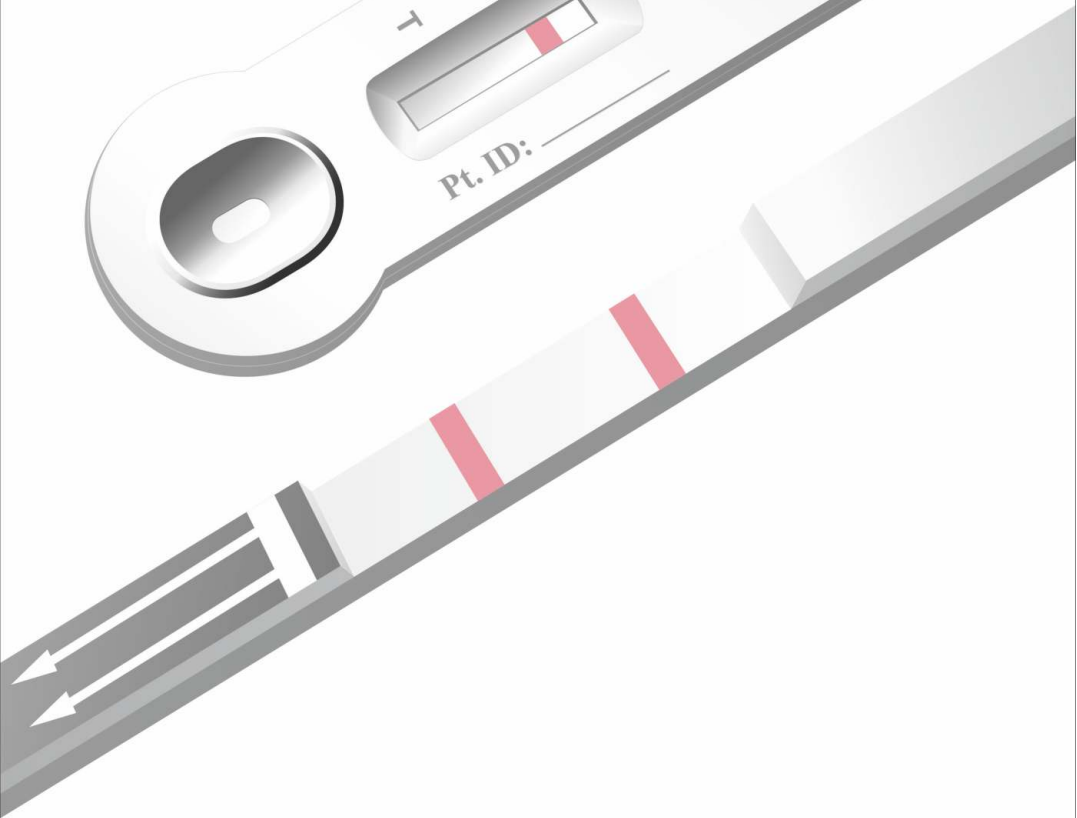
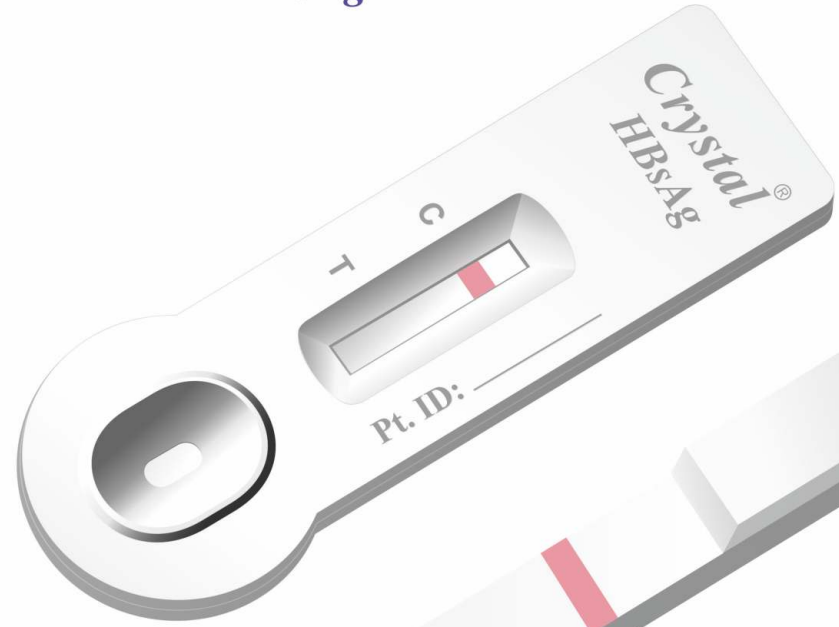




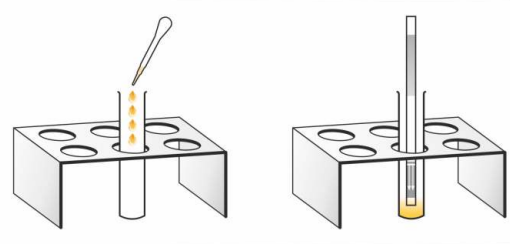
# Crystal<sup>®</sup> HBsAg



Rapid  
immunochromatographic test for qualitative  
detection of HBsAg with enhanced **Sensitivity** and **Specificity**

## Test Procedure

### For Dipstick



Add 4 drops (200 µL) of sample into the test tube

Place the Test Dipstick vertically into the test tube

### For Device



Add 2 drops (100 µL) of sample into the sample well

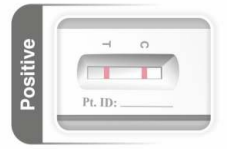
Read the results after 15 minutes.

## Interpretation of Results

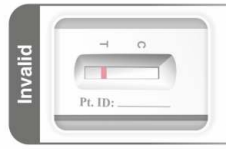
Note: Results should not be read beyond 30 minutes



One band at C



Two bands at T & C



Band only at T




No band

## Ordering Information

Product	Code No.	Pack Size
Crystal <sup>®</sup> HBsAg (Device)	52IC102-25	25 Tests
	52IC102-50	50 Tests
Crystal <sup>®</sup> HBsAg (Dipstick)	52IC101-50	50 Tests



THE MANUFACTURING SITE'S QMS IS CERTIFIED FOR  
ISO 13485:2003, ISO 9001:2008

 **arkray healthcare Pvt. Ltd.**  
(Comprises of former IVD business undertaking of Span Diagnostics Ltd.)  
Plot No. 336, 338, 340, Road No. 3, G.I.D.C., Sachin - 394 230, (Surat), INDIA.  
Telephone: 0261-239 7712 to 15, Facsimile: 0261-239 7719, Website: www.arkray.co.in  
Specifications may change without prior notice

0815 / ver. 1.0

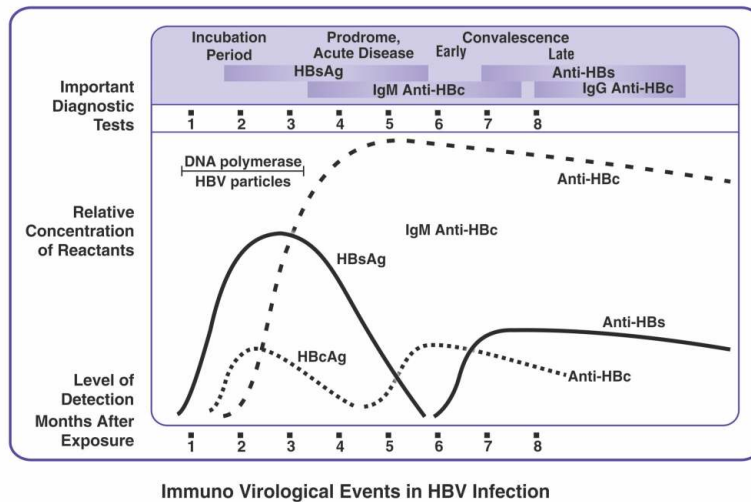
## Fact File

Three quarters of the world's population live in areas where there are high prevalence of HBV infection.

It is estimated that about 2 billion people worldwide have been infected with Hepatitis B virus (HBV) and 360 million are chronically infected.

6,00,000 individuals die every year from HBV associated liver cirrhosis or hepatocellular carcinoma.

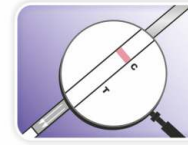
## Diagnosis



HBsAg is heterogeneous antigenically, with a common antigen designated 'a', and two pairs of mutually exclusive antigens, 'd' & 'y' and 'w' & 'r', resulting in 4 major subtypes: adw, ayw, adr & ayr.

HBsAg is the most commonly used marker of infection for diagnosis and blood screening. An individual positive for HBsAg is considered to be infected with HBV and is therefore potentially infectious.

## Salient Features



Visual qualitative immunoassay with inbuilt control band to validate successful completion of assay procedure.



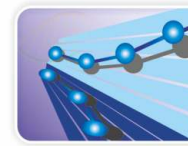
Nitrocellulose membrane with optimum porosity enables smooth and fast migration of sample, gives fast results with unmatched accuracy.



Non instrumental, simple, convenient and rapid assay procedure of 15 minutes. Suitable for field use.



Detects all 4 subtypes & 11 serotypes of HBsAg (ad & ay) including mutant strains ensures high sensitivity & specificity.



Combination of polyclonal capture antibodies and highly specific monoclonal antibodies. No cross reactivity with HAV & HCV.

## Approval & Performance\*

### DGHS

Approved by Directorate General of Health Services for use in Blood Banks

### Sensitivity

Analytical Sensitivity 0.5 PEU / mL of HBsAg

\*Data on Arkray file