Chlamydia Trachomatis Antigen Rapid Test (Cassette)(Swab/Urine)

REF GCCHL-502a

CE 0123

INTENDED USE

The Chlamydia Trachomatis Antigen Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of Chlamydia in female cervical swab, male urethral swab and male urine specimens. The product can detect the Chlamydia serovars (D,E,F,H,I,K,G,J) and intended as a screening test and as an aid in the diagnosis of Chlamydia infection.

INTRODUCTION

Chlamydia trachomatis is the most common cause of sexually transmitted venereal infection in the world. It is composed of elementary bodies (the infectious form) and reticulate or inclusions bodies (the replicating form). Chlamydia trachomatis has both a high prevalence and asymptomatic carriage rate, with frequent serious complications in both women and neonates. Complications of Chlamydia Trachomatis infection in women include cervicitis, urethritis, ndometritis, pelvic inflammatory disease (PID) and increased incidence of ectopic pregnancy and infertility.[1] Vertical transmission of the disease during parturition from mother to neonate can result in inclusion conjunctivitis or pneumonia.

In men, complications of Chlamydia Trachomatis infection include urethritis and epididymitis. At least 40% of the nongonococcal urethritis cases are associated with Chlamydia Trachomatis infection. Approximately 70% of women with endocervical infections and up to 50% of men with urethral infections are asymptomatic. Traditionally, Chlamydia infection has been diagnosed by detection of Chlamydia Trachomatis inclusions in tissue culture cells. Culture method is the most sensitive and specific laboratory method, but it is labor intensive, expensive, long (48-72 hours) and not routinely available in most institutions.

In 2006 a new variant of Chlamydia trachomatis (nvCT) was discovered in Sweden, it belongs to serovar E.[7,8]

The Chlamydia Trachomatis Antigen Rapid Test is a rapid test to qualitatively detect the Chlamydia antigen from female cervical swab, male urethral swab and male urine specimens, providing results in 10 minutes. The test utilizes antibody specific for Chlamydia Trachomatis to selectively detect Chlamydia Trachomatis antigen from female cervical swab male urethral swab and male urine specimens.

PRINCIPLE

The Chlamydia Trachomatis Antigen Rapid Test is a qualitative, lateral flow immunoassay for the detection of Chlamydia Trachomatis antigen from female cervical swab, male urethral swab and male urine specimens. In this test, antibody specific to the Chlamydia Trachomatis antigen is coated on the test line region of the test. During testing, the extracted antigen solution reacts with an antibody to Chlamydia that is coated onto particles. The mixture migrates up to react with the antibody to Chlamydia on the membrane and generate a colored line in the test line region. The presence of this colored line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

1 test strip included; latex Conjugates (as main component): Mouse anti Chlamydia antibody (Conjugation) (0.04± 0.01 μg) and Rabbit IgG (0.04± 0.01 μg), Test Line (as main component): Mouse anti Chlamydia antibody (Coating) (0.24±0.08 μg), Control Line (as main component): Goat anti-Mouse IgG (0.6 μg) and Goat anti-Rabbit IgG (0.2 μg).

MATERIALS PROVIDED

1. Test Device: 20 individually pouched devices. A desiccant is included in each pouch;
2. Specimens extraction tube: 20;
3. 1 Package insert;
4. Female Swab: 20 Puritan Sterile Female Swab CE2797 MDD 93/42/EEC

5. 1 Extraction buffer A (Contain 0.2M NaOH): 8.0 ml.		Warning Causes skin irritation. Causes serious eye irritation. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection. If skin irritation occurs; Get medical advice/attention. If eye irritation persists, Get medical advice/attention Take off contaminated clothing and wash before reuse.
6. 1 Extraction buffer B (Contain 0.2M HCl): 8.0 ml.		

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or Timer 2. To collect Male Uretral Uretral swab specimens: sterile male uretral swabs
3. To collect Male Urine specimens:
   - sterile urine cup
   - centrifuge tube

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Reason: MoldSign Signature
Location: Moldova

PRECAUTIONS

1. For professional in vitro diagnostic use only. Do not use after expiration date. The test must remain in the sealed pouch until use.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Do not use test if pouch is damaged.
4. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow standard procedures for proper disposal of specimens.
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
6. The used test should be discarded according to local regulations.
7. Humidity and temperature can adversely affect results.
8. Use only sterile swabs to obtain endocervical specimens.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use.
DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND STORAGE

- The Chlamydia Trachomatis Antigen Rapid Test can be performed using female cervical swab, male urethral swab and male urine specimens.
- The quality of specimens obtained is of extreme importance. Detection of Chlamydia requires a vigorous and thorough collection technique that provides cellular material rather than just body fluids.
- To collect Female Cervical Swab Specimens:
  1. Use the sterile swab provided in the kit. Alternatively, any plastic-shaft sterile swab may be used.
  2. Before specimen collection, remove excess mucus from the endocervical area with a cotton ball and discard. The swab should be inserted into the endocervical canal, past the squamocolumnar junction until most of the tip is no longer visible. This will permit acquisition of columnar or cuboidal epithelial cells, which are the main reservoir of the Chlamydia organism. Firmly rotate the swab 360° in one direction (clockwise or counterclockwise), let stand for 15 seconds, then withdraw the swab. Avoid contamination from exocervical or vaginal cells. Do not use 0.9% sodium chloride to treat swabs before collecting specimens.
  3. If the test is to be conducted immediately, put the swab into the extraction tube.
- To collect Male Urethral Swab Specimens:
  1. Standard plastic- or wire-shaft sterile swabs should be used for urethral specimen collection. Instruct patients not to urinate for at least one hour prior to specimen collection.
  2. Insert the swab into the urethra about 2-4 cm, rotate the swab 360° in one direction (clockwise or counterclockwise), let stand for 10 seconds, then withdraw. Do not use 0.9% sodium chloride to treat swabs before collecting specimens.
  3. If the test is to be conducted immediately, put the swab into the extraction tube.
- To collect Male Urine Specimens:
  1. Collect 15-30 mL of clean first morning urine in a sterile urine cup. First morning urine specimens are preferred to achieve the highest concentrations of Chlamydia antigen.
  2. Mix the urine specimen by inverting the container. Transfer 10 mL of the urine specimen into a centrifuge tube, add 10 mL distilled water and centrifuge at 3,000 rpm for 15 minutes.
  3. Carefully discard the supernatant, keep the tube inverted and remove any supernatant from the rim of tube by blotting onto absorbent paper.
  4. If the test is to be conducted immediately, treat the urine pellet according to the Directions for Use.
  5. To collection Male urine specimens, customer also need a sterile urine cup and acentrifuge tube.
- It is recommended that specimens be processed as soon as possible after collection. If immediate testing is not possible, the patient swab specimens should be placed in a dry transport tube for storage or transport.
  The swabs may be stored for 4-6 hours at room temperature (15-30°C) or 24-72 hours refrigerated (2-8°C).
- The urine specimens can be stored refrigerated (2-8°C) for 24 hours. Do not freeze. All specimens should be allowed to reach room temperature (15-30°C) before testing.

TEST PROCEDURE

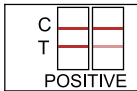
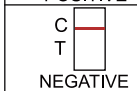
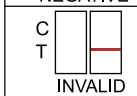
Bring tests, specimens, buffer and/or controls to room temperature (15-30°C) before use.
1. Remove the test device from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the test is performed immediately after opening the foil pouch.
2. Extract the Chlamydia Trachomatis antigen according to the specimen type.

For Female Cervical or Male Urethral Swab Specimens:
- Hold the Reagent A bottle vertically and add 5 drops of Reagent A to the extraction tube. Reagent A is colorless. Immediately insert the swab, compress the bottom of the tube and rotate the swab 15 times. Let stand for 2 minutes.
- Add 6 drops of Reagent B to the extraction tube. The solution will turn cloudy. Compress the bottom of tube and rotate the swab 15 times until the solution turns to a clear color with a slight green or blue tint. If the swab is bloody, the color will turn yellow or brown. Let stand for 1 minute.
- Press the swab against the side of the tube and withdraw the swab while squeezing the tube. Keep as much liquid in the tube as possible. Fit the dropper tip on top of the extraction tube.

For Male Urine Specimens:
- Add 6 drops of Reagent B to the urine pellet in the centrifuge tube, then draw the liquid up and down with a pipette to vigorously mix until the suspension is homogeneous.
- Transfer all the solution in the centrifuge tube to an extraction tube. Let stand for 1 minute. Hold the Reagent A bottle upright and add 5 drops of Reagent A then add to the extraction tube. Vortex or tap the bottom of the tube to mix the solution. Let stand for 2 minutes.
- Fit the dropper tip on top of the extraction tube.

3. Place the test device on a clean and level surface. Add 3 drops of the extracted solution (approximately 100 μL) to the specimen well (S) of the test device, then start the timer. Avoid trapping air bubbles in the specimen well (S).
4. Wait for the colored line(s) to appear. Read the result at 10 minutes. Do not interpret the result after 20 minutes.

INTERPRETATION OF RESULTS

 POSITIVE	Two colored 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 colored band appears in the control region(C).No apparent colored 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 reading 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.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.
Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The Chlamydia Trachomatis Antigen Rapid Test is used for in vitro diagnostic use only. This test should be used for the detection of Chlamydia Trachomatis antigen from female cervical swab, male urethral swab and male urine specimens.
Neither the quantitative value nor the rate of increase in Chlamydia Trachomatis antigen concentration can be determined by this qualitative test.
2. This test will only indicate the presence of Chlamydia Trachomatis antigen in specimens from both viable and non-viable Chlamydia. Performance with specimens other than female cervical swabs, male urethral swabs and male urine has not been assessed.
3. Detection of Chlamydia Trachomatis is dependent on the number of organisms present in the specimen. This can be affected by specimen collection methods and patient factors such as age, history of Sexually Transmitted Diseases (STDs), presence of symptoms, etc.The minimum detection level of this test may vary according to serovar.Therefore, the test results should be interpreted in conjunction with other laboratory and clinical data available to the physician.
4. Therapeutic failure or success cannot be determined as antigen may persist following appropriate antimicrobial therapy.
5. Excessive blood on the swab may cause false positive results.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy
The Chlamydia Trachomatis Antigen Rapid Test has been evaluated with specimens obtained from patients of STD clinics and tested by commercial PCR kit. Commercial Chlamydia Trachomatis Antigen Rapid Test (company A) and PCR kit were used as the reference method. The results show that the Chlamydia Trachomatis Antigen Rapid Test has a high overall relative accuracy.

Table 1: The Chlamydia Trachomatis Antigen Rapid Test vs Commercial Chlamydia Trachomatis Antigen Rapid Test (company A)

		Commercial Rapid test		Total Results
		Positive	Negative	
Orient Gene Rapid test	Positive	106	11	117
	Negative	19	226	245
Total Results		125	237	362

Relative Sensitivity：84.8% (77.28%-90.58%)*
Relative Specificity：95.4% (91.86%-97.66%)*
Accuracy：91.7% (88.36%-94.35%)*
*95% Confidence interval

Table 2: The Chlamydia Trachomatis Antigen Rapid Test vs PCR kit

		PCR kit		Total Results
		Positive	Negative	
Orient Gene Rapid test	Positive	109	8	117
	Negative	16	229	245
Total Results		125	237	362

Relative Sensitivity：87.2 % (80.05%-92.50%)*
Relative Specificity：96.6% (93.44%-98.53%)*
Accuracy：93.4 % (90.32%-95.70%)* *95% Confidence interval

Analytical Sensitivity
The analytical sensitivity of the Chlamydia Trachomatis Antigen Rapid Test was determined by testing serial dilutions of cultures of known infectivity. The Chlamydia trachomatis serovar E were 4.8×10^3 IFU/mL Chlamydia trachomatis.

Interfering substances
No interference was observed by any of the substances at the concentration tested. Each substance was spiked into negative (1×10^3 IFU/mL) and positive (8×10^3 IFU/mL) samples and then tested in duplicate on three lots of Chlamydia Trachomatis Antigen Rapid Test.

Human mucin (0.1 mg/test)	Metronidazole suppository (5 mg/test)
Tinidazole Vaginal Effervescent Tablets (5 mg/test)	Miconazole nitrate suppository (5 mg/ test)
Bifonazole ointment (5 mg/test)	Kangfute suppository (5 mg/ test)
Nystatin effervescent vaginal tablets (5 mg/ test)	Fuyinjie Lotion (20 μl/ test)
Jieeryin Lotion (10 μl/ test)	Vaginal Moisturizing Gel (10 μl/ test)
Nonoxinol Pellicles (5 mg/ test)	Povidone iodine Lotion (20 μl/ test)

Cross-Reactivity
Chlamydia psittaci and Chlamydia pneumoniae strains have been tested with the Chlamydia Trachomatis Antigen Rapid Test and shown to cross react.

The antibodies used in the Chlamydia Trachomatis Antigen Rapid Test have cross-reactivity with the following micro-organisms below 5%（from the product specification sheets of supplier）.

A. lwoffi	*A. baumanii*	*B. fragilis*	*C. freundii*
C. xerosis	*E. aerogenes*	*E. coli*	*Fusobacterium*
L. acidophilus	*M. hominis*	*M. smegmatis*	*Peptococcus*
Peptostreptococcus	*Propionebacterium*	*R. aeruginosa*	*S. cerevisiae*
S. marcescens	*S. pyogenes*	*T. globrata*	*U. urealyticum*

Cross reactivity with other organisms has been studied using suspensions of 1×10^9 CFU/mL. The following organisms were found negative result when tested with the Chlamydia Trachomatis Antigen Rapid Test.

Acinetobacter calcoaceticus	*Candida albicans*	*Pseudomonas aeruginosa*
Streptococcus faecium	*Neisseria gonorrhoeae*	*Gardnerella vaginalis*
Staphylococcus aureus	*Proteus vulgaris*	*Group A streptococci*
Salmonella minnesota	*Vaginal bacteria Gardiner*	*Group C streptococci*
Klebsiella pneumoniae	*Proteus mirabilis*	

REFERRENCE

1. Sanders J.W. et al Evaluation of an Enzyme Immunoassay for Detection of Chlamydia trachmatis in Urine of Asymptomatic Men. J.Clinical Microbiology, 32,24-27, (1994).
2. Jaschek, G. et al Direct Detection of Chlamydia trachomatis in Urine Specimens from Symptomatic and Asymptomatic Men by Using a Rapid Polymerase Chain Reaction Assay. J. Clinical Microbiology, 31,1209-1212, (1993).
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4. Helen Papadogeorgakis. et al. Chlamydia trachomatis Serovar Distribution and Neisseria gonorrhoeae Coinfection in Male Patients with Urethritis in Greece. JOURNAL OF CLINICAL MICROBIOLOGY, June 2010, p. 2231–2234.
5. Antonella Marangoni. et al. Chlamydia trachomatis serovar distribution and other sexually transmitted coinfections in subjects attending an STD outpatients clinic in Italy. NEW MICROBIOLOGICA, 35, 215-219, 2012.
6. Houda Gharsallah. et al. Chlamydia trachomatis genovar distribution in clinical urogenital specimens from Tunisian patients: high prevalence of C. trachomatis genovar E and mixed infections. BMC Infectious Diseases 2012, 12:333.
7. Magnus Unemo. et al. The Swedish new variant of Chlamydia trachomatis: genome sequence, morphology, cell tropism and phenotypic characterization. Microbiology (2010), 156, 1394–1404.
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ORDERING INFORMATION

Cat. No.	Product Name	Specimen	Format	Quantity
GCCHL-502a	Chlamydia Trachomatis Antigen Rapid Test	Swab/Urine	Cassette	20 Tests

INDEX OF SYMBOLS

	Consult instructions for use		Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2~30°C	LOT	Lot Number	REF	Catalog#
	Warning				

Zhejiang Orient Gene Biotech Co.,Ltd
Address: 3787#, East Yangguang Avenue, Dipu Street,
Anji 313300, Huzhou, Zhejiang, China
Tel: +86-572-5226111
Fax: +86-572-5226222
Website: www.orientgene.com

EC REP QARAD BV
Cipalstraat 3, 2440 Geel BELGIUM

Revision Date: 2022-01-13
B21200-04

Procalcitonin Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma)

CE

A rapid test for the Semi-Quantitative detection of Procalcitonin in whole blood, serum or plasma specimens.

For professional *in vitro* diagnostic use only.

INTENDED USE

The Procalcitonin Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) is used for semi-quantitative determination and monitoring of PCT concentrations in whole blood/serum/plasma specimens.

SUMMARY

The Procalcitonin (PCT) is a peptide hormone mainly produced by the C cells of the thyroid and certain endocrine cells of the lung. Under normal expression conditions, procalcitonin is immediately cleaved into three specific fragments, an N terminal residue, calcitonin and katacalcin, Levels of unprocessed procalcitonin rise significantly after bacterial infection, trauma or shock.

The Procalcitonin Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid test that semi-qualitatively detects the presence of Procalcitonin in whole blood, plasma or serum specimens at the sensitivity of 0.5ng/mL, 2ng/mL and 10ng/mL. The test utilizes a combination of monoclonal antibodies to selectively detect elevated levels of Procalcitonin in whole blood, plasma or serum. At the level of claimed sensitivity, the Procalcitonin Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) shows no cross-reactivity interference from the structurally related CRP or others at high physiological levels.

PRINCIPLE

The Procalcitonin Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) detects Procalcitonin through visual interpretation of color development on the internal strip. Anti-PCT antibodies are immobilized on the test region of the membrane. During testing, the specimen reacts with anti-PCT antibodies conjugated to colored particles and precoated on the sample pad of the test. The mixture then migrates through the membrane by capillary action, and interacts with reagents on the membrane. If Test band 3 (T3) appears, it indicates that the PCT level in the specimen is between 0.5-2.0ng/ml. If the Test band 3 and 2 (T3 and T2) appear, it indicates that the PCT level in the specimen is between 2.0-10.0 ng/ml. If all the Test bands (T1, T2, T3), it indicates that the PCT level is above 10.0 ng/ml. The appearance of control line serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

REAGENT

The test contains anti- Procalcitonin particles and anti- Procalcitonin coated on the membrane.

MATERIALS PROVIDED

25 Sealed pouches each containing a test cassette, a dropper and a desiccant

1 Buffer, 4.0 mL

1 Package insert

MATERIALS REQUIRED BUT NOT PROVIDED

1. Specimen collection container 2. Timer 3. Centrifuge

PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to any testing.
- Do not eat, drink or smoke in the area where the specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Do not interchange or mix reagents from different lots.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded in accordance with local regulations.

STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.

Do not freeze.

Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

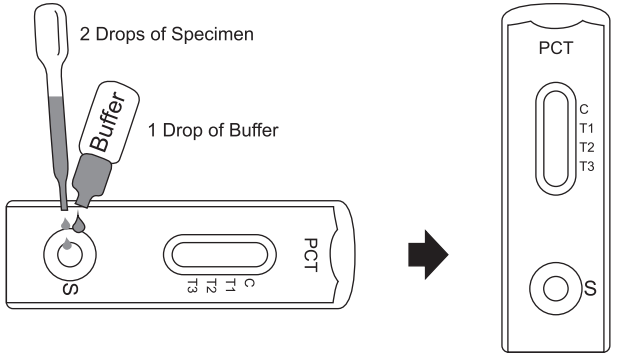
SPECIMEN COLLECTION AND PREPARATION

- The Procalcitonin Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood, serum or plasma.
- Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. Do not freeze whole blood specimens.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

DIRECTIONS FOR USE

Bring tests, specimens, buffer, and/or controls to room temperature (15-30°C) before use.

1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. For best results, the assay should be performed within one hour.
2. Add **2 drops of specimen** above to the specimen well and then add **1 drop of buffer**, start the timer.
3. Wait for the colored bands to appear. The result should be **read at 10 minutes**. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

POSITIVE RESULT:

Possible Interpretation of Procalcitonin Levels

A Control band (C) and a test band (T3) appears indicates a PCT level 0.5 mg/L at least.

A Control band (C) and two test bands (T3 and T2) appear indicates a PCT level 2.0 mg/L at least.

A Control band (C) and three test bands (T1, T2 and T3) appears indicates a PCT level 10.0 mg/L at least.

NEGATIVE RESULT:

Only a Control band (C) appears and no colored band appears in the test region (T) indicates a PCT level is lower than 0.5 mg/L.

INVALID RESULT:

No Control band appears. Results from any test which has not produced 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.

NOTE:

1. The intensity of the color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Please note that this is a semi-quantitative test only, and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

- Internal procedural controls are included in the test. Control band appearing in the control regions 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.

LIMITATIONS

1. The Procalcitonin Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) is for professional *in vitro* diagnostic use, and should only be used for the semi-quantitative detection of Patent Cooperation Treaty.
2. The Procalcitonin Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) will only indicate the semi-quantitative level of PCT in the specimen and should not be used as the sole criteria for evaluating inflammatory conditions.
3. Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
4. PCT values near the cut-off level Test line 3 (T3: 0.5 ng/ml), Test line 2 (T2: 2.0 ng/ml), and Test line 1 (T1: 10.0 ng/ml) should be reported with caution as with all quantitative assays there exists some level of variation. Therefore, a T line with slightly higher intensity than T1 can also represent a value slightly below 10.0 ng/ml. Similar observations may occur with values near 2.0 ng/ml and 0.5 ng/ml. A repeat test or further quantitative test is recommended in such cases.

EXPECTIED VALUES

The Procalcitonin Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) has been compared with a leading commercial Procalcitonin EIA test, demonstrating an overall accuracy of 98.9%.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The Procalcitonin Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) has been evaluated with a leading commercial Procalcitonin EIA test using clinical specimens. The results show that the sensitivity of the Procalcitonin Semi-Quantitative Rapid Test Cassette (Whole Blood/Serum/Plasma) is 98.8% and the specificity is 99.0% relative to the leading EIA test.

Procalcitonin Semi-Quantitative Rapid Test Cassette vs. EIA

Method		**EIA Test**		Total Results
Semi-Quantitative Rapid Test Cassette	Results	Positive	Negative	
	Positive	84	2	86
	Negative	1	193	194
Total Results		85	195	280

Relative Sensitivity: 98.8%(93.6%-99.9%)*

Relative Specificity: 99.0%(96.3%-99.9%)*

Accuracy: 98.9%(96.9%-99.8%)* *95% Confidence Interval

LITERATURE REFERENCES

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9. Chiesa C, Panero A, Rossi N, Stegagno M, De Giusti M, Osborn JF, Pacifico L. Clin Infect Dis (1998), 26: 664-672: Re- liability of Procalcitonin Concentrations for the Diagnosis of Sepsis in Critically Ill Neonates

INDEX OF SYMBOLS

	Consult instructions for use		Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
30°C 2°C	Store between 2~30°C	LOT	Lot Number	REF	Catalog#

Healgen Scientific Limited Liability Company
Address: 3818 Fuqua Street, Houston, TX 77047, USA.
Tel: +1 713-733-8088 Fax: +1 713-733-8848
Website: www.healgen.com

EC REP CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo Nº 18, CP29006, Málaga, Spain
Fax: +34952330100
Email-info@cmcmedicaldevices.com

REF GDPCT-T402a

Revision Date: 2022-03-03
B23104-01

Fecal Occult Blood Rapid Test Cassette (Feces) CE

INTENDED USE

Fecal Occult Blood Rapid Test Cassette (Feces) is a rapid chromatographic immunoassay for the qualitative detection of human occult blood in feces by professional laboratories or physician's offices. It is useful to detect bleeding caused by a number of gastrointestinal disorders, e.g., diverticulitis, colitis, polyps, and colorectal cancer.
Fecal Occult Blood Rapid Test Cassette (Feces) is recommended for use in1) routine physical examinations, 2) hospital monitoring for bleeding in patients, and 3) screening for colorectal cancer or gastrointestinal bleeding from any source.

INTRODUCTION

Most of diseases can cause hidden blood in the stool. In the early stages, gastrointestinal problems such as colon cancer, ulcers, polyps, colitis, diverticulitis, and fissures may not show any visible symptoms, only occult blood. Traditional guaiac-based method lacks sensitivity and specificity, and has diet-restriction prior to the testing.
Fecal Occult Blood Rapid Test Cassette (Feces) is a rapid test to qualitatively detect low levels of fecal occult blood in feces. The test uses double antibod- sandwich assay to selectively detect as low as 50 ng/mL of hemoglobin or 6 µg hemoglobin/g feces. In addition, unlike the guaiac assays, the accuracy of the test is not affected by the diet of the patients.

PRINCIPLE

Fecal Occult Blood Rapid Test Cassette (Feces) is a lateral flow chromatographic immunoassay based on the principle of the double antibody-sandwich technique. The membrane is pre-coated with anti-hemoglobin antibodies on the test line region of the device. During testing, the specimen reacts with the colloidal gold coated withl anti-hemoglobin antibodies. The mixture migrates upward on the membrane chromatographically by capillary action to react with anti-hemoglobin antibodies on the membrane and generate a colored line. The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS PROVIDED

20 Test cassettes
20 Specimen collection tubes with buffer
1 Package insert

MATERIALS REQUIRED BUT NOT PROVIDED

1. Specimen collection containers 2. Clock or timer

STORAGE AND STABILITY

All reagents are ready to use as supplied. Store unused test device unopened at 2°C-30°C. If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test is not stable out of the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
3. Do not use it if the tube/pouch is damaged or broken.
4. Test is for single use only. Do not re-use under any circumstances.
5. Do not use specimen with visible blood for the testing.
6. Handel all specimens as if they contain infectious agents. Observe established standard procedure for proper disposal of specimens.
7. Specimen extraction buffer contains Sodium Azide (0.1%). Avoid contact with skin or eyes. Do not ingest.
8. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assay.
9. Humidity and temperature can adversely affect results.
10. Do not perform the test in a room with strong air flow, ie. electric fan or strong airconditioning.

PATIENT PREPARATION

1. A specimen should not be collected from a patient with following conditions that may interfere with the test results:

- Menstrual bleeding
- Bleeding hemorrhoids
- Constipating bleeding
- Urinary bleeding.

2. Dietary restrictions are not necessary.
3. Alcohol and certain medications such as aspirin, indomethacin, phenylbutazone, reserpine, cortocosteroids, and nonsteroidal anti-inflammatory drugs may cause gastrointestinal irritation and subsequent bleeding, thus gives positive reactions. On the advice of the physician, such substances should be discontinued at least 48 hours prior to testing.

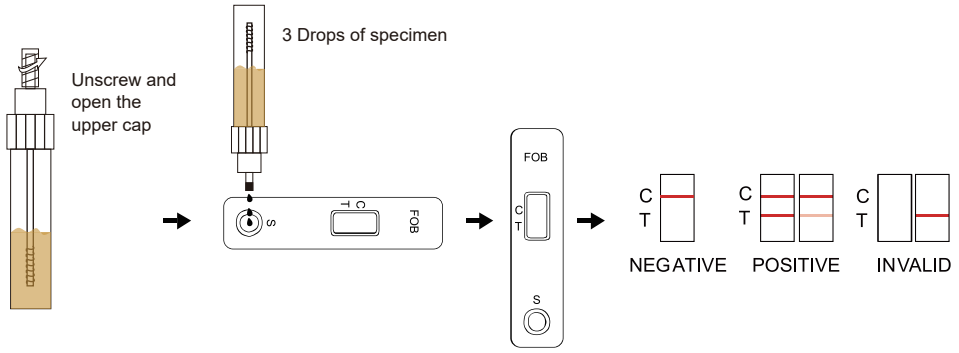
SPECIMEN COLLECTION AND PREPARATION

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.
1. Collect a random sample of feces in a clean, dry receptacle.
2. Unscrew the top of the collection tube and remove the applicator stick.
3. Randomly pierce the fecal specimen in at least five (5) different sites.
4. Remove excess sample off the shaft and outer grooves. Be sure sample remains on inside grooves.
5. Replace the stick in the tube and tighten securely.
6. Shake the specimen collection bottle so that there is proper homogenisation of feces in buffer solution.

Note: Specimens prepared in the specimen collection tube may be stored at room temperature (15-30°C) for 3 days maximum, at 2-8°C for 7 days maximum or at -20°C for 3 months maximum if not tested within 1 hour after preparation.

TEST PROCEDURE

Allow the test cassette, specimen, and/or controls to reach room temperature (15-30°C) prior to testing.
1. Remove the test cassette from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test cassette on a clean, flat surface.
3. Shake the specimen collection tube several times.
4. Hold the specimen collection tube upright and then unscrew and open the upper cap.
5. Squeeze 3 drops (~90 µL) of the sample solution in the sample well of the cassette and start the timer.
6. Wait for the colored line(s) to appear. Read results in 5 minutes. Do not interpret the result after 5 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)
Positive: Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).
Negative: One colored line appears in the control line region(C). No line appears in the test line region (T).
Invalid: Control line fails to appear. The test should be repeated using a new cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.
NOTE:
1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Note that this is a qualitative test only, and

Fecal Occult Blood Rapid Test Cassette (Feces)

cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

An internal procedural control is included in the test. A colored line appearing in the control line region (C) is an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correctl 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

1. This test kit is to be used for the qualitative detection of human hemoglobin in fecal samples. A positive result suggests the presence of human hemoglobin in fecal samples. In addition to intestinal bleeding the presence of blood in stools may have other causes such as hemorrhoids, blood in urine etc.
2. Not all colorectal bleedings are due to precancerous or cancerous polyps. The information obtained by this test should be used in conjunction with other clinical findings and testing methods, such as colonoscopy gathered by the physician.
3. Negative results do not exclude bleeding since some polyps and colorectal region cancers can bleed intermittently or not at all. Additionally, blood may not be uniformly distributed in fecal samples. Colorectal polyps at an early stage may not bleed.
4. Urine and excessive dilution of sample with water from toilet bowl may cause erroneous test results. The use of a receptacle is recommended.
5. Feces specimens should not collect during the menstrual period and not three day before or afterwards, at bleeding due to constipation, bleeding haemorrhoids,or at taking rectally administered medication. It could cause false positive results.
6. This test may be less sensitive for detecting upper g.i. Bleeding because blood degrades as it passes through the g.i. Track.
7. The Fecal Occult Blood Rapid Test Cassette (Feces) is to aid indiagnosis and is not intended to replace other diagnostic procedures such as G.I. fibroscope, endoscopy, colonoscopy, or X-ray analysis. Test results should not be deemed conclusive with respect to the presence or absence of gastrointestinal bleeding or pathology. A positive result should be followed up with additional diagnostic procedures to determine the exact cause and source for the occult blood in the feces.

PERFORMANCE CHARACTERISTICS

1. Sensitivity: 99.6%
Fecal Occult Blood Rapid Test Cassette (Feces) can detect the levels of human occult blood as low as 50 ng/mL hemoglobin or 6 µg hemoglobin/g feces.
2. Prozone Effect:
It is observed that this FOB test can detect 2 mg/mL hemoglobin.
3. Specificity: 99.9%
Fecal Occult Blood Rapid Test Cassette (Feces) is specific to human hemoglobin. Specimen containing the following substances at the standard concentration was tested on both positive and negative controls and showed no effects on test results at standards concentration.

Substances	Concentrations (Diluted with the extraction buffer)
Beef hemoglobin	2 mg/mL
Chicken hemoglobin	0.5 mg/mL
Pig hemoglobin	0.5 mg/mL
Goat hemoglobin	0.5 mg/mL
Horse hemoglobin	20 mg/mL
Rabbit hemoglobin	0.06 mg/mL

REFERENCES

1. Simon J.B. Occult Blood Screening for Colorectal Carcinoma: A Critical Review, Gastroenterology, Vol. 1985;88:820.
2. Blebea J. and Ncpherson RA. False-Positive Guaiac Testing With Iodine, Arch Pathol Lab Med, 1985;109:437-40.

INDEX OF SYMBOLS

	Consult instructions for use		Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
30°C 2°C	Store between 2~30°C	LOT	Lot Number	REF	Catalog#

Zhejiang Orient Gene Biotech Co.,Ltd
Address: 3787#, East Yangguang Avenue, Dipu Street,
Anji 313300, Huzhou, Zhejiang, China
Tel: +86-572-5226111 Fax: +86-572-5226222
Website: www.orientgene.com

EC REP Shanghai International Holding Corp. GmbH (Europe)
Add: Eiffestrasse 80, 20537 Hamburg, Germany

REF GEFOB-602b

Revision Date: 2023-04-18
B21056-04

H. pylori Ag Rapid Test Cassette (Feces)

CE

INTENDED USE

H. pylori Ag Rapid Test Cassette (Feces) is a sandwich lateral flow chromatographic immunoassay for the qualitative detection of H.Pylori antigen in feces.It is for professional *in vitro* diagnostic use only.

INTRODUCTION

H.Pylori is associated with a variety of gastrointestinal diseases included non-ulcer dyspepsia, duodenal and gastric ulcer and active, chronic gastritis.[1,2] The prevalence of H.pylori infection could exceed 90% in patients with signs and symptoms of gastrointestinal diseases. Recent studies indicate an association of H. Pylori infection with stomach cancer.[3]H. Pylori colonizing in the gastrointestinal system elicits specific antibody responses[4,5,6] which aids in the diagnosis of H. Pylori infection and in monitoring the prognosis of the treatment of H. Pylori related diseases. Antibiotics in combination with bismuth compounds have been shown to be effective in treating active H. Pylori infection. Successful eradication of H. pylori is associated with clinical improvement in patients with gastrointestinal diseases providing a further evidence.[7]

PRINCIPLE

H. pylori Ag Rapid Test Cassette (Feces) is a lateral flow chromatographic immunoassay based on the principle of the double antibody–sandwich technique. The test cassette consists of: 1) a burgundy colored conjugate pad containing H. Pylori antibodies conjugated with color particles (H. Pylori conjugates. 2) a nitrocellulose membrane strip containing a test band (T band) and a control band (C band). The T band is pre-coated with non-conjugated H. Pylori antibodies.

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. The antigen of H. Pylori if present in the specimen will bind to the H. Pylori antibodies conjugates. The immunocomplex is then captured on the membrane by the pre-coated H. Pylori antibodies, forming a burgundy colored T band, indicating a H. Pylori antigen positive test result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred. Otherwise, the test result is invalid and the specimen must be retested with another device.

PRODUCT CONTENTS

H. pylori Ag Rapid Test Cassette (Feces) containing anti- H.pylori antibodies particles and anti-H.pylori antibodies coated on the membrane.

MATERIALS SUPPLIED

20 Sealed pouches each containing a test cassette and a desiccant
20 Specimen collection tubes with extraction buffer, 2.0 mL
1 Package insert

MATERIAL REQUIRED BUT NOT PROVIDED

1. Clock or timer
2. Specimen collection containers.

STORAGE AND STABILITY

All reagents are ready to use as supplied. Store unused test device unopened at 2°C-30°C. If stored at 2°C-8°C, ensure that the test device is brought to room temperature before opening. The test is not stable out off the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30°C.

WARNINGS AND PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. Do not use it if the tube/pouch is damaged or broken.
3. Test is for single use only. Do not re- use under any circumstances.
4. Handle all specimens as if they contain infectious agents. Observe established standard procedure for proper disposal of specimens
5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assay.
6. Humidity and temperature can adversely affect results

SPECIMEN COLLECTION

Collect sufficient quantity of feces (1-2 mL or 1-2 g) in a clean, dry specimen collection container to obtain maximum antigens (if present). Best results will be obtained if the assay is performed within 6 hours after collection. Specimen collected may be stored for 3 days at 2-8˚C if not tested within 6 hours. For long term storage, specimens should be kept below -20˚C.

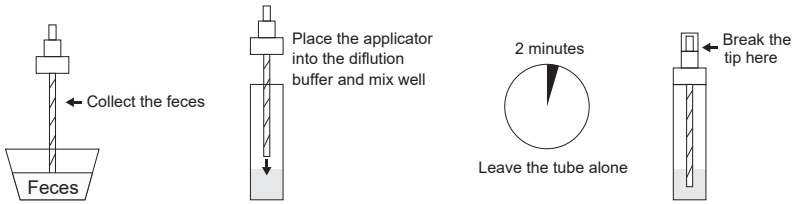
To process fecal specimens:

◦ For Solid Specimens:

Unscrew the cap of the specimen collection tube， then randomly stab the specimen collection applicator into the fecal specimen in at least 3 different sites to collect approximately 50 mg of feces (equivalent to 1/4 of a pea). Do not scoop the fecal specimen.

◦ For Liquid Specimens:

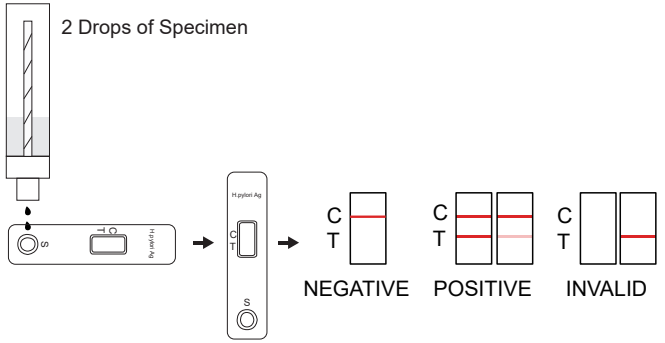
Hold the dropper vertically, aspirate fecal specimens, and then transfer 2 drops (approximately 80 µL) into the specimen collection tube containing the dilution buffer. Screw on and tighten the cap onto the specimen collection tube, then shake the specimen collection tube vigorously to mix the specimen and the dilution buffer. Leave the tube alone for 2 minutes.



TEST PROCEDURE

1. Remove the test device from its foil pouch by tearing along the notch and use it as soon as possible.
2. Specimen collection. See also specimen collection.
3. Holding the sample collection device upright, carefully break off the tip of collection device.
4. Squeeze 2 drops (~80 µL) of the sample solution in the sample well of the cassette, as in the illustration.
5. Read the test results in 10 minutes. It is important that the background is clear before the result is read. Do not read results after 10 minutes. To avoid confusion, discard the test device after interpreting the result.

INTERPRETATION OF RESULTS



H. pylori Ag Rapid Test Cassette (Feces)

Positive: Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T).
Negative: One colored line appears in the control line region(C). No line appears in the test line region (T).
Invalid: Control line fails to appear.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking 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

1. The Assay Procedure and the Assay Result Interpretation must be followed closely when testing the presence of H. Pylori antigen in feces from individual subjects. Failure to follow the procedure may give inaccurate results.
2. H. pylori Ag Rapid Test Cassette (Feces) is limited to the qualitative detection of H. Pylori antigen in feces. The intensity of the test band does not have linear correlation with the antigen titer in the specimen.
3. A negative result for an individual subject indicates absence of detectable H. Pylori antigen. However, a negative test result does not preclude the possibility of exposure to or infection with H. Pylori.
4. A negative result can occur if the quantity of the H. Pylori angtigen present in the specimen is below the detection limits of the assay, or the antigen that are detected are not present during the stage of disease in which a sample is collected.
5. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

PERFORMANCE CHARACTERISTICS

A study was performed with 165 patient feces samples including both symptomatic gastrointestinal disorders and samples from non-symptomatic patients and 100 normal feces samples.Comparison for all subjects with H. pylori Ag Rapid Test Cassette (Feces) and reference ELISA kit is showed in the following table:

Method		EIA		Total Results
H.P Test Cassette	Results	Positive	Negative	
	Positive	163	0	163
	Negative	2	100	102
Total Results		165	100	265

Relative sensitivity: 98.8%
Relative specificity: 100%
Accuracy:98.9%

REFERENCE

1. Marshall,B.J.et.al. Pyloric Campylobacter infection and gastroduodenal disease. Med. J. Australia.149:439-44, 1985.
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4. Soll,A.H. Pathogenesis of peptic ulcer and implications for therapy. New England J. Med.322:909-916,1990.
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6. Ansong,R. et.al. Evaluation of techniques for isolation, subcultivation and preservation of Helicobacter pylori. J.Clin.Micro. 29:51-53,1991.
7. Pronovost,A.P.et.al. Evaluation of a new immunodiagnostic assay for Helicobacter pylori antibody detection: Correlation with histopathological and microbiological results. J.Clin.Microbiol.32:46-50,1994.

INDEX OF SYMBOLS

	Consult instructions for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2~30°C	LOT	Lot Number	REF	Catalog#

Zhejiang Orient Gene Biotech Co.,Ltd
Address: 3787#, East Yangguang Avenue, Dipu Street, Anji 313300, Huzhou, Zhejiang, China.
TEL: +86-572-5226111 FAX: +86-572-5226222
Website: www.orientgene.com

EC REP Shanghai International Holding Corp. GmbH (Europe)
Add: Eiffestrasse 80, 20537 Hamburg, Germany

REF GCHP-602a

Revision Date: 2022-03-08
B20435-03

Influenza A & B Ag Rapid Test Cassette (Swab) CE

INTENDED USE

The Influenza A & B Ag Rapid Test Cassette (Swab) is an *in vitro* immunochromatographic assay for the qualitative detection of influenza A (including the subtype H1N1) and B nucleoprotein antigens in nasopharyngeal swabs, nasal swabs, throat swabs or nasal aspirates specimens. It is intended to aid in the rapid differential diagnosis of influenza A and B viral infections.

SUMMARY AND EXPLANATION

Influenza is an acute and highly contagious viral infection of the respiratory tract. The causative agents of the disease are immunologically diverse, single-strand RNA virus known as influenza viruses. There are three types of influenza viruses: A, B and C.

Type A Viruses are the most prevalent and are associated with most serious epidemics, while Type B infection is generally milder. Type C virus have never been associated with a large epidemic of human disease. Both type A and B viruses can circulate simultaneously, but usually one type is dominant during a given season and particular epidemic area. The disease is easily transmitted through coughing and sneezing of aerosolized droplets containing live virus. Influenza outbreaks normally occur each year during fall and winter seasons. Rapid diagnosis of influenza infection will help healthcare professionals to treat patients and control the disease more efficiently and effectively.

PRINCIPLE OF THE TEST

The Influenza A&B Ag Rapid Test Cassette (Swab) is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect influenza type A and B nucleoprotein antigens in nasopharyngeal swabs, nasal swabs, throat swabs or nasal aspirates specimens. The test strip is composed of the following parts: namely sample pad, reagent pad, reaction membrane, and absorbing pad. The reagent pad contains the colloidal-gold conjugated with the monoclonal antibodies against Influenza virus A and B; the reaction membrane contains the secondary antibodies either for virus A or for B. The whole strip is fixed inside a plastic device. When the sample is added into the sample well, conjugates dried in the reagent pad are dissolved and migrate along with the sample. If influenza A presents in the sample, a complex formed between the anti-influenza A conjugate and the virus will be captured by the specific anti-influenza A monoclonal antibodies coated on the A region (A). If the sample contains influenza B, a complex formed between the anti-influenza B conjugate and the virus will be captured by the specific anti-influenza B monoclonal antibodies coated on the B region (B).

Results appear at 10 minutes in the form of a red line that develops on the membrane. To serve as a procedural control, a red line will always appear in the control region (C) indicating that proper volume of sample has been added and membrane wicking has occurred.

MATERIALS PROVIDED

20 Test cassettes
20 Sterile swabs
20 Extraction tubes and tips
1 Workstation
2 Buffers
1 Package inset

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock, timer, or stopwatch

WARNINGS AND PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. The test cassette should remain in the sealed pouch until use.
3. Do not use kit past its expiration date.
4. Swabs, tubes and test cassettes are for single use only.
5. Solutions that contain sodium azide may react explosively with lead or copper plumbing. Use large quantities of water to flush discarded solutions down a sink.
6. Do not interchange or mix components from different kit lots.
7. Humidity and temperature can adversely affect results.
8. Used testing materials should be discarded in accordance with local regulations.

STORAGE AND STABILITY

1. The kit can be stored at room temperature or refrigerated (2-30℃).
2. Do not freeze any of the test kit components.
3. Do not use test cassette and reagents after expiration date.
4. Test cassettes that have been outside of the sealed pouch for more than 1 hour should be discarded.
5. Close the kit box and secure its contents when not in use.

SPECIMEN COLLECTION

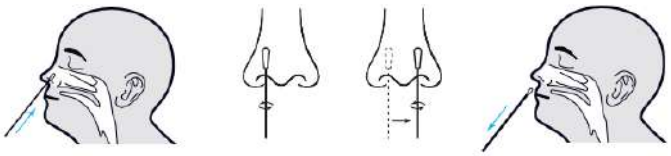
It is applicable to the diagnosis of the influenza virus A and B from the samples of nasopharyngeal swabs, nasal swabs, throat swabs or nasal aspirates. Use freshly collected samples for optimal test performance. Inadequate sample collection or improper sample handling may yield a false-negative result.

For Nasopharyngeal Swab Specimen Collection:

1. Using the sterile swab provided in the kit, carefully insert the swab in the patient's nostril.
2. Swab over the surface of the posterior nasopharynx and rotate the swab several times.
3. Withdraw the swab from the nasal cavity. The specimen is now ready for preparation using the extraction buffer provided in the test kit.

For Nasal Swab Specimen Collection:

1. Using the sterile swab provided in the kit, carefully insert the swab into one nostril of the patient. The swab tip should be inserted up to 2-4 cm until resistance is met.
2. Roll the swab 5 times along the mucosa inside the nostril to ensure that both mucus and cells are collected.
3. Using the same swab, repeat this process for the other nostril to ensure that an adequate sample is collected from both nasal cavities.
4. Withdraw the swab from the nasal cavity. The sample is now ready for processing using the Influenza A & B Ag Rapid Test Cassette (Swab).

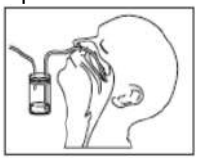


For Throat Swab Specimen Collection:

1. Deeply insert the sterilized swab into the throat and swab several times to collect the epidermal cells of the mucus. Caution has to be paid to avoid the swab to be contaminated with saliva.
2. Withdraw the swab from the throat. The sample is now ready for processing using the Influenza A & B Ag Rapid Test Cassette (Swab).

For Nasal Aspirates Specimen Collection:

Nasal aspirator is not provided in the kit. Collect nasal aspirate fluids according to the instructions for use of the used nasal aspirator.



SAMPLE PREPARATION PROCEDURE

Insert the test extraction tube into the workstation provided in the kit. Make sure that the tube is standing upright and reaches the bottom of the workstation. Add the sample buffer to extraction tube until it reaches the lower mark (about 13-17 drops, 0.5 mL)

For nasopharyngeal, nasal or throat swabs:

Insert the swab into the extraction tube which contains 0.5 mL of the extraction buffer. After mixing, squeeze the tube several times with fingers from outside of the tube to immerse the swab. Remove the swab. The extracted solution will be used as test sample.

For nasal aspirate fluids：

Add 0.5 mL of the nasal aspirate fluids into the extraction tube which contains 0.5 mL of the extraction buffer, and mix well to be used as test sample.

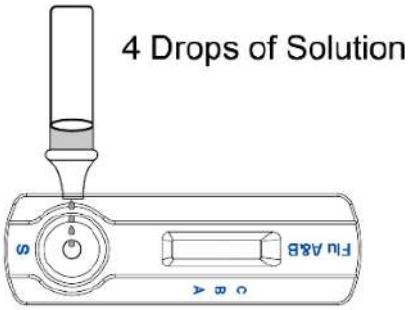
SPECIMEN TRANSPORT AND STORAGE

Specimens should be tested as soon as possible after collection. If transport of the samples is required, the following transport media are recommended and have been tested and shown not to interfere with the performance of the test: Hank's Balanced salt solution, M5 Media, or saline. Alternatively, samples may be stored refrigerated (2-8℃), or at room temperature(15-30℃), in a clean, dry, closed container for up to eight hours prior to testing. Nasal wash/aspirate specimens may also be stored frozen (-70℃ or colder) for up to one month.

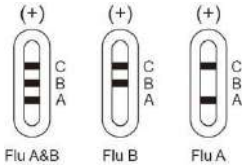
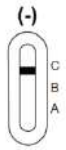
TEST PROCEDURE

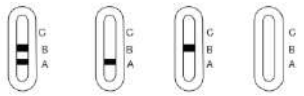
Allow the test cassette, test sample and buffer to equilibrate to room temperature (15-30°C) prior to testing.

1. Just prior to testing remove the test cassette from the sealed pouch and lay it on a flat surface.
2. Push the nozzle which contains the filter onto the extraction tube. Ensure the nozzle has a tight fit.
3. Hold the extraction tube vertically and add 4 drops (approximately 100 µL) of test sample solution tube into the sample well.
4. Start the timer.
5. Read the results at 10 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

	**POSITIVE** **1. Flu A Positive:** The presence of two lines as control line (C) and A test line within the result window indicates a positive result for Influenza A viral antigen. **2. Flu B Positive:** The presence of two lines as control line (C) and B test line within the result window indicates a positive result for Influenza B viral antigen. **3. Flu A+B Positive:** The presence of three lines as control line (C), A test line and B test line within the result window indicates a positive result for Influenza A and Influenza B viral antigen.
	**NEGATIVE** The presence of only control band (C) within the result window indicates a negative result.

	**INVALID** If the control band (C) is not visible within the result window after performing the test, the result is considered invalid. Some causes of invalid results are because of not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the specimen be re-tested using a new test.

NOTE:

1. The intensity of color in the test region (A/B) may vary depending on the concentration of analyses present in the specimen. Therefore, any shade of color in the test region (A/B) should be considered positive. Please note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the 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 test. However, it is recommended that positive and negative controls are sourced from a local competent authority and tested as a good laboratory practice, to confirm the test procedure and verify the test performance.

LIMITATIONS

1. The Influenza A&B Ag Rapid Test Cassette (Swab) is for professional in vitro diagnostic use, and should only be used for the qualitative detection of influenza A and/or B.
2. The etiology of respiratory infection caused by microorganisms other than influenza A or B virus will not be established with this test. The Influenza A&B Ag Rapid Test Cassette (Swab) is capable of detecting both viable and non-viable influenza particles. The performance of the Influenza A&B Ag Rapid Test depends on antigen load and may not correlate with cell culture performed on the same specimen.
3. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at anytime rule out the presence of influenza A and/or B viral antigens in specimen, as they may be present below the minimum detection level of the test. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
4. The validity of Influenza A&B Ag Rapid Test Cassette (Swab) has not been proven for identification or confirmation of cell culture isolates.
5. Inadequate or inappropriate specimen collection, storage, and transport may yield false negative test result.
6. Although this test has been shown to detect cultured avian influenza viruses, including avian influenza A subtype H5N1 virus, the performance characteristics of this test with specimens from humans infected with H5N1 or other avian influenza viruses are unknown.
7. Performance characteristics for influenza A were established when influenza A/H3 and A/H1 were the predominant influenza A viruses in circulation. When other influenza A viruses are emerging, performance characteristics may vary.
8. Children tend to shed virus for longer periods of time than adults, which may result in differences in sensitivity between adults and children.
9. Positive and negative predictive values are highly dependent on prevalence. False positive test results are more likely during periods of low influenza activity when prevalence is moderate to low.

PERFORMANCE CHARACTERISTICS

1. Analytical Sensitivity

The minimum detection limit is 1.5 x 10^4 $TCID_{50}$/test for the Influenza A virus antigen and is 1.5 x 10^5 $TCID_{50}$/test for the Influenza B virus antigen.

2. Analytical Reactivity

The influenza A strain listed tested positive in the Influenza A&B Ag Rapid Test Cassette (Swab). Although the specific influenza strains causing infection in human can very, all contain the conserved nucleoproteins targeted by Influenza A&B Ag Rapid Test Cassette (Swab).

Strains	Sources	Subtypes	Concentration
Flu A/Hubei/PR 8/2001	Human	H1N1	1.8×10^4 $TCID_{50}$/test
Flu A/New Kaledonia/20/99	Human	H1N1	1.8×10^4 $TCID_{50}$/test
Flu A/Yamagata/32/89	Human	H1N1	1.8×10^4 $TCID_{50}$/test
Flu A/Beijing/262/95	Human	H1N1	1.8×10^4 $TCID_{50}$/test
Flu A/Singapore/1/57	Human	H2N2	3.0×10^4 $TCID_{50}$/test
Flu A/Hubei/3/2005	Human	H3N2	3.0×10^4 $TCID_{50}$/test
Flu A/Akita/1/94	Human	H3N2	3.0×10^4 $TCID_{50}$/test
Flu A/Iowa/15/30	Swine	H1N1	3.0×10^4 $TCID_{50}$/test
Flu A/Hongkong/168/93	Swine	H1N1	3.0×10^4 $TCID_{50}$/test
Flu A/Anhui/24/2004	Swine	H5N1	6.0×10^4 $TCID_{50}$/test
Flu A/Hubei/134/2000	Swine	H9N2	6.0×10^5 $TCID_{50}$/test
Flu A/Hubei/251/2001	Swine	H9N2	6.0×10^5 $TCID_{50}$/test
Flu A/Yuyao/1/2006	Chicken	H5N1	6.0×10^4 $TCID_{50}$/test
Flu A/Yuyao/2/2006	Chicken	H5N1	6.0×10^4 $TCID_{50}$/test
Flu A/Jiangsu/2/2004	Chicken	H5N1	6.0×10^4 $TCID_{50}$/test
Flu A/Hubei/216/83	Duck	H7N8	3.0×10^5 $TCID_{50}$/test
Flu A/Hubei/118/2003	Duck	H9N2	1.5×10^5 TC ID_{50}/test
Flu A/Hubei/155/2003	Duck	H9N2	6.0×10^5 $TCID_{50}$/test
Flu A/Hubei/137/1982	Duck	H10N4	3.0×10^5 $TCID_{50}$/test
Flu A/Singapore/3/97	Duck	H5N3	6.0×10^4 $TCID_{50}$/test
Flu A/Henan/1/2004	Tree sparrow	H5N1	6.0×10^5 $TCID_{50}$/test
Flu A/Henan/2/2004	Tree sparrow	H5N1	3.0×10^5 $TCID_{50}$/test
Flu A/Henan/4/2004	Tree sparrow	H5N1	6.0×10^4 $TCID_{50}$/test
Flu A/Wisconsin/66	Turkey	H9N2	6.0×10^4 $TCID_{50}$/test
Flu A/England/1/63	Turkey	H7N3	6.0×10^4 $TCID_{50}$/test
Flu A/Singapore/1/57	Bird	H5N1	6.0×10^4 $TCID_{50}$/test
Flu A/Hunan/71/2004	Bird	H5N1	6.0×10^4 $TCID_{50}$/test
Flu A/Shanxi/50/2006	Bird	H5N1	6.0×10^4 $TCID_{50}$/test
Flu A/Shanxi/42/2006	Bird	H5N1	$6.0\times10_4$ $TCID_{50}$/test
Flu A/Fujian/320/2004	Bird	H5N1	3.0×10^5 $TCID_{50}$/test

Influenza A&B Ag Rapid Test Cassette (Swab) can detect all nine influenza B strains.

3. Clinical Study Data Summary

The Influenza A&B Ag Rapid Test performance vs. Cell Culture

Kind of samples	Type	Sensitivity (%)	Specificity (%)	Accuracy (%)
Nasopharyngeal/Nasal Swab	A	98.0 (49/50)	98.0 (147/150)	98.0 (196/200)
	B	98.7 (77/78)	99.5 (199/200)	99.3 (276/278)

Throat Swab	A	98.3 (59/60)	98.4 (123/125)	98.3 (182/185)
	B	98.0 (98/100)	98.5 (191/194)	98.3 (289/294)
Nasal Aspirate	A	98.7 (77/78)	98.6(148/150)	98.7 (225/228)
	B	99.1 (109/110)	99.5 (197/198)	98.3 (306/308)

4. Analytical Specificity and Cross-reactivity

The Influenza A&B Ag Rapid Test Cassette (Swab) was evaluated with a total of 30 bacterial and viral isolates. Bacterial isolates were evaluated at a concentration between 10^7 and 10^9 or g/mL. Viral isolates were evaluated at a concentration of at least 10^4-10^8 $TCID_{50}$/mL. Adenovirus 18 and Parainfluenza virus 3 were tested at 10^2 $TCID_{50}$/mL. None of the organisms or viruses listed below gave a positive result in the Influenza A&B Ag Rapid Test Cassette (Swab).

Bacterial Panel:		**Viral Panel:**	
Acinetobacter calcoaceticus	Bacteroides fragilis	Human Adenovirus B	Human Rhinovirus 2
Neisseria gonorrhoeae	Neisseria meningitidis	Human Adenovirus C	Human Rhinovirus 14
Pseudomonas aeruginosa	Staphylococcus aureus	Adenovirus type 10	Human Rhinovirus 16
Streptococcus pneumoniae	Streptococcus sanguis	Adenovirus type 18	Measles
Proteus vulgaris	Streptococcus sp. Gp. B	Human Coronavirus OC43	Mumps
Streptococcus sp. Gp. C	Streptococcus sp. Gp. G	Human Coxsackievirus A9	Sendai virus
Mycobacterium tuberculosis	Mycoplasma orale	Coxsackievirus B5	Parainfluenza virus 2
		Human herpesvirus2	Parainfl uenza virus 3

5. Interfering Substances

Whole blood, and several over-the-counter (OTC) products and common chemicals were evaluated and did not interfere with the Influenza A&B Ag Rapid Test Cassette (Swab) at the levels tested: whole blood (2%); three OTC mouthwashes (25%); three OTC throat drops (25%); three OTC nasal sprays (10%); 4-Acetamidophenol (10 mg/mL); Acetylsalicylic Acid (20 mg/mL); Chlorpheniramine (5 mg/mL); Dextromethorphan (10 mg/mL); Diphenhydramine (5 mg/mL); Ephedrine (20 mg/mL); Guaiacol glyceryl ether (20 mg/mL); Oxymetazoline (10 mg/mL); Phenylephrine (100 mg/mL); and Phenylpropanolamine (20 mg/mL).

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3. “Key Facts about Avian Influenza (Bird Flu) and Avian Influenza A (H5N1) Virus” CDC Publication, May 24, 2005. http://www.cdc.gov/flu/avian/gen-info/facts.htm
4. “Avian Influenza Infection in Humans” CDC Publication, May 24, 2005. http://www.cdc.gov/flu/avian/gen-info/avian-flu-humans.htm
5. “Updated Interim Guidance for Laboratory Testing of Persons with Suspected Infection with Avian Influenza A (H5N1) Virus in the United States” CDC Health Alert, June 7, 2006. http://www.phppo.cdc.gov/HAN/ArchiveSys/ViewMsgV.asp?AlertNum=00246

INDEX OF SYMBOLS

	Consult instructions for use		Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2~30°C	LOT	Lot Number	REF	Catalog#

Zhejiang Orient Gene Biotech Co.,Ltd
Address: 3787#, East Yangguang Avenue, Dipu Street, Anji 313300, Huzhou, Zhejiang, China
Tel: +86-572-5226111 Fax: +86-572-5226222
Website: www.orientgene.com

EC REP Shanghai International Holding Corp. GmbH (Europe)
Add: Eiffestrasse 80, 20537 Hamburg, Germany

REF GCFLU(A/B)-502a

Revision Date: 2022-11-14
B21900-03

Malaria P.f./P.v. Ag Rapid Test Cassette (Whole Blood)

CE

INTENDED USE

The Malaria P.f./P.v. Ag Rapid Test Cassette (Whole Blood) is a rapid lateral flow chromatographic immunoassay for the simultaneous detection and differentiation of Malaria P.falciparum specific histidine rich protein-2 (Pf HRP-II) and Malaria P.vivax specific lactate dehydrogenase (Pv-LDH) in human blood specimen as an aid in the diagnosis of Malaria infection.It is for *In-Vitro* Diagnostic use only.

INTRODUCTION

Malaria is a serious, sometimes fatal, parasitic disease characterized by fever, chills, and anemia and is caused by a parasite that is transmitted from one human to another by the bite of infected Anopheles mosquitoes. There are four kinds of malaria that can infect humans: Plasmodium falciparum, P. vivax, P. ovale, and P. malariae. In humans, the parasites (called sporozoites) migrate to the liver where they mature and release another form, the merozoites. The disease now occurs in more than 90 countries worldwide, and it is estimated that there are over 500 million clinical cases and 2.7 million malaria-caused deaths per year. At the present, malaria is diagnosed by looking for the parasites in a drop of blood. Blood will be put onto a microscope slide and stained so that the parasites will be visible under a microscope.

PRINCIPLE

The Malaria P.f./P.v. Ag Rapid Test Cassette (Whole Blood) contains a membrane, which is precoated with mouse monoclonal antibodies specific to HRP-II of P. falciparum on test line Pf region and with mouse monoclonal antibodies specific to lactate dehydrogenase of P.vivax species on test line Pv region respectively. Conjugate pad is dispensed with monoclonal antibodies conjugated to colloidal gold, which are specific to P.falciparum histidine rich protein-2 (Pf HRP-II) and specific to the lactate dehydrogenase of P.vivax.

During the assay, an adequate volume of the blood specimen is dispensed into the sample well (S) of the test cassette, a lysis buffer is added to the buffer well (B). The buffer contains a detergent that lyses the red blood cells and releases various antigens, which migrate by capillary action across the strip held in the cassette. Pv-LDH if presents in the specimen will bind to the Pv-LDH-gold conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-Pv-LDH antibody, forming a burgundy colored Pv band, indicating a Pv positive test result.

Alternatively, pHRP-II if presents in the specimen will bind to the pHRP-II-gold conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-pHRP-II antibodies, forming a burgundy colored Pf band, indicating a Pf positive test result.

Absence of any T bands suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex of goat anti- mouse IgG I mouse IgG (anti-Pv-LDH and anti-pHRP-II)-gold conjugates regardless of the color development on any of the T bands. Otherwise, the test result is invalid and the specimen must be retested with another device.

MATERIALS SUPPLIED

25 Sealed pouches each containing a test cassette, a dropper and a desiccant
1 Buffer, 7.0 mL
1 Package insert

MATERIAL REQUIRED BUT NOT PROVIDED

1. Clock or timer
2. Collection by venipuncture: collection tube (containing EDTA, citrate or heparin)
3. Collection using a lancet: sterile lancet

STORAGE AND STABILITY

All reagents are ready to use as supplied. Store unused test device unopened, preferably at 2°C-30°C. Do not expose the kit over 30°C. Do not freeze the kit. Ensure that the test device is brought to room temperature before opening. The test device is stable through the expiration date printed on the sealed pouch if it is stored at 2°C-30°C.

WARNINGS AND PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Do not use after expiration date.
2. The instruction must be followed exactly to get accurate results. Failure to follow the insert gives inaccurate test results.
3. Do not eat, drink or smoke in the area where the specimens or kits are handled.
4. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
5. Hemolized blood may be used for the testing, but do not take precipitants.
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
7. Humidity and temperature can adversely affect results.
8. Do not perform the test in a room with strong air flow, ie. an electric fan or strong airconditioning.

SPECIMEN COLLECTION

Collection by venipuncture:

1) Collect whole blood into a collection tube (containing EDTA, citrate or heparin) by venipuncture.
2) If specimens are not immediately tested, they should be refrigerated at 2-8°C. For storage periods greater than three days, freezing is recommended. They should be brought to room temperature prior to use. Using the specimen after long-term storage of more than three days can cause non-specific reaction.
3) When stored at 2-8°C, the whole blood sample should be used within three days.

Collection using a lancet:

1) Clean the area to be lanced with an alcohol swab.
2) Squeeze the end of the fingertip and pierce with a sterile lancet.
3) Wipe away the first drop of blood with sterile gauze or cotton.
4) Using the dropper provided, while gently squeezing the tube, immerse the open end in the blood drop and then gently release the pressure to draw blood into the dropper.

TEST PROCEDURE

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

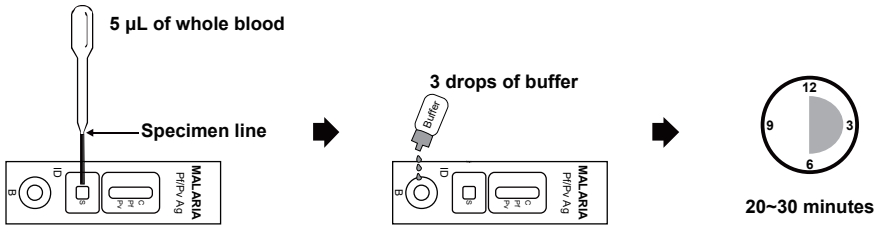
1.Remove the test cassette from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test cassette on a clean and level surface. Be sure to label the device with specimen's ID number.
3. With a 5 µL mini plastic dropper provided, draw whole blood specimen to exceed the specimen line as showed in the following image and then transfer drawn whole blood into the sample well (S). Then add 3 drops (about 120 µL) of Lysis Buffer to the buffer well (B) immediately.

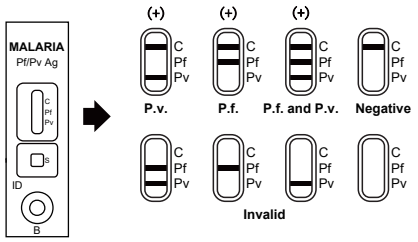
Note: Practice a few times prior to testing if you are not familiar with the mini dropper. For better precision, transfer specimen by pipette capable to deliver 5 µL of volume.

4. Set up timer.

If preferred, after 5 minutes of adding specimen and buffer, you may add one more drop of Lysis Buffer to help the background become clearer.

5. Results can be read in 20 to 30 minutes. It may take more than 20 minutes to have the background become clearer. Don't read results after 30 minutes. To avoid confusion, discard the test cassette after interpreting the result.





Malaria P.f./P.v. Ag Rapid Test Cassette (Whole Blood)

INTERPRETATION OF RESULTS

(Please refer to the illustration above)
POSITIVE:
P.f Positive: One line appears in the control region, and one line appears in P.f. line region.
P.v Positive: One line appears in the control region and one line appears in Pv line region.
P.f and P.v Positive: One line appears in the control region, one line appears in Pv line region and one line appears in P.f. line region.
NEGATIVE: Only one colored line appears in the control region.
INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an 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

1. The Malaria P.f./P.v. Ag Rapid Test Cassette (Whole Blood) is for in vitro diagnostic use only. This test should be used for the detection of P.f and P.v antigens in whole blood specimens only. Neither the quantitative value nor the rate of increase in P.f and P.v concentration can be determined by this qualitative test.
2. The Malaria P.f./P.v. Ag Rapid Test Cassette (Whole Blood) will only indicate the presence of antigens of P.f and / or P.v in the specimen and should not be used as the sole criterion for the diagnosis of malaria infection.
3. As known relevant interference, haemolytic samples, rheumatoid factors-contained samples and lipaemic, icteric samples can lead to impair the test results.
4. The test is limited to the detection of antigen to Malaria Plasmodium sp. Although the test is very accurate in detecting HRP-II specific to P.f or pLDH specific to P.v, a low incidence of false results can occur. Other clinically available tests are required if questionable results are obtained.
5. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of malaria infection.
6. As with all diagnostic tests, a definitive clinical diagnosis should 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

1. Clinical Performance for P.f Ag test:
A total of 352 samples from susceptible subjects were tested by the Malaria P.f./P.v. Ag Rapid Test Cassette (Whole Blood) and by thick blood smear test.

Method		Smear Test		Total Results
Malaria Pf/Pv Ag Rapid Test	Results	Positive	Negative	
	Positive	50	4	54
	Negative	0	298	298
Total Results		50	302	352

Relative Sensitivity: 100%
Relative Specificity: 98.7%
Overall Agreement: 98.9%

2. Clinical Performance for P.v Ag test:
A total of 289 samples from susceptible subjects were tested by the Malaria P.f./P.v. Ag Rapid Test Cassette (Whole Blood) and by thick blood smear test.

Method		Smear Test		Total Results
Malaria Pf/Pv Ag Rapid Test	Results	Positive	Negative	
	Positive	63	3	66
	Negative	0	223	223
Total Results		63	226	289

Relative Sensitivity: 100%
Relative Specificity: 98.7%
Overall Agreement: 99.0%

3. Precision: Within-run and between-run have been determined by the testing 10 replicates of four specimens: a negative, a low positive, a medium positive and a strong positive. All values were correctly identified 100% of the time.
4. Interference: To evaluate the interference of Malaria P.f./P.v. Ag Rapid Test Cassette (Whole Blood) with known relevant interfering specimens, the haemolytic samples, rheumatoid factors-contained samples and lipaemic, icteric samples were investigated. In these studies, those specimens did not interfere with the Malaria P.f./P.v. Ag Rapid Test Cassette (Whole Blood).

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INDEX OF SYMBOLS

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IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2~30°C	LOT	Lot Number	REF	Catalog#

Zhejiang Orient Gene Biotech Co., Ltd
Address: 3787#, East Yangguang Avenue, Dipu Street,
Anji 313300, Huzhou, Zhejiang, China
Tel: +86-572-5226111 Fax: +86-572-5226222
Website: www.orientgene.com

EC REP QARAD BV
Cipalstraat 3, 2440 Geel BELGIUM

REF GCMAL(pf/pv)-402a

Revision Date: 2022-09-26
B20885-03