Chikungunya IgG/IgM Ab Rapid Test Kit (Serum/Plasma/Whole blood)

The Precision's Chikungunya IgG/IgM Ab Rapid Test Kit (Serum/Plasma/Whole blood) is a rapid test that qualitatively detects the presence of IgG and IgM antibodies against Chikungunya virus in human Serum/Plasma/Whole Blood.
For *In-Vitro Diagnostic* Use only

ORDER INFORMATION

Pack Size	REF
01 Test	PCHK 01
05 Tests	PCHK 05
10 Tests	PCHK 10
25 Tests	PCHK 25
50 Tests	PCHK 50

CLINICAL SIGNIFICANCE
Chikungunya is a rare viral infection transmitted by the bite of an infected Aedesaegypti mosquito. It is characterized by a rash, fever, and severe joint pain (arthralgias) that usually lasts for three to seven days. The name is derived from the Makonde word meaning 'that which bends up' in reference to the stooped posture developed as a result of the arthritic symptoms of the disease. It occurs during the rainy season in tropical areas of the world, primarily in Africa, South-East Asia, southern India and Pakistan. The symptoms are most often clinically indistinguishable from those observed in dengue fever. Indeed, dual infection of dengue and chikungunya has been reported in India. Unlike dengue, hemorrhagic manifestations are relatively rare and most often the disease is a self-limiting febrile illness. Therefore, it is very important to clinically distinguish dengue from CHIK infection.
CHIK is diagnosed based on serological analysis and viral isolation in mice or tissue culture. An IgM immunoassay is the most practical lab test method. The test utilizes conserved recombinant antigen to simultaneously detect IgG and IgM to the Chikungunya virus without the restriction on specimen collection.

PRINCIPLE
The Chikungunya IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) conjugate pad containing recombinant Chikungunya antigens conjugated with colloidal gold (Chikungunya conjugates) and a control antibody conjugated with colloidal gold, 2) a nitrocellulose membrane strip containing two test lines (M and G lines) and a control line (C line). The M line is pre-coated with monoclonal Anti-Human IgM for the detection of IgM to Chikungunya, the G line is pre-coated with reagents for the detection of IgG to Chikungunya, and the C line is pre-coated with a control antibody. When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette. Anti-Chikungunya IgM antibodies if present in the specimen will bind to the Chikungunya conjugates. The immunocomplex is then captured on the membrane by the pre-coated Anti-Human IgM antibody forming an M line, indicating an anti- Chikungunya IgM positive test result. Anti- Chikungunya IgG antibodies if present in the specimen will bind to the Chikungunya conjugates. The immunocomplex is then captured by the pre-coated reagents on the membrane forming a G line, indicating an anti- Chikungunya IgG positive test result. Absence of any test lines (M and G) suggests a negative result. The test contains an internal control (C line) which should exhibit a colored line of the immunocomplex of the control antibodies regardless of the color development on any of the test lines. If the C line does not develop, the test result is invalid and the specimen must be retested with another device.

KIT COMPONENTS
• Test Cassettes • Droppers • Buffer • Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED
• Specimen Collection Containers • Centrifuge (For plasma only)
• Timer

PRECAUTIONS
1. For professional *in vitro* diagnostic use only. Do not use after the expiration date.
2. Wear protective gloves while handling specimens wash thoroughly afterwards.
3. The device is sensitive to humidity as well as heat. Therefore, take out the device from seal pouch before test.
4. Do not mix reagents from different lot.
5. Dispose all the samples and kits properly as per the instruction after test in accordance in GLP.
6. Follow the testing procedure exactly as mention in the insert.

STORAGE AND STABILITY
1. The kit can be stored at room temperature or refrigerated (2-30°C). The test device must remain in the sealed pouch until use. DO NOT FREEZE.
2. Do not use beyond the expiration date.
3. Do not use the test kit, if the pouch is damaged or seal is broken.

SPECIMEN COLLECTION & PREPARATION
The Chikungunya IgG/IgM Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood, serum and plasma specimen.

- **Serum (S):** Collect the whole blood into a collection tube (NOT containing anticoagulants such as heparin, EDTA, and sodium citrate) by veinpuncture, leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant.
- **Plasma (P):** Collect the whole blood into a collection tube (containing anticoagulants such as EDTA K2, Heparin sodium, Citrate sodium and Oxalate potassium) by veinpuncture and then centrifuge blood to get plasma specimen.
- **Whole Blood (WB):**Both Fingerstick Whole Blood and Venipuncture Whole Blood can be used.

DIRECTIONS FOR USE

Allow the test device, specimen and/or buffer to equilibrate at room temperature (15-30°C) before testing.

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within 1 hour.
2. Place the cassette on a clean and level surface.
3. **For Serum or Plasma specimen**: Place the cassette on a clean and level surface. For Serum or Plasma specimen: Hold the dropper vertically and transfer approximately 10µL (till the marking on the provided sample dropper) to the specimen well, then add 2 drops of buffer (approximately 80 µL) and start the timer
4. **For Venipuncture Whole Blood specimen**: Hold the dropper vertically and transfer approximately 10 µL (till the marking on the provided sample dropper) to the specimen well, then add 2 drops of buffer (approximately 80 µL) and start the timer
   For Fingerstick Whole Blood specimen: Take sample using sample dropper and transfer approximately 10 µL (till the marking on the provided sample dropper) of fingerstick whole blood specimen to the specimen well of test cassette, then add 2 drops of buffer (approximately 80 µL) and start the timer.
5. Wait for the colored line(s) to appear. Read results at 15 minutes.
   Note: Do not interpret the result after 20 minutes.

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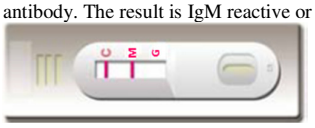
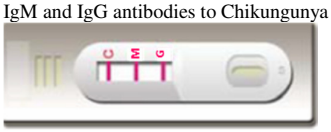
INTERPRETATION OF RESULTS

1) **IgG POSITIVE:**In addition to the presence of the C line, if only the G line develops, the test indicates the presence of Chikungunya virus IgG antibody. The result is IgG reactive or positive.

2) **IgM POSITIVE:** In addition to the presence of the C line, if only the M line develops, the test indicates the presence of Chikungunya virus IgM antibody. The result is IgM reactive or positive.



3) **IgG/IgM POSITIVE:** IgG and IgM Positive The control line (C), IgM (M) and IgG line (G) are visible on the test device. This is positive for both IgM and IgG antibodies to Chikungunya virus.



4) **NEGATIVE:** One distinct red line appears. The control line (c) is the only line visible on the test cassette. No IgM/IgG antibodies were detected. The result does not exclude Chikungunya virusinfection.

5) **INVALID:** Control line fails to appear. The test results are INVALID, if no control line (C) is visible, regardless of the presence or absence of line in the IgM(M)/IgG(G) region of the cassette. Repeat the test using a new cassette.

Quality Control

Internal procedural controls are included in the test individually. A colored line appearing in control line region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, 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.

Limitations of the Test

1. The test procedure, precautions and interpretation of results for this test must be followed when testing.
2. The Chikungunya IgG/IgM Ab Rapid Test (Whole Blood/Serum/Plasma) is for in vitro diagnostic use only. This test should be used for detection of antibodies for Chikungunya in whole blood, serum or plasma specimens. Neither the quantitative value nor the rate of increase in the concentration of Chikungunya can be determined by this qualitative test.
3. A negative result can occur if the quantity of the anti- Chikungunya antibodies present in the specimen is below the detection limits of the assay or the antibodies that are detected are not present during the stage of disease. Other clinically available tests are required. As with all diagnostic tests, a definitive clinical diagnosisshould not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

Performance characteristics

A total of 605 specimens were collected (including susceptible subjects) and tested by Chikungunya IgG/IgM Ab Rapid Test and a commercially available Chikungunya IgG/IgM Ab Rapid Test as reference. Comparison for all subjects is showed in the following table.

	Clinical performance for IgM Test		
IgM Test	Positive	Negative	Total
Positive	148	2	150
Negative	0	305	305
Total	148	307	455

	Clinical performance for IgG Test		
IgG test	Positive	Negative	Total
Positive	149	1	150
Negative	0	305	305
Total	149	306	455

IgM Relative Sensitivity: 100% (95% CI: 98.8-99.9%), IgG Relative Sensitivity: 100% (95% CI: 98.8-99.9%), Relative Specificity: 100% (95% CI: 98.8-99.9%), Overall Agreement: 100% (95% CI: 98.8-99.9%)

Cross-reactivity

The Chikungunya IgG/IgM Ab Rapid Test Cassette (Serum/Plasma/Whole Blood) has been tested HBsAg, anti-HIV, anti-HCV, anti-RF, anti-Spyhilis, anti-H.pylori, anti-Toxo IgG positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following compounds have also been tested using the Chikungunya IgG/IgM Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) and no interference was observed. Caffeine: 20mg/dl, Creatine: 200mg/dl, Acetylsalicylic Acid: 20mg/dl, Gentisic Acid: 20mg/dl, Albumin: 2000mg/dl, Ascorbic Acid: 2g/dl, Hemoglobin: 1000mg/dl, Oxalic acid: 600mg/dl, Bilirubin: 1000mg/dL, Triglycerides: 1600mg/dl & Cholesterol: 800mg/dl

BIBLIOGRAPHY

1. Shah KV, Gibbs CJ Jr, Banerjee G. Virological investigation of the epidemic of haemorrhagic fever in Calcutta: isolation of three strains of Chikungunya virus. Indian J Med Res 1964; 52 :676-83.
2. Powers AM, Brault AC, Tesh RB, Weaver SC. Re-emergence of Chikungunya and O'nyong-nyong
3. viruses: evidence for distinct geographical lineages and distant evolutionary relationships. J Gen Virol 2000;81:471-9
4. Myers RM and Carey DE. Concurrent isolation from patient of two arboviruses, Chikungunya anddengue type 2. Science 1967; 157:1307-8.

IVD In Vitro Diagnostic Use | See Pack Insert For Procedure | Single Use only | CE

Temperature Limit | Manufacturer's Address | Manufacturing Date | Expiry Date | LOT Lot Number

Manufactured in India by :

Precision Biomed Pvt. Ltd.

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