SAMSUNG

PT10V Comprehensive Plus 17V

GLU, BUN, CREA, B/C ratio*, PHOS, Ca, TP, ALB, GLOB*, A/G ratio*, ALT, ALP, GGT, TBIL, CHOL, LIPA, AMY

*Calculated Value

(REF IVR-PT13V)

Intended Use

The PT10V Comprehensive Plus 17V (Comp-17), used with the PT10V analyzer, is intended to be used for the *in vitro* quantitative determination of glucose (GLU), blood urea nitrogen (BUN), creatinine (CREA), BUN/CREA (B/C) ratio, inorganic phosphate (PHOS), calcium (Ca), total protein (TP), albumin (ALB), globulin (GLOB), albumin/globulin (A/G) ratio, alanine aminotransferase (ALT), alkaline phosphatase (ALP), gamma-glutamyl transpeptidase(GGT), total bilirubin (TBIL), total cholesterol (CHOL), Lipase (LIPA), amylase (AMY) in the plasma and serum of canine, feline. The globulin (GLOB), albumin/globulin (A/G) ratio, BUN/CREA (B/C) ratio are calculated in this test.

Order Information (IVR-PT13V)

[Provided Product]

- PT10V Comprehensive Plus 17V (IVR-PT13V) cartridges
- Packing unit: 20 cartridges per box (17 analytes per cartridge)

[Materials/Equipment required but not provided]

- PT10V Analyzer
- General lab tools necessary for the test
- Commercialized quality-control materials (Bio-Rad's Liquid Assayed Multiqual® are recommended)

Clinical Significance and Testing Principles

[Glucose (GLU)]

Glucose (GLU) indicates the glucose levels in the blood. The blood glucose level increases due to glucose absorption in the intestine, production as a byproduct in the liver, or synthesis from other substances. The blood glucose level decreases due to the production of glucogen, oxidative hydrolysis in the tissue, or conversion into fat. Also, the glucose metabolism in the body is controlled by the endocrine system and the autonomic nervous system. Therefore, measuring the glucose levels in the blood and urine has clinical signifi ance in the diagnosis and follow-up of diseases.

Glucose + NAD $\xrightarrow{\text{Glucose dehydrogenase}}$ Glucono-lactone + NADH

NADH + Tetrazolium salt $\xrightarrow{\text{Diaphorase}}$ Formazan + NAD

[Blood Urea Nitrogen (BUN)]

Blood Urea Nitrogen (BUN) level indicates the amount of nitrogen present in the blood urea. Physiologically, BUN is synonymous with urea and is a product of the nitrogen metabolism. Increased BUN levels may indicate a renal disease. If renal function is low, then the kidneys do not properly fil er urea from the blood and it accumulates in the body. Therefore, measuring the BUN level has clinical signifi ance in the diagnosis and follow-up of renal diseases.

Urea (BUN) + H_2O $\xrightarrow{\text{Urease}}$ $2NH_3 + CO_2$

pH indicator + NH_3 $\longrightarrow$ Color change

[Creatinine (CREA)]

Creatinine (CREA), a high-energy compound, is a byproduct of creatine phosphate metabolism and is excreted into the blood from the muscular and nervous tissue. Blood creatinine is fil ered through the glomerulus in the kidney and is usually excreted into the urine instead of being reabsorbed into the blood. Increased blood creatinine levels may indicate renal failure, urinary toxicity, or cardiac failure. Therefore, measuring the blood creatinine levels has clinical signifi ance in the diagnosis and follow-up of these diseases as an indicator of renal function.

Creatinine + H_2O $\xrightarrow{\text{Creatinine amidohydrolase}}$ Creatine

Creatine + H_2O $\xrightarrow{\text{Creatine amidinohydrolase}}$ Sarcosine + Urea

Sarcosine + H_2O $\xrightarrow{\text{Sarcosine oxidase}}$ Glycine + Formaldehyde + H_2O_2

Leuco dye + H_2O_2 $\xrightarrow{\text{Peroxidase}}$ Methylene blue

[Inorganic Phosphate (PHOS)]

Phosphorous (PHOS) plays a role in important compounds on phospholipids, nucleic acids, membranes and cytoplasmic components, biochemical energy storage and exchange of biochemical compounds. The causes of hyperphosphatemia come from hyperlipidemia, hyperparathyroidism, etc.

α-Maltose + Phosphate $\xrightarrow{\text{Maltose phosphorylase}}$ α-D-Glucose + β-D-Glucose-1-phosphate

β-D-Glucose-1-phosphate $\xrightarrow{\text{β-Phosphoglucomutase}}$ β-D-Glucose-6-phosphate

β-D-Glucose-6-phosphate + NAD $\xrightarrow{\text{G-6-PDH}}$ D-Gluconolactone-6-phosphate + NADH

NADH + Tetrazolium salt $\xrightarrow{\text{Diaphorase}}$ Formazan + NAD

[Calcium (Ca)]

Calcium (Ca) exists most abundantly in the bones. The remaining small amount of Ca is responsible for cellular interactions in the extracellular uid, blood clotting, nerve transmission, muscle contraction, and hormone delivery. The causes of hypocalcemia result from chronic renal failure, hypomagnesemia, parathyroid dysfunction, vitamin D deficien y, acute pancreatitis while the causes of hypercalcemia stem from parathyroid hyperactivity, malignant tumors, endocrine diseases, etc.

Calcium + Arsenazo III $\xrightarrow{\text{Acid pH}}$ Arsenazo III-calcium complex

[Total Protein (TP)]

Total Protein (TP) is the total amount of proteins present in the blood. Abnormal levels of total protein may indicate problems in the physiological functions of the body or disorders in various tissues and organs. The reagent changes hue from blue to purple to indicate the total protein level.

Total Protein + Cu^{2+} $\xrightarrow{OH^-}$ Cu-Protein complex

[Albumin (ALB)]

Albumin (ALB) is a major protein in serum and plays a signifi ant role in the maintenance of colloidal osmotic pressure and transportation of substances in the body. Albumin is synthesized in the liver, and abnormal albumin levels may indicate a liver parenchymal disorder or abnormal protein metabolism. The color of the reagent changes as the albumin binds to the bromocresol green (BCG) in an acidic condition to indicate the albumin level.

Albumin + Bromocresol green (BCG) $\xrightarrow{\text{Acid pH}}$ BCG-Albumin complex

[Alanine Aminotransferase (ALT/GPT)]

Alanine Aminotransferase (ALT) is an enzyme that transfers the amine group of an alanine into an α-ketoglutaric acid. This enzyme is present in high concentrations in cardiac muscle, liver, brain, etc. Increased levels of ALT in the blood may indicate liver or biliary tract diseases, particularly acute hepatitis, myocardial infarction, etc.

L-Alanine + α-Ketoglutaric acid $\xrightarrow{\text{ALT}}$ L-Glutamate + Pyruvate

Pyruvate + FAD $\xrightarrow{\text{Pyruvate oxidase}}$ Acetylphosphate + $FADH_2$

$FADH_2$ + Tetrazolium salt $\xrightarrow{\text{Diaphorase}}$ FAD + Formazan

[Alkaline Phosphatase (ALP)]

Alkaline Phosphatase (ALP) is an enzyme that hydrolyzes phosphate compounds and is generally known to be present in high concentrations in tissues such as the kidney (proximal tubule), small intestine (mucous membrane), osteoblast, and liver. Since hepatobiliary diseases, bone diseases, pregnancy, malignant tumors, parathyroid glands, and bowel diseases can elevate ALP levels in the blood, ALP measurements are deemed clinically signifi ant in the diagnosis and treatment of such diseases.

p-Nitrophenyl phosphate + H_2O $\xrightarrow{\text{ALP}}$ Phosphate + *p*-Nitrophenol

[Gamma-glutamyl Transpeptidase (GGT)]

Gamma-glutamyl Transpeptidase (GGT) is an enzyme that hydrolyzes Gamma-glutamyl peptide to gamma-glutamyl, and is found throughout body organs including the kidney, pancreas, prostate, and liver. Elevated GGT levels may indicate obstructive jaundice, liver cancer, or alcoholic liver injuries. The kinetic method of using synthetic substrates is widely used to measure elevated GGT levels.

L-γ-glutamyl-3 carboxyl-4-nitroanilide + Glycylglycine $\xrightarrow{\text{GGT}}$ L-γ-glycyl-glycine + 5-amino-2-nitro-benzoicacid

[Total Bilirubin (TBIL)]

Bilirubin (TBIL) is an endogenous waste material produced when the red blood cells are destroyed. Increased levels of total bilirubin may indicate hepatitis, liver cirrhosis, liver cancer, or a biliary obstruction. Therefore, measuring the total bilirubin has clinical signifi ance in the diagnosis and follow-up of these diseases. Bilirubin changes into a yellow product upon reacting with the reagent.

Total Bilirubin (Direct, Indirect) $\xrightarrow{\text{Bilirubin oxidase}}$ Biliverdin + H_2O

[Total Cholesterol (CHOL)]

Blood Cholesterol (CHOL) is mainly synthesized in the liver, and consists of approximately 70% cholesterol esters and 30% free cholesterol. The measurement of cholesterol is meaningful as an indicator of abnormal lipid metabolism, and the ratio of esterifie cholesterol to free cholesterol is regarded as an important indicator of severe parenchymal liver diseases.

Cholesterol ester $\xrightarrow{\text{Cholesterol esterase}}$ Free cholesterol

Cholesterol + NAD $\xrightarrow{\text{Cholesterol dehydrogenase}}$ Cholest-4-en-3-one + NADH

NADH + Tetrazolium salt $\xrightarrow{\text{Diaphorase}}$ Formazan + NAD

[Lipase (LIPA)]

Lipase (LIPA) is an enzyme that hydrolyzes triglycerides into fatty acid and glycerol. The enzyme is transported through the pancreatic duct and into the first part of the small intestine. When cells in the pancreas is damaged as it is in pancreatitis, or when the pancreatic duct is blocked by a gallstone, or in rare case, by a pancreatic tumor, an increased amount of lipase enters the blood and result in a higher concentration in the blood.

Triolein $\xrightarrow{\text{Lipase, Colipase}}$ 2-monoglyceride + Fatty acid

2-monoglyceride $\xrightarrow{\text{Monoglyceride lipase}}$ Glycerol + Fatty acid

Glycerol + NAD $\xrightarrow{\text{Glycerol dehydrogenase}}$ Dihydroxyacetone + NADH

NADH + Tetrazolium salt $\xrightarrow{\text{Diaphorase}}$ Formazan + NAD

[Amylase (AMY)]

Amylase (AMY) is an enzyme that catalyzes the breakdown of starch into sugars and is secreted by the pancreas and salivary gland. Blood AMY level is used as the marker for distinguishing, diagnosing and tracking pancreatic diseases, since elevated amylase concentration in blood is mainly caused by damaged pancreatic cells.

Gal-G2-α-CNP + H_2O $\xrightarrow{\text{Amylase}}$ Gal-G2 + CNP

Test Procedure

[Calibration]

The calibration data for the test can be found using the QR code attached to the cartridge. You do not need to perform a separate calibration for the test.

[Sample Collection and Preparation]

Always use a designated vessel (Lithium heparin) to collect and analyze a specimen. You can use either serum or plasma as a specimen. Perform the test as soon as the specimen is collected. This test requires a specimen volume of 70 ㎕.

[Testing]

1. Before opening, allow the refrigerated cartridge to reach room temperature (15 to 25 °C/59 to 77 °F).
2. Check that the PT10V Analyzer is turned on.
3. Open the product and dispense the sample into the cartridge. Keep the filled cartridge in horizontal position.

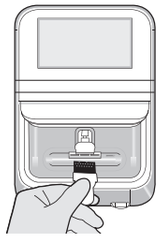
CAUTION:

- Do not touch the cartridge except for its handle with your hands. Contaminants from fingerprints or foreign substances may affect the results.
- Dispense the sample into the center of the sample well. The entire sample well must be fully covered by the sample.

4. Open the door and insert the cartridge containing the sample into the analyzer. Close the door.
5. After pressing the **RUN** button on the analyzer, select the species and sample types to perform the analysis.

   CAUTION: If you cancel the test while it is in progress, the cartridge cannot be reused.

6. After completing the test, the test results will be displayed on the screen and the analyzer will beep.



For more information, refer to the user manual for the PT10V analyzer. We cannot guarantee the validity of any results obtained from unauthorized tests or protocol.

Quality Control

The analyzer includes an embedded e-QC function that automatically performs quality control during the test. The frequency of equipment maintenance for quality control depends on the regulations of each individual lab. The quality control results should be within the specifie range. Each lab must establish a suitable evaluation method in case the results deviate from the specified range. We recommend performing quality control testing upon changes to the cartridge lot, quality control material, or user. After performing maintenance on the equipment, the quality control results must be within the range specified by the manufacturer of the quality control material. If the results deviate from this range, then perform the following procedure to identify the problem:

1. Check the values set for QC materials on the equipment.
2. Check the cleanliness inside the equipment.
3. Inspect for any contamination of the cartridge or sample.
4. Check the expiration date of the cartridge or quality control material.
5. If the problem persists, contact Samsung for technical assistance.

Range of Analysis and Reference Values

Analyte (Unit)	Analysis Range	Reference Range	
		Canine	Feline
GLU (mg/dL)	10 – 1,000	74 – 146	74 – 152
BUN (mg/dL)	5.0 – 200.0	7.0 – 29.0	15.0 – 37.0
CREA (mg/dL)	0.1 – 20.0	0.3 – 1.5	0.7 – 2.1
PHOS (mg/dL)	0.1 – 40.0	2.0 – 6.0	2.6 – 6.4
Ca (mg/dL)	4.0 – 16.0	9.0 – 13.4	8.9 – 12.6
TP (g/dL)	2.0 – 11.0	5.3 – 8.4	5.8 – 9.1
ALB (g/dL)	1.0 – 6.5	2.2 – 3.9	2.2 – 4.1
ALT (U/L)	10 – 1,000	12 – 101	13 – 109
ALP (U/L)	10 – 1,000	18 – 214	9 – 109
GGT (U/L)	5 – 1,500	0 – 7	0 – 2
TBIL (mg/dL)	0.1 – 30.0	0.0 – 1.0	0.0 – 1.0
CHOL (mg/dL)	50 – 450	100 – 330	50 – 230
LIPA (U/L)	20 – 1,000	0 – 155	0 – 32
AMY (U/L)	10 – 2,500	500 – 1,400	500 – 1,400

The lower limit of the analysis range indicates the minimum measurable concentration for the substance.

If you are using the test results for diagnostic purposes, always consider other factors, such as the patient's clinical history, the results of clinical experiments, and other test results, before making a diagnosis.

CAUTION: For optimal analysis, refer to the user manual for the PT10V analyzer and perform the analysis according to the recommended procedure.

Reagent Components in the Cartridge

Analyte	Reagent
GLU	Glucose dehydrogenase
BUN	Urease Bromocresol green
CREA	Creatinine amidohydrolase Creatine amidinohydrolase
PHOS	Maltose
Ca	Arsenazo III
TP	Copper(II) sulfate
ALB	Bromocresol green
ALT	L-Alanine
ALP	AMPD *p*NPP
GGT	Glycylglycine γ-GCN
TBIL	Bilirubin oxidase
CHOL	Cholesterol esterase
LIPA	Triolein
AMY	Gal-G2-α-CNP $CaCl_2$

Performance

[Precision]

We obtained the following results after performing the test for 20 days using the quality control materials according to CLSI EP5-A2.

Analyte	Level	Mean	SD	CV(%)
GLU	Level 1 Level 3	62 mg/dL 382 mg/dL	1.4 7.7	2.3 2.0
BUN	Level 1 Level 3	15.1 mg/dL 69.0 mg/dL	0.4 1.5	2.8 2.2
CREA	Level 1 Level 3	0.7 mg/dL 8.6 mg/dL	0.02 0.20	3.1 2.3
PHOS	Level 1 Level 3	2.2 mg/dL 8.1 mg/dL	0.05 0.21	2.0 2.6
Ca	Level 1 Level 3	6.1 mg/dL 14.0 mg/dL	0.21 0.25	3.5 1.8
TP	Level 1 Level 3	4.2 g/dL 6.4 g/dL	0.19 0.23	4.7 3.5
ALB	Level 1 Level 3	2.3 g/dL 3.2 g/dL	0.05 0.05	2.1 1.7
ALT	Level 1 Level 3	29 U/L 206 U/L	1.1 5.0	3.8 2.4
ALP	Level 1 Level 3	31 U/L 172 U/L	1.6 6.2	5.0 3.6
GGT	Level 1 Level 3	43 U/L 200 U/L	2.6 5.3	4.3 2.1
TBIL	Level 1 Level 3	0.73 mg/dL 6.62 mg/dL	0.04 0.14	4.9 2.2
CHOL	Level 1 Level 3	107 mg/dL 317 mg/dL	3.1 8.4	2.9 2.7
LIPA	Level 1 Level 3	57 U/L 177 U/L	4.8 5.6	8.5 3.2
AMY	Level 1 Level 3	59 U/L 245 U/L	5.3 14.9	6.7 6.1

[Correlation]

We obtained the following results after comparing PT10V with Roche P-modular using patient serum according to CLSI EP9-A2.

Analyte	Species	R	Slope	Intercept	Sample Range
GLU	Canine	0.99	0.94	3.21	18 ~ 912
	Feline	0.99	0.97	-1.94	66 ~ 710
BUN	Canine	1.00	1.00	0.26	6.1 ~ 183.2
	Feline	1.00	1.02	0.56	13.6 ~ 189.3
CREA	Canine	0.99	1.02	-0.02	0.3 ~ 14.1
	Feline	0.99	1.00	0.00	0.6 ~ 18.6
PHOS	Canine	1.00	0.95	-0.06	1.7 ~ 23.6
	Feline	0.99	0.92	0.43	3.8 ~ 13.1
Ca	Canine	0.98	1.00	0.30	7.5 ~ 12.9
	Feline	0.95	1.00	-0.20	5.0 ~ 12.3
TP	Canine	0.98	1.05	-0.24	2.4 ~ 8.1
	Feline	0.95	0.91	0.80	3.0 ~ 9.4
ALB	Canine	0.92	1.07	-0.30	1.1 ~ 3.6
	Feline	0.97	1.00	0.00	1.3 ~ 6.2
ALT	Canine	0.99	0.99	0.24	12 ~ 971
	Feline	0.99	0.93	0.47	10 ~ 926
ALP	Canine	0.98	0.94	2.22	13 ~ 732
	Feline	0.99	0.92	2.72	13 ~ 598
GGT	Canine	1.00	0.97	-2.71	5 ~ 311
	Feline	-	-	-	-
TBIL	Canine	0.96	1.00	0.07	0.00 ~ 1.70
	Feline	1.00	0.90	0.07	0.10 ~ 11.10
CHOL	Canine	0.99	1.02	-7.57	135 ~ 482
	Feline	0.98	1.00	0.17	69 ~ 259
LIPA	Canine	0.99	1.00	-0.04	25 ~ 981
	Feline	0.99	1.00	0.00	14 ~ 880
AMY	Canine	0.99	1.02	-24.10	258 ~ 2,249
	Feline	0.98	1.03	-13.91	434 ~ 2,321

[Interference Substance]

Potential physiological interferents (from hemolysis, icterus, and lipemia) were tested at concentrations based on the testing levels in CLSI EP7-A2.

Analyte	Bilirubin (Icterus)	Triglycerides (Lipemia)	Hemoglobin (Hemolysis)
GLU	40 mg/dL	1,000 mg/dL	500 mg/dL
BUN	40 mg/dL	1,000 mg/dL	500 mg/dL
CREA	5 mg/dL	1,000 mg/dL	500 mg/dL
PHOS	20 mg/dL	1,000 mg/dL	100 mg/dL
Ca	40 mg/dL	1,000 mg/dL	500 mg/dL
TP	10 mg/dL	600 mg/dL	150 mg/dL
ALB	10 mg/dL	1,000 mg/dL	500 mg/dL
ALT	40 mg/dL	1,000 mg/dL	125 mg/dL
ALP	40 mg/dL	1,000 mg/dL	250 mg/dL
GGT	2.5 mg/dL	400 mg/dL	50 mg/dL
TBIL	-	400 mg/dL	100 mg/dL
CHOL	10 mg/dL	1,000 mg/dL	500 mg/dL
LIPA	40 mg/dL	1,000 mg/dL	500 mg/dL
AMY	10 mg/dL	1,000 mg/dL	62.5 mg/dL

The highest tested concentrations may not cause significant interference. No significant interference with the PT10V cartridge was observed for the endogenous materials listed above if kept below the noted limit.

Interference with the results may occur in the following cases:

1. Presence of conjugated/unconjugated bilirubin (Icterus)
2. High hemoglobin concentration (Hemolysis)
3. Turbid specimen (Lipemia)
4. The measurement time can be extended for the CREA interference with high creatine concentration.

Precautions and Warnings

1. For veterinary *in vitro* diagnostic use only.
2. The PT10V cartridge is designed for professional use only.
3. Carefully read the analyzer and reagent manual before using the PT10V cartridge.
4. The results obtained from the PT10V cartridge do not provide a definitive diagnosis and should be interpreted by a veterinarian in conjugation with other appropriate test results and patient clinical finding.
5. Wear disposable gloves while handling specimen.
6. For preparation of specimens, it is recommended to follow the appropriate blood separation protocol.
7. Comply with the general precautions required in all laboratories, and refer to the Material Safety Data Sheet.
8. Samples and used cartridges should be treated as potentially infectious. The used cartridges and other waste should be disposed according to the related regulations and guidelines.
9. Products left at room temperature should be used on the day of opening.
10. Keep the product in a sealed condition until testing. Use opened cartridges immediately.
11. An excessive or insufficient sample volume may result in the contamination or malfunction of the cartridge. You must comply with the recommended sample volume (65–80 ㎕).
12. Do not touch the cartridge except for its handle.
13. Do not reuse the cartridges. Cartridges may only be used once.
14. Do not use whole blood.
15. Close the door when is not using the analyzer.

Storage and Stability

Store the PT10V Comprehensive Plus 17V between 2 and 8 °C (35 to 46 °F).

- The product is usable until the expiration date indicated on the label.
- Do not use expired products. We cannot guarantee the validity of any results obtained from expired products.

For information on Samsung's environmental commitments and product specific regulatory obligations e.g. REACH, WEEE, Batteries, visit: Samsung.com/uk/aboutsamsung/samsungelectronics/corporatecitizenship/data_corner.html

State of California Proposition 65 Warning (US only)

WARNING: This product contains chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.

Warranty

All specifications indicated on the cartridge label of the PT10V Comprehensive Plus 17V are warranted. This product can be exchanged or compensated in accordance with national regulations. If the product is expired or degraded upon purchase, we will exchange it through a vendor.

Symbols Used on the Label

Catalog Number

Batch code

Manufacturer

Do not reuse

Loading Unit/ Avoid loading more than 5 boxes

Keep dry

Contains sufficient for <n> tests

Keep away from sunlight

Fragile, handle with care

Temperature limitation

Consult instructions for use

Use by YYYY-MM-DD or YYYY-MM

Caution, consult accompanying documents

For animal use only

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