



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.

Light may cause total bilirubin to decompose, causing deviations in the test results. Whole blood samples that are not tested immediately should be stored in a dark environment.

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.

Analyte	Interfering substances concentration (≤)						
	Bilirubin mg/dL	Intralipid mg/dL	Hemoglobin mg/dL	Vitamin C mg/dL	Pyruvate mmol/L	Creatine mmol/L	ammonium chloride mmol/L
TP	25	1050	200	—	—	—	—
ALB	40	600	1000	—	—	—	—
TBIL	—	1050	1000	75	—	—	—
ALT	40	600	50	50	1	—	—
UREA	25	600	1000	—	—	—	1
CRE	40	1050	500	25	—	600	—
UA	22.5	120	800	10	—	—	—
GLU	40	600	1000	50	—	—	—
TG	40	—	1000	50	—	—	—
CHOL	40	1000	800	40	—	—	—
HDL-C	20	2200	500	40	—	—	—
AST	40	600	50	25	1	—	—
DBIL	—	1050	200	75	—	—	—
GGT	40	1050	200	—	—	—	—
ALP	40	1050	400	—	—	—	—

#### 【Procedure】

##### Materials Provided

General Chemistry IV Lyophilized Kit

Celcare 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 Celcare M or the Pointcare M chemistry analyzer Operator's Manual.

##### Calibration

Each batch of reagent is calibrated using Rondo standard serum to obtain the disc-specific calibration parameters before shipment.

The calibration parameters stored in the two-dimensional code printed on the sealed pouch are provided to analyzer at the time of scanning the code.

Refer to the Celcare M or the Pointcare M chemistry analyzer Operator's Manual for the specific information.

##### Quality Control

Refer to Operator's Manual of the Celcare M or the Pointcare M chemistry analyzer. Performance of the Celcare 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 distributors for technical support. Do not report the results if controls are outside their labeled limits.

##### Results

The Celcare 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 Celcare 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
TP	65-85 g/L	6.5 - 8.5 g/dL
ALB	40-55 g/L	4.0 - 5.5 g/dL
TBIL	3.4-20 μmol/L	0.20 - 1.17 mg/dL
ALT	Male: 9-50 U/L; Female: 7-40 U/L	Male: 9 - 50 U/L; Female: 7 - 40 U/L
UREA	2.9-8.2 mmol/L	17.42 - 49.25 mg/dL
CRE	Male: 54-109 μmol/L; Female: 45-84 μmol/L	Male: 0.61 - 1.23 mg/dL; Female: 0.51 - 0.95 mg/dL
UA	Male: 208-428 μmol/L; Female: 155-357 μmol/L	Male: 3.50 - 7.20 mg/dL; Female: 2.61 - 6.00 mg/dL
GLU	3.9-6.1 mmol/L	70.2 - 109.8 mg/dL
CHOL	0-5.2 mmol/L	0 - 201.24 mg/dL
HDL-C	Male: 1.16-1.42 mmol/L; Female: 1.29-1.55 mmol/L	Male: 44.61 - 54.61 mg/dL; Female: 49.61 - 59.61 mg/dL
TG	0-1.7 mmol/L	0 - 150.45 mg/dL
AST	Male: 15-40 U/L; Female: 13-35 U/L	Male: 15 - 40 U/L; Female: 13 - 35 U/L
DBIL	0-6 μmol/L	0 - 0.35 mg/dL
GGT	Male: 10- 60 U/L; Female: 7 - 45 U/L	Male: 10 - 60 U/L; Female: 7 - 45 U/L
ALP	Male Adult: 45 - 125 U/L; Female Adult: 35 - 135 U/L Male Children: 0 - 750 U/L; Female Children: 0 - 500 U/L	Male Adult: 45 - 125 U/L; Female Adult: 35 - 135 U/L Male Children: 0 - 750 U/L; Female Children: 0 - 500 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 Celcare 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 Celcare M or the Pointcare M chemistry analyzer.

#### 【Limitations of Procedure】

The General Chemistry IV Lyophilized Kit should be used with the Celcare 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
TP	B% ≤ 5.0%
ALB	B% ≤ 6.0%
TBIL	B% ≤ 10.0%
ALT	B% ≤ 15.0%
UREA	B% ≤ 15.0%
CRE	B% ≤ 10.0%
UA	B% ≤ 10.0%
GLU	B% ≤ 20.0%
CHOL	B% ≤ 10.0%
HDL-C	B% ≤ 10.0%
TG	B% ≤ 15.0%
AST	B% ≤ 15.0%
DBIL	B% ≤ 10.0%
GGT	B% ≤ 15.0%
ALP	B% ≤ 10.0%

#### Batch precision

Analyte	Coefficient of variation (≤ %)
TP	2.0%
ALB	2.0%
TBIL	5.0%
ALT	5.0%
UREA	5.0%
CRE	5.0%
UA	4.0%
GLU	5.0%
CHOL	4.0%
HDL-C	4.0%
TG	5.0%
AST	5.0%
DBIL	5.0%
GGT	5.0%
ALP	5.0%

#### Inter batch precision

Analyte	Relative Range (≤ %)
TP	5.0%
ALB	5.0%
TBIL	10.0%
ALT	10.0%
UREA	10.0%
CRE	10.0%
UA	6.0%
GLU	10.0%
CHOL	6.0%
HDL-C	10.0%
TG	10.0%
AST	10.0%
DBIL	10.0%
GGT	10.0%
ALP	10.0%

#### Dynamic Ranges

Analyte	Dynamic Ranges
TP	30-100 g/L
ALB	10-60 g/L
TBIL	2-800 μmol/L
ALT	5-1100 U/L
UREA	0.9-35.7 mmol/L
CRE	20-1500 μmol/L
UA	150-900 μmol/L
GLU	1-30 mmol/L
CHOL	2-14 mmol/L
HDL-C	0.2-3 mmol/L
TG	1.13-9.04 mmol/L
AST	5 - 1100 U/L
DBIL	2-200 μmol/L
GGT	5 - 1100 U/L
ALP	25 - 1200 U/L

#### 【Notes】

Used reagent discs contain human body fluids. Follow good laboratory safety practices when handling and disposing of used discs. See the Celcare 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°C) 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
	In vitro diagnostic medical device
	Manufacturer
	Authorized representative in the European Community
	Use-by date
	Batch code
	Date of manufacture
	CE MARK
	Consult instructions for use
	Limit of temperature
	Unique device identifier
	Do not re-use

#### 【Manufacturer】

Tianjin MNCHIP Technologies Co., Ltd.  
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