Abbott

A NEW LEVEL OF SENSITIVITY

DETERMINE™ HBsAg 2

Rapid, Accurate Hepatitis B Virus (HBV) Screening in Many Healthcare Settings

LEAVE NO PATIENTS BEHIND

Determine™ HBsAg 2, with an analytical sensitivity of just 0.1 IU/mL, is a **highly sensitive**, **easy-to-use** rapid lateral flow test

Enables accurate identification of HBsAg-positive patients with results in **just 15 minutes**

Detects major HBsAg **vaccine escape mutants**

Ideal for use in a **wide variety** of healthcare settings

EVERY

40

SECONDS

one person in the world dies from consequences of **hepatitis B**.[1]

These deaths could be prevented with vaccination and protective measures.

In high HBV prevalence areas, the WHO recommends that all adults have routine access to and be offered HBsAg serological testing with linkage to prevention, care and treatment services.[2]

Here are some concrete actions to take once these populations are screened:

Prevent HBV infection by identifying persons suitable for **vaccination**.

Prevent HBV **transmission** by identifying and educating all infected people.

Prevent health **deterioration** by providing recommendations on food and medicines for infected people to avoid.

Provide **treatment** to patients who need it.

FROM THE FEBRUARY 2017 GUIDELINES ON HEPATITIS B AND C TESTING, AS WRITTEN BY THE WORLD HEALTH ORGANIZATION (WHO)

WHO TO TEST FOR CHRONIC HBV INFECTION

TESTING APPROACH AND POPULATION	RECOMMENDATIONS*
General population testing	1. In settings with a ≥2% or ≥5%[1] HBsAg seroprevalence in the general population, it is recommended that all adults have routine access to and be offered HBsAg serological testing with linkage to prevention, care and treatment services. General population testing approaches should make use of existing community- or health facility-based testing opportunities or programmes such as at antenatal clinics, HIV or TB clinics. *Conditional recommendation, low quality of evidence*
Routine testing in pregnant women	2. In settings with a ≥2% or ≥5%[1] HBsAg seroprevalence in the general population, it is recommended that HBsAg serological testing be routinely offered to all pregnant women in antenatal clinics[2], with linkage to prevention, care and treatment services. Couples and partners in antenatal care settings should be offered HBV testing services. *Strong recommendation, low quality of evidence*
Focused testing in most affected populations	3. In all settings (and regardless of whether delivered through facility- or community-based testing), it is recommended that HBsAg serological testing and linkage to care and treatment services be offered to the following individuals: • **Adults and adolescents from populations most affected by HBV infection[3]** (i.e. who are either part of a population with high HBV seroprevalence or who have a history of exposures and/or high-risk behaviours for HBV infection); • **Adults, adolescents and children with a clinical suspicion of chronic viral hepatitis[4]** (i.e. symptoms, signs, laboratory markers); • **Sexual partners, children and other family members, and close household contacts** of those with HBV infection[5]; • **Health-care workers:** in all settings, it is recommended that HBsAg serological testing be offered and hepatitis B vaccination given to all health-care workers who have not been vaccinated previously *(Adapted from existing guidance on Hepatitis B vaccination[6])* *Strong recommendation, low quality of evidence*
Blood donors *Adapted from existing 2010 WHO guidance (Screening donated blood for transfusion transmissible infections[7])*	4. In all settings, screening of blood donors should be mandatory with linkage to care, counselling and treatment for those who test positive.

Abbreviations: HBsAg: Hepatitis B surface antigen; PWID: People who inject drugs; MSM: Men who have sex with men

*The GRADE system (Grading of Recommendations, Assessment, Development and Evaluation) was used to categorise the strength of recommendations as strong or conditional (based on consideration of the quality of evidence, balance of benefits and harms, acceptability, resource use and programmatic feasibility) and the quality of evidence as high, moderate, low or very low.

1. A threshold of ≥2% or ≥5% seroprevalence was based on several published thresholds of intermediate or high seroprevalence. The threshold used will depend on other country considerations and epidemiological context.
2. Many countries have chosen to adopt routine testing in all pregnant women, regardless of seroprevalence in the general population, and particularly where seroprevalence ≥2%. A full vaccination schedule including birth dose should be completed in all infants, in accordance with WHO position paper on Hepatitis B vaccines 2009.[6]
3. Includes those who are either part of a population with higher seroprevalence (e.g. some mobile/migrant populations from high/intermediate endemic countries, and certain indigenous populations) or who have a history of exposures or high-risk behaviours for HBV infection (e.g. PWID, people in prisons and other closed settings, MSM and sex workers, HIV-infected persons, partners, family members and children of HBV infected persons).
4. Features that may indicate underlying chronic HBV infection include clinical evidence of existing liver disease, such as cirrhosis or hepatocellular carcinoma (HCC), or where there is unexplained liver disease, including abnormal liver function tests or liver ultrasound.
5. In all settings, it is recommended that HBsAg serological testing with hepatitis B vaccination of those who are HBsAg negative and not previously vaccinated be offered to all children with parents or siblings diagnosed with HBV infection or with clinical suspicion of hepatitis, through community- or facility-based testing.
6. WHO position paper. Hepatitis B vaccines. Weekly epidemiological record. 2009;4 (84):405–20.
7. Screening donated blood for transfusion transmissible infections. Geneva: World Health Organization; 2010

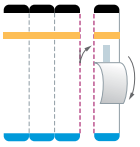
Original Source:
World Health Organization. Guidelines on Hepatitis B and C Testing February 2017. https://apps.who.int/iris/bitstream/handle/10665/254621/9789241549981-eng.pdf;jsessionid=36D2C766E7471A095B4CC9D485E5F601?sequence=1. Updated 2017. Accessed March 2020.

Please note that the Determine™ HBsAg 2 should not be used for screening of donated blood.

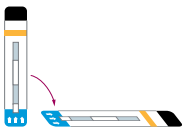
DETERMINE™ HBSAG 2 IS SIMPLE TO USE AND FACILITATES RAPID AND ACCURATE HEPATITIS B DIAGNOSIS IN MANY HEALTHCARE SETTINGS

SIMPLE PROCEDURE

1 **Prepare Test**
Tear one strip from the right and remove cover.

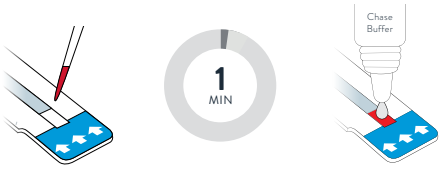


2 **Place Strip**
Place one strip on a flat surface where the test is to be performed.



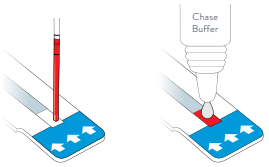
3 **Add Sample**

Venipuncture Whole Blood
Add 50 µL of whole blood (precision pipette) to the middle of the sample pad. Wait 1 minute and add one drop of chase buffer.



Fingerstick Whole Blood
Add 50 µL of whole blood to the sample pad. When all the blood is transferred from the capillary tube to the middle of the sample pad, immediately apply one drop of chase buffer to the sample pad.

Caution
Do not lift the capillary tube from the sample pad before all the blood has been transferred.



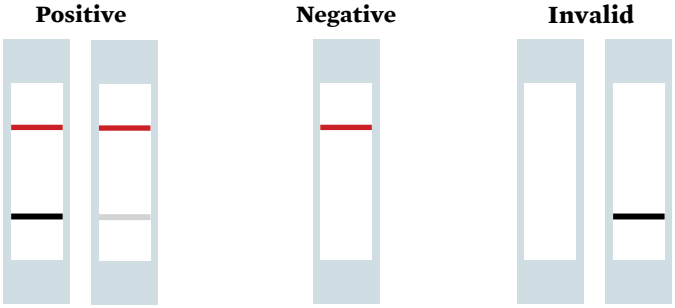
Serum or Plasma
Add 50 µL of serum or plasma (precision pipette) to the sample pad.

4 **Read Results**
Read the test result between 15 and 30 minutes after the addition of the sample.
Do not read the test result after 30 minutes.
The control line should appear for all results.
If it does not appear, the results are invalid and should be repeated.

Control

Patient

Interpret any visible bar (even very faint) in the window as a valid result.



ORDER INFORMATION

PRODUCT NAME	PRODUCT CODE
Determine™ HBsAg 2 (20 Tests, CE)	7D2946
Determine™ HBsAg 2 (100 Tests, CE)	7D2947
Determine™ HBsAg 2 (20 Tests, Non-CE)	7D2942
Determine™ HBsAg 2 (100 Tests, Non-CE)	7D2943
Determine™ HBsAg 2 SET (Non-CE) Includes 100 Tests, Chase Buffer, 100 EDTA Capillaries, 100 Sterilized Blood Lancets	7D2943SET
Chase Buffer (2.5 mL, 100 Tests)	7D2243
EDTA Capillaries (100 Tests, CE)	7D2227
EDTA Capillaries (100 Tests, Non-CE)	7D2222

PRODUCT SPECIFICATIONS

Method	Lateral Flow
Sensitivity	Analytical Sensitivity of 0.1 IU/mL
Specificity	99.6 %
Time to Result	15 Minutes
Storage Conditions	2°C–30°C
Test Conditions	18°C–40°C
Sample Volume	50 µL
Test Shelf Life	18 Months
Sample Types	Serum/Plasma, Fingerstick Whole Blood and Venipuncture Whole Blood

1. WHO Hepatitis B Key Facts July 18 2019. https://www.who.int/news-room/fact-sheets/detail/hepatitis-b.

2. WHO Guidelines on Hepatitis B and C Testing, Feb 2017. https://apps.who.int/iris/bitstream/handle/10665/254621/9789241549981-eng.pdf;jsessionid=36D2C766E7471A095B4CC9D485E5F601?sequence=1.

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