

【Product Name】

Liver Profile (11+4)

【Packing Specification】

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

Type B with diluent container.

【Testing Instrument】

CareSign-C chemistry analyzer

【Intended Use】

The Liver Profile (11+4) used with CareSign-C chemistry analyzer, is intended to be used for the in vitro quantitative determination of total Protein (TP), albumin (ALB), alanine aminotransferase (ALT), aspartate aminotransferase (AST), gamma glutamyltransferase (GGT), alkaline phosphatase (ALP), total bilirubin (TBIL), direct bilirubin (DBIL), total bile acids (TBA), urea nitrogen(BUN), total cholesterol (CHOL) in heparinized plasma, or serum in a clinical laboratory setting or point-of-care location.

The Liver Profile (11+4) measurements are used in the diagnosis of liver and gallbladder diseases.

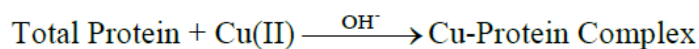
【Principles of Testing】

The Liver Profile (11+4) is used to quantitatively test the concentration of the 11 biochemical indicators in the sample, which is based on the spectrophotometry. The principles are as follows:

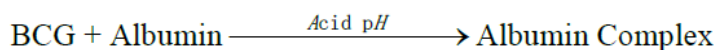
1. Total Protein (TP)

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)**

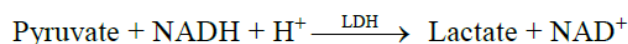
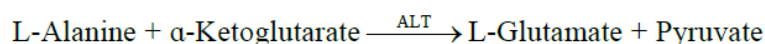
Bromcresol green (BCG), when bound with albumin, changes color from a yellow to green color. The absorbance maximum changes with the color shift.



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. Alanine Aminotransferase (ALT)

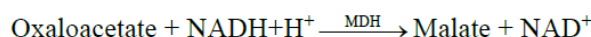
ALT catalyzes the transfer of an amino group from L-alanine to α -ketoglutarate to form L-glutamate and pyruvate. Lactate dehydrogenase catalyzes the conversion of pyruvate to lactate. Concomitantly, NADH is oxidized to NAD^+ , as illustrated in the following reaction scheme.



The rate of change of the absorbance difference between 340 nm and 405 nm is due to the conversion of NADH to NAD^+ and is directly proportional to the amount of ALT present in the sample.

4. Aspartate Aminotransferase (AST)

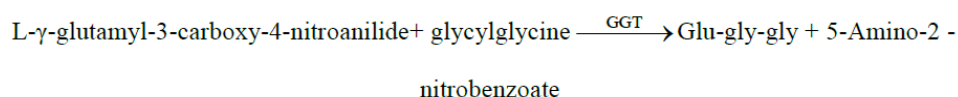
AST catalyzes the reaction of L-aspartate and α -ketoglutarate into oxaloacetate and L-glutamate. Oxaloacetate is converted to malate and NADH is oxidized to NAD^+ by the catalyst MDH.



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.

5. Gamma Glutamyltransferase (GGT)

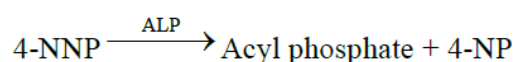
The addition of sample containing gammaglutamyltransferase to the substrates L- γ -glutamyl-3-carboxy-4-nitroanilide and glycylglycine causes the formation of L- γ -glutamyl-glycylglycine (glu-gly-gly) and 5-Amino-2-nitrobenzoate.



The absorbance of this rate reaction is measured at 405/505 nm. The production is directly proportional to the GGT activity in the sample.

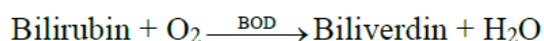
6. Alkaline Phosphatase (ALP)

Under the catalysis of ALP, the Phosphoric acid on nitrobenzene (4-NNP) was turned into Para nitro phenol (4-NP). 4-NP shows a yellow color in alkaline solution. At the wavelength of 405/505nm, the ALP activity can be calculated by monitoring the absorbance change rate.



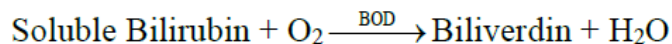
7. Total Bilirubin (TBIL)

In the enzyme procedure, bilirubin is oxidized by bilirubin oxidase (BOD) into biliverdin. Bilirubin is quantitated as the difference in absorbance between 450nm and 546 nm. The initial absorbance of this endpoint reaction is determined from the bilirubin blank cuvette and the final absorbance is obtained from the bilirubin test cuvette. The amount of bilirubin in the sample is proportional to the difference between the initial and final absorbance measurements.



8. Direct Bilirubin (DBIL)

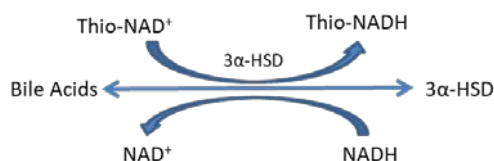
In the enzymatic procedure, the soluble bilirubin complex (direct bilirubin) is oxidized by bilirubin oxidase (BOD) into biliverdin.



Direct Bilirubin is quantitated as the difference in absorbance between 450 nm and 546 nm. The initial absorbance of this end point reaction is determined from the direct bilirubin blank cuvette and the final absorbance is obtained from the direct bilirubin test cuvette. The amount of direct bilirubin in the sample is proportional to the difference between the initial and final absorbance measurements.

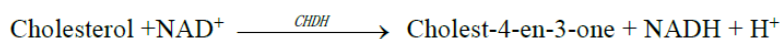
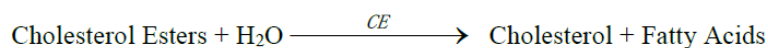
9. Total Bile Acids (TBA)

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.



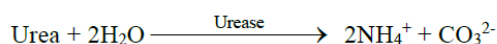
10. Total Cholesterol (CHOL)

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 405 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.



11. Urea Nitrogen (BUN)

In the coupled-enzyme reaction, urease hydrolyzes urea into ammonia and carbon dioxide. Upon combining ammonia with α -oxoglutarate and reduced nicotinamide adenine dinucleotide (NADH), the enzyme glutamate dehydrogenase (GLDH) oxidizes NADH to NAD⁺.



The rate of change of the absorbance difference between 340 nm and 405 nm is caused by the conversion of NADH to NAD⁺ and is directly proportional to the amount of urea present in the sample.

【Principle of Operation】

Refer to CareSign-C chemistry analyzer Operator's Manual, for the Principles and Limitations of the Procedure.

【Description of Reagents】

Each Liver Profile (11+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 Liver Profile (11+4) is as follows (after redissolution):

Component	Quantity
Total protein assay reagent	13.5 μL
Albumin assay reagent	13.5 μL
Alanine aminotransferase assay reagent	13.5 μL
Aspartate aminotransferase assay reagent	13.5 μL
Gamma glutamyltransferase assay reagent	13.5 μL
Alkaline Phosphatase assay reagent	13.5 μL
Total bilirubin assay reagent	13.5 μL
Direct bilirubin assay reagent	13.5 μL
Total bile acids assay reagent	13.5 μL
Urea assay reagent	13.5 μL
Total Cholesterol 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 CareSign-C chemistry analyzer Operator’s Manual.

The required sample usage is 100 μ L 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.

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 ($\leq$)					
	Bilirubin mg/dL	Intralipid mg/dL	Hemoglobin mg/dL	Vitamin C mg/dL	Pyruvate mmol/L	NH ₄ Cl mmol/L
TP	25	1050	200	—	—	
ALB	40	600	1000	—	—	
ALT	40	600	50	50	1	
AST	40	600	50	25	1	
GGT	40	1050	200	—	—	
ALP	40	1050	400	—	—	
TBIL	—	1050	1000	75	—	
DBIL	—	1050	200	75	—	
TBA	50	600	500	50	—	
BUN	25	600	1000	—	—	1
CHOL	40	1000	800	40	—	—

【Procedure】

■ Materials Provided

Liver Profile (11+4)

CareSign-C chemistry analyzer

Please tear off the aluminum strip before using Type B.

Transfer pipettes (fixed volume 100 μ L 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 CareSign-C 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 CareSign-C chemistry analyzer. Performance of CareSign-C 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 i-SENS customer service or local distributors for technical support. Do not report the results if controls are outside their labeled limits.

■ Results

CareSign-C chemistry analyzer automatically calculates and prints the analyte concentrations in the sample. Details regarding endpoint and rate reaction calculations can be found in CareSign-C 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	Dog: 52 ~ 82g/L; Cat: 54 ~ 89g/L	Dog: 5.2 ~ 8.2g/dL; Cat: 5.4 ~ 8.9g/dL
ALB	Dog: 22 ~ 44g/L; Cat: 22 ~ 45g/L	Dog: 2.2 ~ 4.4 g/dL; Cat: 2.2 ~ 4.5 g/dL
ALT	Dog: 10 ~ 140U/L; Cat: 8.2 ~ 123U/L	Dog: 10 ~ 140U/L; Cat: 8.2 ~ 123U/L
AST	Dog: 8.9 ~ 55U/L; Cat: 9.2 ~ 60U/L	Dog: 8.9 ~ 55U/L; Cat: 9.2 ~ 60U/L
GGT	Dog: 0 ~ 7U/L; Cat: 0 ~ 2U/L	Dog: 0 ~ 7U/L; Cat: 0 ~ 2U/L
ALP	Dog: 20 ~ 150U/L; Cat: 10 ~ 90U/L	Dog: 20 ~ 150U/L; Cat: 10 ~ 90U/L
TBIL	Dog: 2 ~ 15μmol/L; Cat: 2 ~ 15μmol/L	Dog: 0.1 ~ 0.9mg/dL; Cat: 0.1 ~ 0.9mg/dL
DBIL	Dog: 0 ~ 3.4μmol/L; Cat: 0 ~ 3.4μmol/L	Dog: 0 ~ 0.2mg/dL; Cat: 0 ~ 0.2mg/dL
TBA	Dog: 0 ~ 20μmol/L; Cat: 0 ~ 15μmol/L	Dog: 0 ~ 20μmol/L; Cat: 0 ~ 15μmol/L
BUN	Dog: 2.5 ~ 11.5mmol/L; Cat: 3.6 ~ 15.5mmol/L	Dog: 7 ~ 32mg/dL; Cat: 10 ~ 43mg/dL
CHOL	Dog: 2.84 ~ 8.26mmol/L; Cat: 1.68 ~ 5.81mmol/L	Dog: 110 ~ 320mg/dL; Cat: 65 ~ 225mg/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.

CareSign-C 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 CareSign-C chemistry analyzer.

【Limitations of Procedure】

The Liver Profile (11+4) should be used with CareSign-C 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	$B\% \leq 6.0\%$
ALT	$B\% \leq 15.0\%$
AST	$B\% \leq 15.0\%$
GGT	$B\% \leq 15.0\%$
ALP	$B\% \leq 10.0\%$
TBIL	$B\% \leq 10.0\%$
DBIL	$B\% \leq 10.0\%$
TBA	$B\% \leq 15.0\%$
BUN	$B\% \leq 15.0\%$
CHOL	$B\% \leq 10.0\%$

Batch precision

Analyte	Coefficient of variation ($\leq *$)
TP	2.0%
ALB	2.0%
ALT	5.0%
AST	5.0%
GGT	5.0%
ALP	5.0%
TBIL	5.0%
DBIL	5.0%
TBA	5.0%
BUN	5.0%

CHOL

4.0%

Inter batch precision

Analyte	Relative Range ($\leq$ *)
TP	5.0%
ALB	5.0%
ALT	10.0%
AST	10.0%
GGT	10.0%
ALP	10.0%
TBIL	10.0%
DBIL	10.0%
TBA	10.0%
BUN	10.0%
CHOL	6.0%

Dynamic Ranges

Analyte	Dynamic Ranges
TP	20 ~ 100g/L
ALB	10 ~ 60g/L
ALT	5 ~ 1500U/L
AST	5 ~ 1600U/L
GGT	5 ~ 1500U/L
ALP	5 ~ 2000U/L
TBIL	2 ~ 800 μ mol/L
DBIL	2 ~ 200 μ mol/L
TBA	0 ~ 150 μ mol/L
BUN	0.9 ~ 35.7mmol/L
CHOL	0.5 ~ 14mmol/L

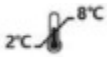
【Notes】

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 CareSign-C 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

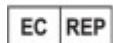
【Manufactured for i-SENS by MNCHIP】



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