Urinalysis Strips

CE

SUMMARY AND INTENDED USE

The content of the instruction includes usage, reaction principle, and notification.
Urinalysis strips are intended for qualitative and semi-quantitative urinalysis and for *in vitro* diagnostics use.
The strips are for professional use only.
The strips may be read visually or instrumentally. Please read the instruction carefully before use.
There are the test items of every products type.

Products type	Packaging	Test item
URS 14	25/50/100 strips per canister	Urobilinogen, Bilirubin, Ketone (acetoacetic acid), Blood, Protein, Nitrite, Leukocytes, Glucose, Specific Gravity, pH, and Ascorbic Acid, Microalbumin, Creatinine, Calcium
URS 13, URS 12, URS 11, URS 10, URS 9, URS 8, URS 7, URS 6, URS 5, URS 4, URS 3, URS 2, URS 1	25/50/100 strips per canister	The items of product type from URS 2 to URS 13 can be combined randomly from URS 14 test items mentioned above. US1 item can be any item from URS 14.

SPECIMEN COLLECTION AND PREPARATION

Collect fresh urine in a clean dry container. Use uncentrifuged urine and mix the sample before testing. The sample should not be more than 2 hours old at the time of testing. Always handle specimens under sanitary conditions.
Note: Water should not be used as negative control. Preservatives will not prevent the deterioration of ketones, bilirubin or urobilinogen. Bacterial growth from contaminating organisms may affect glucose, pH, nitrite and blood test results.

VISUAL READING TECHNIQUE

1. Immerse all reagent areas in specimen and remove strip immediately.
2. Run edge of strip against the rim of the container to remove excess urine.
3. Hold strip horizontally and compare test areas closely with color chart on bottle label. Record the results.

For a semi-quantitative result read the reagent areas at the time specified on the color chart. The pH and Protein areas may also be read immediately or at any time up to 60 seconds after dipping. For a qualitative result read the reagent areas between 1 and 2 minutes. If a positive result is obtained, repeat the test, reading each reagent at the time specified on the color chart.
Color changes after 2 minutes are of no diagnostic value.

INSTRUMENT READING TECHNIQUE

Follow the directions given in the appropriate instrument-operating manual.

STORAGE AND HANDLING PROCEDURES

Store only in original bottle. Do not use after expiry date. Every strip can be used only once. Do not remove desiccant(s). Do not remove strip from the bottle until immediately before it is to be used for testing. Replace cap immediately and tightly after removing reagent strip. Shelf life: 24 months. Stability period after opening: 3 months
Store at temperatures between 2℃-30℃.Don't store in refrigerator. Keep away from direct sunlight.
Do not touch test areas of reagent strips. PROTECTION AGAINST AMBIENT MOISTURE, LIGHT AND HEAT IS ESSENTIAL TO GUARD AGAINST ALTERED REAGENT REACTIVITY. Deterioration may result in discoloration or darkening of the reagent areas. If this is evident or if test results are questionable or inconsistent with expected results, confirm that strips are within the expiry dates and compare with control urine. Please deal with the waste strips according to "Treatment Regulations of Lab Biohazard Materials".

LIMITATIONS OF PROCEDURES

As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be made or based on any single result or method.

TEST PRINCIPLES

Glucose: One enzyme, glucose oxidize catalyzes the formation of gluconic acid and hydrogen peroxide from the oxidation of glucose. Hydrogen peroxide releases neo-ecotypes oxide [O] under the function of peroxidase, [O] oxidates potassium. iodides chromogen, so that it makes the color change.
Bilirubin: This test is based on coupling the direct bilirubin with diazotized dichloroaniline in a strongly acid medium, which produce the diazotizing colors.
Ketone: This test is based on that acetoacetate acid react with sodium nitroprusside in an alkaline medium, producing violet color.
Specific gravity: Electrolyte (M+X-) in the form of salt in urine reacts with poly (methyl vinyl ether/maleic anhydride (-COOH), which is weakly acid ionic exchanger. And then hydrogenous ion is replaced from it and reacts with pH indicator in order to make the color change.
Blood: This test is based on the peroxidase activity of hemoglobin and myoglobin, which makes peroxide release neo-ecotypic Oxide [O]. Indicator is oxidized by [O] and shows color change subsequently.
pH: This test is based on a double indicator principle.
Protein: The test is based on the protein-error-of-indicators principle. Anion on the specific pH indicator is absorbed by cation on protein molecule, which make the indicator ionize and present color change at critical point of color.
Urobilinogen: This test is based on coupling the urobilinogen with diazotized salt in a strongly acid medium, which produce the pink-red azo dye.
Nitrite: This test depends upon the nitrite diazotize with aromatic amino sulphanilamide to form a diazonium compound. This diazonium compound in turn couples with 1,2,3,4-tetrahydro-benzo(h)quinolin-3-phenol to produce a pink color.
Leucocytes: Granulocytic leukocytes in urine contain esterase's that catalyze the hydrolysis of the privatized pyrrole amino acid ester to liberate 3-hydroxy-5-pheny pyrrole. This pyrrole then reacts with a diazonium salt to form a purple color.
Ascorbic acid: Ascorbic acid, with 1,2-dihydroxy alkenes, under alkaline condition, deoxidizes blue 2,6-dichloroindophenolate form into colorless N-(P-phenol)-2,6-dichloro–P- amine phenol.
Microalbumin: Based on the protein deviation method, utilizing the sulfone phthalein dyestuff only specific to Microalbumin.
Creatinine： Creatinine can act with 3, 5-2 nitro benzoic acid in strong alkalinity, generating colored compound.
Calcium： Calcium can with o-Cresol phthalein complex one in an alkaline medium, producing violet color.

Note:

GLUCOSE: The test is specific for glucose, no substance excreted in urine other than glucose is known to give a positive result. In dilute urine containing less than 0.28 mmol/L ascorbic acid, as little as 2.2 mmol/L glucose may produce a color change that might be interpreted as positive. Ascorbic acid concentrations of 2.8 mmol/L or greater and/or high acetoacetic concentrations (1.0 mmol/L) may influence test. Small amounts of glucose may normally be excreted by the kidney. These amounts are usually below the sensitivity of this test.
BILIRUBIN: Normally no bilirubin is detectable in urine by even the most sensitive methods. Even trace amounts of bilirubin are sufficiently abnormal to require further investigation. Medicines that color the urine red or that are themselves red in an acid medium, e.g., phenazopyridine may influence the test. Large ascorbic acid concentration may cause false negatives.
KETONES: The test reacts with acetoacetic acid in urine. It does not react with acetone or β-hydroxybutyric acid. Normal urine specimens usually yield negative results with this reagent. False positive results may occur with highly pigmented urine specimens or those containing large amounts or levodopa metabolites.
SPECIFIC GRAVITY: The specific gravity permits determination of urine specific gravity between 1.000 and 1.030. In general, it correlates within 0.005 with values obtained with the refractive index method. For increased accuracy, 0.005 may be added to readings from urines with pH equal to or greater than 6.5. Strips read instrumentally are automatically adjusted for pH by the instrument. The SG test is not affected by certain nonionic urine constituents such as glucose or by the presence of radiopaque dye. Highly buffered alkaline urines may cause low readings relative to other methods. Elevated specific gravity readings may be obtained in the presence of moderate quantities (1-7.5 g/L) of protein.
BLOOD: The significance of the 'Trace' reaction may vary among patients, and clinical judgment is required for assessment in an individual case. Development of green spots (intact erythrocytes) or green color (free hemoglobin/ myoglobin) on the reagent area within 60 seconds indicates the need for further investigation. Blood is often found in the urine of menstruating females. Hemoglobin concentration of 150-620 μg/L is approximately equivalent to 5-15/μL intact red blood cells per microlite.
This test is highly sensitive to hemoglobin and thus complements the microscopic examination. The sensitivity of this test may be reduced in urines with high specific gravity. This test is equally sensitive to myoglobin as to hemoglobin. Certain oxidizing contaminants, such as hypochlorite, may produce false positive results. Microbial peroxidase associated with urinary tract infection may cause a false positive reaction. Levels of 5.0 mmol/L ascorbic acid normally found in urine do not interfere with this test.
pH: The pH test area measures pH values generally to within 1 unit in the range of 5.0-8.5 visually and 5.0-9.0 instrumentally.

PROTEIN and MICROALBUMIN:

The Protein reagent area can detect albumin in urine and has low sensitivity to mucoprotein, generally up to 0.6 g/L concentration.

The Microalbumin reagent area is to detect the microalbumin. Beyond 0.15 g/L indicate albuminuria clinically. The Microalbumin reagent can detect specifically microalbumin, and 9 times more sensitive than other protein.
Visible blood urine (⩾0.05 g/L) can be false negative action.

UROBILINOGEN: This test area will detect urobilinogen in concentrations as low as 3 μmol/L (approximately 0.2 Ehrlich unit/dL) in urine. The normal range with this test is 3-16 μmol/L. a result of 33 μmol/L represents the transition from normal to abnormal, and the patient and/or urine specimen should be evaluated further. The absence of urobilinogen cannot be determined with this test.

NITRITE: This test depends upon the conversion of nitrate (derived from the diet) to nitrite by the action of principally Gram-negative bacteria in the urine. The test is specific for nitrite and will not react with any other substance normally excreted in urine. Pink spots or pink edges should not be interpreted as a positive result. Any degree of uniform pink color development should be interpreted as a positive nitrite test suggesting the presence of 10^5 or more organisms per mL, but color development is not proportional to the number of bacteria present. A negative result does not prove that there is no significant bacteriuria. Negative results may occur ① when urinary tract infections are caused by organisms which do not contain reductase to convert nitrate to nitrite; ② when urine has not been retained in the bladder long enough (four hours or more) for reduction of nitrate to occur, ③ or when dietary nitrate is absent. Sensitivity of the nitrite test is reduced for urines with high specific gravity. It may resist 2.8mmol/L Ascorbic Acid.

LEUKOCYTES: Test area react with esterase in leucocytes (granulocytic leukocytes). Normal urine specimens generally yield negative result; positive results (+ or greater) are clinically significant. Individually observed 'Trace' results may be of questionable clinical significance; however, 'Trace' results observed repeatedly may be clinically significant. 'Positive' results may occasionally be found with random specimens from females due to contamination of the specimen by vaginal discharge. Elevated glucose concentrations (160 mmol/L) or high specific gravity may cause decreased test results.

ASCORBIC ACID: The test area can detect the ascorbic acid in urine. Through the ascorbic acid detection, we will know the level of ascorbic acid in the body and the effect degree that the ascorbic acid brings to the test on glucose, bilirubin, blood and nitrite. It will reduce the sensitivity when the oxidant (such as potassium permanganate, hypochlorite) in the urine.

Creatinine: Adult normal urine creatinine is 0.6-2.0 g/24 hour (the Creatinine reagent area results is about 50-200 mg/dL). Result of random urine sample differ largely, from 10 mg/dL to 300 mg/dL. Concentrated urine and morning urine have high concentration (possibly over 200 mg/dL). Because of diuresis, excessive drinking water, or other urine dilution, resulting in testing analyte concentration decrease (result can be less than 50 mg/dL).

SPECIFIC PERFORMANCE CHARACTERISTICS

Specific performance characteristics are based on clinical and analytical studies. In clinical specimens, the sensitivity depends upon several factors; the variability of color perception, the presence or absence of inhibitory factors typically found in urine, specific gravity, pH, and the lighting conditions when the product is read visually. Each color block or instrumental display value represents a range of values. Because of specimen and reading variability, specimens with analyte concentrations that fall between nominal levels may give results at either level. Results at levels greater than the second positive level for the Protein, Glucose, Ketone, and Urobilinogen tests will usually be within one level of the true concentration. Exact agreement between visual results and instrumental results might not be found because of the inherent differences between the perception of the human eye and the optical system of the instruments.

Sensitivity and test range of urinalysis strips

Item	Sensitivity	Instrumental test range	Visual test range
Glucose (mmol/L)	2.8-5.5	Neg-55	
Protein (g/L)	0.15-0.3	Neg -3.0	Neg – 20.0
Microalbumin (g/L)	0.08-0.15	0-0.15	
Ketone (acetoacetic acid) (mmol/L)	0.5-1.0	Neg-7.8	Neg-16
Blood (Ery/uL)	5-15	Neg.- 200	
Bilirubin (μmol /L)	3.3-8.6	Neg.-100	
Nitrite (μmol /L)	13-22	Neg. or Pos.	
Leukocytes (cells/μL)	5-15	Neg. - 500	
Urobilinogen (μmol /L)	3.3-16	3.3-131	
Ascorbic acid (mmol/L)	0.3-0.6	0-5.0	
Creatinine (mg/dL)	25-75	10-300	
pH	——	5.0-9.0	5.0-8.5
Specific Gravity	——	1.005-1.030	1.000-1.030
Calcium (mmol/L)	2.5-3.5	2.5-10.0	2.5-10.0

REACTIVE INGREDIENTS (based on dry weight at time of impregnation)

Protein: 0.1% m/m tetrabromphenol blue; 97.4% w/w buffer; 2.5% w/w nonreactive ingredients

Blood: 26.0% w/w diisopropylbenzene dihydro peroxide; 1.5% w/w tetramethylbenzidine; 35.3% w/w buffer; 37.2 % nonreactive ingredients.

Glucose: 1.7% w/w glucose oxidase (microbial.123U); 0.2 % w/w peroxidase (horseradish. 203 IU); 0.1% w/w potassium iodide; 71.8% w/w buffer; 26.2% w/w nonreactive ingredients.

Ketone: 5.7% w/w sodium nitroprusside; 29.9% w/w nonreactive ingredients;64.4% w/w buffer;

Leukocytes: 4.3% w/w pyrrole amino acid ester; 0.4% w/w diazonium salt; 92.6% w/w buffer; 2.7% w/w nonreactive ingredients.

Nitrite: 1.3% w/w1,2,3,4-Tetrahydrobenzo(h)quinolin-3-ol; 89.6% w/w buffer; 9.1% w/w nonreactive ingredients**.**

Specific Gravity: 4.8% w/w bromothymol blue; 90.2% w/w poly (methyl vinyl ether co maleic anhydride); 5.0% w/w sodium hydroxide.

pH: 3.3% w/w bromocresol green; 55.0% w/w bromothymol blue; 41.7% w/w nonreactive ingredients.

Bilirubin: 0.6% w/w 2.4-dichlorbenzene amine diazonium salt; 57.3% w/w buffer; 42.1% w/w nonreactive ingredients.

Urobilinogen: 0.2% w/w fast B blue; 98.0% w/w buffer; 1.8% w/w nonreactive ingredients.

Ascorbic acid: 0.8% w/w 2,6-dichloroindophenolate hydrate; 40.7% w/w buffer; 58.5% w/w nonreactive ingredients.

Microalbumin: 2.2% w/w sulfone phthalein dyestuff; 96.0% w/w buffer; 1.8 w/w nonreactive ingredients.

Creatinine: 4.8% w/w 3, 5-2 nitro benzoic acid; 85.2% w/w buffer; 10% w/w nonreactive ingredients.

Calcium: 2.5% W/W o-Cresol phthalein Complex one; 87.5% w/w buffer; 10% w/w nonreactive ingredients.

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

Revision Date：2023-02-28
B20952-05

Reference number	Measured parameters	Reference number	Measured parameters
URS-1T-ASC	ASC	URS-4T-004	GLU-01，PH-01，SG-01，PRO-01
URS-1T-BIL	BIL	URS-4T-005	LEU-01，NIT-01，BLO-01，PH-01
URS-1T- BLO	BLO	URS-4T-006	LEU-01, NIT-01,BLO-01,PRO-01
URS-1T- CA	CA	URS-5T-001	PRO/PH/BLO/KET/GLU
URS-1T-CRE	CRE	URS-5T-002	GLU/PRO/BLO/LEU/NIT
URS-1T-GLU	GLU	URS-5T-003	GLU/KET/MA/PH/SG
URS-1T-KET	KET	URS-5T-004	GLU/PRO/PH/BLO/KET
URS-1T-LEU	LEU	URS-5T-005	MA/BLO/ASC/CRE/CA
URS-1T-MA	MA	URS-6T-001	LEU/NIT/PRO/BLO/GLU/KET
URS-1T- NIT	NIT	URS-6T-002	OXI/SG/PH/NIT/GLUT/CRE
URS-1T- PH	PH	URS-8T-001	LEU/NIT/PRO/PH/BLO/SG/KET/GLU
URS-1T-PRO	PRO	URS-9T-001	LEU/NIT/URO/PRO/PH/BLO/KET/BIL/GLU
URS-1T- SG	SG	URS-9T-002	BLO/BIL/URO/KET/PRO/NIT/GLU/PH/SG
URS-1T- URO	URO	URS-10T-001	LEU/NIT/URO/PRO/PH/BLO/SG/KET/BIL/GLU
URS-1T-ASC	ASC	URS-10T-002	LEU/NIT/URO/PRO/PH/BLO/SG/KET/BIL/GLU
URS-1T-BIL	BIL	URS-10T-003	URO/GLU/BIL/KET/SG/BLO/PH/PRO/NIT/LEU
URS-1T- BLO	BLO	URS-10T-004	LEU/NIT/URO/PRO/PH/BLO/SG/KET/BIL/GLU
URS-1T- CA	CA	URS-11T-001	LEU/NIT/URO/PRO/PH/BLO/SG/ASC/KET/BIL/GLU
URS-1T-CRE	CRE	URS-11T-002	URO/BLO/BIL/KET/LEU/GLU/PRO/PH/NIT/SG/MA
URS-2T-001	GLU/PRO	URS-11T-003	LEU/NIT/URO/PRO/PH/BLO/SG/ASC/KET/BIL/GLU
URS-2T-002	LEU/NIT	URS-11T-004	URO/BIL/KET/BLO/PRO/NIT/LEU/GLU/SG/PH/ASC
URS-2T-003	GLU/KET	URS-11T-005	31ET/URO/GLU/BIL/KET/SG/BLD/pH/PRO/NIT/LEU
URS-2T-004	pH/pH	URS-12T-001	(LEU/NIT/URO/MA/PRO/PH/BLO/SG/ASC/KET/BIL/GLU)
URS-3T-001	GLU/PRO/PH	URS-12T-002	URO/BIL/KET/BLO/PRO/MA/NIT/LEU/GLU/SG/PH/ASC
URS-3T-002	GLU/KET/PRO	URS-13T-001	LEU/NIT/URO/MA/PRO/PH/BLO/SG/ASC/CRE/KET/BIL/GLU
URS-4T-001	GLU-01，PRO-01，pH-01，BLO-01	URS-14T-001	LEU/NIT/URO/MA/PRO/PH/BLO/SG/ASC/CRE/KET/BIL/GLU/CA
URS-4T-002	PRO-01，GLU-01，pH-01，SG-01b	URS-14T-002	URO/BIL/KET/CRE/BLO/PRO/MA/NIT/LEU/GLU/SG/PH/ASC/CA
URS-4T-003	KET-01，BLO-01，BIL-01，NIT-01		

H. pylori Ab Rapid Test Cassette (Whole blood/Serum/Plasma)

CE

INTENDED USE

The H. pylori Ab Rapid Test Cassette (Whole blood/Serum/Plasma) is a sandwich lateral flow chromatographic immunoassay for the qualitative detection of antibodies (IgG, IgM, and IgA) anti- *Helicobacter pylori* （*H.pylori*）in human whole blood, serum or plasma. It is intended to be used as a screening test and as an aid in the diagnosis of infection with *H.pylori.* Any reactive specimen with the H.pylori Ab Rapid Test must be confirmed with alternative testing method(s) and clinical findings.

SUMMARY

Helicobacter 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].

The H. pylori Ab Rapid Test Cassette (Whole blood/Serum/Plasma) is a latest generation of chromatographic immunoassay which utilizes recombinant antigens to detect the antibodies to H.pylori in human whole blood, serum or plasma. The test is user friendly, highly sensitive and specific.

PRINCIPLE

The H. pylori Ab Rapid Test Cassette (Whole blood/Serum/Plasma) is a lateral flow chromatographic immunoassay based on the principle of the double antigen–sandwich technique. The test cassette consists of: 1) a burgundy colored conjugate pad containing H.pylori antigens conjugated with colloidal gold (H.pylori conjugates) and rabbit IgG-gold 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 antigens, and the C band is pre-coated with goat anti-rabbit IgG.

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 antibodies: either the IgG, the IgM, or the IgA, to H.pylori if present in the specimen will bind to the H.pylori conjugates. The immunocomplex is then captured on the membrane by the pre-coated H.pyloriantigens, forming a burgundy colored T band, indicating a H.pylori Ab positive test result. Absence of the T band 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-rabbit IgG/rabbit IgG-gold conjugate regardless the presence of any antibodies to H. pylori. Otherwise, the test result is invalid and the specimen must be retested with another device.

PRECAUTIONS

1. For professional *in vitro* diagnostic use only. Do not use beyond expiration date.
2. Do not eat, drink or smoke in the area where the specimens or kits are handled.
3. Handle all specimens as if they contain infectious agents. Observe established precautions against micro-biological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. Humidity and temperature can adversely affect test results.

STORAGE AND STABILITY

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

SPECIMEN COLLECTION AND PREPARATION

1.The H.pylori Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.

2.To collect Fingerstick Whole Blood specimens:

◦Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.

◦Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.

◦ Puncture the skin with a new sterile lancet for each person. Wipe away the first sign of blood.

◦ Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.

◦ Add the Fingerstick Whole Blood specimen to the test device by using a capillary tube:

・Touch the end of the capillary tube to the blood until filled to approximately 50 µL. Avoid air bubbles.

・ Place the bulb onto the top end of the capillary tube, then squeeze the bulb to dispense the whole blood into the specimen well (S) of the test device.

◦ Add the Fingerstick Whole Blood specimen to the test device by using hanging drops:

・Position the patient's finger so that the drop of blood is just above the specimen well (S) of the test device.

・Allow 2 hanging drops of fingerstick whole blood to fall into the center of specimen well (S) on the test device, or move the patient's finger so that the hanging drop touches the center of the specimen well (S). Avoid touching the finger directly to the specimen well (S).

3.Separate serum or plasma from blood as soon as possible to avoid hemolysis. Use only clear, non-hemolyzed specimens.

4.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. Whole blood collected by fingerstick should be tested immediately.

5.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.

6.If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

MATERIALS PROVIDED

25 sealed pouches each containing a test cassette, a dropper and a desiccant
1 Buffer, 4.0 mL
1 package insert

MATERIAL REQUIRED BUT NOT PROVIDED

1.Specimen collection containers 2.Lancets (for fingerstick whole blood only)
3.Centrifuge (for plasma only) 4.Timer
5.Heparinized capillary tubes and dispensing bulb (for fingerstick whole blood only)

DIRECTIONS FOR USE

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

1.Remove the test device 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 device on a clean and level surface.

For Serum or Plasma Specimens: Hold the dropper vertically and transfer 1 drop of serum or plasma (approximately 30 µL) to the specimen well (S) of the test device, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.

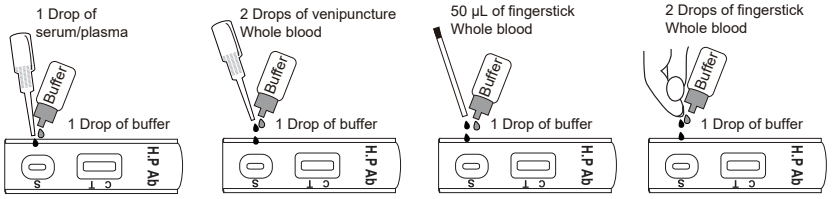
For Venipuncture Whole Blood Specimens: Hold the dropper vertically and transfer 2 drops of venipuncture whole blood (approximately 50µL) to the specimen well (S) of the test device, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.

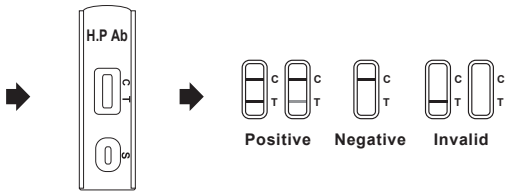
For Fingerstick Whole Blood Specimens: Allow 2 hanging drops of fingerstick whole blood (approximately 50 µL) to fall into the center of the specimen well (S) on the test device, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.

3. Wait for the red line(s) to appear. The result should be read in 15 minutes.

Note: Low levels of H.plori antibodies might result in a faint line appearing in the test region(T) after an extended period of time; therefore ,do not interpret the result after 15 minutes.

H. pylori Ab Rapid Test Cassette
(Whole Blood/Serum/Plasma)





INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE*: Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T).

***NOTE:** *The intensity of the red color in the test line region (T) will vary depending on the concentration of H.p antibodies in the specimen. Therefore, any shade of red in the test region (T) should be considered positive.*

NEGATIVE: One red line appears in the control region (C). No apparent red or pink line appears in the test region (T).

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

A procedural control is included in the test. A red line appearing in the control 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

1.H. pylori Ab Rapid Test Cassette (Whole Blood/Serum/Plasma) is for *in vitro* diagnostic use only. The test should be used for the detection of H.pylori antibodies in whole blood, serum or plasma specimen only.

2.H. pylori Ab Rapid Test Cassette (Whole blood/Serum/Plasma) will only indicate the presence of H.pylori antibodies in the specimen and should not be used as the sole criteria for the diagnosis of H.pylori infection.

3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

4. 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 H.pylori infection.

PERFORMANCE CHARACTERISTICS

Clinical Performance

A study was performed with 175 patient specimen including both symptomatic gastrointestinal disorders and samples from non-symptomatic patients and 100 normal specimen. Comparison for all subjects with the H.pylori Ab Rapid Test Cassette (Whole Blood / Serum/Plasma) and reference ELISA kit is showed in the following table:

Method		H.pylori Ab Rapid Test		Total Results
ELISA	Results	Positive	Negative	
	Positive	170	5	175
	Negative	1	99	100
Total Results		171	104	275

Relative Sensitivity: 97.1%
Relative Specificity: 99.0%
Accuracy: 97.8%

REFERENCE

1. Marshall,B.J.et.al.1985. Med. J. Australia. 149:439-44,
2. Soll,A.H. 1990. New England J. Med.322:909-916.
3. Parsonnet,J.et.al.1991. New England J. Med. 325:1127-31.
4. Ansong,R. et.al.1991. J.Clin.Micro. 29:51-53,
5. Pronovost,A.P.et.al. 1994. J.Clin.Microbiol.32:46-50.
6. Megraud,F.et.al.1989. 27:1870-3,1989
7. Marshall,B.J.et.al. 1988. Lancet. Dec.1437-42

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-402a

Revision Date: 2024-04-09
B21762-02

CK-MB Rapid Test Cassette (Whole Blood/Serum/Plasma)

CE

A rapid test for the qualitative detection of CK-MB in whole blood, serum or plasma.
For professional *in vitro* diagnostic use only.

INTENDED USE

The CK-MB Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of human CK-MB in whole blood, serum or plasma as an aid in the diagnosis of myocardial infarction (MI).

SUMMARY

Creatine Kinase MB (CK-MB) is an enzyme present in the cardiac muscle with a molecular weight of 87.0 kDa. Creatine Kinase is a dimeric molecule formed from two subunits designated as "M" and "B" which combine to form three[1] different isoenzymes, CK-MM, CKBB, and CK-MB. CK-MB is the isoenzyme of Creatine Kinase most involved in the metabolism of cardiac muscle tissue.[2] The release of CK-MB into the blood following MI can be detected within 3-8 hours after the onset of symptoms. It peaks within 9 to 30 hours, and returns to baseline levels within 48 to 72 hours.[3] CK-MB is one of the most important cardiac markers and is widely recognized as the traditional marker for the diagnosis of MI. The CK-MB Rapid Test Cassette (Whole Blood/Serum/Plasma) is a simple test that utilizes a combination of anti -CK-MB antibody coated particles and capture reagent to detect CK-MB in whole blood, serum or plasma. The minimum detection level is 5 ng/mL.

PRINCIPLE

The CK-MB Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative, membrane based immunoassay for the detection of CK-MB in whole blood, serum or plasma. The membrane is pre-coated with capture reagent on the test line region of the test. During testing, the whole blood, serum or plasma specimen reacts with the particle coated with anti-CK-MB antibodies.The mixture migrates upward on the membrane chromatographically by capillary action to react with capture reagent on the membrane and generate a colored line. 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

The test contains anti-CK-MB antibody coated particles and capture reagent coated on the membrane.

PRECAUTIONS

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

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 PREPARATION

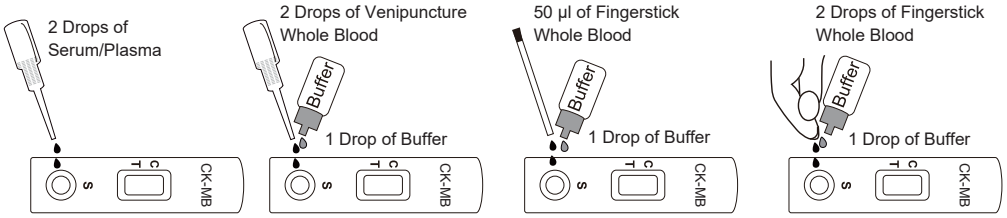
- The CK-MB Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
- To collect Fingerstick Whole Blood specimens:
- Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
- Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
- Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
- Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Position the patient's finger so that the drop of blood is just above the specimen well (S) of the test device.
- Allow 2 hanging drops of fingerstick whole blood to fall into the specimen well (S) of the test device, or move the patient's finger so that the hanging drop touches the specimen well (S). Avoid touching the finger directly to the specimen well (S).
- 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. Whole blood collected by fingerstick should be tested immediately.
- 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.

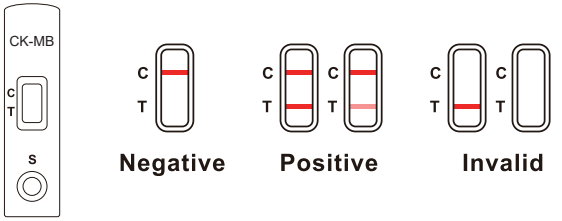
MATERIALS

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
- Specimen collection containers
- Centrifuge
- Lancets (for fingerstick whole blood only)
- Timer

DIRECTIONS FOR USE

Allow the test, specimen and/or controls to reach room temperature (15-30°C) prior to testing.
1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed 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. Place the test device on a clean and level surface.
For Serum or Plasma specimens: Hold the dropper vertically and transfer 2 drops of serum or plasma (approximately 50 µL) to the specimen well (S) of the test device, then start the timer. See illustration below.
For Venipuncture Whole Blood specimens: Hold the dropper vertically and transfer 2 drops of venipuncture whole blood (approximately 50 µL) to the specimen well (S) of the test device, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.
For Fingerstick Whole Blood specimens: Allow 2 hanging drops of fingerstick whole blood specimen (approximately 50 µL) to fall into the center of the specimen well (S) on the test device, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.
3. Wait for the colored line(s) to appear. Read results at 10 minutes. Do not interpret results after 20 minutes.





INTERPRETATION OF RESULTS

(Please refer to the illustration above)
POSITIVE: Two distinct colored 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 (C) 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. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

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 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 CK-MB Rapid Test Cassette (Whole Blood/Serum/Plasma) is for *in vitro* diagnostic use only. This test should be used for the detection of CK-MB in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in CK-MB can be determined by this qualitative test.
2. The CK-MB Rapid Test Cassette (Whole Blood/Serum/Plasma) will only indicate the qualitative level of CK-MB in the specimen and should not be used as the sole criteria for the diagnosis of myocardial infarction.
3. The CK-MB Rapid Test Cassette (Whole Blood/Serum/Plasma) can detect no less than 5 ng/mL of CK-MB in specimens. A negative result at any time does not preclude the possibility of myocardial infarction.
4. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
5. Unusually high titers of heterophile antibodies or rheumatoid factor (RF) may affect results. Even if the test results are positive, further clinical evaluation should be considered with other clinical information available to the physician.
6. There is a slight possibility that some whole blood specimens with very high viscosity or which have been stored for more than 2 days may not run properly on the test device. Repeat the test with a serum or plasma specimen from the same patient using a new test device.

EXPECTED VALUES

The CK-MB Rapid Test Cassette (Whole Blood/Serum/Plasma) has been compared with a leading commercial CK-MB EIA test, demonstrating an overall accuracy of 99.8%.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The CK-MB Rapid Test Cassette (Whole Blood/Serum/Plasma) has been evaluated with a leading commercial CK-MB EIA test using clinical specimens. The results show that the sensitivity of the CK-MB Rapid Test Cassette (Whole Blood/Serum/Plasma) is 100% and the specificity is 99.8% relative to the leading EIA test.

CK-MB Rapid Test vs. EIA

Method		EIA		Total Results
CK-MB	Results	Positive	Negative	
	Positive	54	1	55
	Negative	0	422	422
Total Results		54	423	477

Relative Sensitivity: 100% (93.4%-100.0%) *
Relative Specificity: 99.8% (98.7%-99.9%)*
Accuracy: 99.8% (98.8%-99.9%)* * 95% Confidence Interval

PRECISION

Intra-Assay
Within-run precision has been determined by using replicates of 10 tests for each of three lots using CK-MB specimen levels at 0 ng/mL, 5 ng/mL, 10 ng/mL, 20 ng/mL and 40 ng/mL. The specimens were correctly identified >99% of the time.
Inter-Assay
Between-run precision has been determined by 3 independent assays on the same five specimens: 0 ng/mL, 5 ng/mL, 10 ng/mL, 20 ng/mL and 40 ng/mL of CK-MB. Three different lots of the CK-MB Rapid Test Cassette (Whole Blood/Serum /Plasma) have been tested using these specimens. The specimens were correctly identified >99% of the time.
Cross-Reactivity
Sera containing known amounts of 1,390 ng/mL CK-MM and 1,000 ng/mL CK-BB have been tested . No cross-reactivity was observed, indicating that the CK-MB Rapid Test Cassette (Whole Blood/Serum/Plasma) has a high degree of specificity for CK-MB.
Interfering Substances
The CK-MB Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested and no interference was observed in specimens containing 110 mg/mL human albumin, 6 mg/mL bilirubin, 10 mg/mL hemoglobin, 5 mg/mL cholesterol and 15 mg/mL triglycerides.

BIBLIOGRAPHY

1. Apple FS, Preese LM. Creatine kinase-MB: detection of myocardial infarction and monitoring reperfusion. J Clin Immunoassay, 17:24-9, 1994.
2. Lee, T.H., Goldman, L. Serum enzyme assays in the diagnosis of acute myocardial infarction. Ann Intern Med, 105:221-233, 1986.
3. Kallner A, Sylven C, Brodin. U, et al. Early diagnosis of acute myocardial infarction; a comparison between chemical predictors. Scand J Clin Lab Invest, 49:633-9, 1989.

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 GDCKM-402a

Revision Date: 2022-12-09
B20866-03

D-Dimer Rapid Test Cassette (Whole Blood/Plasma)

CE

INTENDED USE

The D-Dimer Rapid Test Cassette (Whole Blood/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of D-dimer in human whole blood or plasma. It is intended to be used as a screening test and as an aid in the diagnosis of disseminated intravascular coagulation (DIC), deep vein thrombosis (DVT). Any reactive specimen with the D-Dimer Rapid Test Cassette (Whole Blood/Plasma) must be confirmed with alternative testing method(s) and clinical findings.

INTRODUCTION

During blood coagulation process, fibrinogen is converted to fibrin by the activation of thrombin. The resulting fibrin monomers polymerise to form a soluble gel of non-cross-linked fibrin. This fibrin gel is then converted to cross-linked fibrin by thrombin activated Factor XIII to form an insoluble fibrin clot. Production of plasmin, the major clot-lysing enzyme, is triggered when a fibrin clot is formed. Although fibrinogen and fibrin are both cleaved by the fibrinolytic enzyme plasmin to yield degradation products, only degradation products from cross-linked fibrin contain D-dimer and are called cross-linked fibrin degradation products. Therefore, fibrin derivatives in human blood or plasma containing D-dimer are a specific marker of fibrinolysis.

The D-Dimer Rapid Test Cassette (Whole Blood/Plasma) is a rapid test that qualitative detects the presence of D-dimer in whole blood or plasma specimens at the sensitivity of 500 ng/mL. The test utilizes a combination of monoclonal antibodies to selectively detect elevated levels of D-dimer in whole blood or plasma. At the level of claimed sensitivity, the D-Dimer Rapid Test Cassette (Whole Blood/Plasma) shows no cross-reactivity interference from the related Troponin I, Troponin T, CK-MB, Myoglobin or others at high physiological levels.

PRINCIPLE

The D-Dimer Rapid Test Cassette (Whole Blood/Plasma) is immunochromatographic assay including D-Dimer specific monoclonal antibody conjugated to colloidal gold particles, second D-Dimer specific monoclonal antibody on test line and Goat anti-mouse IgG antibody on the control line. When the specimen containing D-Dimer is added to sample pad, it moves to conjugate pad and forms a complex (D-Dimer and antibody-gold conjugate). The complex migrates through a nitrocellulose membrane by capillary action and captured at test line which is second D-Dimer specific monoclonal antibody has been bound. The complex is concentrated at test line and a pink or purple line is showed if the D-Dimer concentration is higher than the clinically established cut-off. Uncaptured gold conjugate continues to flow towards control line which Goat anti-mouse IgG is bound and forms a pink or purple color line, indicating test is working as designed and the result is valid. If the control line does not appear, the test result is not valid.

PRODUCT CONTENTS

The D-Dimer Rapid Test Cassette (Whole Blood/Plasma) containing Anti-D-dimer particles and Anti-D-dimer coated on the membrane.

MATERIALS SUPPLIED

25 Sealed pouches each containing a test cassette, a pipette dropper and a desiccant
1 Buffer, 4.0 mL
1 Package insert

MATERIAL REQUIRED BUT NOT PROVIDED

Timer Lancing device for whole blood test

STORAGE AND STABILITY

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

WARNINGS AND PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. 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.
3. 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 by observing usual safety precautions (e.g., do not ingest or inhale).
4. Read the entire procedure carefully prior to testing.
5. Do not eat, drink or smoke in any area where specimens and kits are handled.
6. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7. Do not interchange or mix reagents from different lots. Do not mix solution bottle caps.
8. Humidity and temperature can adversely affect results.

SPECIMEN COLLECTION AND PREPARATION

1. The D-Dimer Rapid Test Cassette (Whole Blood/Plasma) is intended for use with human whole blood or plasma specimens only.
2. Only clear, non-hemolyzed specimens are recommended for use with this test. Whole blood or Plasma should be separated as soon as possible to avoid hemolysis.
3. Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. 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. Whole blood collected by fingerstick should be tested immediately.
4. Containers containing anticoagulants such as EDTA, citrate, or heparin should be used for whole blood storage.
5. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
6. If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.
7. Icteric, lipemic, hemolysed, heat treated and contaminated specimens may cause erroneous results.

TEST PROCEDURE

Bring tests, specimens, reagents and/or controls to room temperature (15-30°C) prior to testing.

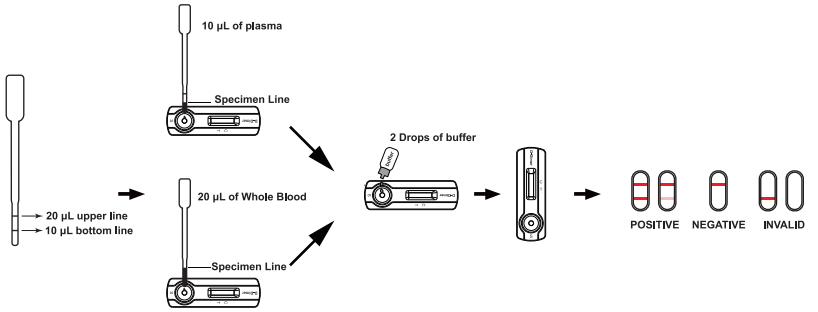
1. Remove the test cassette from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test cassette on a clean and level surface.

For Whole Blood Specimen: With the 10/20µL mini plastic dropper provided, draw the whole blood specimen to the upper scale line as showed in the following image and then transfer drawn whole blood into the sample well (S) of the test device., then add 2 drops of buffer (approximately 80µL) and start the timer. See illustration below.

For Plasma Specimen: With the 10/20µL mini plastic dropper provided, draw the plasma specimen to the bottom scale line as showed in the following image and then transfer drawn plasma into the sample well (S) of the test device. Then add 2 drops of buffer (approximately 80µL) and start the timer. See illustration below.

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 10 and 20µL of volume.

3. As the test begins to work, color will migrate across the membrane.
4. Wait for the colored band(s) to appear. The result should be read in 10 minutes. Do not interpret the result after 15 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. 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 Cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control 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 D-Dimer Rapid Test Cassette (Whole Blood/Plasma) is for in vitro diagnostic use only. This test should be used for the detection of D-dimer in whole blood or plasma specimens only. Neither the quantitative value nor the rate of increase in D-dimer can be determined by this qualitative test.
2. The D-Dimer Rapid Test Cassette (Whole Blood/Plasma) will only indicate the qualitative level of D-dimer in the specimen and should not be used as the sole criteria for the diagnosis of Disseminated Intravascular Coagulopathy (DIC), Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE).
3. During the process of serum is formed, also fibrinogen is converted to fibrin by the activation of thrombin and it also can be detected by D-dimer antibody. So serum specimen can't be used for D-Dimer Rapid Test Device (Whole Blood/Plasma).
4. The D-Dimer Rapid Test Cassette (Whole Blood/Plasma) cannot detect less than 500 ng/mL D-dimer in specimens. A negative result at any time does not preclude the possibility of Disseminated Intravascular Coagulopathy (DIC), Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE).
5. False negative readings can occur if the sample is taken either too early after thrombus formation, if testing is delayed for several days or if the sample was take too later after the occurrence of thromboembolic infarction, because the D-dimer concentration may decrease to normal values after one week already. Additionally, a treatment with anti-coagulants prior sample collection can render the test negative because it prevents thrombus extension.
6. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician. E.g. use "Wells score" for DVT resp. PE, Ultrasound, quantitative laboratory D-Dimer results etc.
7. Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor (RF) may affect expected results. Even if the test results are positive, further clinical evaluation should be considered with other clinical information available to the physician

PERFORMANCE CHARACTERISTICS

1. Sensitivity and Specificity

The D-Dimer Rapid Test Cassette (Whole Blood/Plasma) has been evaluated with a leading commercial D-dimer EIA test using clinical specimens. The results show that the sensitivity of the D-Dimer Rapid Test Cassette (Whole Blood/Plasma) is 98.6% and the specificity is 98.6% relative to the leading EIA test.

Method		EIA		Total Results
D-Dimer Rapid Test Cassette	Results	Positive	Negative	
	Positive	71	3	74
	Negative	1	211	212
Total Results		72	214	286

Relative Sensitivity: 98.6%
Relative Specificity: 98.6%
Accuracy: 98.6%

2. Precision

Within-run precision has been determined by using 15 replicates of below five specimens: D-dimer specimen levels at 0 ng/mL, 500 ng/mL, 1,000 ng/mL, 1,500 ng/mL and 3,000 ng/mL. The specimens were correctly identified at the prescribed reading time.

3. Inter-Assay

Between-run precision has been determined by 3 independent assays on the same five specimens: 0 ng/mL, 500 ng/mL, 1,000ng/mL, 1,500 ng/mL and 3,000 ng/mL of D-dimer. Three different lots of the D-Dimer Rapid Test Cassette (Whole Blood/Plasma) have been tested using these specimens. The specimens were correctly identified at the prescribed reading time.

4. Cross-reactivity

The D-Dimer Rapid Test Cassette (Whole Blood/Plasma) has been tested with HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, anti-syphilis, anti-HIV, anti-H.pylori, IM heterophile antibodies, anti-CMV, anti-Rubella and anti-Toxoplasma positive specimens. The results showed no cross-reactivity.

5. Interfering Substances

The following potentially interfering substances were added to D-dimer negative and positive specimens, repectively.

Substances	Concentration
Acetaminophen	20 mg/dL
Caffeine	20 mg/dL
Acetylsalicylic Acid	20 mg/dL
Gentisic Acid	20 mg/dL
Ascorbic Acid	20 mg/dL
Albumin	10,500 mg/dL
Creatin	200 mg/dL
Hemoglobin	1,000 mg/dL
Bilirubin	1,000 mg/dL
Oxalic Acid	600 mg/dL
Cholesterol	800 mg/dL
Triglycerides	1,600 mg/dL

None of the substances at the concentration tested interfered in the assay.

REFERENCE

1. Gaffney, P.J. D-dimer History of Discovery, Characterisation and Utility of this and other Fibrin Fragments. Fibrinolysis 7 Suppl 2:2-8; 1993
2. Lane, D.A. et al. Characterisation of Serum Fibrinogen and Fibrin Fragments Produced During Disseminated Intravascular Coagulation. Haematology. 40: 609-615; 1978.
3. Scarvelis, D and Wells, P.S. Diagnosis and Treatment of Deep Vein Thrombosis. Can. Med. Assoc. J. 175 (9):1087-92; 2006
4. Bick, R.L. et al. Diagnostic Efficacy of the D-dimer assay in Disseminated Intravascular Coagulation (DIC) Thromb. Res. 65:785-790; 1992.
5. Bick, R.L. et al. Disseminated Intravascular Coagulation: Objective Clinical and Laboratory Diagnosis, Treatment, and Assessment of Therapeutic Response. Semin. Thromb. Hemost. 22(1): 69-88; 1996.
6. Hunt, F.A. et al. Serum Cross-Linked Fibrin (XDP) and Fibrinogen/Fibrin Degradation Products (FDP) in Disorders Associated with Activation of the Coagulation or Fibrinolytic Systems. Br. J. Haematol. 60: 715-722; 1985.
7. Subramanian, R.M. et. al. Does an Immunochromatographic D-dimer exclude acute lower limb deep venous thrombosis? Emer. Med. Austral. 18: 457-463; 2006.
8. Runyon, M.S. et. al. Comparison of the Simplify D-dimer assay performed at the bedside with a laboratory based quantitative D-dimer assay for the diagnosis of pulmonary embolism in a low prevalence emergency department population. Emerg. Med. J. 25:70-75; 2008.

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: +86-572-5226 111 Fax: +86-572-5226222
Website: www.orientgene.com

EC REP QARAD BV
Cipalstraat 3, 2440 Geel BELGIUM

REF GDDDI-402b

Revision Date: 2022-10-08
B22211-02

Myoglobin/CK-MB/Troponin I Combo Rapid Test Cassette (Whole Blood/Serum/Plasma)

CE

A rapid test for the qualitative detection of Myoglobin, CK-MB, and Troponin I in whole blood, serum or plasma.
For professional in vitro diagnostic use only.

INTENDED USE

The Myoglobin/CK-MB/Troponin I Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of human Myoglobin, CK-MB and cardiac Troponin I in whole blood , serum or plasma as an aid in the diagnosis of myocardial infarction (MI).

SUMMARY

Myoglobin (MYO), Creatine Kinase MB (CK-MB) and cardiac Troponin I (cTnI) are proteins released into the bloodstream after cardiac injury. Myoglobin is a heme-protein normally found in skeletal and cardiac muscle with a molecular weight of 17.8 kDa. It constitutes about 2 percent of total muscle protein and is responsible for transporting oxygen within muscle cells1. When muscle cells are damaged, Myoglobin is released into the blood rapidly due to its relatively small size. The level of Myoglobin increases measurably above baseline within 2-4 hours post-infarct, peaking at 9-12 hours, and returning to baseline within 24-36 hours2,3. CK-MB is an enzyme also present in the cardiac muscle, with a molecular weight of 87.0 kDa4. Creatine Kinase is a dimeric molecule formed from two subunits designated as “M” and “B”, which combine to form three different isoenzymes, CK-MM, CK-BB and CK-MB. CK-MB is the isoenzyme of Creatine Kinase most involved in the metabolism of cardiac muscle tissue5. The release of CK-MB into the blood following an MI can be detected within 3-8 hours after the onset of symptoms. It peaks within 9 to 30 hours, and returns to baseline levels within 48 to 72 hours6. Cardiac Troponin I is a protein found in cardiac muscle, with a molecular weight of 22.5 kDa7. Troponin I is part of a three subunit complex comprised of Troponin T and Troponin C. Along with tropomyosin, this structural complex forms the main component that regulates the calcium sensitive ATPase activity of actomyosin in striated skeletal and cardiac muscle8. After cardiac injury occurs, Troponin I is released into the blood 4-6 hours after the onset of pain. The release pattern of Troponin I is similar to CK-MB, but while CK-MB levels return to normal after 72 hours, Troponin I remains elevated for 6-10 days, thus providing for a longer window of detection for cardiac injury.
The Myoglobin/CK-MB/Troponin I Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) utilizes a combination of antibody coated particles and capture reagents to qualitatively detect Myoglobin, CK-MB and Troponin I in whole blood, serum or plasma. The minimum detection level is 50 ng/mL Myoglobin, 5 ng/mL CK-MB and 0.5 ng/mL Troponin I.

PRINCIPLE

The Myoglobin/CK-MB/Troponin I Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) is a qualitative, membrane based immunoassay for the detection of Myoglobin, CK-MB and Troponin I in whole blood, serum
or plasma. The membrane is pre-coated with specific capture antibodies in each of the test line regions of the test. During testing, the whole blood, serum or plasma specimen reacts with the particle coated with specific antibodies. The mixture migrates upward on the membrane chromatographically by capillary action to react with specific capture reagents on the membrane and generate a colored line. The presence of this colored line in the specific 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

The test contains anti-Myoglobin antibody coated particles, anti-CK-MB antibody coated particles, anti-Troponin I antibody coated particles, and capture reagents coated on the membrane.

PRECAUTIONS

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

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

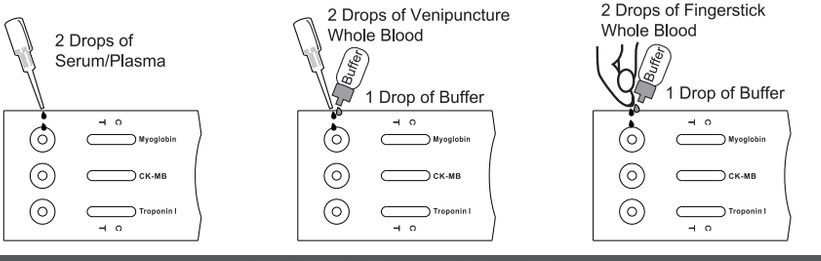
- The Myoglobin/CK-MB/Troponin I Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) can be performed using whole blood (from venipuncture or fingerstick), serum or plasma.
- <u>To collect Fingerstick Whole Blood specimens:</u>
  - Wash the patient’s hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
  - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
  - Position the patient’s finger so that the drop of blood is just above the specimen well (S) of the test device.
  - Allow 2 hanging drops of fingerstick whole blood to fall into the specimen well (S) of the test device, or move the patient’s finger so that the hanging drop touches the specimen well (S). Avoid touching the finger directly to the specimen well (S).
- 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. Whole blood collected by fingerstick should be tested immediately.
- 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.

MATERIALS

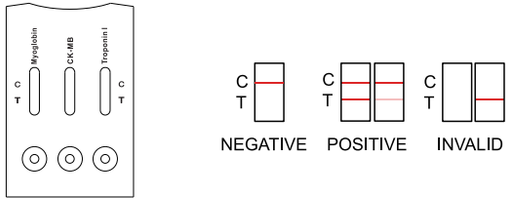
Materials Provided:
1. 25 Sealed pouches each containing a test cassette, a dropper and a desiccant 2. 1 Buffer, 4.0 mL
3. 1 Package insert
Materials Required But Not Provided:
1. Specimen collection containers 2. Lancets (for fingerstick whole blood only) 3. Centrifuge 4. Timer

PROCEDURE

Allow the test, specimen and/or controls to reach room temperature (15-30°C) prior to testing.
1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed 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. Place the test device on a clean and level surface.
<u>For Serum or Plasma specimens:</u> Hold the dropper vertically and transfer 2 drops of serum or plasma (approximately 50 µL) to the specimen well (S) of the test device, then start the timer. See illustration below.
<u>For Venipuncture Whole Blood specimens:</u> Hold the dropper vertically and transfer 2 drops of venipuncture whole blood (approximately 50 µL) to the specimen well (S) of the test device, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.
<u>For Fingerstick Whole Blood specimens:</u> Allow 2 hanging drops of fingerstick whole blood specimen (approximately 50 µL) to fall into the center of the specimen well (S) on the test device, then add 1 drop of buffer (approximately 40 µL) and start the timer. See illustration below.
3. Wait for the colored line(s) to appear. Read results at 10 minutes. Do not interpret results after 20 minutes.



INTERPRETATION OF RESULTS



(Please refer to the illustration above)
POSITIVE: A colored line in the control line region (C) and the presence of one or more colored lines in the test line regions indicates a positive result. This indicates that the concentration of Myoglobin, CK-MB and/or Troponin I is above the minimum detection level.
NEGATIVE: One colored line appears in the control line region (C). No apparent colored lines appear in any of the test line region(s). This indicates that the concentration of Myoglobin, CK-MB and Troponin I are below the minimum detection levels.
INVALID: Control line (C) 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. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

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 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 Myoglobin/CK-MB/Troponin I Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) is for *in vitro* diagnostic use only. This test should be used for the detection of Myoglobin, CK-MB, and Troponin I in whole blood, serum or plasma specimens only. Neither the quantitative value nor the rate of increase in Myoglobin, CK-MB and Troponin I can be determined by this qualitative test.
2. The Myoglobin/CK-MB/Troponin I Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) will only indicate the qualitative level of Myoglobin, CK-MB and Troponin I in the specimen and should not be used as the sole criteria for the diagnosis of myocardial infarction.
3. The Myoglobin/CK-MB/Troponin I Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) cannot detect less than 50 ng/mL Myoglobin, 5 ng/mL CK-MB and 0.5 ng/mL Troponin I in specimens. A negative result at any time does not preclude the possibility of myocardial infarction.
4. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
5. Unusually high titers of heterophile antibodies or rheumatoid factor (RF) may affect the results. Even if test results are positive, further clinical evaluation should be considered with other clinical information available to the physician.
6. There is a slight possibility that some whole blood specimens with very high viscosity or which have been stored for more than 2 days may not run properly on the test device. Repeat the test with a serum or plasma specimen from the same patient using a new test device.

EXPECTED VALUES

The Myoglobin/CK-MB/Troponin I Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) has been compared with a leading commercial Myoglobin/CK-MB/T EIA test, demonstrating an overall accuracy of 98.0% with Myoglobin, 99.8% with CK-MB, and 98.5% with Troponin I.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The Myoglobin/CK-MB/Troponin I Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) has been evaluated with a leading commercial Myoglobin/CK-MB/Troponin I EIA test using clinical specimens. The results show that relative to leading EIA tests, the Myoglobin/CK-MB/Troponin I Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) exhibits 100% sensitivity and 97.7% specificity for Myoglobin, 100% sensitivity and 99.8% specificity for CK-MB, and 98.7% sensitivity and 98.4% specificity for Troponin I.

Myoglobin Test vs. EIA

Method		EIA		Total
Myoglobin Test	Results	Positive	Negative	Results
	Positive	60	9	69
	Negative	0	374	374
Total Results		60	383	443

Relative Sensitivity: 100% (94.0%-100.0%)*
Relative Specificity: 97.7% (95.6%-98.9%)*
Accuracy: 98.0% (96.2%-99.1%)*
* 95% Confidence Interval

CK-MB Test vs. EIA

Method		EIA		Total
CK-MB Test	Results	Positive	Negative	Results
	Positive	54	1	55
	Negative	0	422	422
Total Results		54	423	477

Relative Sensitivity: 100% (93.4%-100.0%)*
Relative Specificity: 99.8% (98.7%-99.9%)*
Accuracy: 99.8% (98.8%-99.9%)*
* 95% Confidence Interval

Troponin I Test vs. EIA

Method		EIA		Total
Troponin I Test	Results	Positive	Negative	Results
	Positive	225	8	233
	Negative	3	505	508
Total Results		228	513	741

Relative Sensitivity: 98.7% (96.2%-99.7%)*
Relative Specificity: 98.4% (97.0%-99.3%)*
Accuracy: 98.5% (97.4%-99.3%)*
* 95% Confidence Interval

Precision

Intra-Assay
Within-run precision has been determined by using replicates of 10 tests for each of three lots using Myoglobin specimen levels at 0 ng/mL, 50 ng/mL and 400 ng/mL, CK-MB specimen levels at 0 ng/mL, 5 ng/mL and 40 ng/mL and Troponin I specimen levels at 0 ng/mL, 1 ng/mL and 10 ng/mL. The specimens were correctly identified >99% of the time.
Inter-Assay
Between-run precision has been determined by 3 independent assays on the same fifteen specimens: 0 ng/mL, 50 ng/mL and 400 ng/mL of Myoglobin, 0 ng/mL, 5 ng/mL and 40 ng/mL of CK-MB and 0 ng/mL, 1 ng/mL and 10 ng/mL of Troponin I. Three different lots of the Myoglobin/CK-MB/Troponin I Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) have been tested using these specimens. The specimens were correctly identified >99% of the time.
Cross-Reactivity
Sera containing known amounts of 10,000 ng/mL Skeletal Troponin I, 2,000 ng/mL Troponin T, 1,390 ng/mL CK-MM, 1,000 ng/mL CK-BB and 20,000 ng/mL Cardiac Myosin have been tested. No cross-reactivity was observed, indicating that the Myoglobin/CK-MB/Troponin I Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) has a high degree of specificity for Myoglobin, CK-MB and Troponin I.
Interfering Substances
The Myoglobin/CK-MB/Troponin I Combo Rapid Test Cassette (Whole Blood/Serum/Plasma) has been tested and no interference was observed in specimens containing 110 mg/mL human albumin, 6 mg/mL bilirubin, 10 mg/mL hemoglobin, 5 mg/mL cholesterol and 15 mg/mL triglycerides.

BIBLIOGRAPHY

1. Wong SS. Strategic utilization of cardiac markers for diagnosis of acute myocardial infarction. Ann Clin Lab Sci, 26:301-12, 1996.
2. Kagen LJ. Myoglobin methods and diagnostic uses. CRC Crit. Rev. Clin. Lab. Sci., 2:273, 1978.
3. Chapelle JP. et al. Serum myoglobin determinations in the assessment of acute myocardial infarction. Eur. Heart Journal, 3:122, 1982.
4. Apple FS, Preese LM. Creatine kinase-MB: detection of myocardial infarction and monitoring reperfusion. J Clin Immunoassay, 17:24-9, 1994.
5. Lee TH, Goldman L. Serum enzyme assays in the diagnosis of acute myocardial infarction. Ann Intern Med, 105:221-233, 1986.
6. Kallner A, Sylven C, Brodin. U, et al. Early diagnosis of acute myocardial infarction; a comparison between chemical predictors. Scand J Clin Lab Invest, 49:633-9, 1989.
7. Adams, et al. Biochemical markers of myocardial injury, Immunoassay Circulation 88: 750-763, 1993.
8. Mehegan JP, Tobacman LS. Cooperative interaction between troponin molecules bound to the cardiac thin filament. J.Biol.Chem. 266:966, 1991.

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 GDCAR-W435a

Revision Date: 2022-12-09
B20858-03

Troponin I

Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma)

Package Insert

A rapid visual immunoassay for the qualitative presumptive detection of cardiac Troponin I in human whole blood, serum, or plasma specimens. For professional in vitro diagnostic use only.

INTENDED USE

The Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma) is a rapid visual immunoassay for the qualitative presumptive detection of cardiac Troponin I in human whole blood, serum, or plasma specimens. This kit is intended to be used as an aid in the diagnosis of myocardial infarction (MI).

SUMMARY

Cardiac Troponin I (cTnI) is a protein found in cardiac muscle with a molecular weight of 22.5 kDa.[1] Troponin I is part of a three subunit complex comprising of Troponin T and Troponin C. Along with tropomyosin, this structural complex forms the main component that regulates the calcium sensitive ATPase activity of actomyosin in striated skeletal and cardiac muscle.[2] After cardiac injury occurs, Troponin I is released into the blood 4-6 hours after the onset of pain. The release pattern of cTnI is similar to CK-MB, but while CK-MB levels return to normal after 72 hours, Troponin I remains elevated for 6-10 days, thus providing for a longer window of detection for cardiac injury. The high specificity of cTnI measurements for the identification of myocardial damage has been demonstrated in conditions such as the perioperative period, after marathon runs, and blunt chest trauma.[3] cTnI release has also been documented in cardiac conditions other than acute myocardial infarction (AMI) such as unstable angina, congestive heart failure, and ischemic damage due to coronary artery bypass surgery.[4] Because of its high specificity and sensitivity in the myocardial tissue, Troponin I has recently become the most preferred biomarker for myocardial infarction.[5]

PRINCIPLE

The Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma) has been designed to detect cardiac Troponin I through visual interpretation of color development in the strip. The membrane was immobilized with anti-cTnI antibodies on the test region. During the test, the specimen is allowed to react with colored anti-cTnI antibodies colloidal gold conjugates, which were precoated on the sample pad of the test. The mixture then moves on the membrane by a capillary action, and interact with reagents on the membrane. If there were enough cTnI in specimens, a colored band will form at the test region of the membrane.

Presence of this colored band indicates a positive result, while its absence indicates a negative result. Appearance of a colored band at the control region serves as a procedural control. This indicates that proper volume of specimen has been added and membrane wicking has occurred.

PRECAUTIONS

1. For professional *in vitro* diagnostic use only.
2. Warning: the reagents in this kit contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up.
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. Handle all specimens as if they contain infectious agents. Observe established standard procedure for proper disposal of specimens
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assay.
7. Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

All reagents are ready to use as supplied. Store unused test cassette unopened at 2°C-30°C. If stored at 2°C-8°C, ensure that the test cassette 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.

SPECIMEN COLLECTION AND PREPARATION

- The Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma) is intended only for use with human whole blood, serum, or plasma specimens.
- Only clear, non-hemolyzed specimens are recommended for use with this test.
- Serum or plasma should be separated with soonest possible opportunity to avoid hemolysis.
- Perform the testing immediately after the specimen collection. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- Pack the specimens in compliance with applicable regulations for transportation of etiological agents, in case they need to be shipped.
- Icteric, lipemic, hemolysed, heat treated and contaminated sera may cause erroneous results.
- There is a slight possibility that some whole blood specimens with very high viscosity or which have been stored for more than 2 days may not run properly on the test cassette. Repeat the test with a serum or plasma specimen from the same patient using a new test cassette.

Materials Provided

1. Test cassettes 2. Droppers 3. Package insert

Materials Required But Not Provided

1. Specimen collection containers 2. Centrifuge (for plasma only)
3. Clock or Timer

DIRECTIONS FOR USE

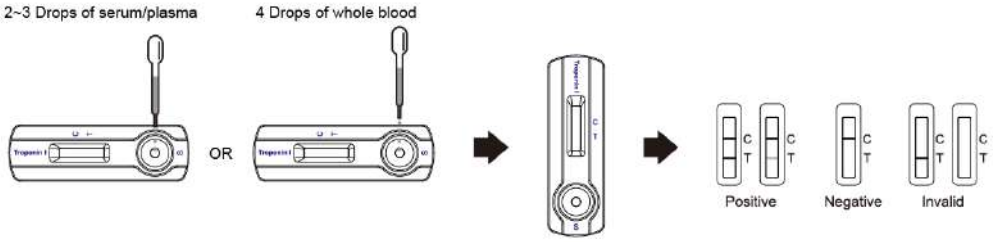
Allow test cassette, specimen, buffer and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the cassette with patient or control identification. To obtain a best result, the assay should be performed within one hour.
2. Transfer **2-3 drops of serum or plasma** to the specimen well(S) of the cassette with a disposable pipette provided in the kit, and then start the timer.

OR

Transfer **4 drops of whole blood** specimen to the specimen well(S) of the cassette with a disposable pipette provided in the kit, and then start the timer.

2. Wait for the colored band(s) to appear. The result should be read at 15 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

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.

NOTE: Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control. It confirms 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 Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma) is for professional in vitro diagnostic use, and should be used for the qualitative detection of cardiac Troponin I only. There is no meaning attributed to line color intensity or width.
2. The Troponin I Rapid Test Cassette (Whole Blood/Serum/Plasma) will only indicate the presence of Troponin I in the specimen and should not be used as the sole criteria for the diagnosis.
3. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. The test cannot detect less than 0.25 ng/mL of cTnI in specimens. Thus, a negative result does not at any time rule out the existence of Troponin I in blood, because the antibodies may be absent or below the minimum detection level of the test.
4. Like with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
5. Some specimens containing unusually high titers of heterophile antibodies or rheumatoid factor (RF) may affect expected results. Even if the test results are positive, further clinical evaluation should be considered with other clinical information available to the physician.

PERFORMANCE CHARACTERISTICS

Table: Troponin I Rapid Test vs. EIA

Method		Troponin I Rapid Test Cassette		Total Results
		Positive	Negative	
EIA	Positive	138	2	140
	Negative	1	315	316
Total Results		139	317	456

Relative Sensitivity: 98.6% (94.9%-99.8%)* Relative Specificity: 99.7% (98.3%-99.9%)*
Overall Agreement: 99.3% (98.1%-99.9%)* *95% Confidence Interval

BIBLIOGRAPHY

1. Adams, et al. Biochemical markers of myocardial injury, Immunoassay Circulation 88:750-763, 1993.
2. Mehegan JP, Tobacman LS. Cooperative interaction between troponin molecules bound to the cardiac thin filament. J.Biol.Chem. 266:966, 1991.
3. Adams, et al. Diagnosis of Perioperative myocardial infarction with measurements of cardiac troponin I. N.Eng.J.Med 330:670, 1994.
4. Hossein-Nia M, et al. Cardiac troponin I release in heart transplantation. Ann. Thorac.Surg. 61: 227, 1996.
5. Alpert JS, et al. Myocardial Infarction Redefined, Joint European Society of Cardiology American College of Cardiology: J. Am. Coll. Cardio., 36(3):959, 2000.

REF GDTRO-402b

B21611-02

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.

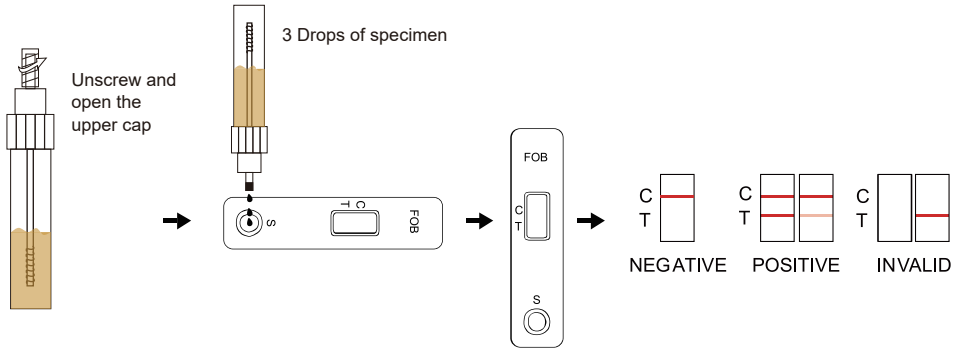
SPECIMEN COLLECTION AND PREPARATION

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

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Revision Date: 2023-04-18
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