MaHTAS
Malaysian Health Technology Assessment Section

RAPID BLOOD TEST DEVICE FOR HIV, HBV, HCV, & SYPHILIS
Executive Summary
[Adapted from the report by NOORMAH MOHD DARUS]

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Introduction
In many developing areas worldwide, field and clinic laboratory capabilities may be insufficient for the detection of infectious agents for definitive clinical diagnostic purposes. The absence of simple, rapid diagnostic testing methods for sexually transmitted diseases (STDs) and hepatitis has significantly hampered public health efforts to retard the spread of these diseases. The inability to provide tests for quick recognition of human immunodeficiency virus (HIV), hepatitis B, and syphilis has allowed infected individuals to unknowingly spread the disease through sexual contacts, blood donations, and intravenous needle sharing.1 In cities throughout Asia, current laboratory evaluation of blood specimens may preclude case follow-up and counseling due to a long time lag between initial sample collection and conventional test completion. High-risk populations typically seek treatment during clinic visits in association with acute episodes and are not likely to return a second time for test results. Diagnostic technology is adapting itself for application in developing countries. Advancements in the laboratory diagnosis of HIV/acquired immunodeficiency syndrome (AIDS), hepatitis B, and syphilis have considered the following conditions, including: 1) speed of results; 2) test validity and accuracy; 3) minimal specimen requirement; 4) variable type of specimen, including whole blood; 5) ease of test kit use, with few requirements for specialized laboratory equipment; and 6) stable reagents, requiring no refrigeration.

Diagnostic test kits can be easily used in small, rural laboratories for serologic screening of high-risk clients. However, all such devices should be initially evaluated by professional laboratory staffs that are experienced in the field of human immunodeficiency virus (HIV), hepatitis B (HBV), hepatitis C (HCV), and syphilis screening and diagnosis. Once an on-site or near-patient testing device is evaluated and reviewed in a controlled laboratory setting, a cost–benefit analysis should be performed to determine whether the use of that device is cost-effective, taking into account both staff time and consumables. Adequate training must be given to all those wishing to use the on-site or near-patient testing device in those areas that cannot be adequately controlled by laboratory testing. Such training must ensure that operators fully understand the method and its limitations and they are responsible for any errors that may arise in interpretation of results. Any on-site or near-patient testing device should also undergo a rigorous evaluation to determine its suitability or whether it is “fit for purpose” before it can be marketed.

This review was requested by YBhg. Datuk Dr. Jeyaindran Tan Sri Sinnadurai, Deputy Director General of Health (Medical) to assess the effectiveness, safety and cost effectiveness of this device (BPC Labmen 4 in 1 RDT), following a request by MK Tron Sdn Bhd. to supply this technology to the Ministry of Health facilities in Malaysia.

Objective/Aim
The objective of this systematic review was to assess the effectiveness, safety and cost effectiveness of the rapid blood test device (BPC Labmen 4 in 1 RDT) for HIV, HBV, HCV, & Syphilis for the rapid diagnosis of human immunodeficiency virus (HIV), hepatitis B (HBV), hepatitis C (HCV), and syphilis.

Results and Conclusions
There was no retrievable scientific evidence or clinical studies to support the efficacy / effectiveness, safety and cost effectiveness of this rapid blood test device (BPC Labmen 4 in 1 RDT) for HIV, HBV, HCV, & Syphilis for the rapid diagnosis of human immunodeficiency virus (HIV), hepatitis B (HBV), hepatitis C (HCV), and syphilis

Methods
Electronic databases were searched through the Ovid interface: Ovid MEDLINE® In-process and other Non-indexed citations and Ovid MEDLINE® 1948 to present, EBM Reviews - Cochrane Central Register of Controlled Trials – August 2014, EBM Reviews - Cochrane Database of Systematic Reviews - 2009 to September 2014, EBM Reviews - Health Technology Assessment – 2nd Quarter 2014, EBM Reviews - Database of Abstracts of Reviews of Effects – 2nd Quarter 2014, EBM Reviews – NHS Economic Evaluation Database 2nd Quarter 2014, Embase – 1988 to 2014 week 35. Searches were also run in PubMed. Google was used to search for additional web-based materials and information. No limits were applied. Additional articles were identified from reviewing the references of

retrieved articles. Last search was conducted on 29th September 2014.