

ADVANCED QUALITY™ ONE STEP HBsAg TEST
 (Whole Blood/Serum/Plasma)

FOR IN VITRO DIAGNOSTIC USE ONLY

INTENDED USE

THE ADVANCED QUALITY™ ONE STEP HBSAG TEST IS A RAPID, IMMUNOCHROMATOGRAPHIC ASSAY FOR THE QUALITATIVE DETECTION OF HEPATITIS B SURFACE ANTIGEN (HBSAG) IN HUMAN WHOLE BLOOD, SERUM OR PLASMA. THE PRESENCE OF HBSAG CAN BE DETECTED WITHIN 10 MINUTES AT THE CONCENTRATION OF 5NG/ML OR HIGHER, AND 15 MINUTES AT 1NG/ML. THE TEST IS INTENDED FOR HEALTHCARE PROFESSIONAL USE.

SUMMARY AND EXPANATION OF THE TEST

The Advanced Quality One Step HBsAg Test is a colloidal gold enhanced immunoassay for the determination of HBV surface antigen (HBsAg) in human whole blood, serum, or plasma. Goat anti-HBsAg antibody is immobilized in the test region on nitrocellulose membrane. During the assay specimen is allowed to react with the colored conjugate (antibody-colloidal gold conjugate); the mixture then migrates chromatographically on the membrane by the capillary action. An HBsAg positive specimen produces a distinct color band in the test region, formed by the specific antibody-HBsAg-colored conjugate complex. Absence of this colored band in the test region suggests a negative result. A colored band always appears in the control region serving as procedural control regardless of the test result.

MATERIALS PROVIDED

Each Kit Contains:

- Test cards individually foil pouched with a desiccant.
- plastic dropper
- safety lancet
- alcohol swab
- Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED:

- Positive and negative controls

STORAGE CONDITIONS

The test kits must be stored at 2-30°C in the sealed pouch and under dry conditions.

WARNINGS AND PRECAUTIONS

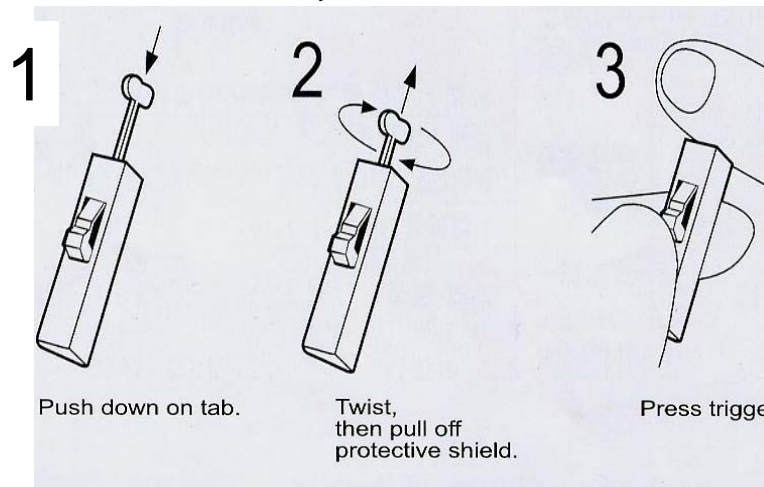
It is recommended that all specimens be handled in accordance with Biosafety Level 2 practices as described in the CDC NIH Publication, Biosafety in Microbiological and Biomedical Laboratories⁹ or other equivalent guidelines.¹⁰⁻¹¹

1. For *in vitro* diagnostic use only.
2. Wear gloves to perform this procedure and treat all specimens and used devices as potentially infectious.
3. Clean and disinfect all spills of specimens and reagents using a suitable disinfectant, such as 1% Sodium Hypochlorite¹².

4. Sterilize all devices used in this assay prior to disposal.
5. Do not use test beyond the expiration date.
6. ALL positive results must be confirmed by an alternative method.
7. Do not interchange reagents from one kit lot to another.

BEFORE TESTING

1. Bring the test device, sample diluent, alcohol swab, safety lancet, plastic tube.
2. Remove test card from the sealed pouch.
3. Read the instruction for safety lancet.



SPECIMEN COLLECTION

1. clean the area to be lanced with an alcohol swab.
2. Squeeze the end of the fingertip and pierce with the safety lancet as instructions below.



1 Push the safety lancet firmly onto the chosen site, then press trigger



2 Dispose of the lancet in a suitable container

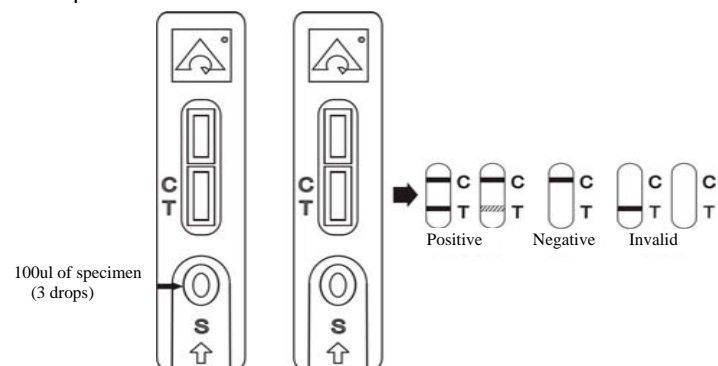


3 Massage the site as directed to get blood flow

Note: Whole blood, serum or plasma collected following regular clinical Laboratory Procedures can be used for this test.

ASSAY PROCEDURE

1. Bring all reagents and specimens to room temperature.
2. Remove the test card from the foil pouch and place on a clean dry surface.
3. Identify the test card for each specimen or control.
4. Dispense 100µl (3 drops) of the specimen or control into the sample well on the card.
5. Interpret test results at 15 minutes.



Caution: Use a clean capillary tube or pipette tip for every sample to avoid cross-contamination.

Note: A positive result may develop even sooner at a high concentration. However, the lower the concentration of the HBsAg, the longer time it takes to develop a test band; therefore, a negative result should be determined at 15 minutes to ensure it is truly negative instead of weak positive.

HBsAg Level	Time to Read Result
≥ 5 ng/mL	5 - 10 min.
1 ng/mL	15 min.
Negative	15 min.

READING THE TEST RESULTS

Do not interpret test results after 20 minutes

1. **Positive:** A purplish red test band appearing in the test region indicates a positive result. The lower the concentration is, the weaker the test band may be.
2. **Negative:** The absence of a purplish red test band in the test region indicates a negative result.
3. **Invalid:** There should always be a purplish red control band in the control region regardless of test result. If control band is not seen, the test is considered invalid and should be repeated using a new test strip.

PERFORMANCE CHARACTERISTICS

The Advanced Quality One Step HBsAg Test can detect HBsAg at concentration as low as 1ng/ml (including both ad and ay subtype). Clinical studies have been carried out to determine the correlation of the Advanced Quality One Step HBsAg Test to EIA and RIA tests:

Table-1: Comparison with EIA (1070 specimens)

Advanced Quality	EIA Positive	EIA Negative

Positive	356	8
Negative	4	702
Total	360	710

Sensitivity = 98.89 % (356/360)

Specificity = 98.87 % (702/710)

Predictive value of a positive test = 97.80 % (356/364)

Table-1: Comparison with RIA (493 specimens)

Advanced Quality	RIA Positive	RIA Negative
Positive	138	2
Negative	0	353
Total	138	355

Sensitivity = 100.00 % (138/138)

Specificity = 99.43 % (353/355)

Predictive value of a positive test = 98.57 % (138/140)

LIMITATIONS

Although the association between the presence of HBsAg and infection is strong, available methods for HBsAg detection are not sensitive enough to detect all potentially infectious units of blood or possible hepatitis infections.

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