

Please read this Package Insert carefully before use

Canine α -fetoprotein measurement Kit

Canine AFP

This product is a Latex Agglutination Immuno-assay reagent kit for measuring α -fetoprotein (AFP) in canine serum or plasma for research purposes.

This kit allows automated processing of multiple specimens by using automated analyzers.

[GENERAL PRECAUTIONS]

1. This is a reagent kit developed to measure canine specimen. Do not use for any other purposes.
2. Clinical diagnosis using measurement by this kit should be made by qualified veterinarians by comprehensively reviewing the clinical symptoms and other test results.
3. Follow the TEST PROCEDURE described in this Package Insert for its usage. If the Kit is used not following the TEST PROCEDURE herein, the reliability of results may be compromised.
4. For the handling of equipment to be used for the test read carefully manual and package insert that come with such equipment and follow instructions therein.

[KIT COMPONENTS]

1. Buffer (R1)
2. Latex Reagent (R2)
Latex particles sensitized with anti-human α -fetoprotein antibodies

[INTENDED USE]

Measurement of α -fetoprotein (AFP) in canine serum or plasma.

[TEST PRINCIPLE]

1. Test Principle

Latex particles sensitized with anti-human α -fetoprotein antibodies and AFP in the sample react immunologically, and cause the latex particles to agglutinate. The level of agglutination correlates with the AFP concentration. The absorbance of agglutination is measured to determine the concentration of AFP in the sample.

2.Features

- (1) This kit is based on the latex agglutination immuno-assay method that enables rapid assay.
- (2) Applicable to automated analyzers for processing multiple specimens
- (3) Preparation of reagents is not necessary.

- (4) Pre-treatment of specimen (dilution of the specimen) is not necessary

[PRECAUTIONS ON HANDLING]

1. Specimen handling

- (1) Use canine serum or plasma as specimen.
- (2) Centrifuge specimen before use, if there is insoluble matter or is turbid.
- (3) Specimens should be frozen at -35 degrees centigrade or under for long-term storage. Avoid multiple freezing and thawing.

2. Interfering substances

Perform dilution test for the specimen with questionable result, and confirm its dilution linearity.

Interfering matter may exist in specimens for which linearity has not been confirmed.

[TEST PROCEDURE]

1. Preparation of reagents

Buffer (R1) and Latex Reagent (R2) can be used without any preparation.

2. Assay procedure

Standard method example for HITACHI 7170

Sample 10 μ L		WL 700nm	WL 700nm
R1 200 μ L	R2 100 μ L	Absorbance	Absorbance
↓	↓	↑	↑
0	5		10

Reaction temperature : 37degrees centigrade Reaction time : min.

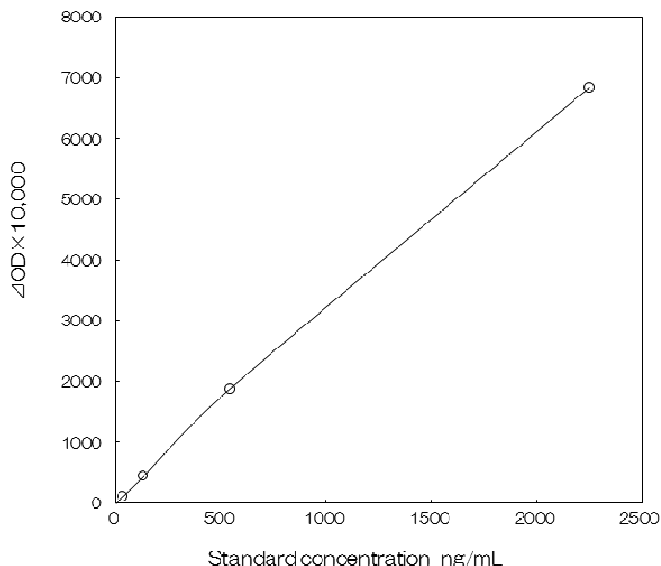
3. Calibration curve

Follow the measurement procedure described above to create multi-point calibration curve by using AFP Calibrators, sold separately, as specimen.

[ASSAY RANGE AND VALIDATION]

1. Sensitivity

Example of Standard Curve by HITACHI 7170.



2. Accuracy

When a specimen of known concentration is measured, the value should be within $\pm 15\%$ of that concentration.

3. Reproducibility

When a sample is measured 5 times in single run, the CV of the change in absorbance should be not more than 10%.

4. Assay range

Measurable range of this kit is 20 - 2500 ng/mL.

[WARNINGS]

1. Warnings for handling (hazard control)

- (1) Handle all specimens carefully as potentially infectious with infectious microbes.
- (2) Reagents in this kit contain 0.09 (W/V) % Sodium Azide as preservative. If direct contact of Reagents occurs with eye, mouth or skin, flush with abundant water and seek medical treatment, if necessary.

2. Warnings for operation

- (1) Do not use reagents beyond the expiration date.
- (2) Use reagents soon after opening. To store reagents, close the cap and keep them at 2-10 degrees centigrade.
Do not freeze the reagents.
- (3) Do not use bottles and components in this kit for any other purposes.
- (4) Buffer and Latex Reagent should be gently shaken by inverting the bottle a few times and be placed in the specified position. Remove all bubbles from reagents before use.
- (5) Do not combine reagents in this kit with those of different lot numbers. Do not add, fill or mix a reagent in this kit with the same reagent even of the same lot number.
- (6) Calibration curve should be measured in every test.
Each calibration sample should be tested twice or more.
- (7) When the measurement value exceeds the measurable range, dilute the sample with saline and measure the diluted specimen. Measurements are compensated by the dilution

factor for the correct values.

- (8) Use calibration specimens, sold separately.

Refer to the use instructions included therein for usage.

- (9) Please inquire for the measurement parameters to the address below.

3. Warnings for disposal

- (1) Reagents in this kit contain 0.09 (W/V) % Sodium Azide as preservative. For disposal drain off the reagents with abundant water so as to prevent reacting with lead or copper pipes and formation of explosive metal azide.
- (2) Dispose all used specimens, reagent bottles and accessories by sterilization, disinfection (with 0.5% sodium hypochlorite solution), or incineration. Specimens may contain infectious microbes.
- (3) Follow all local laws and regulations for waste disposal and water pollution control, when dispose reagents or equipment.

[STRAGE • EXPIRY]

1. Store at : 2-10 degrees centigrade (Do not freeze)
2. Expiry : 12 months after manufacturing
Expiry date is printed on the package.

[PACKAGING UNIT]

Product Name	Package
Canine AFP	Buffer (R1) 50 mL x 1 Latex Reagent (R2) 25 mL x 1

[SOLD SEPARATELY]

Product Name	Package
AFP Calibrators (for Canine AFP)	Calibrators 6 Conc. x 2 mL x 1 each
Canine AFP Controls (for Canine AFP)	Controls 2 Conc. x 2 mL x 1 each

[INQUIRIES]

SHIMA Laboratories Co., Ltd.

Department for Animal Testing Reagent

3-36-3 Maeno-cho, Itabashi-ku, Tokyo 174-0063 Japan

TEL: +81-3-3967-7277 FAX : +81-3-3967-3241

<http://www.shimalab.co.jp/>



Manufactured by

SHIMA Laboratories Co., Ltd.

3-36-3 Maeno-cho, Itabashi-ku, Tokyo 174-0063 Japan

TEL: +81-3-3967-7277 FAX : +81-3-3967-3241