Plasma/Serum test for Bile acids (BA) For veterinary use only

FUJI DRI-CHEM IMMUNO AU CARTRIDGE v-BA

[Warnings and precautions]
1. Only the required number of cartridges should be taken out of the refrigerator and warmed up to room temperature before opening the individual packages.
2. Do not touch either the Excitation Light Entrance or the Detection Window of the cartridge.
3. Do not touch the seal on the cartridge. Do not Use a cartridge with broken seal.
4. When a cartridge is once set to an ANALYZER and the ‘START’ key is pressed, the seal will be broken. Do not reuse besides the following exception. A cartridge can be used again as long as, i) the error code shown below is displayed on the analyzer, and ii) a cartridge seal is broken within 60 minutes. (For further details on error code, consult "INSTRUCTION MANUAL" for FUJI DRI-CHEM IMMUNO AU10V.)

<table>
<thead>
<tr>
<th>Error code</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>EO102</td>
<td>Suction clog error</td>
</tr>
<tr>
<td>E0112</td>
<td>No sample aspirated</td>
</tr>
<tr>
<td>E1013</td>
<td>Liquid surface error</td>
</tr>
<tr>
<td>E1014</td>
<td>Sample shortage error</td>
</tr>
</tbody>
</table>

5. Do not use a cartridge dropped to the floor. There is a possibility that the cartridge is damaged.
6. A new cartridge must be used for each measurement. Do not reuse.
7. Handle all patient specimens carefully as biohazardous samples. Wear proper gloves, glasses and other protective gear for your safety.
8. Used cartridges are categorized as infectious waste. Make sure to dispose them in accordance with the Waste Disposal Law and other related regulations, which prescribe the proper method of disposal, such as incineration, melting, sterilization or disinfection.

[Composition of the cartridge]
1. Top side of the cartridge
   - Excitation Light Entrance
   - Detection Window
   - Seal

2. Ingredients enclosed in the cartridge
   - Fluorescence particle-labeled anti- Bile acids (BA) mouse monoclonal antibody
   - Bile acids binding bovine serum albumin (BA-BSA)

[Intended use]
Quantitative measurement of Bile acids (BA) concentration in plasma or serum from canine and feline. For veterinary use only.

[Principle of the measurement]
The FUJI DRI-CHEM IMMUNO AU CARTRIDGE v-BA test is based on Competitive Immunoassay method. When a specimen is applied to a cartridge, the specimen and the dried fluorescence particle-labeled anti-BA mouse monoclonal antibody (referred to as “fluorescence particle-labeled antibody” from hereon) enclosed in the cartridge are mixed. BA in the specimen reacts with a fluorescence particle-labeled antibody. The mixture then reacts continuously with BA-BSA (referred to as “solid-phase antigen” from hereon) immobilized on the cartridge. Here, the BA non-binding fluorescence particle-labeled antibody binds to the solid-phase antigen. These fluorescence particles are activated by excitation light (excitation wavelength 650-665nm) through the gold coating film. The fluorescence generated is inversely proportional to the BA concentration of the specimen.

[Additional special equipment]
Analyzer: FUJI DRI-CHEM IMMUNO AU10V
Other implements: FUJI DRI-CHEM AUTO TIPS, FUJI HEPARIN/PLAIN TUBE (0.5 mL or 1.5 mL)

[Specimen requirements]
1. Immediately carry out the measurement after collecting the blood specimen.
2. For plasma, heparin can be used as the anticoagulant. When using heparin, less than 50 units of heparin should be used per 1 mL of whole blood. Do not use EDTA salt, sodium fluoride, citric acid, oxalic acid and moniodoacetic acid.
3. Avoid using plasma/serum with precipitate such as fibrin.
4. Do not use diluted plasma/serum.

[Procedure]
1. Set a cartridge, a sample tube and a FUJI DRI-CHEM AUTO TIPS on an Analyzer.
2. Input Sequence No. and Sample ID, if necessary.
3. Close the sample set cover and press the “START” key to initiate testing. The calibration of this product has already been accomplished in our factory before shipping using internal calibrators which are not commercially available. Based on the calibration data stored in QR Code pasted on the cartridge, a test result will be displayed. For further details on operation procedure, consult "INSTRUCTION MANUAL" for FUJI DRI-CHEM IMMUNO AU10V.
4. Do not touch either the Excitation Light Entrance or the Detection Window.
5. Do not use a cartridge dropped to the floor. There is a possibility that the cartridge is damaged.
6. A new cartridge must be used for each measurement. Do not reuse.
7. Handle all patient specimens carefully as biohazardous samples. Wear proper gloves, glasses and other protective gear for your safety.
8. Used cartridges are categorized as infectious waste. Make sure to dispose them in accordance with the Waste Disposal Law and other related regulations, which prescribe the proper method of disposal, such as incineration, melting, sterilization or disinfection.

[Reference intervals]
Canine: Fasting: ≤7.9μmol/L, Postprandial: ≤24.5μmol/L
Feline: Fasting: ≤5μmol/L, Postprandial: ≤15μmol/L

As the reference intervals depend on the population of the test, it is required that each laboratory set its own reference intervals. The clinical diagnosis must be carried out by the veterinarian in charge based on the measured results in the light of clinical symptoms and other test results.

[Performance characteristics]
1. Dynamic range: 2.0 - 150.0 μmol/L
2. Accuracy:
   - Concentration range: 2.0 - 16.0 μmol/L
   - Accuracy: Within ± 3.2 μmol/L
   - Concentration range: 16.0 - 150.0 μmol/L
   - Accuracy: Within ± 20%

3. Precision:
   - Concentration range: 2.0 - 16.0 μmol/L
   - Precision: SD ≤ 2.4 μmol/L
   - Concentration range: 16.0 - 150.0 μmol/L
   - Precision: CV ≤ 15%

4. Correlation
   (1) Correlations were evaluated between Enzyme Cycling method and FUJI DRI-CHEM IMMUNO AU CARTRIDGE v-BA using canine and feline sera. These examinations were carried out at the laboratory of FUJIFILM Corporation.
   | Canine Serum | Feline Serum |
   | Slope | Intercept | Correlation Coefficient | Slope | Intercept | Correlation Coefficient |
   | 62 | 1.01 | -0.29 | 0.947 |
   | 53 | 0.97 | 0.27 | 0.986 |

   (2) Correlations were evaluated between plasma and serum from canine and feline using FUJI DRI-CHEM IMMUNO AU CARTRIDGE v-BA. These examinations were carried out at the laboratory of FUJIFILM Corporation.
   | Canine | Feline |
   | Slope | Intercept | Correlation Coefficient | Slope | Intercept | Correlation Coefficient |
   | 53 | 0.98 | -0.03 | 0.990 |
   | 50 | 1.02 | -0.01 | 0.998 |

5. Known interfering substances
(1) No significant effect was observed up to the following concentration for each substance.
   - Chyle: 2000 FTU
   - Hemoglobin: 4000 mg/L
   - Bilirubin: 340 μmol/L
   - Total Protein: 60-80 g/L
**Cross reactivity**

<table>
<thead>
<tr>
<th>Compound</th>
<th>Concentration [µmol/L]</th>
<th>Cross reactivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cholesterol</td>
<td>259</td>
<td>not detectable</td>
</tr>
<tr>
<td>Cortisol</td>
<td>276</td>
<td>not detectable</td>
</tr>
<tr>
<td>Spironolactone</td>
<td>480</td>
<td>not detectable</td>
</tr>
<tr>
<td>Aldosterone</td>
<td>277</td>
<td>not detectable</td>
</tr>
<tr>
<td>Estradiol</td>
<td>347</td>
<td>not detectable</td>
</tr>
<tr>
<td>Testosterone</td>
<td>35</td>
<td>not detectable</td>
</tr>
<tr>
<td>Ursodeoxycholic acid</td>
<td>100</td>
<td>39%</td>
</tr>
</tbody>
</table>

(2) Cross reactivity

(3) In specimen having non-specific reactive substances such as heterophilic antibody, interference to the reaction system occurs. In this case, measurement may not be accurate. Clinical diagnosis must be carried out by the veterinarian in charge based on the measured results in the light of clinical symptoms and other test results.

These results are representative;
- Test condition may have some influence on your results.
- Interferences from other substances are not predictable.

**Internal quality control**

1. The accuracy and precision of this product can be evaluated with control materials such as pooled canine serum.
2. Concentration levels of the control materials should be adjusted in accordance with clinically significant levels or individual purpose.
3. The control materials should be measured in the same way as patient samples.
4. We recommend that control limits be established for assayed analytes so as to enable assessment of the control status.
   If results are found outside of the control limits, investigate the cause before submitting reports.

**Storage and shelf life**

1. Storage: This product must be stored between 2–8 °C (35.6–46.4 °F) before use.
2. Expiry date is printed on the carton.
3. Use immediately after opening the individual package.

**Contents**

- Cartridge 10

**References**

[1] The reference interval of canine was carried out at the laboratory of FUJIFILM Corporation.


http://www.fujifilm.com/products/medical/

For EU only: Imported by:
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Oudenstaart 1, 5047 TK Tilburg, The Netherlands

FUJIFILM Corporation
26-30, Nishiazabu 2-Chome, Minato-ku, Tokyo 106-8620, JAPAN

**Symbols**

- Do not reuse
- Lot number
- Use by
- Contains sufficient for <n> tests
- Temperature limitation
- Consult instructions for use
- Manufacturer