

PRODUCT: Keul-o-test CK-MB	Date: 04.09.2011
Ref.-No.: KGST210	DIMDI Reg.-Nr.: DE/CA22/1116-166-IVD
Lot-No.: 201107131	Expiration date: 2013/12

Raw materials:

1. All reagents and raw materials used in the manufacture of the one step tests are qualified for use by many different parameters.
2. Only qualified materials are released to manufacturing for product preparation.
3. All the reagents are uniformly dissolved in the solution during the production process.

Visual Result Description:

 Positive: 2 colored lines visible in the result window within the maximum reading time.

 Negative: 1 colored lines visible in the result window within the maximum reading time.

Invalid: No lines visible in the result window within the maximum reading time.

Storage: Product must be stored at room temperature avoid direct sunlight.

Functional Quality Inspection:

The functional ability of the product is tested by randomly chosen samples from the finished products. Follow the procedure specified in the insert.

Analyte	Controls	Expected Results	Results obtained
CK-MB	4 negative Specimen of Whole Blood	Negative	Negative
	4 positive Specimen of Whole Blood 5 ng/ml	Positive	Positive

Analyte	Sensitivity	Time of Reaction
CK-MB	5 ng/ml	15 minutes

 Conclusion: Pass x Not Pass

This batch of the product is assigned to the following lot number and expiration date.



 QM-Manager
 Günter Keul

2011-09-04
 Date