

# Equine Serum Albumin (ALB) -TurboReader™ Assay

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

A quantitative point-of-care assay for Albumin in equine (horse) plasma or serum using the TurboReader $^{\text{TM}}$  instrument.

FOR VETERINARY AND RESEARCH USE ONLY.

#### 1 INTENDED USE

The equine serum albumin (ALB) TurboReader<sup>TM</sup> assay is an immunoturbidimetric point-of-care immunoassay for the quantitative, *in vitro* determination of albumin (ALB) in horse serum or plasma, which can be a useful tool for assessing liver and kidney diseases.

#### Art No.

2535-01 Test Cuvettes (with blue cap) 20 pcs
Dilution Vials 20 pcs
R2 eALB Bottle 1 x 2.2 ml
Instruction For Use (IFU) 1 pc

#### 2 GENERAL DESCRIPTION1-6

Serum Albumin (ALB) is a globular protein synthesized in the liver with a molecular weight of 69 kDa [1]. Albumin makes up 35-50% of the total plasma proteins, thus, contributing largely to the plasma colloid osmotic pressure. It also serves as a carrier protein for many insoluble organic substances. Its normal plasma concentrations in healthy horses is approximately 26-37 g/l [2,3]. Raised levels of serum albumin indicate animal dehydration. When levels of albumin are low this suggests either a failure of protein production in liver or protein loss [4]. Protein can be lost from the body through the intestine or the kidney [5,6].

# 3 ASSAY PRINCIPLE

The equine serum albumin (ALB) TurboReader™ assay is a quantitative immunoturbidimetric point-of-care immunoassay for the detection of albumin in equine (horse) plasma or serum. The R2 eALB 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
Dilution Vials (1502-54)	max 4% Polyethylene Glycol max 50 mM Tris buffer, pH 7.6 150 mM NaCl
R2 eALB Bottle (1502-55)	goat anti(ALB) serum
Instruction For Use (IFU) (1810-08)	1 copy for laboratory

## **5 MATERIALS NEEDED BUT NOT SUPPLIED**

- Sample (S) pipette (10 µl)
- R2 pipette (100 μl)
- Pipette tips
- Equine ALB Level 2 Control
- Disposable gloves
- TurboReader™ instrument

#### **6 STORAGE & STABILITY**

The test cuvette (with blue cap), dilution vials and R2 eALB 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 eALB 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.

#### 9 SPECIMEN COLLECTION

Collect equine (horse) 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 equine ALB 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  $\mbox{^{TM}}$  instrument:

• Volume S (sample):  $10 \ \mu l$ • Volume R2 eALB Bottle:  $100 \ \mu l$ • 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  $10~\mu l$  of the equine serum/plasma sample into the dilution vial. Mix well. **Note:** Equine ALB Level 2 Control does not need to be diluted prior to use. Go directly to measurement below

Measurement: Start TurboReader™ instrument and select NEW TEST. Then press TEST and immediately scan the R2 eALB 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 10 μl of the diluted equine serum/plasma sample (prepared above) 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 ALB.

# 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 5.0-75 g/l.

Sensitivity: The minimum level of detection is approximately 5.0 g/l.

**Prozone limit:** No prozone effect can be observed for equine ALB concentrations of up to 150 g/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	SD	CV
	mg/L	mg/L	%
Equine sample	33.2	1.6	4.9

**Normal ranges:** The normal range of the serum albumin ALB concentration in healthy horses is 27-39 g/l. For clinical use, the equine ALB concentration can be classified into the following three categories: low, normal and elevated.

Clinical Classification	ALB (g/l)
Hypoalbuminemia:	<27
Normal level:	27-39
Hyperalbuminemia:	>39

Equine ALB levels above >39 g/l indicate hyperalbuminemia, most likely due to dehydration. Conversely, ALB levels lower than <27 g/l indicate hypoalbuminemia due to reduced protein production in the liver or protein loss in the intestine or kidney. It is recommended each laboratory should establish its own normal range which corresponds to local genetic and environmental factors.

- Repetitive measurement of equine ALB can be used for the monitoring.
- Equine ALB results should be used with other clinical and diagnostic information for forming a diagnosis and for health management.

#### 14 SYMBOLS KEY



Lot number



Consult IFU



Temperature limit



Manufacturer



Use by date



Catalogue number



Irritant



Content

### 15 REFERENCES

- [1] Cornell University College of Veterinary Medicine. ECLINPATH. http://www.eclinpath.com/chemistry/proteins/albumin/
- [2] Kaneko JJ , Harvey JW, Bruss ML (eds). 1997. Clinical biochemistry of domestic animals, ed 5. Academic Press, San Diego, CA. Appendix VIII: Blood analyte reference values in large animals.
- [3] Riond B, et al. Serum protein concentrations from clinically healthy horses determined by agarose gel electrophoresis. Vet Clin Pathol. 2009, 38(1), 73-7.
- [4] Parraga ME, et al. Serum Protein Concentrations in Horses With Severe Liver Disease: A Retrospective Study and Review of the Literature. J Vet Intern Med. 1995. 9(3), 154-61.
- [5] Dietz HH, Nielsen K. Turnover of 131I-labelled albumin in horses with gastrointestinal disease. Nord Vet Med. 1980, 32(9), 369-73.
- [6] Staempfli HR, et al. Prognostic features and clinical presentation of acute idiopathic enterocolitis in horses. Can Vet J. 1991, 32, 232-37.

Manufactured by: European Institute of Science AB

#### Install Equine ALB: 18A-110

