SAMSUNG

PT10V Diabetes 4V

GLU, FRUC, CHOL, TRIG

(REF IVR-PT10V)

Intended Use

The PT10V Diabetes 4V, used with the PT10V analyzer, is intended to be used for the *in vitro* quantitative determination of glucose (GLU), fructosamine (FRUC), total cholesterol (CHOL), triglyceride (TRIG) in the plasma and serum of canine and feline.

Order Information (IVR-PT10V)

[Provided Product]

- PT10V Diabetes 4V (IVR-PT10V) cartridges
- Packing unit: 20 cartridges per box (4 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)
  (Roche's precinorm/precipath Fructosamine® 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 significance in the diagnosis and follow-up of diseases.

Glucose + NAD —(Glucose dehydrogenase)→ Glucono-lactone + NADH

NADH + Tetrazolium salt —(Diaphorase)→ Formazan + NAD

[Fructosamine (FRUC)]

Fructosamine is a compound that is formed when glucose combines with protein. This test measures the total amount of fructosamine (glycated protein) in the blood. Serum proteins are present in the blood about 14 to 21 days, so glycated proteins, and the fructosamine test, reflect average glucose levels over a 2 to 3 week time period.

Glycated-albumin —(Protease)→ Fructosamine

Fructosamine + O_2 + H_2O —(FOD)→ Glucosone + Amino acid + H_2O_2

H_2O_2 + DA-67 —(Peroxidase)→ Blue color + 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 esterified cholesterol to free cholesterol is regarded as an important indicator of severe parenchymal liver diseases.

Cholesterol ester —(Cholesterol esterase)→ Free cholesterol

Cholesterol + NAD —(Cholesterol dehydrogenase)→ Cholest-4-en-3-one + NADH

NADH + Tetrazolium salt —(Diaphorase)→ Formazan + NAD

[Triglyceride (TRIG)]

Triglyceride (TRIG) is an ester derived from glycerol and three fatty acids, and is the main constituent of body fat. Measuring triglyceride levels is useful to diagnose lipid metabolic disorders, and especially draws attention to its correlation to arteriosclerosis and coronary risks.

Triglyceride —(Lipoprotein lipase)→ Glycerol + Fatty Acids

Glycerol + ATP —(Glycerol kinase)→ Glycerol-3-phosphate + ADP

Glycerol-3-phosphate + NAD —(Glycerol-3-phosphate dehydrogenase)→ Dihydroxyacetone-3-phosphate + NADH

NADH + Tetrazolium salt —(Diaphorase)→ Formazan + NAD

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]

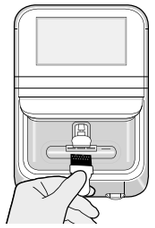
1. Before opening, allow the refrigerated cartridge to reach room temperature (15 to 25 °C/59 to 77 °F).
2. Check that the PT10V Analyzer is turned on.
3. Open the product and dispense the sample into the cartridge. Keep the filled cartridge in horizontal position.

CAUTION:

- Do not touch the casing of the cartridge 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 specified 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
FRUC(μmol/L)	100 ~ 1,000	203 ~ 343	189 ~ 361
CHOL(mg/dL)	50 ~ 450	100 ~ 330	50 ~ 230
TRIG(mg/dL)	10 ~ 600	8 ~ 100	8 ~ 100

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 equipment manual and perform the analysis according to the recommended procedure. We cannot guarantee the validity of any results obtained from unauthorized tests or protocol.

Reagent Components in the Cartridge

Analyte	Reagent
GLU	Glucose dehydrogenase
FRUC	Ketoamine oxidase
CHOL	Cholesterol esterase
TRIG	Lipoprotein lipase

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	62 mg/dL	1.4	2.3
	Level 3	382 mg/dL	7.7	2.0
FRUC	Level 1	312 μmol/L	7.0	2.2
	Level 2	537 μmol/L	11.8	2.2
CHOL	Level 1	107 mg/dL	3.1	2.9
	Level 3	317 mg/dL	8.4	2.7
TRIG	Level 1	81 mg/dL	2.5	3.1
	Level 3	301 mg/dL	7.1	2.3

[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
FRUC	canine	0.99	0.98	8.22	126 ~ 1000
	feline	0.99	0.96	7.49	167 ~ 1060
CHOL	canine	0.99	1.02	-7.57	135 ~ 482
	feline	0.98	1.00	0.17	69 ~ 259
TRIG	canine	0.99	1.00	-11.00	26 ~ 240
	feline	0.96	0.92	8.11	33 ~ 394

[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
FRUC	10 mg/dL	200 mg/dL	125 mg/dL
CHOL	10 mg/dL	1,000 mg/dL	500 mg/dL
TRIG	5 mg/dL	-	100 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)

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 findings.

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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 Diabetes 4V 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 Diabetes 4V 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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