SAMSUNG

# PT10V Bovine 5V

AST, Ca, CK, Mg, PHOS

(REF IVR-PT14V)

## Intended Use

The PT10V Bovine 5V (Bovine-5), used with the PT10V analyzer, is intended to be used for the *in vitro* quantitative determination of aspartate aminotransferase(AST), calcium(Ca), creatine kinase(CK), magnesium(Mg), inorganic phosphate(PHOS) in the plasma and serum of bovine.

## Order Information(IVR-PT14V)

### [Provided Product]

- PT10V Bovine 5V (IVR-PT14V)
- Packing unit : 20 cartridges per box (5 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

### [Aspartate Aminotransferase (AST/GOT)]

Aspartate Aminotransferase (AST) is an enzyme that catalyzes the transfer of an amino group between an amino acid and an α-keto acid. This enzyme is highly present in cardiac muscles, liver, brain, and other tissues. Increased levels of AST in the blood may indicate liver or biliary tract diseases, myocardial infarctions, or acute hepatitis.

L-Aspartate + α-Ketoglutaric acid —AST→ L-Glutamate + Oxaloacetate

Oxaloacetate —Oxaloacetate decarboxylase→ Pyruvate + $CO_2$

Pyruvate + Pi + FAD —Pyruvate oxidase→ Acetylphosphate + $FADH_2$

$FADH_2$ + Tetrazolium salt —Diaphorase→ Formazan + FAD

### [Calcium (Ca)]

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

Calcium + Arsenazo III —Acid pH→ Arsenazo III-calcium complex

### [Creatine Kinase (CK)]

Creatine Kinase (CK) is utilized as a marker of damage to various muscles. Elevation of Creatine kinase is therefore indicative of injury, severe muscle breakdown, myocardial infarction, myositis and myocarditis.

Creatine phosphate + ADP —Creatine Kinase→ Creatine + ATP

Glucose + ATP —Hexokinase→ Glucose-6-phosphate + ADP

Glucose-6-phosphate + Thio-NAD —G-6-PDH→ Thio-NADH + Gluconolactone-6-phosphate

### [Magnesium(Mg)]

Magnesium (Mg) is an element with high contents of minerals which are essential factors of enzymatic activities directly related to all major metabolic paths. It is a crucial element for normal neurotransmission, muscle function, and bone formation.

Glucose + ATP —Hexokinase, Mg→ Glucose-6-phosphate + ADP

Glucose-6-phosphate + Thio-NADP —G-6-PDH→ Thio-NADPH + Gluconolactone-6-phosphate

### [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 —Maltose phosphorylase→ α-D-Glucose + β-D-Glucose-1-phosphate

β-D-Glucose-1-phosphate —β-Phosphoglucomutase→ β-D-Glucose-6-phosphate

β-D-Glucose-6-phosphate + NAD —G-6-PDH→ D-Gluconolactone-6-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.

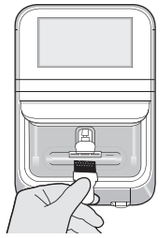
   **CAUTION:**

   - 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 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 |
|---|---|---|
| | | Bovine |
| AST (U/L) | 10 ~ 1,300 | 0 ~ 103 |
| Ca (mg/dL) | 4.0 ~ 16.0 | 9.3 ~ 13.0 |
| CK (U/L) | 35 ~ 15,000 | 25 ~ 418 |
| Mg (mg/dL) | 0.5 ~ 8.0 | 1.3 ~ 3.0 |
| PHOS (mg/dL) | 0.1 ~ 40.0 | 3.7 ~ 8.3 |

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 |
|---|---|
| AST | Sodium L(+)-aspartate |
| Ca | Arsenazo III |
| CK | ADP K |
| Mg | Thio-NADP |
| PHOS | Maltose |

## 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(%) |
|---|---|---|---|---|
| AST | Level 1<br>Level 3 | 33 U/L<br>142 U/L | 0.9<br>4.2 | 2.8<br>3.0 |
| Ca | Level 1<br>Level 3 | 6.1 mg/dL<br>14.0 mg/dL | 0.21<br>0.25 | 3.5<br>1.8 |
| CK | Level 1<br>Level 3 | 119 U/L<br>682 U/L | 6.16<br>29.34 | 5.2<br>4.3 |
| Mg | Level 1<br>Level 3 | 1.1 mg/dL<br>4.7 mg/dL | 0.08<br>0.22 | 7.1<br>4.7 |
| PHOS | Level 1<br>Level 3 | 2.2 mg/dL<br>8.1 mg/dL | 0.05<br>0.21 | 2.0<br>2.6 |

## [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 |
|---|---|---|---|---|---|
| AST | Bovine | 0.95 | 0.99 | -2.46 | 26 ~ 280 |
| Ca | Bovine | 0.98 | 1.00 | 0.00 | 4.5 ~ 16.2 |
| CK | Bovine | 1.00 | 1.01 | -9.16 | 43 ~ 13,694 |
| Mg | Bovine | 0.96 | 1.01 | -0.05 | 0.8 ~ 7.4 |
| PHOS | Bovine | 0.96 | 1.01 | -0.04 | 2.9 ~ 10.8 |

## [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) |
|---|---|---|---|
| AST | 10 mg/dL | 1,000 mg/dL | 50 mg/dL |
| Ca | 40 mg/dL | 1,000 mg/dL | 500 mg/dL |
| CK | 10 mg/dL | 200 mg/dL | 400 mg/dL |
| Mg | 20 mg/dL | 1,000 mg/dL | 100 mg/dL |
| PHOS | 20 mg/dL | 1,000 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 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 Bovine 5V 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.

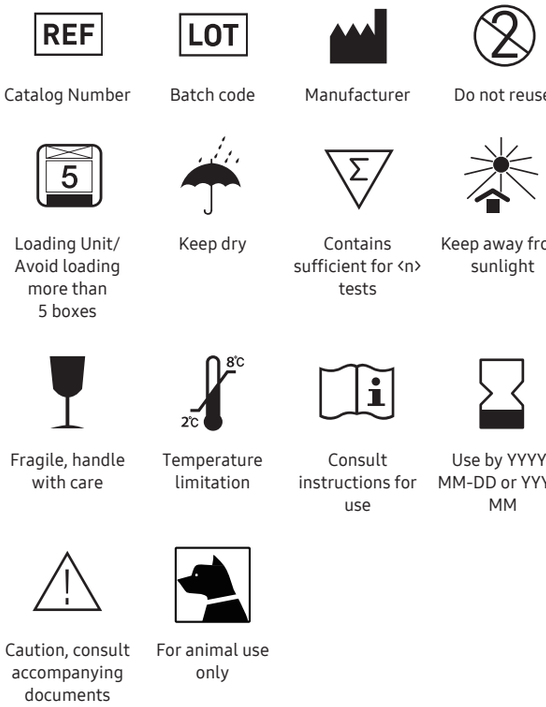
## Warranty

All specifications indicated on the cartridge label of the PT10V Bovine 5V 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




**SAMSUNG ELECTRONICS CO., LTD.**
129, Samsung-ro, Yeongtong-gu, Suwon-si, Gyeonggi-do, Korea
Service E-mail: ivd.support@samsung.com