【Product Name】

Coagulation 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 Coagulation 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 thrombin time (TT), prothrombin time (PT), activated partial thromboplastin time (APTT), fibrinogen (FIB) in sodium citrate anticoagulant whole blood or plasma in a clinical laboratory setting or point-of-care location.
The Coagulation Profile (4) measurements are used in the clinical monitoring of coagulation function and fibrinolytic function.

【Principles of Testing】

The Coagulation 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. Thrombin Time (TT)

Thrombin hydrolyzes its substrate, fibrinogen, converting it from liquid to solid fibrin. The time it takes for plasma to clot after the addition of a "standardized" thrombin solution to the plasma to be tested is the thrombin time (TT).

2. Prothrombin Time (PT)

Excessive tissue thromboplastin diffuse fluid and Ca^{2+} are added to the plasma to be tested to convert prothrombin to thrombin, which converts fibrinogen in plasma into fibrin, and the time required for plasma to coagulate is the prothrombin time (PT).

3. Activated Partial Thromboplastin Time (APTT)

A standard amount of partial thromboplastin solution is added to the plasma to be tested to activate Factors Ⅻ and Ⅺ. Platelets are replaced by ceruloplasmin to provide a catalytic surface for coagulation, and the time required for plasma to clot in the presence of a standard amount of Ca^{2+} is the Activated Partial Thromboplastin Time (APTT).

4. Fibrinogen (FIB)

According to the principle that fibrinogen and thrombin interact to finally form fibrin. The standard was used as the reference plasma to make a standard curve, and the plasma coagulation time was determined by thrombin, and the coagulation time obtained was negatively correlated with the fibrinogen concentration, so as to obtain the fibrinogen content.

【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 Coagulation Profile (4) contains lyophilized test-specific reagent beads.
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 Coagulation Profile (4) is as follows (after redissolution):

Component	Quantity
Thrombin Time assay reagent	13.5 μL
Prothrombin Time assay reagent	13.5 μL
Activated Partial Thromboplastin Time assay reagent	13.5 μL
Fibrinogen 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 Vchemistry analyzer Operator's Manual.
The required sample usage is 100 μL of sodium citrate anticoagulant whole blood, sodium citrate anticoagulant plasma 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 sodium citrate blood collection tube gently upside down several times.
Use only sodium citrate vacuated specimen collection tubes for whole blood or plasma samples.
The test was started within 10 minutes after transferring the sample to the reagent disc.

【Procedure】

■ **Materials Provided**

Coagulation 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.

■ **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
APTT	Dog: 21 ~ 80s; Cat: 18 ~ 90s	Dog: 21 ~ 80s; Cat: 18 ~ 90s
TT	Dog: 7 ~ 40s; Cat: 7 ~ 40s	Dog: 7 ~ 40s; Cat: 7 ~ 40s
PT	Dog: 5 ~ 18s; Cat: 5 ~ 25s	Dog: 5 ~ 18s; Cat: 5 ~ 25s
FIB	Dog: 1.4 ~ 4.0g/L Cat: 1.2 ~ 3.6g/L	Dog: 0.14 ~ 0.4.g/dL Cat: 0.12 ~ 0.36g/dL

【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.
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】

The Coagulation 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
TT	B% ≤ 20.0%
PT	B% ≤ 20.0%
APTT	B% ≤ 20.0%
FIB	B% ≤ 20.0%

Batch precision

Analyte	Coefficient of variation (≤ *)
TT	10.0%
PT	10.0%
APTT	10.0%
FIB	10.0%

Inter batch precision

Analyte	Relative Range (≤ *)
TT	10.0%
PT	10.0%
APTT	10.0%
FIB	10.0%

Dynamic Ranges

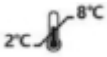
Analyte	Dynamic Ranges
FIB	0.8 ~ 8 g/L

【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
	Use-by date
	Batch code
	Date of manufacture
	Consult instructions for use
	Limit of temperature
	Do not re-use

【Manufacturer】

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