eurisTest™

Equine Urinary Albumin (UALB) - TurboReader™ Assay

Instruction For Use (IFU) manual- Version 1, February 2019

A quantitative point-of-care assay for Albumin in equine (horse) urine using the TurboReader™ instrument.

FOR VETERINARY AND RESEARCH USE ONLY.

1 INTENDED USE

The equine urinary albumin (UALB) TurboReader™ assay is an immunoturbidimetric point-of-care immunoassay for the quantitative, *in vitro* determination of albumin in horse urine, which can be a useful tool for assessing kidney function.

Art No.		
2535-02	Test Cuvettes (with blue cap)	20 pcs
	R2 eUALB Bottle	1 x 2.2 ml
	Instruction For Use (IFU)	1 pc

2 GENERAL DESCRIPTION[1-3]

In healthy kidneys, very little albumin is filtered across the glomerus, but rather it is almost completely reabsorbed by the proximal tubule preventing excretion of albumin into the urine [1]. Microalbuminuria (MA) is defined as concentrations of albumin in the urine greater than normal (>10 mg/l), but below the detection limit of conventional urine protein dipsticks (≤300 mg/l) [2]. Microalbumin concentrations in animals below <20-25 mg/l are considered normal [3]. Conversely, urine albumin concentrations above >300 mg/l are viewed as clear albuminuria [2]. Measurement of microalbuminuria in healthy and sick horses can be used for assessing kidney function.

3 ASSAY PRINCIPLE

The equine urinary albumin (UALB) TurboReader™ assay is a quantitative immunoturbidimetric point-of-care immunoassay for the detection of albumin in equine (horse) urine [1]. The R2 eUALB bottle contains polyclonal antibodies against albumin. Upon mixing of reagents, the ALB antigen present in the equine 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 albumin present in the equine sample.

4 COMPOSITION OF SUPPLIED REAGENTS

Contents	**Substance & Concentration**
Test Cuvette (with blue cap)	max 4% Polyethylene Glycol max 50 mM Tris buffer, pH 7.6 150 mM NaCl
R2 eUALB Bottle (1502-55)	goat anti(ALB) serum
Instruction For Use (IFU) (1810-09)	1 copy for laboratory

5 MATERIALS NEEDED BUT NOT SUPPLIED

- Sample (S) pipette (25 µl)
- R2 pipette (100 µl)
- Pipette tips
- Equine UALB Level 2 Control
- Disposable gloves
- TurboReader™ instrument

6 STORAGE & STABILITY

The test cuvette (with blue cap), dilution vials and R2 eUALB 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 blue cap) and dilution vials can be stored at room temperature for one month. The R2 eUALB 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.
- Grossly haemolytic samples, significant lipaemina 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.

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9 SPECIMEN COLLECTION

Collect equine (horse) urine. The stability of equine urine is 1 week at room temperature or 1 month 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): 25 µl
- Volume R2 eUALB Bottle: 100 µl
- Reaction Time 1 (S): 1 min
- Reaction Time 2 (S+R2): 3 min
- Calibration: Multi-point (8 points)

11 PROCEDURE

Measurement: Start TurboReader™ instrument and select NEW TEST. Then press TEST and immediately scan the R2 eUALB bottle to control the lot of reagent matches the stored calibration curve. Press RUN on the instrument touch screen. Use the sample pipette to transfer 25 µl of equine urine or control 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 Equine UALB.

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 ALB Level 2 Control (Art. No. 2535-10). The Equine ALB Level 2 Control is supplied separately.

13 PERFORMANCE

Assay measuring range: The measuring range of the assay is 25–375 mg/l.

Sensitivity: The minimum level of detection is approximately 25 mg/l.

Prozone limit: No prozone effect can be observed for equine UALB concentrations of up to 1500 mg/l.

Specificity & Interference: The antiserum used is monospecific for albumin (ALB). 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 %
Equine urine sample	152.0	5.0	3.3

Normal ranges: The normal range of the urine albumin UALB concentration in healthy horses is <25 mg/l. For clinical use, the microalbumin concentration can be classified into the following three categories: mild, moderate and severe.

Clinical Classification	**Microalbumin (mg/l)**
Mild:	25-75
Moderate:	75-200
Severe:	200-300

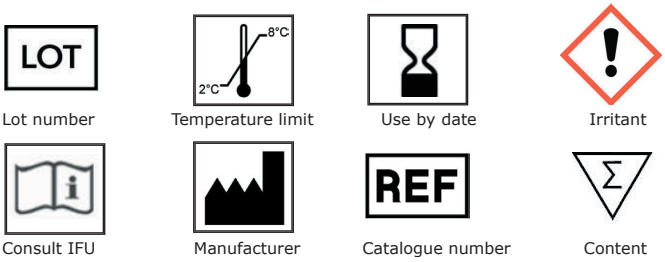
Concentrations above >300 mg/l are clinically classified as Albuminuria.

It is recommended each laboratory should establish its own normal range which corresponds to local genetic and environmental factors.

- Repetitive measurement of equine UALB can be used for the monitoring.

- Equine UALB 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] Toribio, Ramiro E. Essentials of equine renal and urinary tract physiology. Vet Clin Equine. 2007, 23, 533-561.
[2] Grauer, Gregory F. 2016. Measurement and interpretation of proteinuria and albuminuria. International Renal Interest Society. http://www.iris-kidney.com/education/proteinuria.html
[3] Young, Annalisa. Laboratory investigation of equine kidney disease. Equine Vet Educ. 1990, 2(3), 130-134.

Manufactured by: European Institute of Science AB

Install Equine UALB: 18A-110

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