LifeAssays® Feline Haptoglobin Test Kit

Intended Use
LifeAssays® Feline Haptoglobin Test Kit is an in vitro veterinary diagnostic system for quantitative determination of haptoglobin in cat serum. It is intended to be used as an aid in the diagnosis, progression and treatment of various conditions associated with inflammation. For professional use only.

Content Information
- **Reagent Vial** (Art.No. 40101-16/10/11) ........................................... 5/10/20 pcs
- **Dilution vials** (Art.No. 40301-22) .................................................. 5/10/20 pcs
- **Glass Capillaries** (5μL, Art.No. 40301-03) ........................................ 25 pcs
- **Algorithm Chip** (50501-09) ....................................................... 1 pcs
- **Instructions for Use Leaflet** (E-25-0016) ......................................... 1 pcs
- **Liquid Control** (50μL, Art.No. 40201-09) ....................................... 1 pcs

Material Required but Not Supplied with Kit
- LifeAssays® VetReader (Art.No. 50101-04)
- Vortex, e.g. LifeAssays® vortex (Art.No. 50201-04)
- Capillary Holder (Art.No. 40301-04)
- Fixed –volume 25μL pipette (Art.No.40301-21)

Stability and Storage
Store test kit and all components at 2–8°C. Do not freeze.

Test Principle
LifeAssays® Feline Haptoglobin Test is a two-site heterogenous immunoassay. When the sample is placed into the reagent vial and the contents are mixed, polyclonal antibody coated silica microparticles, used as the solid phase in the assay, capture the haptoglobin present in the sample. Polyclonal antibody coated magnetic nanoparticles detect the haptoglobin bound to the silica surfaces in a sandwich- binding format. The reagent vial is then loaded into the LifeAssays® VetReader and the instrument waits eleven minutes before measuring the test result. During these eleven minutes the silica microparticles sediment to the bottom of the reagent vial forming a solid phase pellet. The magnetic property of the solid phase pellet is measured quantitatively with the LifeAssays® VetReader by detecting the induction change of the internal coil.

Each LifeAssays® Feline Haptoglobin Test Kit is delivered with one disposable algorithm chip. The chip contains all reagent data and a self-executable algorithm which will calculate the haptoglobin test result in mg/dL for the number of purchased tests. When the chip calculates a haptoglobin result, it transfers the result back to the LifeAssays® VetReader for display.

Warnings and Precautions
- For in vitro veterinary diagnostic use only.
- Do not mix components from different kit containers.
- Do not use test kits after the expiry date.
- Do not use damaged or contaminated kits.
- Bring all test kit components to room temperature (18-25 °C) before use.
- The reagents contain sodium azide in concentrations <0.1% as a preservative. Sodium azide is a toxic agent. Avoid contact with skin and eyes. Flush abundantly with water upon disposal or if direct contact occurs.
- Wear disposable gloves while handling samples, kit reagents and wash hands thoroughly afterwards.
- Disposal of all specimen and test material should be in accordance with state and local law.

Specimen Collection and Preparation
LifeAssays® Feline Haptoglobin test can only be performed with serum samples. A normal venous blood sample should be taken and the serum separated appropriately. If not immediately tested, the serum can be stored at 2-8 °C for up to two days or at -20 °C for one month.

Note: Repeated freezing and thawing of samples should be avoided. All samples must reach room temperature (18-25 °C) before testing. Frozen samples must be thawed completely, mixed thoroughly and brought to room temperature before testing is carried out.

Interferences
Free hemoglobin present in the serum will interfere with test results. The presence of free hemoglobin in serum can, however, easily be identified by the presence of a pink or red color in the serum sample. Careful note should thus be made of samples containing free hemoglobin, indicating abnormality and basis for further investigation.

Assay Procedure

1. **Turn on Instrument**
   Insert the disposable algorithm chip provided with the LifeAssays® Feline Haptoglobin Test Kit and turn on the LifeAssays® VetReader. The instrument performs a reagent chip control and displays, “wait 113” (with a numerical countdown from 113). The instrument will stabilize for about 10 minutes and display during this time, “Stab 1”.

2. **Start-up**
   Remove a reagent vial from storage and allow it to reach room temperature. It is recommended to remove the reagent vial at least 15 minutes before a measurement is performed. Reagent vials with reagent caught in the cap due to transport handling should be shaken (remove reagent from cap) and allowed to sediment for 15 minutes prior to use. Never open a reagent vial that has reagent caught in the cap. This could lead to loss of reagent and erroneous results.
   Follow the instructions given on the display of the VetReader. Once stabilization is complete, the instrument is ready for use and will display, “Fe-Hapt X/XX Tests” To start a measurement press and hold the enter button. The instrument will display, “wait” (3-second pause) followed by “Insert vial”. Load a reagent vial into the VetReader. The instrument will display, “wait 5” and count down 5 seconds before displaying “Collect + Add Sample”.

3. **Dilute Sample**
   Dispense 25 μL sample (serum) into the dilution vial. Mix by end- end agitation or by using the Vortex mixer for a few seconds. The sample is now diluted and ready for addition to the reagent vial, see 4. below.

4. **Add Sample**
   “Collect + Add Sample” will be displayed on the VetReader. Collect a 5μL diluted serum sample using the glass capillary provided with the kit.
   **Note**: Use the capillary holder (sold as an accessory) for capillary handling. Avoid the introduction of air bubbles into the glass capillary. Be sure to fill the entire length of the capillary with serum. Avoid excess sample on the outside of the capillary by "wiping off" excess with a clean tissue.
5. Add Sample
Unload the reagent vial from the VetReader. Open the cap of the reagent vial. Drop the capillary into the reagent vial and close the cap.

**Note:** The VetReader allows 5 seconds for adding sample before automatically switching to vortexing mode.

6. Mix using Vortex
“Vortex 30” will be displayed on the VetReader. Vortex the reagent vial for 30 seconds using the timer on display. Once the countdown has reached “0” the instrument will display, “Vortex OK”.

**Note:** Make sure the pellet is completely suspended after vortexing by turning the reagent vial upside down.

7. Loading of Reagent Vial into Instrument
“Insert Vial 10” will be displayed on the VetReader with a numerical countdown from 10 seconds. Load the reagent vial back into the VetReader before the display shows “0”. The instrument will display “Wait 660” and count down from 660 seconds (11 minutes). The user is now free to leave the instrument!

**Note:** The reagent vial must be loaded into the VetReader within 10 seconds after vortexing is completed. Otherwise, the measurement is aborted and the reagent chip will count down 1 measurement (the user loses one test).

8. Measurement
After 11 minutes the instrument will automatically perform 5 measurements, by moving the reagent vial in and out of the internal coil. The result is shown on the display in mg/dL and will remain on the display until the reagent vial is unloaded from the instrument. The display on the instrument will show, “Fe-Hapto XX mg/dL” where XX indicates a numerical value.

**Note:** The user should never press or push the reagent vial back into the instrument during movement. Such an action could damage the mechanical moving parts of the instrument.

9. Starting a New Measurement
Unload the reagent vial from the instrument. The display will show, “Fe-Hapto Test XX” where XX indicates the number of tests left of the reagent chip. To begin a new measurement press and hold the enter button. The instrument will display, “Wait” (3-second pause) followed by “Insert vial”. Repeat the assay procedure from this point outlined in step 2.

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**Performance Characteristics**

**Linearity range**
40–600 mg/dL

**Imprecision**

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<tr>
<th>Feline Haptoglobin Mean (mg/dL)</th>
<th>CV (%)</th>
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<tr>
<td>234</td>
<td>8</td>
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<td>466</td>
<td>5</td>
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**Reference Range**
The reference range for haptoglobin in feline serum is reported as less than 250 mg/dL (Refs. 1, 2). We thus recommend that haptoglobin concentrations above 250 mg/dL should be seen as an indication for systemic inflammation.

**References**

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