CMV IgM Device (4 – 30°C)

CATALOGUE NUMBER	KIT SIZE (TESTS)
RADCMV1	20 Tests

Intended Use:
The reagent is used to detect the cytomegalovirus IgM antibody in serum /plasma qualitatively.

Test Principle:
The test utilizes antibodies including a recombinant CMV antigen and goat anti-rat IgM antibody on the nitrocellulose membrane with colloidal gold marked anti-human IgG as a mark tracer. Double Antibody sandwich method is deployed to detect the CMV IgM. The presence of CMV IgM will elicit a positive response in the form of a red line in the T area and the C area. (T is the test area and C is the control area).

Main Components:
The testing kit is in the form of cassette. Colloidal gold marked pad coated with anti-human IgM, nitrocellulose membrane coated with a recombinant CMV antigen, control line coated with goat anti-rat IgG antibody.

Materials Provided
Individually pouched test devices
Package Insert

Precautions:
- Do not use the device after the expiration date.
- The test device should remain in the sealed pouches until use. If the sealing problem happens, do not use the test.
- The colour depth of the detection line is not necessarily associated with the antibody titre of the specimen, positive results cannot be used as the only basis for diagnosis; further confirm experiment should be taken.
- The strength of the quality control line doesn't indicate the quality problem of the reagent, a test result that is clearly visible demonstrates the reagent is effective.

Reagent Storage and Expiry:

- The kit should be stored at 4-30°C until the expiry date printed on the sealed pouch.
- Keep away from direct sunlight, in a dry dark place.
- The test must remain in the sealed pouch until use.
- **Do not freeze.**
- Do not open the inner packaging until ready; it must be used in one hour if opened.

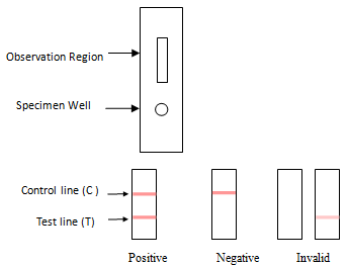
Specimen Collection:

1. **Serum:** Collect serum using approved methods.
2. **Plasma**: EDTA, Sodium citrate, oxalate and heparin can be used as anticoagulants.
3. Serum and plasma specimens may be stored at 2-8°C for 3 days prior to assay, and at -20°C for 2 years. Repeat freeze and thaw for no more than 3 times.

Assay Procedure:
Bring tests, specimens, and/or controls to room temperature (15-30°C) before use. Instruction must be read entirely before taking the test. Do not open the inner packaging until ready, it must be used within 1 hour if opened (Humidity: 20%~90%, Temp: 10-50°C).

1. Remove the test from its sealed pouch, and place it on a clean, level surface.
2. Transfer 2 drops (80~100ul) of specimen to the specimen well of the device and start the timer.
3. Observe the test results immediately within 30 minutes; the result is invalid after 30 minutes.

Interpretation of Results:



POSITIVE: Two red bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

NEGATIVE: Only one red band appears, in the control region (C). No apparent red or pink band appears in the test region (T).

INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

Limitations of the test:
1. This reagent is designed for the qualitative screening test. Concentration of CMV IgM cannot be determined by this qualitative test.
2. The results of the reagent are only for clinical reference, which is not the only basis for clinical diagnosis and treatment. A confirmed diagnosis and treatment should only be made by a physician after all clinical and laboratory findings have been evaluated.
3. Negative results may occur when detecting short-term infected specimens, indicate that the specific IgM antibodies of CMV does not exist or the concertation is below detection limit. If CMV infection is still suspected, the specimen should be collected 2 weeks later and carry the parallel detection with the first specimen.
4. Negative results of CMV IgM may occur at the beginning of acute infection; other testing method and analysis with clinical symptoms are suggested.
5. The tests are not suggested to apply to women because of the high risk of false positive in the laboratory examination of CMV IgM antibody in pregnant women. The results should not be used as a basis for termination of pregnancy.
6. Results of patients who used to receive immunosuppressive therapy or with immune function damage (for example HIV), may have a low serology reference value.
7. Positive results of the patients, who used to receive blood transfusions or other blood products therapy, should be analysed cautiously.
8. Positive results of patients whose CMV IgM antibody can be detected long time after the first infection, should be analysed cautiously.

Quality Controls:

- Internal procedural controls are included in the test. A coloured band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
- External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

Performance Characteristics:

1. Diagnostic specificity and sensitivity

A clinical evaluation was conducted on 442 specimens (including 152 positive specimens and 290 negative specimens). The results are as follows:

Positive specimens	152	**CMV IgM kits of PRESTIGE**	**Predicate Assay**
		149/152 (98.0%)	147/152 (96.7%)
Negative specimens	290	**CMV IgM kits of PRESTIGE**	**Predicate Assay**
		286/290 (98.6%)	288/290 (99.3%)

1.1 Cross-reactivity: The addition of HBV, HAV, HB-IgA, varicella virus, RF, ASO, ENA, ANA, MP, and other TORCH causative agents showed no cross-reactivity.

1.2 1000 mol/L bilirubin, 5.65mmol/L triglyceride, 10g/L haemoglobin has no effect on the detection result.

1.3 Hook effect: No Hook effect seen.

REF	Catalog number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by
	Manufacturer		Do not reuse

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V1: rev Jun 2016