



CERTIFICATE OF ANALYSIS
(BATCH RELEASE)

1. PRODUCT NAME: **CK-MB**
 DILUENT LOT#: 32751 EXP. DATE: 06/2013
2. METHOD/PROCEDURE: KINETIC
3. DESCRIPTION: POWDERED REAGENT & LIQUID DILUENT
4. KEY INGREDIENTS: REAGENT: Creatine Phosphate, Adenosine-5'-phosphate,
 Nicotinamide Adenine Dinucleotide (NAD), Hexokinase (Yeast),
 Glucose-6-Phosphate Dehydrogenase (Bacterial)
 DILUENT: Buffer, Anti-Human CK-M Antibody (Goat)
5. CONTROL MANUFACTURER: TECO
6. MANUFACTURE DATE: 05/23/2011

TOLERANCE LEVELS OF CONTROLS

<u>CONTROLS</u>	<u>LOT#</u>	<u>EXP. DATE</u>	<u>TOLERANCE RANGE</u> (TC MATRIX)	<u>TARGET</u> (IU/L)
LEVEL I	I-74-25	12/2012	<25	<25
LEVEL II	I-74-26	12/2012	40-60	50
LEVEL III	I-74-27	12/2012	73-105	89

TEST VALUES/RESULTS

<u>CONTROLS</u>	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>MEAN</u>	<u># PASS</u>
LEVEL I	17	17	17	17	17	17	17	6/6
LEVEL II	47	47	47	47	47	47	47	6/6
LEVEL III	82	82	73	82	83	84	81.5	6/6

COMMENTS: VISUAL CHECK OK

APPROVED
 BY:


Quality Control

DATE: 05/27/2011