority of results) can be delivered to patient in the initial consultation. This saves the expense to the health system of the patient returning for a follow-up consultation where the results are delivered.

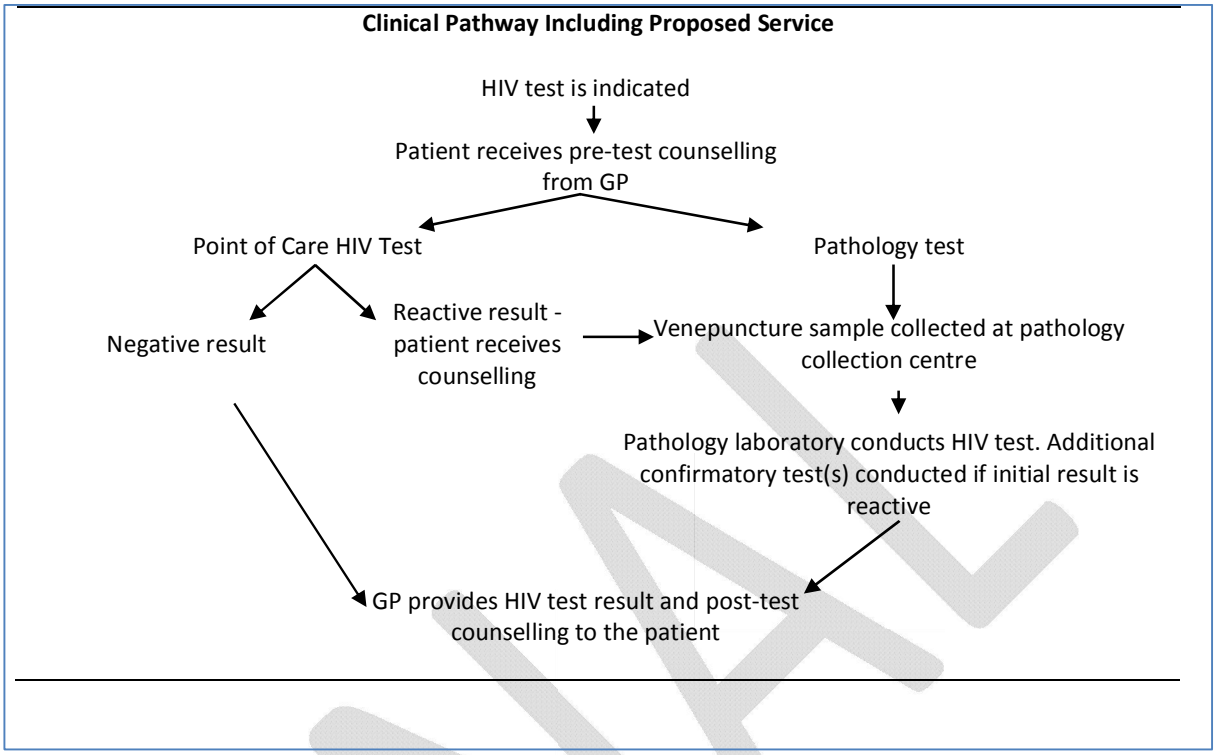
9) Clinical Management Algorithm - clinical place for the proposed intervention

Provide a clinical management algorithm (e.g.: flowchart) explaining the current approach (see (6) Comparator section) to management and any downstream services (aftercare) of the eligible population/s in the absence of public funding for the service proposed preferably with reference to existing clinical practice guidelines.

Current Clinical Pathway



Provide a clinical management algorithm (e.g.: flowchart) explaining the expected management and any downstream services (aftercare) of the eligible population/s if public funding is recommended for the service proposed.



10) Regulatory Information

Please provide details of the regulatory status. Noting that regulatory listing must be finalised before MSAC consideration.

The Alere Determine™ HIV-1/2 Ag/Ab Combo is registered by the TGA for point of care use (ARTG 203911).

Additional 4th generation, combined Antigen/Antibody HIV tests may be registered by the TGA for point of care use in due course.

11) Decision analytic

Provide a summary of the PICO as well as the health care resource of the comparison/s that will be assessed, define the research questions and inform the analysis of evidence for consideration by MSAC.

The key research question is:

In patients where an HIV test is indicated, is rapid point of care combined Antigen/Antibody HIV testing at least as cost-effective as laboratory-based HIV testing for the early diagnosis of HIV infection?

The PICO is summarised as follows:

Patients: High-risk patients where an HIV test is indicated.

Intervention: Rapid point of care combined Antigen/Antibody HIV test

Comparator: Laboratory-based HIV test

Outcomes: Early diagnosis of HIV infection

12) Healthcare resources

Provide a list of the health care resources whose utilisation is likely to be impacted should the proposed intervention be made available as requested whether the utilisation of the resource will be impacted due to differences in outcomes or due to availability of the proposed intervention itself.

A list of impacted healthcare resources is provided in Table 2.

13) Questions for public funding

Please list questions relating to the safety, effectiveness and cost-effectiveness of the service / intervention relevant to this application, for example:

- *Which health / medical professionals provide the service*
- *Are there training and qualification requirements*
- *Are there accreditation requirements*

The National HIV Testing Policy and the TGA registration conditions describe who can provide the service and the training/ qualification requirements.

Table 2: List of resources to be considered in the economic analysis

	Provider of resource	Setting in which resource is provided	Proportion of patients receiving resource	Number of units of resource per relevant time horizon per patient receiving resource	Disaggregated unit cost					
					MBS[a]	Safety nets*	Other government budget	Private health insurer	Patient	Total cost
Resources provided to identify eligible population – Patient where an HIV test is indicated										
Consultation with GP MBS23	GP	Consulting Room	100%	1	$37.05					$37.05
Resources provided to deliver proposed intervention – Point of care HIV Test										
Point of Care HIV Test	GP or Nurse	Consulting rooms	100%	1	$30.00					$30.00
Resources provided in association with proposed intervention – Confirmatory testing for reactive result										
Pathology laboratory HIV Test MBS69384	Pathology laboratory	Pathology laboratory	1 - 4%[b]	1	$15.65					$15.65
Additional pathology laboratory MBS Items[c]	Pathology laboratory	Pathology laboratory	1 - 4%[b]	1	$4.00 – $20.60					$4.00 – $20.60

Resources provided to deliver comparator 1 – Pathology laboratory HIV test										
Pathology laboratory HIV Test MBS69384	Pathology laboratory	Pathology laboratory	100%	1	$15.65					$15.65
Additional pathology laboratory MBS Items[c]	Pathology laboratory	Pathology laboratory	100%	1	$4.00 – $20.60					$4.00 – $21.00
Resources provided in association with comparator 1 – Follow up consultation with GP to deliver test results										
Consultation with GP for Test Results MBS23	GP	Consulting Room	-[d]	1	$37.05					$37.05

***** Include costs relating to both the standard and extended safety net

[a] As at January 2015

[b] A confirmatory pathology laboratory HIV test is required when the point of care HIV test is reactive. Proportion of patients requiring follow-up testing will depend on prevalence of HIV infection in the population using the service.

[c] Additional MBS benefits are applicable to a pathology laboratory HIV test depending on the circumstance in which it is delivered including: Patient Episode Initiation fees such as MBS73928, MBS73929; Management of Bulk-Billed Services fees such as MBS74990, MBS74991; and Bulk Billed Pathology Incentive Items such as MBS74995, MBS74999.

[d] The National HIV Testing Policy dictates that clinical judgement should be used to deliver negative test-results (e.g. in person, by phone, etc.) and that positive results should always be provided in person