Rapid Bovine Pregnancy Test Kit

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For Veterinary Use Only

READ ALL INSTRUCTIONS BEFORE BEGINNING THE TEST

RIDX™ Bovine Pregnancy Test Kit
[Catalogue Number: LGM-BPG-11]

Introduction

Pregnancy diagnosis is an important part in reproduction management of ruminants. In the 1970s, many studies related to cattle pregnancy were conducted, and various substances were discovered and identified[1, 2, 3]. A polymorphic family of placenta-expressed proteins has been discovered in ruminant species and used for pregnancy diagnosis in the last years.
Among them, the pregnancy-associated glycoproteins (PAG) are synthesized in the mono- and bi-nucleate cells of the ruminant's trophectoderm and is secreted from the conceptus between days 20 and 28 as the extra embryonic trophoblastic cell layer relocates to the endometrium, enabling successful implantation and continuation of pregnancy in ruminants[4, 5].
The PAG is widely recognized as one of the most efficient markers for detecting pregnancy in cattle[6, 7].

Principle

The RIDX™ Bovine Pregnancy Test Kit is a lateral flow chromatographic immunoassay that detects early PAG contained in bovine whole blood, serum, and plasma.
If PAG is present in the sample, it binds to the PAG-specific antibody-nanoparticle conjugate. A red line appears at the location of the test line due to binding to the PAG-specific antibody that moves through the membrane by capillary action and is dispensed on the membrane. If PAG is not present in the sample, no reaction occurs on the test line and a red line appears only on the control line.
The highly selective and sensitive two monoclonal antibodies to PAG are used as capture and detector in the kit. This kit detects PAG quickly and simply within 20 minutes after applying the sample. The RIDX™ Bovine Pregnancy Test Kit is a diagnostic reagent for pregnancy of cattle with high accuracy.

Performance

1. Sensitivity & Specificity
[Enzyme-Linked Immunosorbent Assay]

		ELISA		
		+	-	Total
RIDX™ Bovine Pregnancy Test	+	354	6	360
	-	3	195	198
	Total	357	201	558

Sensitivity: 99.16% (354/357, *95% CI: 97.56% ~ 99.71%)
Specificity: 97.01% (195/201, 95% CI: 93.64% ~ 98.62%)
Diagnostic Agreement: 98.39% (549/558, 95% CI: 96.96% ~ 99.15%)

* 95% CI: 95% Confidence Interval

2. Limit of Detection: 0.3 ng/mL of PAG

3. No cross-reactivity with Progesterone and Early Conception Factor (also known as Early Pregnancy Factor) of cattle.

Kit Components

	Component	Quantity/kit
1	PAG test strip	25
2	Sample dilution buffer	1
3	Disposable dropper	25
4	Test tube	25
5	Paper rack for standing test tubes	1
6	Instructions for use	1

Storage & Stability

1. Store the test kit at 2~30℃ (35.6~86.0℉). **Do not freeze.**
2. Do not store the test kit in direct sunlight.
3. The test kit is stable within the expiration date marked on the package label.

Sample Preparation

Precaution: Whole blood, serum, or plasma from cattle **28 days** after artificial insemination or mating should be used as specimens.

[Whole blood]

1. Whole blood collected with a sterilized syringe is treated with an anticoagulant (EDTA, heparin, or citrate) and used as a sample. Syringe and anticoagulants are not provided in this kit.
2. For the best result, the anticoagulated whole blood specimens should be used instantly after collection. If you cannot use the specimens immediately, store them refrigerated (4~8℃/39.2~46.4℉) for up to 5 days. Do not freeze the anticoagulated whole blood samples. If you cannot use the samples within 24 hours, store them in a form of serum or plasma.

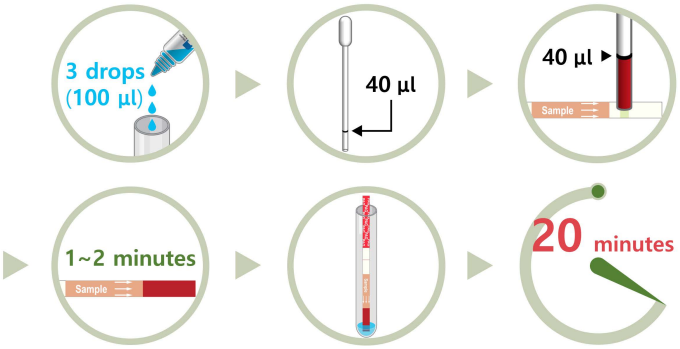
[Serum or plasma]

1. Prepare serum and plasma using a standard procedure of clinical laboratory.
2. Serum or plasma, either fresh or stored at 4~8°C (39.2~46.4°F) for up to 72 hours, can be used. For longer storage, freeze below −20°C (−4°F) or below. But, results from samples frozen for over one month may differ from those obtained before freezing.

Test Procedure

[Whole blood]

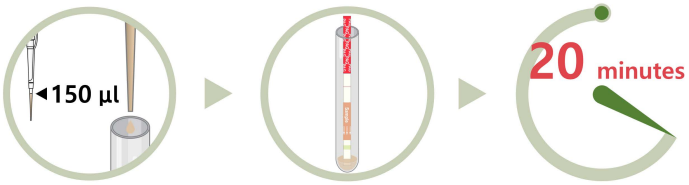
1. All samples and test components should be at room temperature (15~30°C/59~86℉) before use.
2. Transfer 3 drops (approximately 100 µL) of the sample dilution buffer to a test tube.
3. Take 40 µL of the anticoagulated whole blood using a disposable dropper unto the black line on the dropper and instill it onto the green line of the sample pad on the PAG strip. When instilling anticoagulated whole blood onto the sample pad of the strip, be sure to use the provided disposable dropper.
4. After all the whole blood has been absorbed into the sample pad (approximately 1~2 minutes), place the PAG strip into the test tube containing the sample dilution buffer.
5. Read test results at 20 minutes. **Do not read results after 20 minutes.**



[Summary of Test Procedure 1. Whole blood]

[Serum or plasma]

1. All samples and test components should be at room temperature (15~30°C/59~86°F) before use.
2. Using a micropipette, transfer 150 µL of serum or plasma into a test tube.
3. Place the PAG strip into the test tube containing the serum or plasma sample.
4. Read test results at 20 minutes. **Do not read results after 20 minutes.**



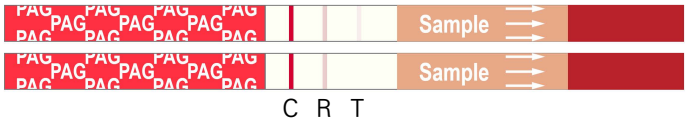
[Summary of Test Procedure 2. Serum or plasma]

Interpretation of Results

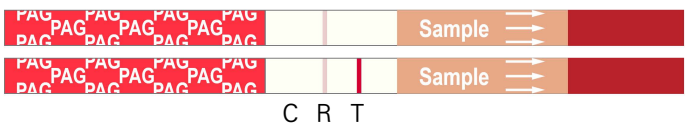
1. Positive result: Pregnant (Band intensity: R < T)
A red line appears on the control line (C) and if the color of the test line (T) is stronger than the color of the reference line (R), this indicates pregnancy.

2. Suspected pregnant (Band intensity: R ≒ T)
A red line appears on the control line (C) and if the color of the test line (T) and the reference line (R) are similar, pregnancy is suspected and a retest is recommended after 7 days.

3. Negative result: Non-pregnant (Band intensity: R > T)
A red line appears on the control line (C) and if the color of the test line (T) is lighter than the color of the reference line (R) or if no line appears on the test line (T), these indicate no pregnancy.



4. Invalid results
If the control (C) line does not appear, the results might be considered invalid. The sample should be retested.



Precautions

1. This test kit is for veterinary *in vitro* diagnostic use only for cattle. Do not use this test kit for other animals.
2. The test device is sensitive to humidity and heat. Use the test device within 10 minutes after removing the foil pouch.
3. Do not touch the membrane of the test device.
4. The device should not be used if the foil pouch is damaged or opened.
5. Do not use an expired test kit. The expiration date is marked on the package label.
6. Do not reuse the test components (strip, dropper, and test tube).
7. Do not mix components from different lot numbers because the components in this kit have been quality control tested as a standard batch unit.
8. Decontaminate and dispose of all samples, used kits, and potentially contaminated materials following national and local regulations.

References

1. Roberts GP *et al.*, Macromolecular components of the luminal fluid from the bovine uterus. *J. Reprod. Fertil.* 1974; 40: 291–303.
2. Laster DB. A pregnancy-specific protein in the bovine uterus. *Biol. Reprod.* 1977; 16: 682–690.
3. Butler JE *et al.*, Detection and Partial Characterization of Two Bovine Pregnancy-Specific Proteins. *Biol. Reprod.* 1982; 26: 925–933.
4. Atkinson YH *et al.*, Characterization of placentation-specific binucleate cell glycoproteins possessing a novel carbohydrate. *J. Biol. Chem.* 1993; 265(35): 26679–26685.
5. Bazer FW *et al.*, Physiological mechanisms of pregnancy recognition in ruminants. *J. Reprod. Fertil.* 1991; Suppl 43: 39–47.
6. Green JA *et al.*, The establishment of an ELISA for the detection of pregnancy-associated glycoproteins (PAGs) in the serum of pregnant cows and heifers. *Theriogenol.* 2005; 63: 1481–1503.
7. Balhara AK *et al.*, Early Pregnancy Diagnosis in Bovines: Current Status and Future Directions. *Sci. World. J.* 2013; 2013: 958540.

Symbol Descriptions

LIC	License number
CAT	Catalogue number
LOT	Batch code, Lot number
	Consult instructions for use
Σn	Contains sufficient for ⟨n⟩ tests
	Do not reuse
IVD	*In vitro* diagnostic medical device
	Temperature limitation
	Do not use, if the package is damaged
	Upper side
	Manufacturer

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