MNCHIP

Ammonia Panel Lyophilized Kit

【Product Name】
Ammonia Panel Lyophilized Kit
【Packing Specification】
1 Test / Disc, 10 Discs / Box
【Testing Instrument】
Celercare M or Pointcare M chemistry analyzer
【Intended Use】
The Ammonia 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 ammonia (NH_3) in heparinized whole blood, or heparinized plasma,in a clinical laboratory setting or point-of-care location.
The Ammonia Panel Lyophilized Kit measurements are used in the diagnosis of liver diseases.
【Principles of Testing】
The Ammonia Panel Lyophilized Kit is used to quantitatively test the concentration of the ammonia in the sample, which is based on the spectrophotometry. The principles are as follows:
Ammonia
The ammonia converts NADH to NAD^+ under the action of excess α-ketoglutaric acid, NADH and sufficient GLDH, and the rate of decrease in absorbance is proportional to the concentration of ammonia.

$$NH_4^+ + \alpha\text{-Oxoglutarate} + NADH \xrightarrow{GLDH} \text{L-Glutamate} + H_2O + NAD^+$$

【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 Ammonia Panel Lyophilized Kit contains lyophilized test-specific reagent beads.
Calibration information is included in barcode code. Please check it on the label.
The component of each Ammonia Panel Lyophilized Kit is as follows (after redissolution):

Component	Quantity
Ammonia assay reagent	6.6 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 or quality controls.
Kindly use anticoagulant blood collection tube with heparin sodium, heparin lithium, or EDTA anticoagulant, including which tubes with heparin lithium are recommended the most. Besides, the blood collection tube should be made of deaminized material.
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 30 minutes. Before taking the test, shake the lithium heparin blood collection tube gently upside down several times. The accuracy of the test results may be affected when the sample's collection has finished for a long time. If not analyzed immediately, whole blood should be separated into plasma and be stored in a frozen, dark and airtight manner. All the frozen samples must be analyzed within 24 hours and can be used directly without warming-up to room temperature.
Due to the high ammonia concentration in red blood cells, which leads to an increase in the concentration of ammonia in plasma, it is recommended to place the blood in an ice bath (or refrigerated transportation) after blood collection, and separate the plasma immediately.
【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
NH_3	40	1000	200	100

【Procedure】
Materials Provided
Ammonia Panel Lyophilized Kit
Celercare M or Pointcare M chemistry analyzer
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 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
NH_3	Male: 18 ~ 72 μmol/L; Female: 16 ~ 65 μmol/L	Male: 30.6 ~ 122.4 μg/dL; Female: 27.2 ~ 110.7 μg/dL

【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 Ammonia 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
NH_3	B% ≤ 10.0%

Batch precision

Analyte	Coefficient of variation (≤ *)
NH_3	5.0%

Inter batch precision

Analyte	Relative Range (≤ *)
NH_3	10.0%

Dynamic Ranges

Analyte	Dynamic Ranges
NH_3	10 ~ 600 μmol/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 reagent discs 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
	Limit of temperature
UDI	Unique device identifier
	Do not re-use

【Manufacturer】

Tianjin MNCHIP Technologies Co., Ltd.
Add.: 1-4F, Area, No.122 Dongting Rd, Development Zone, 300457 Tianjin P.R. China
SRN: CN-MF-000029863
Technical support Telephone:+86-131-6318-8628
Service email: service@mnchip.com
Learn more about MNCHIP, other products can log in: http://www.mnchip.com

EC REP Umedwings Netherlands B.V.
Add.:Treubstraat 1, 2288EG, Rijswijk, the Netherlands
SRN: NL-AR-000000444
Email: ar@umedwings.eu