Rapid Diagnostic Test Kits

Medical diagnostic tests that are quick and easy to perform. Suitable for preliminary or emergency medical screening and for use in medical facilities with limited resources

Description (test device)

Malaria version

Malaria P. F/PV qualitative detection of Plasmodium falciparum and P.vivax

Malaria P. F/Pan qualitative detection of Plasmodium falciparum, P. vivax, P. ovale and P. malariae

Dengue combo detects

for NSI (protein produced in viral replication) and serological makers for IgM and IgG

Tuberculosis

qualitative detection of anti-TB antibodies (Isotypes IgG, IgM and IgA)

Combo HIV, Syphilis, HBsAg, HCV

qualitative detection of the HIV 1/2 antibody, Anti HCV, HBsAg and Syphilis Antibodies & Combination, other kits on request.

Principle:

The principle of assay is based on lateral flow technology of the sample.

General schematic of the assays for each test.

Malaria P.F/PV and Malaria P.F/Pan

The Malaria P.f./P.v. Rapid Test Cassette (Whole Blood) is a qualitative, membrane based immunoassay for the detection of P.f.and P.v. antigens in Whole Blood. The membrane is precoated with anti-HRP-II antibodies and anti-pLDH antibodies. During testing, the whole blood specimen reacts with the dye conjugate, which has been pre-coated on the test cassette. The mixture then migrates upward on the membrane by capillary action, reacts with anti-Histidine-Rich Protein II (HRP-II) antibodies on the membrane on P.f. Test Line region and with anti-pLDH antibodies on the membrane on P.v. Line region. If the specimen contains HRP-II or Plasmodium-specific P. vivax LDH or both, a coloured line will appear in P.f. line region or P.v. line region or two colored lines will appear in P.f. line region and P.v. line region. The absence of the coloured lines in P.f. line region or P.v. line region indicates that the specimen does not contain HRP-II and/or Plasmodium-specific P. vivax LDH. To serve as a procedure control, a coloured line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

Illustrations
As shown in illustration above, the specimen (A) migrates via capillary action along the membrane to react with the coloured conjugate (B). HRP-II or Plasmodium-specific pLDH or both present in the specimen bind to the conjugate, forming a coloured antibody-antigen complex. The anti-Histidine-Rich Protein II (HRP-II) antibodies and anti-pLDH antibodies immobilized in the test zone of the membrane captures the complex (C and/or D). The formation of a visible coloured line in the test region indicates a positive result (C and/or D). The absence of a coloured line in the test zones (C and D) suggests a negative result. In the control zone of the membrane, immobilized reagents capture coloured conjugate regardless of test specimen composition. The resulting visible red line (E) confirms that the assay is functioning correctly.

Dengue IgG/IgM

The Dengue IgG/IgM Rapid Test (Whole Blood/Serum/Plasma) is a qualitative membrane-based immunoassay for the detection of Dengue antibodies in whole blood, serum, or plasma. This test consists of two components, an IgG component and an IgM component. In the IgG component, anti-human IgG is coated in IgG test line region. During testing, the specimen reacts with Dengue antigen-coated particles in the test cassette. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with the anti-human IgG in IgG test line region. If the specimen contains IgG antibodies to Dengue, a coloured line will appear in IgG test line region. In the IgM component, anti-human IgM is coated in IgM test line region. During testing, the specimen reacts with anti-human IgM. Dengue IgM antibodies, if present in the specimen reacts with the anti-human IgM and the Dengue antigen-coated particles in the test cassette, and this complex is captured by the anti-human IgM, forming a coloured line in IgM test line region. Therefore, if the specimen contains Dengue IgG antibodies, a coloured line will appear in IgG test line region. If the specimen contains Dengue IgM antibodies, a coloured line will appear in IgM test line region. If the specimen does not contain Dengue antibodies, no coloured line will appear in either of the test line regions, indicating a negative result. To serve as a procedural control, a coloured line will always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

Dengue NS1

The Dengue NS1 Rapid Test (Whole Blood/Serum/Plasma) is a qualitative membrane-based immunoassay for the detection of Dengue NS1 antigen in whole blood, serum, or plasma. During testing, the specimen reacts with Dengue antibody-conjugate in the test cassette. The Gold antibody conjugate will bind to Dengue antigen in the specimen sample which in turn will bind with Anti-Dengue NS1 coated on the membrane. As the reagent moves across the membrane, the Dengue NS1 antibody on the membrane will bind the antibody-antigen complex.
causing pale or dark pink line to form at the test line region of the test membrane. The intensity of the lines will vary depending upon the amount of antigen present in the sample. The appearance of pink line in the test region should be considered as positive result.

**Illustration**

![Illustration](image)

**Figure 1: Test Principle for Dengue IgG/IgM**

**Dengue IgG/IgM**

As shown in illustration above, the specimen (A) migrates via capillary action along the membrane to react with the gold conjugate (B). Dengue IgG or/and IgM present in the specimen binds to the conjugate, forming a coloured antibody-Dengue antigen complex. The mouse antihuman IgM and mouse anti-human IgG immobilized in the test zone of the membrane captures the test.

**Tuberculosis**

The Tuberculosis Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative membrane-based immunoassay for the detection of anti-TB antibody in whole blood, serum, or plasma. During testing, the specimen reacts with Tuberculosis antigen-conjugate in the test cassette. The Gold antigen conjugate will bind to anti-TB antibody in the specimen sample which in turn will bind with Tuberculosis antigen coated on the membrane. As the reagent moves across the membrane, the Tuberculosis antigen on the membrane will bind the antibody-antigen complex causing pale or dark pink line to form at the test line region of the test membrane. The intensity of the lines will vary depending upon the amount of antigen present in the sample. The appearance of pink line in the test region should be considered as positive result.

**Illustration**

![Illustration](image)
**Figure 1: Test Principle**

The Tuberculosis Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative membrane-based immunoassay for the detection of anti-TB antibody in whole blood, serum, or plasma. During testing, the specimen reacts with Tuberculosis antigen-conjugate in the test cassette. The Gold antigen conjugate will bind to anti-TB antibody in the specimen sample which in turn will bind with Tuberculosis antigen coated on the membrane. As the reagent moves across the membrane, the Tuberculosis antigen on the membrane will bind the antibody-antigen complex causing pale or dark pink line to form at the test line region of the test membrane. The intensity of the lines will vary depending upon the amount of antigen present in the sample. The appearance of pink line in the test region should be considered as positive result. common way to determine whether an individual has been exposed to HIV and to screen blood and blood products for HIV. Despite the differences in their biological characteristics, serological activities and genome sequences, HIV 1 and HIV 2 show strong antigenic cross-reactivity. Most HIV 2 positive sera can be identified by using HIV 1 based serological tests.

**The HBsAg Rapid Test (Serum /Plasma)** is a rapid test to qualitatively detect the presence of HBsAg in serum or plasma specimen. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of HBsAg in serum or plasma. Viral hepatitis is a systemic disease primarily involving the liver. Most cases of acute viral hepatitis are caused by Hepatitis A virus, Hepatitis B virus (HBV) or Hepatitis C virus. The complex antigen found on the surface of HBV is called HBsAg. Previous designations included the Australia or Au antigen.1 The presence of HBsAg in serum or plasma is an indication of an active Hepatitis B infection, either acute or chronic. In a typical Hepatitis B infection, HBsAg will be detected 2 to 4 weeks before the ALT level becomes abnormal and 3 to 5 weeks before symptoms or jaundice develop. HBsAg has four principal subtypes: adw, ayw, adr and ayr. Because of antigenic heterogeneity of the determinant, there are 10 major serotypes of Hepatitis B virus.

**The HCV Rapid Test (Serum /Plasma)** is a rapid test to qualitatively detect the presence of antibody to HCV in a serum or plasma specimen. The test utilizes colloid gold conjugate and recombinant HCV proteins to selectively detect antibody to HCV in serum or plasma. The recombinant HCV proteins used in the test kit are encoded by the genes for both structural (nucleocapsid) and non-structural proteins. Hepatitis C Virus (HCV) is a small, enveloped, positive-sense, single-stranded RNA Virus. HCV is now known to be the major cause of parenterally transmitted non-A, non-B hepatitis. Antibody to HCV is found in over 80% of patients with well-documented non-A, non-B hepatitis. Conventional methods fail to isolate the virus in cell culture or visualize it by electron microscope. Cloning the viral genome has made it possible to develop serologic assays that use recombinant antigens. Compared to the first-generation HCV EIAs using single recombinant antigen, multiple antigens using recombinant protein and/or synthetic peptides have been added in new serologic tests to avoid nonspecific cross-reactivity and to increase the sensitivity of the HCV antibody tests.

**The HIV 1 and 2 Rapid Test (Serum /Plasma)** is a rapid test to qualitatively detect the presence of antibody to HIV 1 and/or HIV 2 in whole blood, serum or plasma specimen. The test utilizes latex conjugate and multiple recombinant HIV proteins to selectively detect antibodies to the HIV 1.2 in serum or plasma. HIV is the etiologic agent of Acquired Immune Deficiency Syndrome (AIDS). The virion is surrounded by a lipid envelope that is derived from host cell membrane. Several viral glycoproteins are on the envelope. Each virus contains two copies of positive-sense genomic RNAs. HIV 1 has been isolated from patients with AIDS and AIDS-
related complex, and from healthy people with high potential risk for developing AIDS. HIV 2 has been isolated from West African AIDS patients and from seropositive asymptomatic individuals. Both HIV 1 and HIV 2 elicit immune response. Detection of HIV antibodies in serum, plasma is the most efficient and

**The Syphilis Rapid Test (Serum /Plasma)** utilizes a double antigen combination of a Syphilis antigen coated particle and Syphilis antigen immobilized on membrane to detect TP antibodies (IgG and IgM) qualitatively and selectively in serum or plasma. *Treponema Pallidum (TP)* is the causative agent of the venereal disease Syphilis. TP is a spirochete bacterium with an outer envelope and a cytoplasmic membrane. Relatively little is known about the organism in comparison with other bacterial pathogens. According to the Centre for Disease Control (CDC), the number of cases of Syphilis infection has markedly increased since 1985. Some key factors that have contributed to this rise include the crack cocaine epidemic and the high incidence of prostitution among drug users. One study reported a substantial epidemiological correlation between the acquisition and transmission of the HIV virus and Syphilis

**Illustrations**

Multiple clinical stages and long periods of latent, asymptomatic infection are characteristic of Syphilis. Primary Syphilis is defined by the presence of a chancre at the site of inoculation. The antibodies response to the TP bacterium can be detected within 4 to 7 days after the chancre appears. The infection remains detectable until the patient receives adequate treatment.

![Illustration of Test Principle](image)

**Figure 1: Test Principle**

**HBsAg**

As shown in illustration above, the specimen (A) migrates via capillary action along the membrane to react with the coloured conjugate (B). HBsAg present in the specimen binds to the conjugate, forming a coloured antibody-antigen complex. The goat anti-HBsAg in the test zone of the membrane captures the test region (C). The formation of a visible coloured line in the test region indicates a positive result (C). The absence of a coloured line in the test zones suggests a negative result. In the control zone of the membrane, immobilized reagents capture coloured conjugate regardless of test specimen composition. The resulting visible coloured band (D) confirms control line.

**Anti HCV**

As shown in illustration above, the specimen (A) migrates via capillary action along the membrane to react with the coloured conjugate (B). HCV antibody present in the specimen binds to the conjugate, forming a coloured antibody-antigen complex. The HCV recombine
antigen in the test zone of the membrane captures the test region (C). The formation of a visible coloured line in the test region indicates a positive result (C). The absence of a coloured line in the test zones suggests a negative result. In the control zone of the membrane, immobilized reagents capture coloured conjugate regardless of test specimen composition. The resulting visible coloured band (D) confirms control line.

**HIV 1 and 2**

As shown in illustration above, the specimen (A) migrates via capillary action along the membrane to react with the coloured conjugate (B). HIV 1.2 antibody present in the specimen binds to the conjugate, forming a coloured antibody-antigen complex. The HIV type 1 antigen and type 2 antigen in the test zone of the membrane captures the test region (C). The formation of a visible coloured line in the test region indicates a positive result (C). The absence of a coloured line in the test zones suggests a negative result. In the control zone of the membrane, immobilized reagents capture coloured conjugate regardless of test specimen composition. The resulting visible coloured band (D) confirms control line.

**Syphilis**

As shown in illustration above, the specimen (A) migrates via capillary action along the membrane to react with the coloured conjugate (B). Syphilis antibody present in the specimen binds to the conjugate, forming a coloured antibody-antigen complex. The Syphilis recombine antigen in the test zone of the membrane captures the test region (C). The formation of a visible coloured line in the test region indicates a positive result (C). The absence of a coloured line in the test zones suggests a negative result. In the control zone of the membrane, immobilized reagents capture coloured conjugate regardless of test specimen composition. The resulting visible coloured band (D) confirms control line.