

FACT SHEET

DETERMINE™ HBsAg 2 (FOR CE PRODUCTS)

PRODUCT DESCRIPTION

Determine™ HBsAg 2 is an *in vitro*, visually read, qualitative immunoassay for the detection of Hepatitis B Surface Antigen (HBsAg) in human serum, plasma or whole blood. The test is intended as an aid to detect HBsAg from infected individuals. The test is for professional use only.

PRODUCT CODES

- 7D2946: Determine™ HBsAg 2 (20 Tests, CE)
- 7D2947: Determine™ HBsAg 2 (100 Tests, CE)
- 7D2243: Chase Buffer (2.5 mL, 100 Tests)
- 7D2227: EDTA Capillaries (100 Tests, CE)

KIT CONTENTS

Determine™ HBsAg 2 Test Cards:
2 or 10 cards (containing 10 tests/card),
sufficient to perform 20 tests or 100 tests

ACCESSORIES
For testing Whole Blood Samples:

- Chase Buffer 1 bottle (2.5 mL) containing phosphate buffered saline, preservative and antimicrobial agent.

For testing Whole Blood Samples

(fingerstick assay):

- Lancet
- EDTA capillary tube

Materials required but not provided:

- Disposable gloves
- Timing device
- Micropipette capable of delivering 50 µL (not required for fingerstick method)
- Alcohol swab, gauze pad

SPECIMEN TYPE

Human serum, plasma or whole blood

PERFORMANCE

- Analytical sensitivity of 0.1 IU/mL (WHO International Standard for HBsAg, NIBSC code 12/226) or 0.19ng/mL (calculated based on WHO/BS/03.1987)
- Sensitivity: 98.4% (96.7-99.4%)
- Specificity: 99.6% (99.1-99.8%)

RUNNING TIME FOR TEST RESULT INTERPRETATION

15-30 minutes

QUALITY CONTROL

To ensure assay validity, a procedural control system is incorporated in the device. A red control bar will appear in the window. If the control bar does not appear by assay completion, the test result is invalid. Repeat the test using a new test strip.

PACKING INFORMATION
100 tests per kit (pouch)

- Dimensions: 272 x 160 x 20 mm
- Volume: 800 cm³
- Weight: 150 g

20 tests per kit (pouch)

- Dimensions: 272 x 160 x 9 mm
- Volume: 360 cm³
- Weight: 66 g

SHIPPING CARTON
100 tests per kit, 50 kits per carton

- Dimensions: 460 x 340 x 270 mm
- Volume: 42,228 cm³
- Weight: 8,800 g

20 tests per kit, 90 kits per carton

- Dimensions: 460 x 340 x 270 mm
- Volume: 42,228 cm³
- Weight: 7,280 g

STORAGE CONDITIONS

- Storage temperature : 2-30 °C
- Store serum and plasma specimens at 2-8 °C and run the test within 7 days of collection. If testing is delayed more than 7 days, the specimens should be frozen (-20 °C or colder).
- Avoid repeated freeze/thaw cycles.
- For whole blood collected by venipuncture, store at 2-8 °C. Do not freeze whole blood specimens. Run the test within 2 days (48 hours) of collection.
- For whole blood collected by fingerstick, test immediately.

SHELF LIFE

18 months

