Healvet®

Equine Progesterone (eProg) Rapid Quantitative Test

INTENDED USE

The Healvet™ Equine Progesterone (eProg) Rapid Quantitative Test is a fluorescence immunoassay used with the Healvet™ FIA series for the quantitative determination of progesterone concentration in equine serum or plasma specimen。 The test is used as an aid to track ovulation, determine the best time for breeding or detect early pregnancy failure.

For *in vitro* diagnostic use only. For veterinary use only.

TEST PRINCIPLE

This test employs a quantitative competitive fluorescence immunoassay technique. A competitive binding assay is based upon the competition of labelled and unlabelled analytes for a limited number of antibody binding sites. Unbound antibodies and immunocomplexes migrate along the nitrocellulose membrane towards the Test line. The unbound antibodies are then captured by antigens immobilised on the test line. The more progesterone in the patient sample, the more immunocomplexes are formed, thus the less fluorescent-labelled antibodies captured on the test line. The fluorescent signal intensity reflects the amount of eProg captured and is processed in Healvet™ FIA series The eProg concentration is expressed in ng/mL or nmol/L.

WARNINGS AND PRECAUTIONS

1.This kit is for in vitro diagnostic use only. Do not swallow.

2.The Lot No. of all the test components (test device, ID chip and buffer) must match each other. Do not mix components from different kit lots.

3.Inspect the packaging and labels before use. Do not use if the pouch is broken, torn, unsealed or the cartridge/buffer is damaged.

4.Carefully follow the instructions and procedures described in this insert.

5.Do not use the test device beyond the expiration date. The test device must remain in its original sealed pouch until ready to use. Do not use if the pouch or the device itself is damaged, torn or unsealed.

6.A buffer tube should be used for processing one sample only.

7.The operation shall be conducted away from vibration and magnetic field. Healvet™ FIA series may generate minute vibration during use, which should be regarded as normal.

8.One pipette tip should be used for one specimen only.

9.Do not touch the test area of the test device.

10.All specimens and used test materials are considered as potentially infectious. The used pipette tips, buffer tubes, test devices and specimens must be handled carefully and disposed of in accordance with local regulations and procedures.

11. Recommend the use of serum or plasma. Maybe there are some interfering substances in whole blood, which may affect the accuracy of test results.

12. Please do not use the serum separator tube for testing，which may affect the accuracy of test results.

MATERIAL

Material Provided

Each box contains:

1.10 individual sealed pouches, each containing:

- a test device
- a desiccant pouch

2.One test device ID chip

3.Instructions for use

4.10 tubes of Tris-HCl buffer

5. 10 pipette tips

Material Required But Not Provided

1.Healvet™ FIA series

2.Transfer pipette

3.Timer

4.Centrifuge

STORAGE AND STABILITY

1.Store the test kit at 4℃～30℃ up to the expiration date.

2.Once the pouch is opened, the test should be performed within an hour.

3.If removed from refrigerator, allow the test for 30 minutes to attain room temperature before testing.

SPECIMEN COLLECTION AND PREPARATION

The test can be performed with either equine serum or plasma. It should be obtained and handled by standard methods for the sample collection.

Serum collection: use blood collection tubes without anticoagulants, and separate serum as soon as possible after blood collection to avoid hemolysis. The separated serum should be tested as soon as possible. If it cannot be used in time, it should be stored at 2℃～8℃ and should not exceed 48 hours.

Plasma collection: EDTA anticoagulant blood collection tubes should be used to separate plasma as soon as possible after blood collection. Samples should be used as soon as possible after collection. If the blood cannot be tested within 2 hours after blood collection, it should be

stored at 2℃～8℃ and should not exceed 48 hours.
If the sample has severe hemolysis, severe jaundice or high lipid content, it should not be used, as it will affect the accuracy of the results.
The serum or plasma sample must be tested as soon as they are prepared.
Bring all materials to room temperature before use. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly. Only clear, non-hemolyzed specimens can be used.

TEST PROCEDURE

Refer to Healvet™ FIA series Operation Manual for complete instructions for use of the test device.
1.Set a Test Device on a clean, level horizontal place.
2.Make sure that the Test Device lot No. matches with ID chip No. Insert ID chip into the meter. Be aware not to touch the insertion tip of the ID chip.
3.Pipette 75μL of prepared sample into the buffer, gently mix well. Vigorous agitation and foaming should be avoided.
4.Pipette 75μL of mixed sample to add into the sample of the test device. Avoid forming bubbles.
5.Please refer to the Section V Operation in Operation Manual for details.
a) Quick Test mode: start the timer right after adding the sample mixture to the sample well. Leave the Test Device at room temperature for 15 minutes. Then insert test device immediately onto the holder of the meter and click Test. The instrument will scan the Test Device automatically and show the test result.
b) Standard Test mode: insert the Test Device into the device holder of the meter right after adding the sample to the sample well, click Test. The meter will start to countdown and read the test result automatically.
6.Results are displayed on the main screen or be printed by click Print.

INTERPRETATION OF RESULTS

1.The Healvet™ FIA series calculates progesterone test results automatically and displays the concentration of progesterone on the screen right after correctly adding the sample to the sample well for 15 minutes. For further information, refer to the Operation Manual for the Healvet™ FIA series.
2.Healvet™ FIA series will prompt "Abnormal C-line/This test is invalid!" when insufficient sample volume or liquid is not fully crawled across the test line, retest with a new reagent is suggested.

QUALITY CONTROL

Each Healvet™ eProg Rapid Quantitative Test contains an internal control for routine quality control requirements. This internal quality control is performed each time a patient sample is tested. If an invalid result from the internal control occurs, the analyser will display an error message, indicating that another new test should be conducted.

LIMITATIONS OF PROCEDURE

1.This test is developed for testing equine serum or plasma only.
2.The results of Healvet™ eProg Rapid Quantitative Test should be evaluated with all clinical and laboratory data available. If test results do not agree with the clinical evaluation, additional tests should be performed accordingly.
3.The false positive results include cross-reactions with some components of blood from individual to antibodies; and non-specific adhesion of some components in Equine blood that have similar epitopes to capture and detector antibodies. In the case of false negative results, the most common factors are: non-responsiveness of antigen to the antibodies by that certain unknown components are masking its epitope, such that antigen cannot be seen by the antibodies; instability of progesterone antigen, resulting in degradation with time and, or temperature, such that they become no longer recognizable by antibodies; and degraded other test components. The performance of the test is highly sensitive to the storage and handling conditions of kits and sample specimens at optimal conditions.
4.There is the possibility that factors such as technical or procedural errors, as well as additional substances in blood specimens that are not listed in the Cross-Reactivity section, may interfere the test and cause erroneous results.

INTERPRETATION

Reference range of eProg in Equine blood:
1.Detection Range: 1-20 ng/mL / 3.18-63.6 nmol/L
2.Reference Range:

Reference	ng/mL	nmol/L
Low	≤2	≤6.36
High (Gestation)	>2	>6.36

*1ng/mL=3.18nmol/L
Each Laboratory should establish a reference range that is representative of the population to be evaluated.

MANUFACTURED BY

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