MNCHIP

Myocardial Enzyme Panel Lyophilized Kit

【Product Name】
Myocardial Enzyme Panel Lyophilized Kit
【Packing Specification】
Type A: 1 Test / Disc, 10 Discs / Box;
Type B: 1 Test / Disc, 10 Discs / Box.
Type A without diluent container; Type B with diluent container.
【Testing Instrument】
Celercare M or Pointcare M chemistry analyzer
【Intended Use】
The Myocardial Enzyme Panel Lyophilized Kit used with the Celercare M or the Pointcare M chemistry analyzer, is intended to be used for the in vitro quantitative determination of creatinekinase (CK), creatine kinase-MBisoenzyme (CK-MB), lactate dehydrogenase (LDH), a-hydroxybutyrate dehydrogenase (α-HBDH) and aspartate aminotransferase (AST) inheparinized plasmaor serum in a clinical laboratory setting or point-of-care location.
The Myocardial Enzyme Panel Lyophilized Kit measurements are used in the diagnosis of the cardiovascular disease.
【Principles of Testing】
The Myocardial Enzyme Panel Lyophilized Kit is used to quantitatively test the concentration of the five biochemical indicators in the sample, which is based on the spectrophotometry. The principles are as follows:
Creatine Kinase (CK)
Creatine kinase catalyzes the formation of creatine and adenosine triphosphate (ATP) from creatine phosphate and adenosine diphosphate (ADP). With hexokinase (HK) as a catalyst, ATP reacts with D-glucose to form ADP and D-glucose-6-phosphate (G-6-P), which is reacted with nicotinamide adenine dinucleotide phosphate (NADP) in the presence of glucose-6-phosphate dehydrogenase (G-6-PDH) to produce 6-Phosphogluconate (6-PG) and NADPH.
The formation of NADPH is measured as a change in absorbance at 340 nm relative to 405 nm. This absorbance change is directly proportional to creatine kinase activity in the sample.
Creatine phosphate + ADP $\xrightarrow{CK}$ Creatine + ATP
ATP + D-glucose $\xrightarrow{HK}$ ADP + G-6-P
G-6-P + NADP$^+$ $\xrightarrow{G\text{-}6\text{-}PDH}$ 6-Phosphogluconate + NADPH +H$^+$
Creatine Kinase-MBisoenzyme (CK-MB)
The sample is incubated in the CK-MB reagent which includes the anti-CK-M antibody. The activity of the non-inhibited CK-B is then determined using the following series of reactions:
Creatine phosphate + ADP $\xrightarrow{CK\text{-}B}$ Creatine + ATP
ATP + D-glucose $\xrightarrow{HK}$ ADP + G-6-P
G-6-P + NADP$^+$ $\xrightarrow{G\text{-}6\text{-}PDH}$ 6-Phosphogluconate + NADPH + H$^+$
CK-B catalyzes the formation of creatine and adenosine triphosphate (ATP) from creatine phosphate and adenosine diphosphate (ADP). The auxiliary enzyme hexokinase (HK) catalyzes the phosphorylation of glucose by the ATP format, to produce ADP and glucose-6-phosphate (G-6-P) is oxidized to 6-phosphogluconate with the concomitant production of NADH. The rate of NADH formation, measured at 340 /405 nm, is directly proportional to serum CK-B activity. Multiplying the obtained test result by 2 is CK-MB activity.
Lactate Dehydrogenase (LDH)
Lactate dehydrogenase (LDH) catalyzes the oxidation of L-lactate to pyruvate with the concurrent reduction of nicotinamide adenine dinucleotide (NAD$^+$) to reduced nicotinamide adenine dinucleotide (NADH). The NADH is then oxidized with the simultaneous reduction of INT in a reactioncatalyzed by diaphorase. The intensity of the highly colored formazan is measured bichromatically at 505/800 nm and is directly proportional to the concentration of lactate dehydrogenase (LDH) in the sample.
L-Lactate + NAD$^+$ $\xrightarrow{LDH}$ Pyruvate + NADH + H$^+$
NADH + H$^+$ + INT $\xrightarrow{Diaphorase}$ NAD$^+$ + Formazan
a-Hydroxybutyrate Dehydrogenase (α-HBDH)
LDH isoenzyme in the presence of NADH and H$^+$ converts a-oxobutyrate substrate into α-hydroxybutyrate while NAD$^+$ is formed. The rate of decrease in absorbance is proportional to the α-hydroxybutyrate dehydrogenase (α-HBDH) activity at 340/405 nm.
α-oxobutyrate + NADH + H$^+$ $\xrightarrow{\alpha\text{-}HBDH}$ α-hydroxybutyrate + NAD$^+$
Aspartate Aminotransferase (AST)
AST catalyzes the reaction of L-aspartate and α-ketoglutarate into oxaloacetate and L-glutamate. Oxaloacetate is converted to malate and NADH is oxidized to NAD$^+$ by the catalyst MDH.
L-aspartate + α-ketoglutarate $\xrightarrow{AST}$ Oxaloacetate + L-glutamate
Oxaloacetate + NADH $\xrightarrow{MDH}$ Malate + NAD$^+$
The rate of absorbance change at 340/405 nm caused by the conversion of NADH to NAD$^+$ is directly proportional to the amount of AST present in the sample.
【Principle of Operation】
Refer to the Celercare M or the Pointcare M chemistry analyzer Operator's Manual, for the Principles and Limitations of the Procedure.
【Description of Reagents】
Each Myocardial Enzyme Panel Lyophilized Kit contains lyophilized test-specific reagent beads. A lyophilized blank reagent bead includes in each disc fora judgment of error 0209.
Type B is the reagent disc with diluent container.
Type A is the reagent disc without diluent container.
Calibration information is included in barcode code. Please check it on the label.
The component of each Myocardial Enzyme Panel Lyophilized Kit is as follows (after redissolution):

Component	Quantity
Creatine kinase assay reagent	13.5 μL
Creatine kinase-MB isoenzyme assay reagent	13.5 μL
Lactate dehydrogenase assay reagent	13.5 μL
a-hydroxybutyrate dehydrogenase assay reagent	13.5 μL
Aspartate Aminotransferase assay reagent	13.5 μL
Stabilizer	Appropriate amount

【Storage】
Store reagent discs in their sealed pouches at 2-8°C (36-46°F). Do not expose opened or unopened discs to direct sunlight or temperatures above 32°C (90°F).
Reagent discs may be used until the expiration date included on the package. The expiration date is also encoded in the unique code printed on the sealing pouch.
An error message will appear on the Celercare M or the Pointcare M chemistry analyzer display if the reagents have expired.
A torn or otherwise damaged pouch may allow moisture to reach the unused disc and adversely affect reagent performance. Do not use a disc from a damaged pouch.
【Sample Requirements】
Sample collection techniques are described in the "Sample requirement" section of the Celercare M or the Pointcare M chemistry analyzer Operator's Manual.
The required sample usage is 100 μL of lithium heparin whole blood, lithium heparin plasma, serum or quality controls. Please add diluent when using Type A. The required diluent usage is 430 μL of sterilized water for injection.
Whole blood samples collected by venipuncture must be homogeneous before transferring the sample to a reagent disc.
At the same time, it is necessary to carry out the test within 60 minutes. Before taking the test, shake the lithium heparin blood collection tube gently upside down several times.
Use only lithium heparin evacuated specimen collection tubes for whole blood or plasma samples.
The test was started within 10 minutes after transferring the sample to the reagent disc.
【Interfering Substances】
Studies on known drugs or chemicals have found that when the interfering substances contained in the sample exceed the contents in the table below, the final test results are affected.

Interfering substances concentration （≤）					
Analyte	Bilirubin	Intralipid	Hemoglobin	Vitamin C	Pyruvate
	mg/dL	mg/dL	mg/dL	mg/dL	mmol/L
CK	40	1000	400	100	——
CK-MB	10	125	100	100	——
LDH	40	1000	50	100	——
α-HBDH	40	250	50	100	——
AST	40	600	50	25	1

【Procedure】
Materials Provided
Myocardial Enzyme Panel Lyophilized Kit
Celercare M or Pointcare M chemistry analyzer
Please add diluent into the diluent port when using Type A (sterilized water for injection); please tear off the aluminum strip before using for Type B.
Transfer pipettes (fixed volume 100 μL for sample and 430 μL for diluent) and tips
Test Procedure
The complete sample collection and step-by-step operating procedures are detailed in the Celercare M or the Pointcare M chemistry analyzer Operator's Manual.
Calibration
Each batch of reagent is calibrated using Rondox standard serum to obtain the disc-specific calibration parameters before shipment.
The calibration parameters stored in the two-dimentional code printed on the sealed pouch are provided to analyzer at the time of scanning the code.
Refer to the Celercare M or the Pointcare M chemistry analyzer Operator's Manual for the specific information.

Quality Control

Refer to Operator's Manual of the Celercare M or the Pointcare M chemistry analyzer. Performance of the Celercare M or the Pointcare M chemistry analyzer can be verified by running controls. For a list of approved quality control materials with acceptance ranges.

If control results are out of range, repeat one time. If still out of range, call MNCHIP customer service or local distributers for technical support. Do not report the results if controls are outside their labeled limits.

Results

The Celercare M or the Pointcare M chemistry analyzer automatically calculates and prints the analyte concentrations in the sample. Details of the endpoint and rate reaction calculations are found in the Celercare M or the Pointcare M chemistry analyzer Operator's Manual.

【Normal Reference Ranges】

These ranges are provided as a guideline only. It is recommended that your office or institution establish normal ranges for your particular patient population.

Analyte	SI Units	Common Units
CK	Male: 38 ~ 174 U/L; Female: 26 ~ 140 U/L	Male: 38 ~ 174 U/L; Female: 26 ~ 140 U/L
CK-MB	0 ~ 25 U/L	0 ~ 25 U/L
LDH	109 ~ 245 U/L	109 ~ 245 U/L
α-HBDH	72 ~ 182 U/L	72 ~ 182 U/L
AST	Male: 15 ~ 40 U/L; Female: 13 ~ 35 U/L	Male: 15 ~ 40 U/L; Female: 13 ~ 35 U/L

【Interpretation of Results】

Physiological interferents (hemolysis, icterus and lipemia) cause changes in the reported concentrations of some analytes. The sample indices are printed on the bottom of each printout to inform the operator about the abnormal sample. The operator should avoid sample hemolysis caused by irregular blood collection.

The Celercare M or the Pointcare M chemistry analyzer suppresses any results that are affected by >10% interference from hemolysis, lipemia or icterus. "HEM", "LIP", or "ICT" respectively, is printed on the printout in place of the result.

Any result for a particular test that exceeds the assay range should be analyzed by another approved test method or sent to a referral laboratory. Do not dilute the sample and run it again on the Celercare M or the Pointcare M chemistry analyzer.

【Limitations of Procedure】

The Myocardial Enzyme Panel Lyophilized Kit should be used with the Celercare M or the Pointcare M chemistry analyzer, and is just used for in vitro diagnosis (IVD).

As with any diagnostic test procedure, all other test procedures including the clinical status of the patient should be considered prior to final diagnosis.

【Performance Characteristics】

Accuracy

Analyte	The relative deviation or absolute deviation should meet the following requirements
CK	B% ≤ 10.0%
CK-MB	B% ≤ 10.0%
LDH	B% ≤ 10.0%
α-HBDH	B% ≤ 10.0%
AST	B% ≤ 15.0%

Batch precision

Analyte	Coefficient of variation (≤ *)
CK	5.0%
CK-MB	6.0%
LDH	5.0%
α-HBDH	5.0%
AST	5.0%

Inter batch precision

Analyte	Relative Range(≤ *)
CK	10.0%
CK-MB	10.0%
LDH	10.0%
α-HBDH	10.0%
AST	10.0%

Dynamic Ranges

Analyte	Dynamic Ranges
CK	20 ~ 1000 U/L
CK-MB	5 ~ 200 U/L
LDH	25 ~ 800 U/L
α-HBDH	25 ~ 800 U/L
AST	5 ~ 1100 U/L

【Notes】

Used reagent discs contain human body fluids. Follow good laboratory safety practices when handling and disposing of used discs. See the Celercare M or the Pointcare M chemistry analyzer Operator's Manual for instructions on cleaning biohazardous spills.

The reagent discs are plastic and may crack or chip if dropped. Never use a dropped disc as it may spray biohazardous material throughout the interior of the analyzer.

Reagent beads may contain acids or caustic substances. The operator does not come into contact with the reagent beads when following the recommended procedures. The operator should avoid ingestion, skin contact, or inhalation of the reagent beads.

The diluent can be selected from purified water having a conductivity (measured at 25℃) greater than 10 MΩ/cm, we recommend using the sterilized water for injection to reduce discrepancies or errors in test results due to the water, and it should be prevented from being exposed to the air for a long time after opening.

【Symbols Used in Labelling】

Symbol	Explanation
IVD	In vitro diagnostic medical device
	Manufacturer
EC REP	Authorized representative in the European Community
	Use-by date
LOT	Batch code
	Date of manufacture
CE	CE MARK
	Consult instructions for use
2℃ 8℃	Limit of temperature
UDI	Unique device identifier
	Do not re-use

【Manufacturer】

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