

# TORCH IgG 5 in 1 DEVICE (4–30°C)

CATALOGUE NUMBER	KIT SIZE
RADTOR2	25 Tests

## Intended Use:

For *In Vitro* Diagnostic Use Only

This method is intended for the qualitative determination of the antibodies Toxo IgG, Rubella IgG, CMV IgG, HSV 1 IgG and HSV 2 IgG in human serum or plasma

The product is intended for use by qualified laboratory personnel only.

## Test Principle:

The TORCH 5in1 rapid test device uses a colloidal gold immunochromatography method with highly specific and sensitive antibodies to qualitatively detect the IgG antibodies to TORCH assays. A positive test is indicated by a purple line across the T area. The device also contains an inbuilt control line which indicates if the assay has been performed correctly. If the Control line (c) does not appear, discard the cassette and use a fresh one.

## Reagent Composition

Anti Human IgG monoclonal antibody (solid phase), Toxoplasma recombinant antigen, Rubella recombinant antigen, CMV recombinant antigen, HSV 1 recombinant antigen, HSV2 recombinant antigen, goat anti mouse IgG control line.

## Reagent Preparation and Stability:

The device is provided ready to use. Store at 4–30°C.

## Sample / Sample Preparation / Sample Stability:

- Collect serum or plasma samples by conventional methods. EDTA, Sodium citrate and Sodium oxalate can be used as anticoagulants.
- Perform the assay as soon as the sample collection is done.
- Serum plasma samples that are stored between 2–8°C are stable for 3 days.

## Assay Procedure:

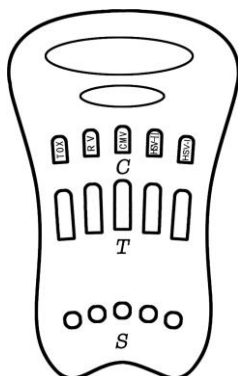
- Bring the assay device to room temperature prior to testing
- Remove the test device from the foil pouch and lay it on a flat surface.
- Dispense 2 drops (80–100ul) of the sample in each sample well and read results within a period of 25 – 30 minutes.
- DO NOT READ RESULTS AFTER 30 MINUTES.

## Interpretation:

**Negative:** A single line appears in the control region (C). No line in any other area.

**Positive:** In addition to the control line, a coloured line appears in the test region.

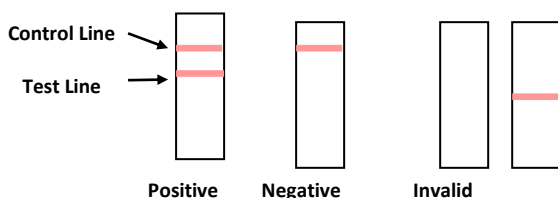
**Invalid:** No control line appears or no line appears in the Test or the control region of the device. This indicates that the test has been performed incorrectly and the test should be repeated.



S – Sample Well

T – Test Region.

C – Control Region.



Positive

Negative

Invalid

## Precautions:

1. Using fresh specimen is critical to the test results.
2. Do not read after 30 minutes. The results may be erroneous.
3. Do not use after the expiry date.

## Notes:

- This is a qualitative assay. A single result cannot be used as an indicator of infection. This result has to be used in conjunction with other clinical findings and laboratory data.
- The test line colour does not in any way inform the user about the antibody titre. Positive results have to be confirmed with other tests where suitable

REF	Catalog number	LOT	Temperature limitation
i	Consult instructions for use	LOT	Batch code
IVD	In vitro diagnostic medical device	Use by	
	Manufacturer		