【Product Name】

Diabetes Profile (4)

【Packing Specification】

Type B: 1 Test / Disc, 10 Discs / Box.
Type B with diluent container.

【Testing instrument】

Celercare V or Pointcare V chemistry analyzer

【Intended Use】

The Diabetes Profile (4) used with the Celercare V or the Pointcare V chemistry analyzer, is intended to be used for the in vitro quantitative determination of triglycerides (TG), total cholesterol (CHOL), glucose (GLU) and fructosamine (FRU) in heparinized whole blood, heparinized plasma, or serum in a clinical laboratory setting or point-of-care location.
The Diabetes Profile (4) measurements are used in the diagnosis of carbohydrate and lipid metabolism disorders.

【Principles of Testing】

The Diabetes Profile (4) is used to quantitatively test the concentration of the 4 biochemical indicators in the sample, which is based on the spectrophotometry. The principles are as follows:

1. Triglycerides (TG)

The TRIG assay is an enzymatic end-point method that makes use of four enzymes. The reaction mechanism follows:

$$\text{Triglycerides} + 3H_2O \xrightarrow{LPL} \text{Glycerol} + 3\text{Fatty Acids}$$

$$\text{Glycerol} + \text{ATP} \xrightarrow{GK,Mg^{2+}} \text{G-3-P} + \text{ADP}$$

$$\text{G-3-P} + NAD^+ + O_2 \xrightarrow{G\text{-}3PDH} \text{DAP} + \text{NADH} + H^+$$

$$\text{NADH} + H^+ + \text{INT} \xrightarrow{\text{Diaphorase}} NAD^+ + \text{Formazan}$$

In the first step, the triglycerides are hydrolyzed into glycerol and fatty acids in a reaction catalyzed by lipoprotein lipase. Glycerol is then phosphorylated in an ATP-requiring reaction catalyzed by glycerol kinase (GK). The glycerolphosphate is then oxidized to dihydroxyacetone phosphate with the simultaneous reduction of NAD^+ to NADH in a reaction catalyzed by glycerol-3-phosphate dehydrogenase (G-3-PDH). The NADH is then oxidized with the simultaneous reduction of INT in a reaction catalyzed by diaphorase. The intensity of the highly colored formazan is measured bichromatically at 505/800 nm and is directly proportional to the concentration of triglycerides in the sample.

2. Total Cholesterol (CHOL)

The reaction of CHOL is an enzymatic end-point method that uses cholesterol esterase (CE) and cholesterol dehydrogenase (CHDH). CE hydrolyzes cholesterol esters to form cholesterol and fatty

acids. The CHDH reaction converts cholesterol to cholest-4-en-3-one. The NADH is measured bichromatically at 340 nm and 546 nm. NADH production is directly proportional to the amount of cholesterol present. An assay-specific blank is also monitored to ensure no extraneous reactions interfere with the calculations of CHOL levels.

$$\text{Cholesterol Esters} + H_2O \xrightarrow{CE} \text{Cholesterol} + \text{Fatty Acids}$$

$$\text{Cholesterol} + NAD^+ \xrightarrow{CHDH} \text{Cholest-4-en-3-one} + NADH + H^+$$

3. Glucose (GLU)

The reaction of glucose with adenosine triphosphate (ATP) catalyzed by hexokinase (HK), produces glucose-6-phosphate (G-6-P) and adenosine diphosphate (ADP). Glucose-6-phosphate dehydrogenase (G-6-PDH) catalyzes the reaction of G-6-P into 6-phosphogluconate and the reduction of nicotinamide adenine dinucleotide phosphate ($NADP^+$) to NADPH.

$$\text{Glucose} + ATP \xrightarrow{HK} \text{Glucose-6-Phosphate} + ADP$$

$$\text{G-6-P} + NADP^+ \xrightarrow{\text{G-6-PDH}} \text{6-Phosphogluconate} + NADPH + H^+$$

The absorbance is measured bichromatically at 340 nm and 405 nm. The production of NADPH is directly proportional to the amount of glucose present in the sample.

4. Fructosamine (FRU)

Serum glucose can react with the amino group at the end of albumin and other serum proteins to produce the polymer structure of Keto-amine. This Keto-amine structure reacts with nitro blue tetrazolium (NBT) to form a blue complex in an alkaline environment. The absorbance of 546/800nm wavelength is proportional to the concentration of fructosamine in the sample.

【Principle of Operation】

Refer to the Celercare V or the Pointcare V chemistry analyzer Operator's Manual, for the Principles and Limitations of the Procedure.

【Description of Reagents】

Each Diabetes Profile (4) contains lyophilized test-specific reagent beads. A lyophilized blank reagent bead includes in each disc for a judgment of error 0233.
Type B is the reagent disc with diluent container.
Calibration information is included in barcode code. Please check it on the label.
The component of each Diabetes Profile (4) is as follows (after redissolution):

Component	Quantity
Triglycerides assay reagent	13.5μL
Total Cholesterol assay reagent	13.5 μL
Glucose assay reagent	6.6 μL
Fructosamine assay reagent	13.5 μL
Stabilizer	Appropriate amount

【Storage】

Store reagent discs in their sealed pouches at a temperature of 2-8°C (36-46°F). Do not expose opened or unopened discs to direct sunlight or temperatures exceeding 32°C (90°F). Reagent discs may be used until the expiration date indicated on the package, which is also encoded in the unique code printed on the sealing pouch.

A torn or damaged pouch may allow moisture to reach the unused disc, adversely affecting its performance. Therefore, do not use any disc from a damaged pouch.

【Sample Requirements】

Sample collection techniques are described in the “Sample requirement” section of the Celercare V or the Pointcare V chemistry analyzer Operator’s Manual.

The required sample usage is 100 μL of lithium heparin whole blood, lithium heparin plasma, serum or quality controls.

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.

The glucose concentration is affected by the patient's feeding time and the storage environment after the sample is collected. In order to accurately measure glucose, a sample of the patient should be taken after at least 12 hours of fasting. For uncentrifuged samples stored at room temperature, the glucose concentration is reduced by about 5-12 mg / dL in 1 hour.

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 mg/dL	Intralipid mg/dL	Hemoglobin mg/dL	Vitamin C mg/dL
TG	40	——	1000	50
CHOL	40	1000	800	40
GLU	40	600	1000	50
FRU	10	500	200	10

【Procedure】

■ **Materials Provided**

Diabetes Profile (4)

Celercare V or Pointcare V chemistry analyzer

Please tear off the aluminum strip before using Type B.

Transfer pipettes (fixed volume 100 μL for sample) and tips

■ **Test Procedure**

The complete sample collection and step-by-step operating procedures are detailed in the Operator's Manual for the Celercare V or Pointcare V chemistry analyzer.

■ **Calibration**

Each batch of reagent is calibrated using Randox 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 Operator's Manual for specific information.

■ **Quality Control**

Refer to Operator's Manual of the Celercare V or the Pointcare V chemistry analyzer. Performance of the Celercare V or the Pointcare V chemistry analyzer can be verified by running controls. For a list of approved quality control materials with acceptance ranges, please consult the manual.
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 V or the Pointcare V chemistry analyzer automatically calculates and prints the analyte concentrations in the sample. Details regarding endpoint and rate reaction calculations can be found in the Celercare V or the Pointcare V 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
TG	Dog: 0.10 ~ 0.90mmol/L Cat: 0.10 ~ 0.90mmol/L	Dog: 9 ~ 80mg/dL Cat: 9 ~ 80mg/dL
CHOL	Dog: 2.84 ~ 8.26mmol/L Cat: 1.68 ~ 5.81mmol/L	Dog: 110 ~ 320mg/dL Cat: 65 ~ 225mg/dL
GLU	Dog: 3.89 ~ 7.95mmol/L Cat: 4.11 ~ 8.84mmol/L	Dog: 70 ~ 143mg/dL Cat: 74 ~ 159mg/dL
FRU	Dog: 150 ~331μmol/L; Cat: 190~ 383μmol/L	Dog: 150 ~ 331μmol/L; Cat: 190~ 383μmol/L

【Interpretation of Results】

Physiological interferents, such as hemolysis, icterus, and lipemia, can cause changes in the reported concentrations of certain analytes. Sample indices are printed at the bottom of each printout to inform the operator about any abnormalities in the sample. The operator should take care to avoid hemolysis caused by improper blood collection techniques.
The Celercare V or the Pointcare V 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 V or the Pointcare V chemistry analyzer.

【Limitations of Procedure】

Diabetes Profile (4) should be used with the Celercare V or the Pointcare V 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 (at least one)
TG	B% ≤ 15.0%
CHOL	B% ≤ 10.0%
GLU	B% ≤ 20.0%
FRU	B% ≤ 20.0%

Batch precision

Analyte	Coefficient of variation (≤ *)
TG	5.0%
CHOL	4.0%
GLU	5.0%
FRU	10.0%

Inter batch precision

Analyte	Relative Range (≤ *)
TG	10.0%
CHOL	6.0%
GLU	10.0%
FRU	10.0%

Dynamic Ranges

Analyte	Dynamic Ranges
TG	0 ~ 9.04mmol/L
CHOL	0.5 ~ 14mmol/L
GLU	1 ~ 35mmol/L

FRU	0~ 1500 μmol/L

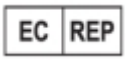
【Notes】

Used reagent discs contain animal body fluids. It is essential to follow good laboratory safety practices when handling and disposing of these used discs. For instructions on cleaning biohazardous spills, refer to the Celercare V or Pointcare V chemistry analyzer Operator's Manual.

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

Reagent beads may contain acids or caustic substances. Operators do not come into contact with the reagent beads when following the recommended procedures. It is important to avoid ingestion, skin contact, or inhalation of the reagent beads.

【Symbols Used in Labelling】

Symbol	Explanation
	Veterinary use only
	Manufacturer
	Unique device identifier
	Authorized representative in the European Community
	Use-by date
	Batch code
	Date of manufacture
	Consult instructions for use
	Limit of temperature
	Do not re-use

【Manufacturer】

Tianjin MNCHIP Technologies Co., Ltd.

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Service email: service@mnchip.com

Learn more about MNCHIP, other products can log in: http://www.mnchip.com

EC REP

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