DyonMed S.A.
Point of Care Solutions

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ISO 9001:2008 (No. 010110003)| ISO 13485:2003 (No 01210005)
by TÜV Austria Hellas

DyonCardiac 3 in 1®
(Cardiac Troponin, Myoglobin, CK-MB)

No of Cat:DNAT707.

SUGGESTED USE

DyonCardiac 3 in 1® is intended for the qualitative determination of Troponin I / CK-MB / myoglobin in human serum, plasma or whole blood.

GENERAL INFORMATION

Cardiac Troponin I, Creatine kinase MB (CK-MB) and myoglobin are key indicators for the diagnosis of acute myocardial infarction. The Troponin I (TnI), with molecular weight 23,000, along with troponin C and T forms a structural complex. Cardiac troponin I (cTnI) and the complex of released into the blood immediately after the onset of acute myocardial infarction (AMI). Elevated troponin levels can be detected in about 3-6 hours immediately after the onset of AMI reach the maximum concentration of about 12 hours and remains elevated for 5-7 days after AMI. Two types cTnI released in the bloodstream after cardiac injury: the free and the complex cTnI cTn ITC. Although TnI occurs and the skeletal muscles (sTnI), differs in amino acid sequence from the cTnI and in this way the two separated immunologically troponins. The CK-MB is an isomer of the enzyme creatine kinase having a molecular weight of 85,745, Released in the blood immediately after the failure of the heart cells. Detection of elevated CK-MB performed 4-6 hours after the onset of AMI levels of CK-MB in saline smaller than 5ngM. The mean peak concentration of CK-MB after AMI is at least 21 ng / ml or higher. Myoglobin is a low molecular weight protein of the cytoplasm. When muscle cells are damaged, the blood is released faster than any other myocardial index. Elevated levels of myoglobin detected about 24 hours after initiation of AMI. The maximum concentration occurs 6 ~ 12 hours after AMI. The level of myoglobin in saline is 30 ~ 90 ng / ml and can be increased to 200 ng / ml or more and 1 hour after the AMI. During the time of maximum concentration levels reach 900 ng / ml and usually return to normal levels 24 hours after the onset of AMI. **DyonCardiac 3 in 1®** is a qualitative rapid test for the detection of troponin IV CK-MV/ myoglobin in human serum, plasma or whole blood.

PRINCIPLE

DyonCardiac 3 in 1® is based on the principle of immunochromatography for in vitro qualitative determination Troponin I / CK-MB / Myoglobin. After adding the sample to a specific region, it moves and interacts with anti - troponin I / anti -CK-MB / anti-myoglobin antibody colloidal gold those are in the film. The mixture moved along the membrane by capillary action and interacts with anti -troponin 11 avn-CK-M3 I anti- myoglobin which is immobilized in the test region. In the case where troponin I, CK-MB and myoglobin at levels greater than or equal to 1.0 ng/ml, 5.0 ng / ml and 70 ng / ml respectively, a colored line appears in the test region. In the absence of cardiac Troponin I / CK-MB I myoglobin or insufficient amount of sample, the area remains colorless. The sample continues to move to the control area (control) showing red or purple color, indicating that the test is working properly and that the result is valid.

CONTENTS

1. Test devices enclosed in an aluminum case with a dehumidifier and dispenser.
2. Directions for use.

SAMPLING AND SAMPLE PREPARATION

1. Collection of whole blood samples. 1) Collection of whole blood in a syringe or airtight (evacuated) tubes with heparin- like / anticoagulants. 2) Whole blood samples must be tested immediately after collection. In case stored at 2 ~ 8 ° C, should be considered within 3 hours.

2. Collection of serum / plasma. 1) Samples of serum or heparinized plasma should be tested immediately after collection. 2) Do not leave specimens at room temperature for a long time. Samples should be stored 2 ~ 8 ° C and examined within 3 days. If desired storage for longer time, samples should be stored at -20oC.

* Serum or plasma samples containing sediment can cause non-relevant results. Such samples must be purified before analysis.

* The results in samples of whole blood is more valid in 30 minutes.

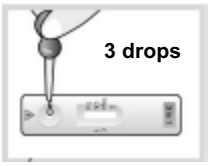
* Do not use haemolysed samples.

TEST PROCEDURE

Bring the test devices and specimens to room temperature before removing the sheath before use.

1. Remove the test device from the sealed pouch and place it on a clean, flat surface.

2. Hold the dispenser vertically and transfer **3 drops** of normal sample (about 120m) in the specimen well (S) of the device.



3. Wait for the red or purple line in the area of effect.

4. Interpret the result in 15-20 minutes. Do not read result after 30'.

Warning:

- Samples containing very low levels of myoglobin and CK-MB may develop positive result after 30 minutes.
- Perform the test immediately after removing the device from the case.

READING INTERPRETATION OF RESULTS

NEGATIVE: The presence of the line in the area of control (C) indicates a negative result.

POSITIVE: The presence of «C» line and at least one colored line (TnI, CK, Myo) in effect, regardless of which band appears first indicates a positive result.

Observe the following results and interpretations given.

Myo	CK-MB	TnI	result	explanation
-	-	-	negative	Probability of acute myocardial infarction. If you suspect heart failure, repeat in 24 hours
+	-	-	positive	Early cardiac muscle damage. Recommended repetition of cTnI 4 and 8 hours to check the case acute cardiovascular events
+	+	-	positive	Early muscle or cardiac damage. Recommended repetition of cTnI at 4 and 8 hours to check the case acute cardiovascular events
-	+	-	positive	Early muscle or cardiac damage. Recommended repetition of cTnI at 4 and 8 hours to check the case acute cardiovascular events
+	+	+	positive	Myocardial necrosis within 12 hours of the onset of symptoms
-	+	+	positive	Acute myocardial infarction fraud 12 hours of symptom onset
-	-	+	positive	Acute myocardial infarction after 24-96 hours
+	-	+	positive	Possible myocardial necrosis

INVALID: If after analyzing control line does not appear in the test region, the results are invalid. Either the instructions are not followed carefully whether the test device is not in good condition. Recommended: repeating the sample with a new device.

MONITORING

1. **DyonCardiac 3 in 1®** kit is for quality land. If you wish quantitative results Troponin I / CK-MB I myoglobin should be held an additional quantitative test.
2. If inconclusive results, an analysis with other available tests. As with all diagnostic tests, the diagnosis should not be based on the results of a single test, but the doctor will need to take into account the results of other tests and clinical findings.

LIMITATIONS

1. The test results should be evaluated in conjunction with clinical information such as clinical signs and symptoms as well as results of other tests for the diagnosis of AMI. A negative result of which the patient sample is obtained from 2 to 16 hours after onset of chest pain helps excluded AMI. A positive result can be used as an indicator of myocardial damage and requires further confirmation.

24-hour Help Line for Medical Devices
Tel. (+30) 211.800.8167
Strictly professional in vitro diagnostic use

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Repeated sampling is recommended in patients suspected of AMI because of the delay between symptom onset and release into the blood stream of protein markers.
2. Samples containing unusually high titers of specific antibodies such as human anti-mouse or human anti-goat, may affect the proper functioning of the examination

FUNCTIONAL CHARACTERISTICS

1. Expected Values

DyonCardiac 3 in 1® is designed to give a positive result for concentrations of 1.0 ng / ml or greater cardiac troponin I, 5.0ng/ml or greater CK-MB, and 70 ng / ml or greater myoglobin. The time required levels cTnl and CK-MB to reach the upper limit of normal in blood is 4-6 hours after the onset of symptoms. The levels of cTnl and CK-MB reach the highest concentration of 12 to 24 hours after the onset of symptoms, and then the cTnl (remains high for 5 ~ 7 days in some cases. Therefore, a negative result in first hours of the start of symptoms did not exclude with certainty AMI. If it is suspected redo the test again at appropriate intervals.

2. Sensitivity and Specificity

A study held using positive and negative samples for cTnl, CK-MB and myoglobin respectively. Each sample was analyzed with **DyonCardiac 3 in 1®** and compared with a commercially available test Troponin I (ELISA) I CK-MB (ELISA) / Myoglobin (ELISA) in accordance with their instructions.

Troponin I		DyonCardiac 3in1®		total
		positive	negative	
ELISA	Positive	60	4	64
	Negative	2	158	160
Total		62	162	224
Sensitivity/Specificity /accuracy		96,8%	97,5%	97,3%(218/224)

CK - MB		DyonCardiac 3in1®		total
		positive	negative	
ELISA	Positive	65	1	66
	Negative	2	71	73
Total		67	72	139
Sensitivity/Specificity /accuracy		97%	98,6%	97,8%(136/139)

Myoglobin		DyonCardiac 3in1®		total
		positive	negative	
ELISA	Positive	74	2	76
	Negative	1	84	85
Total		75	86	161
Sensitivity/Specificity /accuracy		98,7%	97,7%	98,1%(158/161)

3. Reproducibility

1) The performance of the examination within range determined by analysis of an experimenter four different samples with different concentrations of human cardiac troponin I, CK-MB, myoglobin with 10 devices from three different batches. There were no differences between the test devices each batch and between three different batches. 2) The performance review out of sequence determined by three experimenters by analyzing four different samples with different concentrations of human cardiac troponin I, CK-MB, myoglobin with 10 devices from three different batches. There were no differences between the test devices each batch and between experimenters.

4. Analytical Specificity and Interference test

1) There is no cross-reaction with the following materials in **DyonCardiac 3 in 1®**:

human cardiac troponin T	1.000 ng/ml	human cardiac troponin C	1.000 ng/ml
human skeletal muscle troponin I	300 ng/ml	CK - MM	1.000 ng/ml
CK- BB	1.000 ng/ml		

WARNINGS AND PRECAUTIONS

1. For professional in vitro diagnostic use.
2. Do not eat or drink while handling specimens.
3. Wear protective gloves while handling specimens.
4. Do not use the kit if the package is damaged or unsealed.
5. Avoid spraying or aerosolization.
6. Thoroughly clean any stains using a disinfectant.
7. De-contaminate and dispose of all specimens, apparatus and other contaminated materials as if they are pathogens and waste in special containers.
8. Do not reuse the device.

STORAGE AND SHELF LIFE

DyonCardiac 3 in 1® should be stored at 2 ~ 30°C. The test device is sensitive to moisture and heat. Do not use beyond the expiration date or 24 months from production date.

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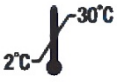



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