GIMA
PROFESSIONAL MEDICAL PRODUCTS

TEST MARKER CARDIACO COMBO A DISCHETTO PER SANGUE INTERO, PLASMA O SIERO

STEP CARDIAC COMBO MARKER TEST DISK FOR WHOLE BLOOD, PLASMA OR SERUM

TEST MARQUEUR CARDIAQUE COMBO SUR CASSETTE SUR SANG TOTAL, PLASMA OU SÉRUM

MARKER TEST CARDIACO COMBO DE DISCO PARA SANGRE ENTERA, PLASMA O SUERO

Manuale d'uso - User manual
Manuel de l'utilisateur - Guía de uso

PER USO PROFESSIONALE
FOR PROFESSIONAL USE
POUR USAGE PROFESSIONNEL
PARA USO PROFESIONAL

ATTENZIONE: *Gli operatori devono leggere e capire completamente questo manuale prima di utilizzare il prodotto.*
ATTENTION: *The operators must carefully read and completely understand the present manual before using the product.*
AVIS: *Les opérateurs doivent lire et bien comprendre ce manuel avant d'utiliser le produit.*
ATENCIÓN: *Los operadores tienen que leer y entender completamente este manual antes de utilizar el producto.*

GIMA 24525

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4°C 30°C IVD

M-24525-M-Rev.5-12.25

EXPLANATION OF THE TEST

A creatine phosphokinase/creatine kinase or isoenzymes test system is a device intended to measure the activity of the enzyme creatine phosphokinase or its isoenzymes (a group of enzymes with similar biological activity) in plasma, serum or whole blood. Measurements of creatine phosphokinase and its isoenzymes are used in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne-type muscular dystrophy.

The One Step Cardiac Combo Marker Whole Blood, Plasma or Serum Test is a rapid assay test. The analytical sensitivity of Troponin I, CK-MB and Myoglobin is 1 ng/ml, 5 ng/ml and 50 ng/ ml respectively.

PRECAUTIONS

The One Step Cardiac Combo Marker test kit should be stored at room temperature. The test device is sensitive to humidity as well as to heat. Perform the test immediately after removing the test device from the foil pouch. Do not use it beyond the expiration date.

SPECIMEN COLLECTION AND STORAGE

Whole Blood specimen collection: Collect an anticoagulated blood sample by using heparin as the anti-coagulant (finger tip blood can be used directly). Troponin I, CK-MB or Myoglobin is very unstable in serum or whole blood specimen. Whole blood or serum specimen must be tested as soon as possible.

PLASMA/SERUM SPECIMEN COLLECTION

1. Centrifuge whole blood to get plasma/serum specimen.
2. If specimens are not immediately tested, they should be refrigerated at 2-8 degrees C. Specimens should be at room temperature before running a test.
3. Specimens containing precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.

Warnings

1. For in vitro diagnostic use only.
2. Do not eat or smoke while handling specimens.
3. Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
4. Avoid splashing or aerosol formation.
5. Clean up spills thoroughly using an appropriate disinfectant.
6. Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
7. Do not use the test kit if the pouch is damaged or the seal is broken.

PROCEDURE

1. Remove the test disk from the foil pouch, and place it on a flat, dry surface.
2. Holding the sample dropper above the test disk (Figure 1) and add 1 hanging drop into the Sample Well. Note: wait for about 10 seconds. After the previous drop is absorbed into the Sample Well, add another hanging drop, repeat the procedure until a total of 3 hanging drops (if blood is added directly from finger tip, each droplet may vary in size, be sure to add a total about 100µl to 120µl of blood, typically 3 to 5 drops of finger tip droplets) have been added to the Sample Well. If specimen drops are added too quickly, specially for blood specimen, it may cause clogging of the Sample Well.
3. As the test begins to work, you will see purple color move across the Result Window in

the center of the test disk. Note: If purple color dye does not begin to flow through the "Result Window" within 1 minute, add more drops of sample (one drop at time) until the purple color dye begins to flow.

4. Interpret test results at 10 to 15 minutes. Do not interpret test results after 20 minutes.

CAUTION

The above interpretation time is based on reading the test results at room temperature of 15 to 30°C. If your room temperature is significantly lower than 15°C, then the interpretation time should be properly increased.

INTERPRETATION OF THE TEST

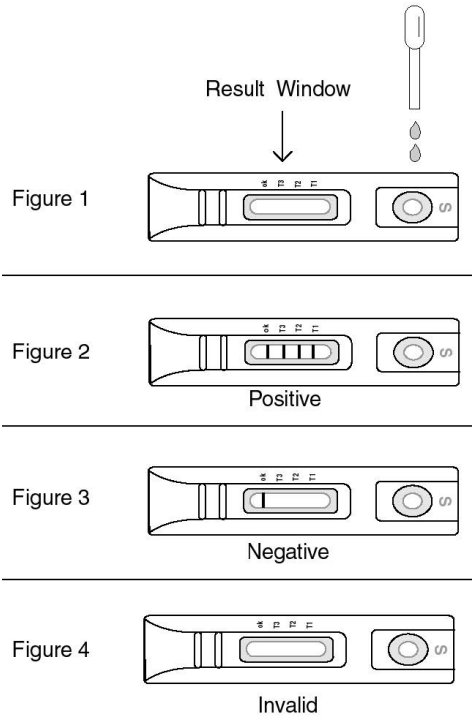
1. A purple band in the "C" area is the Control Line.
2. There are three Test Lines. TI as Troponin I, CKMB as CK-MB and MB as Myoglobin.

Positive Result: The presence of purple color "C" control line together with any purple color of "TI", "CKMB" or "MB" test line, regardless of which band appears first, indicates a positive result (Figure 2). Note: Generally, the higher the analyte level in the specimen, the stronger the Test Line band color will be. When the specimen analyte level is close to but still within the sensitivity limit of the test, the color of the Test Line band will be very faint.

Note: Specimens containing very low levels of Myoglobin may develop color "MB" band over 20 minutes.

Negative Result: The presence of only one purple color "C" control line indicates a negative result (Figure 3).

Invalid Result: If after performing the test no purple color control line is visible within the Result Window, this result is considered invalid (Figure 4). Not following the procedures correctly or using a test kit that has deteriorated can cause invalid results. It is recommended that the specimen be re-tested.



Note: A positive result will not change once you have established your answer at 20 minutes. However, in order to prevent any incorrect results, the test result should not be interpreted after 20 minutes. Some specimens with a high rheumatoid factor concentration may yield a nonspecific positive result.

LIMITATIONS OF THE TEST

Although the One Step Cardiac Combo Marker Test is accurate in detecting cTnI,CK-MB and MB, a low incidence of false results can occur. Other clinically available tests are re-

quired if questionable results are obtained. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

REFERENCE

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GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies.

Indice dei simboli - Symbol index - Index des symboles - Índice de símbolos

IVD	**IT** **GB** **FR** **ES**	Solo per uso diagnostico in vitro For in vitro diagnostic use only Uniquement pour usage diagnostique in vitro Solo para uso diagnóstivo in vitro
	**IT** **GB** **FR** **ES**	Limite di temperatura Temperature limit Limite de température Límite de temperatur
EC REP	**IT** **GB** **FR** **ES**	Rappresentante autorizzato nella Comunità europea Authorized representative in the European community Représentant autorisé dans la Communauté européenne Representante autorizado en la Comunidad Europea
	**IT** **GB** **FR** **ES**	Fabbricante Manufacturer Fabricant Fabricante
	**IT** **GB** **FR** **ES**	Dispositivo monouso, non riutilizzare Disposable device, do not re-use Dispositif pour usage unique, ne pas réutiliser Dispositivo monouso, no reutilizable
	**IT** **GB** **FR** **ES**	Data di scadenza (vedi scatola / bustina) Expiration date (see box / package) Date d'échéance (voir boîte/sachet) Fecha de caducidad (ver caja / sobre)
LOT	**IT** **GB** **FR** **ES**	Numero di lotto (vedi scatola / bustina) Lot number (see box / package) Numéro de lot (voir boîte/sachet) Número de lote (ver caja / sobre)
	**IT** **GB** **FR** **ES**	Leggere attentamente le istruzioni per l'uso Please read instructions carefully Lire attentivement la notice Leer atentamente las instrucciones de uso
	**IT** **GB** **FR** **ES**	Contiene <n> di test Contains sufficient for "n" tests Contient <n> de test Contiene <n> de test
CE	**IT** **GB** **FR** **ES**	Dispositivo medico-diagnostico in vitro conforme alla direttiva 98/79/CE In vitro diagnostic medical device compliant with Directive 98/79 / EC Dispositif médical de diagnostic in vitro conforme à la directive 98/79/CE Producto sanitario para diagnóstico in vitro conforme con la Directiva 98/79/CE
REF	**IT** **GB** **FR** **ES**	Codice prodotto Product code Code produit Código producto
	**IT** **GB** **FR** **ES**	Importato da Imported by Importé par Importado por