1 INTENDED USE

The equine serum albumin (ALB) TurboReader™ 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.

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 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 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™ instrument:
- Volume S (sample): 10 µl
- Volume R2 eALB 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 10 µl 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) to 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 lipaemia, haemolysis or detergents.

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

<table>
<thead>
<tr>
<th>Precision (n=5)</th>
<th>Mean mg/L</th>
<th>SD mg/L</th>
<th>CV %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Equine sample</td>
<td>33.2</td>
<td>1.6</td>
<td>4.9</td>
</tr>
</tbody>
</table>

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

15 REFERENCES

Manufactured by: European Institute of Science AB