eurisTest™

Equine Serum Amyloid A (SAA) - TurboReader™ Assay

Instruction For Use (IFU) manual- Version 3, January 2019

A quantitative point-of-care assay for Serum Amyloid A (SAA) in equine (horse) serum using the TurboReader™ instrument.

FOR VETERINARY AND RESEARCH USE ONLY.

1 INTENDED USE

The equine Serum Amyloid A (SAA) TurboReader™ assay is a particle-enhanced immunoturbidimetric point-of-care immunoassay for the quantitative, in vitro determination of SAA in horses, which can be a useful tool for monitoring infection and systemic inflammation.

Art No.		
2534-01	Test Cuvettes (with red cap)	20 pcs
	R2 eSAA Bottle	2 x 4.2 ml
	Instruction For Use (IFU)	1 pc

2 GENERAL DESCRIPTION[1-6]

Serum Amyloid A (SAA, 12 kDa) is a major acute phase plasma protein associated with high density lipoproteins (HDL) in plasma [1]. Its normal plasma concentrations in healthy horses is much lower than <30 mg/l [2]. SAA is a real-time diagnostic marker for systemic inflammation and infection with plasma concentrations increasing approximately 4 hrs after stimulation, peaking around 24-48 hrs and clearing between 48-72 hrs after cessation of inflammatory conditions [3]. Measurement of SAA has a large diagnostic window, increasing above 100x the normal plasma concentrations during inflammatory activity. SAA is a specific and sensitive marker of infection and tissue injury in horses [4]. Clinical use of SAA is not limited to monitoring systemic inflammation, but can also be used for determination if selected antibiotic treatment is effective, confirming presence of infection and monitoring postoperative recovery [5-6].

3 ASSAY PRINCIPLE

The equine SAA TurboReader™ assay is a quantitative particle-enhanced immunoturbidimetric point-of-care immunoassay for the detection of SAA in equine (horse) serum, lithium heparin plasma or alternatively synovial fluid. The R2 eSAA bottle contains latex particles coated with rabbit polyclonal and mouse monoclonal antibodies against Serum Amyloid A (SAA). Upon mixing of reagents, the SAA antigen present in the equine sample together with the R2 reagent forms an agglutination reaction which yields a turbid solution. The turbidity of the solution is measured turbidimetrically (470 nm) and is directly proportional to the concentration of SAA present in the equine sample.

4 COMPOSITION OF SUPPLIED REAGENTS

Contents	**Substance & Concentration**
Test Cuvette (with red cap)	25 mmol/L Good's buffer
R2 eSAA Bottle (1502-52)	latex particles coated with anti-SAA antibodies (40 vol%)
Instruction For Use (IFU) (1810-07)	1 copy for laboratory

5 MATERIALS NEEDED BUT NOT SUPPLIED

- Sample (S) pipette (5 µl)
- R2 pipette (200 µl)
- Pipette tips
- Equine SAA Level 2 Control
- Disposable gloves
- NaCl solution, 0.9 % (w/v)
- TurboReader™ instrument

6 STORAGE & STABILITY

The test cuvette (with red cap) and R2 eSAA 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 red cap) can be stored at room temperature for one month. The R2 eSAA bottle must be stored at +2-8 °C and must reach room temperature before use. Additionally, be sure to mix R2 eSAA bottle before use by gently inverting the bottle several times. 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.
- Significant lipemia, hemolytic samples or high levels of detergents in sample may interfere with assay 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.

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9 SPECIMEN COLLECTION

Collect equine (horse) serum, lithium heparin plasma or alternatively synovial fluid using a collection tube according to the manufacturer's instructions. The stability of equine SAA serum is 2-3 days at +2-8 °C. For long-term storage, the specimen must be kept frozen (<-20°C) for maximum 3 months. 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): 5 µl
- Volume R2 eSAA Bottle: 2 x 200 µl
- Reaction Time (S+R2): 9.5 min
- Calibration: Multi-point (8 points)

11 PROCEDURE

Start TurboReader™ instrument and select NEW TEST. Then press TEST and immediately scan the bar code on the R2 eSAA bottle to control the lot of reagent matches the stored calibration curve. Then press RUN on the instrument touch screen. Add 5 µl of the equine sample (or control) into the cuvette using the sample (S) pipette. Gently invert R2 bottle to mix (it must be at room temperature before use). Then, use the R2 pipette to transfer 200 µl R2 into red cuvette cap. Repeat this step, by adding another 200 µl R2 into the red cuvette cap (total of 400 µl R2 added). Slowly, pour the R2 reagent in the cap into the cuvette and close the cuvette by placing the cap firmly onto the 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. The operator may now leave the instrument. Do not remove cuvette. After 9.5 minutes the TurboReader™ will display the concentration of SAA in the equine sample.

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 Equine SAA Level 2 Control (Art. No. 2534-10). The Equine SAA Level 2 Control is supplied separately.

13 PERFORMANCE

Assay measuring range: The measuring range of the assay is 10 – 600 mg/l. Samples with equine SAA levels larger than 600 mg/l should be diluted 1:4 with 0.9 % (w/v) NaCl solution and the result multiplied with 4. For samples that are grossly lipemic or hemolytic, it is recommended to centrifuge samples before use.

Sensitivity: The minimum level of detection is approximately 10 mg/l.

Interferences: No interferences are known to occur.

Precision: The precisions of the assay is given below:

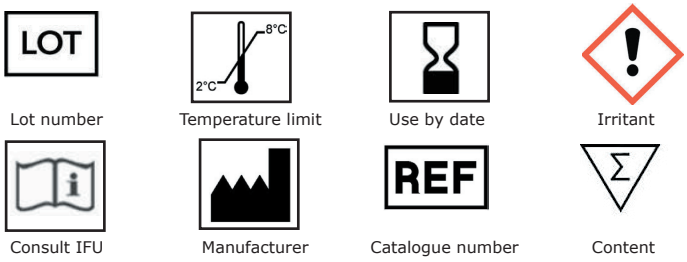
Precision (n=5)	Mean mg/L	SD mg/L	CV %
Equine sample	80.2	3.6	4.5

Normal ranges[7]: The normal range of the SAA concentration in healthy horses is <30 mg/l (<30 µg/ml). Each laboratory should establish its own normal range which corresponds to local genetic and environmental factors.

- Repetitive measurement of equine SAA can be used to determine if selective antibiotic treatment is effective, confirming the presence of infection and screening for subclinical infection.

- Equine SAA 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

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Manufactured by: European Institute of Science AB

Lot: 18J-105

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