



Feline Haptoglobin (Hp) - TurboReader™ Assay

Instruction For Use (IFU) manual- Version 1, March 2018

A quantitative point-of-care assay for Haptoglobin in feline (cat) plasma or serum using the TurboReader™ instrument.

FOR VETERINARY AND RESEARCH USE ONLY.

1 INTENDED USE

The feline haptoglobin (Hp) TurboReader™ assay is an immunoturbidimetric point-of-care immunoassay for the quantitative, *in vitro* determination of haptoglobin (Hp) in cats, which can be a useful tool for monitoring inflammation.

Art No.

2532-01	Test Cuvettes (with cap)	20 pcs
	Dilution Vials	20 pcs
	R2 fHp Bottle	1 x 2.2 ml
	Instruction For Use (IFU)	1 pc

2 GENERAL DESCRIPTION¹⁻³

Haptoglobin (Hp) is a positive moderate acute phase protein in cats. Its normal plasma concentrations in healthy cats is <250 mg/dl. After stimulation from infection, disease, trauma or inflammation, plasma concentrations of Hp increase 2-10x, peaking around 48-72 hrs and then begin to decrease after cessation of inflammatory conditions. Repeated measurement of Hp in veterinary medicine, can be used as a tool for the diagnosis, progression and monitoring of treatment of conditions associated with inflammation, as well as, general health screening in cats.

3 ASSAY PRINCIPLE

The feline haptoglobin (Hp) TurboReader™ assay is a quantitative immunoturbidimetric point-of-care immunoassay for the detection of haptoglobin in feline (cat) plasma or serum. The R2 fHp bottle contains polyclonal antibodies against haptoglobin. Upon mixing of reagents, the Hp antigen present in the feline sample together with the R2 reagent forms a precipitation reaction which yields a turbid solution. The turbidity of the solution is measured nephelometrically and is directly proportional to the concentration of haptoglobin present in the feline sample.

4 COMPOSITION OF SUPPLIED REAGENTS

Contents	Substance & Concentration
Test Cuvette (with cap)	max 4% Polyethylene Glycol max 50 mM Tris buffer, pH 7.6 150 mM NaCl
Dilution Vials (1502-49)	max 4% Polyethylene Glycol max 50 mM Tris buffer, pH 7.6 150 mM NaCl
R2 fHp Bottle (1502-48)	goat anti(Hp)serum
Instruction For Use (IFU) (1810-04)	1 copy for laboratory

5 MATERIALS NEEDED BUT NOT SUPPLIED

- Sample (S) pipette (20 µl)
- R2 pipette (100 µl)
- Pipette tips
- Feline Hp Level 2 Control
- Disposable gloves
- TurboReader™ instrument

6 STORAGE & STABILITY

The test cuvette (with cap), dilution vials and R2 fHp bottle are supplied ready-to-use and are stable up to 12 months when stored at +2-8 °C. They may not be frozen. The test cuvette (with cap) and dilution vials can be stored at room temperature for one month. The R2 fHp bottle must be stored at +2-8 °C, but can be used directly cold. Place caps carefully after use of kit reagents to avoid evaporation.

7 PRECAUTIONS

- FOR VETERINARY AND RESEARCH USE ONLY.
- Do not use after expiration date.
- Do not freeze any test reagents.
- Haptoglobin (Hp) binds hemoglobin (Hb). Thus, grossly haemolytic samples, significant lipaemia or high levels of detergents in sample may interfere with results.
- Follow Good Laboratory Practices. Wear a lab coat, use disposable gloves and keep laboratory area clean.
- Reagents are from animal origin and should always be handled with due caution.
- After use, the test should be discarded according to local regulations regarding biological and hazardous material.
- Make sure to insert the cuvette into the TurboReader™ instrument in the correct orientation (the arrow on the cuvette wall and on instrument must align).
- Avoid evaporation of reagents.

8 SAFETY & WASTE HANDLING

Only qualified laboratory personnel under appropriate laboratory conditions may use the reagents. CAUTION: kit components contain sodium azide (<0.1%) as preservative. Therefore, handle as hazardous material and wear disposable gloves, eye protection and a lab coat. Do not ingest! Avoid contact with skin, mucous membranes and eyes. If uncertain, consult expertise for help. Health and Data Sheets are available at request. Handling of waste should be done in accordance with national laws and local regulations.

9 SPECIMEN COLLECTION

Collect feline (cat) lithium heparin plasma or serum sample using a blood collection tube according to the manufacturer's instructions. Do not use EDTA collection tubes. The stability of feline Hp serum or plasma is 2 weeks at +2-8 °C. For long-term storage, the specimen must be kept frozen (<-20°C). Repetitive freezing and thawing cycles is not recommended. The sample must be completely thawed, thoroughly mixed and at room temperature before testing can occur.

10 INSTRUMENT PARAMETERS

Recommended parameter settings for the TurboReader™ instrument:

- Volume S (sample): 20 µl
- Volume R2 fHp Bottle: 100 µl
- Reaction Time 1 (S): 1 min
- Reaction Time 2 (S+R2): 3 min
- Calibration: Multi-point (8 points)

11 PROCEDURE

Sample preparation: Use the sample (S) pipette to transfer 20 µl of the feline serum/plasma sample (or control) into the dilution vial. Mix well.

Measurement: Start TurboReader™ instrument and select NEW TEST. Scan the R2 fHp bottle to control the lot of reagent matches the stored calibration curve and then press RUN on the instrument touch screen. Use the sample pipette to transfer 20 µl of the diluted feline serum/plasma sample or control (prepared above) to an unused cuvette. Turn the cuvette slowly upside down 4 times (no bubbles should be introduced). Place the cuvette into the TurboReader™ and make sure it has the correct orientation (the arrow on the cuvette wall and on instrument must align). Select OK on the touch screen. After 1 minute the TurboReader™ will request the operator to remove the cuvette and add 100 µl R2 using the R2 pipette. Turn the cuvette slowly upside down 4 times (no bubbles should be introduced). Place the cuvette into the TurboReader™ and make sure it has the correct orientation (the arrow on the cuvette wall and on instrument must align). Select OK on the touch screen. After 3 minutes the TurboReader™ will display the concentration of Feline Hp.

12 CALIBRATION & QUALITY CONTROL

The TurboReader™ instrument is precalibrated (multi-point calibration) for each reagent lot and the lot specific calibration data is automatically transferred into the instrument using the 2D scanner. For more information refer to the Calibration section in the TurboReader™ instrument manual.

In order to survey accuracy and precision, periodic Quality Control is recommended using Feline Hp Level 2 Control (Art. No. 2532-10). The Feline Hp Level 2 Control is supplied separately.

13 PERFORMANCE

Assay measuring range: The measuring range of the assay is 17–1000 mg/dl.

Sensitivity: The minimum level of detection is approximately 17 mg/dl.

Prozone limit: No prozone effect can be observed for feline Hp concentrations of up to 1500 mg/dl.

Specificity & Interference: The antiserum used is monospecific for haptoglobin (Hp). It has not been shown to cross-react with other serum proteins under the conditions of the assay. However, the assay may be interfered by samples containing significant levels of lipaemina, haemolysis or detergents.

Precision: The precisions of the assay is given in tables below.

Precision (n=5)	Mean mg/L	SD mg/L	CV %
Feline sample	381	40	10.5


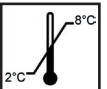






Normal ranges: The normal range of the feline Hp concentration in healthy cats is <250 mg/dl. For clinical use, the feline Hp concentration can be classified into the following three categories: normal, intermediate and acute phase.

Clinical Classification	Hp (mg/dl)
Normal level:	0-250
Intermediate level:	250-300
Acute Phase level:	>300

Feline Hp levels above >300 mg/dl clearly indicate an ongoing inflammatory response, while levels below <250 mg/dl are in the normal healthy range. For feline Hp values between 250-300 mg/dl, heavy consideration into the overall health of the animal should be considered. It is recommended each laboratory should establish its own normal range which corresponds to local genetic and environmental factors.

- Repetitive measurement of feline Hp can be used to determine if selective treatment is effective and for the monitoring of post-operative conditions and surgery recovery.
- Feline Hp results should be used with other clinical and diagnostic information for forming a diagnosis and for health management.

14 SYMBOLS KEY

Lot number 	Temperature limit 	Use by date 	Irritant 
Consult IFU 	Manufacturer 	Catalogue number 	Content 

15 REFERENCES

- [1] Silvestre-Ferreira, A.C., et al. Acute phase proteins response in cats naturally infected by hemotropic mycoplasmas., Comp. Imm. Micro. and Infect. Disease, 2018, 56, 1-5.
- [2] Céron J.J., Eckersall P.D. and Martínez-Subiela S. Acute phase proteins in dogs and cats: current knowledge and future perspectives. Vet. Clin. Pat. 2005, 34(2): 85-99.
- [3] Kann R.K.C., Seddon J., Henning J and Meers J. Acute Phase Proteins in Healthy and Sick Cats. Res. In Vet. Sci. 2012, 93, 649-654.

Manufactured by: *European Institute of Science AB*

Install Feline Hp:

