

【Product Name】

Avian Reptilian Profile (12+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 Avian Reptilian Profile (12+4) used with the Celercare V or the Pointcare V chemistry analyzer, is intended to be used for the in vitro quantitative determination of total Protein (TP), albumin (ALB), aspartate aminotransferase (AST), creatine kinase (CK), glucose (GLU), uric acid (UA), calcium (Ca), phosphorus (P), potassium (K⁺), sodium (Na⁺) chloride (Cl⁻), total bile acid(TBA) in heparinized plasma, or serum in a clinical laboratory setting or point-of-care location.

The Avian Reptilian Profile (12+4) measurements are used in the diagnosis of hepatobiliary system diseases, urinary system diseases, glucose metabolism and lipid metabolism disorders, pancreatic diseases, cardiovascular diseases.

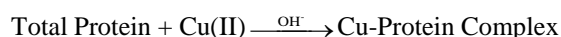
【Principles of Testing】

The Avian Reptilian Profile (12+4) is used to quantitatively test the concentration of the 12 biochemical indicators in the sample, which is based on the spectrophotometry. The principles are as follows:

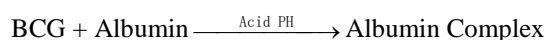
1. Total Protein (TP)

The total protein method is a Biuret reaction, the protein solution is treated with cupric [Cu(II)] ions in a strong alkaline medium. The Cu(II) ions react with peptide bonds between the carbonyl oxygen and amide nitrogen atoms to form a colored Cu-protein complex.

The amount of total protein present in the sample is directly proportional to the absorbance of the Cu-protein complex. The total protein test is an endpoint reaction and the absorbance is measured as the difference in absorbance between 546 nm and 800 nm.

**2. Albumin (ALB)**

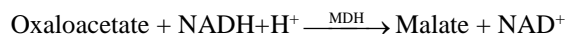
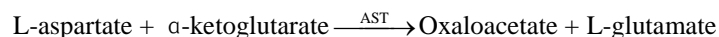
Bromcresol green (BCG), when bound with albumin, changes color from a yellow to green color. The absorbance maximum changes with the color shift.



Bound albumin is proportional to the concentration of albumin in the sample. This is an endpoint reaction that is measured as the difference in absorbance between 600 nm and 700 nm.

3. 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.

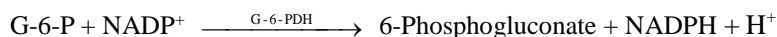
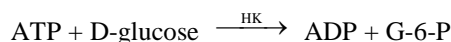


The rate of absorbance change at 340 /405 nm caused by the conversion of NADH to NAD⁺ is directly proportional to the amount of AST present in the sample.

4. Creatine Kinase (CK)

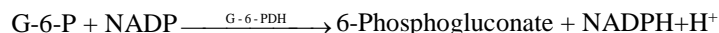
Creatine kinase catalyzes the formation of creatine and adenosine triphosphate (ATP) from creatine phosphate and adenosine diphosphate (ADP). With hexokinase (HK) as a catalyst, ATP reacts with D-glucose to form ADP and D-glucose-6-phosphate (G-6-P), which is reacted with nicotinamide adenine dinucleotide 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.



5. 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.



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.

6. Uric Acid (UA)

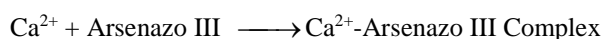
The uricase method is coupled through a Trinder peroxidase finish. In this method, uricase catalyzes the oxidation (UAO) of uric acid to allantoin and hydrogen peroxide. Peroxidase (POD) catalyzes the reaction among the hydrogen peroxide (H₂O₂), 4-aminoantipyrine (4-AAP) and 3,5-dichloro-2-hydroxybenzenesulfonic acid (DHBSA) into a red quinoneimine dye. Sodium ferrocyanide and ascorbate oxidase are added to the reaction mixture to minimize the potential interference of bilirubin and ascorbic acid.



The amount of uric acid in the sample is directly proportional to the absorbance of the quinoneimine dye. The final absorbance of this endpoint reaction is measured bichromatically at 505 nm and 600 nm.

7. Calcium (Ca)

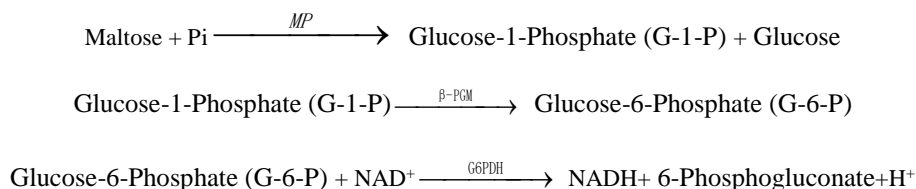
Calcium in the patient sample binds with arsenazo III to form a calcium-dye complex.



It is an endpoint reaction. The amount of total calcium in the sample is proportional to the absorbance.

8. Phosphorus (P)

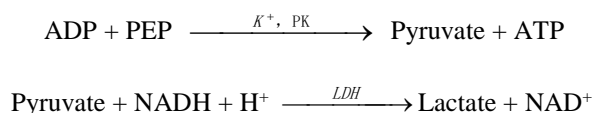
The enzymatic method for the MNCHIP system uses maltose phosphorylase (MP) coupled through β -phosphoglucomutase (β -PGM) and glucose-6-phosphate dehydrogenase (G6PDH). The amount of NADH formed can be measured as an endpoint at 340/405 nm.



9. Potassium (K⁺)

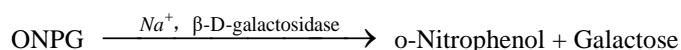
In the coupled enzyme reaction, pyruvate kinase (PK) dephosphorylates phosphoenolpyruvate (PEP) to form pyruvate. Lactate dehydrogenase (LDH) catalyzes conversion of pyruvate to lactate. Concomitantly, NADH is oxidized to NAD⁺. The rate of change in absorbance due to the conversion of NADH to NAD⁺ is directly proportional to the amount of potassium in the sample.

Interferences from other ions are minimized with the addition of some special ingredients.



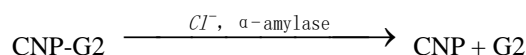
10. Sodium (Na⁺)

In the enzymatic reaction, β -D-galactosidase is activated by the sodium in the sample. The activated enzyme catalyzes the reaction of o-nitrophenyl- β -D-galactopyranoside (ONPG) to o-nitrophenol and galactose.



11. Chloride (Cl⁻)

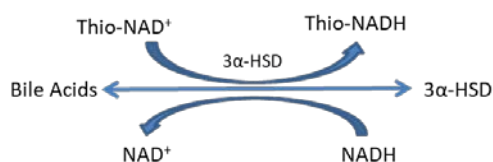
The method is based on the determination of chloride-dependent activation of α -amylase activity. Deactivated α -amylase is reactivated by addition of the chloride ion. The reactivation of α -amylase activity is proportional to the concentration of chloride ion in the sample. The reactivated α -amylase converts the substrate, 2-chloro-4-nitrophenyl- β -1,4-galactopyranosylmaltoside (CNP-G2) to 2-chloro-4-nitrophenol (CNP) producing color and 1,4-galactopyranosylmaltoside. The reaction is measured bichromatically and the increase in absorbance is directly proportional to the reactivated α -amylase activity and the concentration of chloride ion in the sample.



12. Total Bile Acids (TBA)

In the presence of the thio-derivative of nicotinamide adenine dinucleotide (Thio-NAD⁺) the enzyme 3- α -Hydroxysteroid Dehydrogenase (3- α -HSD) reversibly oxidizes bile acids to oxidized bile acids (3- α -keto forms) with the concomitant conversion of Thio-NAD⁺ to its reduced form Thio-NADH. In a cycling reaction, the oxidized bile acids are returned to their reduced state when excess NADH is present. The NADH is converted to NAD⁺. The rate of increase in absorbance at 405nm (Thio-NADH)

is measured and is proportional to the concentration of bile acids in the sample. The rate is measured bichromatically at 405 and 500nm.



【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 Avian Reptilian Profile (12+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 componen of each Avian Reptilian Profile (12+4) is as follows (after redissolution):

Component	Quantity
Total protein assay reagent	13.5 μL
Albumin assay reagent	13.5 μL
Aspartate Aminotransferase assay reagent	13.5 μL
Creatine Kinase assay reagent	13.5μL
Glucose assay reagent	6.6 μL
Uric Acid assay reagent	13.5 μL
Calcium assay reagent	9.7 μL
Phosphorus assay reagent	13.5 μL
Potassium assay reagent	13.5 μL
Sodium assay reagent	13.5 μL
Chloride assay reagent	13.5 μL
Total bile acid 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 plasma, serum or quality controls.

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.

Use only lithium heparin evacuated specimen collection tubes for 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	Mg ²⁺ mmol/L
TP	25	1050	200	—	—	—
ALB	40	600	1000	—	—	—
AST	40	600	50	25	1	—
CK	40	1000	400	100	—	—
GLU	40	600	1000	50	—	—
UA	22.5	120	800	10	—	—
Ca	180	210	200	75	—	3
P	45	525	100	27	—	—
K ⁺	16	150	50	75	—	—
Na ⁺	10	150	50	75	—	—
Cl ⁻	18	210	50	75	—	—
TBA	50	600	500	50	—	—

【Procedure】

■ Materials Provided

Avian Reptilian Profile (12+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-dimensional 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 distributors 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】

It is recommended that your office or institution establish normal ranges for your particular patient population. Test results should be interpreted in conjunction with the patient's clinical signs.

【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.

For the same sample, the result of using anticoagulant whole blood and plasma is 0.2 - 0.5 mmol/L lower than those using serum.

The potassium assay is a coupled pyruvate kinase (PK) / lactate dehydrogenase (LDH) assay. Therefore, in cases of extreme muscle trauma or highly elevated levels of creatine kinase (CK), The Celercare V or the Pointcare V chemistry analyzer may report a falsely elevated potassium (K⁺) value. In such cases, unexpected high potassium recoveries need to be confirmed utilizing a different methodology.

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 Avian Reptilian Profile (12+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
TP	B% \leq 5.0%
ALB	B% \leq 6.0%
AST	B% \leq 15.0%
CK	B% \leq 10.0%
GLU	B% \leq 20.0%
UA	B% \leq 10.0% or Absolute deviation \leq 50 μ mol/L
Ca	B% \leq 5.0%
P	B% \leq 10.0%
K ⁺	B% \leq 15.0%
Na ⁺	B% \leq 15.0%
Cl ⁻	B% \leq 15.0%
TBA	B% \leq 15.0%

Batch precision

Analyte	Coefficient of variation (\leq *)
TP	2.0%
ALB	2.0%
AST	5.0%
CK	5.0%
GLU	5.0%
UA	4.0%
Ca	3.0%
P	5.0%
K ⁺	5.0%
Na ⁺	5.0%
Cl ⁻	5.0%
TBA	5.0%

Inter batch precision

Analyte	Relative Range (\leq *)
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TP	5.0%
ALB	5.0%
AST	10.0%
CK	10.0%
GLU	10.0%
UA	6.0%
Ca	5.0%
P	10.0%
K ⁺	10.0%
Na ⁺	10.0%
Cl ⁻	10.0%
TBA	10.0%

Dynamic Ranges

Analyte	Dynamic Ranges
TP	20 ~ 100g/L
ALB	10 ~ 60g/L
AST	5 ~ 1600U/L
CK	5 ~ 3000 U/L
GLU	1 ~ 35 mmol/L
UA	15 ~ 900 µmol/L
Ca	0.5 ~ 4mmol/L
P	0.2 ~ 7mmol/L
K ⁺	1 ~ 8 mmol/L
Na ⁺	90 ~ 170mmol/L
Cl ⁻	60 ~ 140mmol/L
TBA	0 ~ 150µmol/L

【Notes】




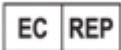




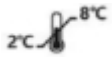

Used reagent discs contain animal body fluids. It is essential to follow good laboratory safety practices when handling and disposing of these used discs. For instructions on cleaning biohazardous spills, refer to the Celercare V or Pointcare V chemistry analyzer Operator's Manual.

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
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	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】



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