**FUJI DRI-CHEM IMMUNO AU CARTRIDGE v-COR**

Date of issue: 31/Jul/2014

**Serum test for Cortisol (COR)**

**[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 cartridges with broken seals.

4. When a cartridge is once set to an ANALYZER and the "START" key is pressed, the seal will be broken. Do not reuse.

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.

9. In the case the Cortisol level is estimated to be above 30.0μg/dL, dilute the specimen to obtain a result within 50.0μg/dL.

10. Use pharmaceutical grade saline for diluting the specimen.

11. Measurements with dilution, once the diluent has been dispensed, immediately set the specimen and press the start button as instructed. If the time elapsed after the diluent has been dispensed exceeds 10 minutes, a test result error will occur ("?” mark will be shown with the results). Measure the specimen again.

12. Test results from manually diluted specimens are not guaranteed to be accurate.

13. Be sure to set a specimen after the diluent has been dispensed in measurements with dilution. (If the diluent is set as a specimen, a test result will be obtained.)

**[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-Cortisol (COR) mouse monoclonal antibody
   - Cortisol binding bovine serum albumin (COR-BSA)

**[Intended use]**

Quantitative measurement of Cortisol (COR) concentration in canine serum.

For veterinary use only.

**[Principle of the measurement]**

The FUJI DRI-CHEM IMMUNO AU CARTRIDGE v-COR test is based on Competitive Immunoassay method. When a canine serum specimen is applied to a cartridge, the specimen and the dried fluorescence particle-labeled anti-COR mouse monoclonal antibody (referred to as "fluorescence particle-labeled antibody" from hereon) enclosed in the cartridge are mixed. COR in the specimen reacts with a fluorescence particle-labeled antibody. The mixture then reacts continuously with COR-BSA (referred to as "solid-phase antigen" from hereon) immobilized on the cartridge. Here, the COR 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 COR concentration of the specimen.

**[Additional special equipment]**

**Analyzer**
- FUJI DRI-CHEM IMMUNO AU10V
- FUJI DRI-CHEM AUTO TIPS

**Other implements**
- FUJI PLAIN TUBE (0.5 mL or 1.5 mL)
- Pharmaceutical grade saline (for measurements with dilution)

**[Specimen requirements]**

1. Immediately carry out the measurement after collecting the blood specimen.

2. Use serum samples only.

3. Avoid using serum with precipitate such as fibrin.

**[Procedure]**

1. Set a FUJI DRI-CHEM IMMUNO AU CARTRIDGE v-COR, a specimen containing FUJI PLAIN TUBE and a FUJI DRI-CHEM AUTO TIPS (henceforth ‘tip’) in the 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, refer to the "INSTRUCTION MANUAL" for FUJI DRI-CHEM IMMUNO AU10V.

In case of measurements with dilution, please follow the procedure below.

1. Prepare the FUJI DRI-CHEM IMMUNO AU CARTRIDGE v-COR, the specimen containing FUJI PLAIN TUBE, the diluent containing FUJI PLAIN TUBE, and a tip in the analyzer.

2. Input Sequence No. and Sample ID, if necessary.

3. Simultaneously press the right (>) and down (▼) cursor keys to switch to the measurement with dilution mode. [SET TIP & DILUENT then START] will be displayed. The specimen will be diluted 5 folds prior to measuring.

4. Set a FUJI DRI-CHEM IMMUNO AU CARTRIDGE v-COR, a diluent containing FUJI PLAIN TUBE and a tip in the analyzer.

5. Close the sample set cover and press the “START” key.

6. The machine will automatically dispense the diluent. After dispensing, the diluent containing FUJI PLAIN TUBE and cartridge will return back to their consumables set positions. [SET TIP & SAMPLE then START] will be displayed.

7. Take out the diluent containing FUJI PLAIN TUBE.

8. Set a specimen containing FUJI PLAIN TUBE and a tip in the analyzer.

9. Close the sample set cover and press the "START" key.

10. The analyzer will dispense the specimen into the cartridge and will automatically perform the fluorescence measurement. 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. Test results from measurements with dilution are shown with "D" marks.

QR Code is registered trademark of DENSO WAVE INCORPORATED.

**Other implements**
- FUJI PLAIN TUBE (0.5 mL or 1.5 mL)
- Pharmaceutical grade saline (for measurements with dilution)

**[Procedure]**

1. Set a FUJI DRI-CHEM IMMUNO AU CARTRIDGE v-COR, a specimen containing FUJI PLAIN TUBE and a FUJI DRI-CHEM AUTO TIPS (henceforth ‘tip’) in the analyzer.

2. Input Sequence No. and Sample ID, if necessary.

3. Simultaneously press the right (>) and down (▼) cursor keys to switch to the measurement with dilution mode. [SET TIP & DILUENT then START] will be displayed. The specimen will be diluted 5 folds prior to measuring.

4. Set a FUJI DRI-CHEM IMMUNO AU CARTRIDGE v-COR, a diluent containing FUJI PLAIN TUBE and a tip in the analyzer.

5. Close the sample set cover and press the “START” key.

6. The machine will automatically dispense the diluent. After dispensing, the diluent containing FUJI PLAIN TUBE and cartridge will return back to their consumables set positions. [SET TIP & SAMPLE then START] will be displayed.

7. Take out the diluent containing FUJI PLAIN TUBE.

8. Set a specimen containing FUJI PLAIN TUBE and a tip in the analyzer.

9. Close the sample set cover and press the "START" key.

10. The analyzer will dispense the specimen into the cartridge and will automatically perform the fluorescence measurement. 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. Test results from measurements with dilution are shown with "D" marks.

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### Interpretation of Test Results

#### ACTH Stimulation Test

<table>
<thead>
<tr>
<th>Pre-ACTH</th>
<th>Post-ACTH</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0-6.0 μg/dL</td>
<td>24.0 μg/dL</td>
<td>Consistent with Cushing's syndrome.</td>
</tr>
<tr>
<td>19.0-34.0 μg/dL</td>
<td></td>
<td>Equivocal; Cushing's syndrome possible.</td>
</tr>
<tr>
<td>&gt;34.0 μg/dL</td>
<td></td>
<td>Normal</td>
</tr>
<tr>
<td>&lt;8.0 μg/dL</td>
<td></td>
<td>Consistent with idiopathic Cushing's syndrome.</td>
</tr>
<tr>
<td>&gt;8.0 μg/dL</td>
<td></td>
<td>Consistent with hypoadrenocorticism.</td>
</tr>
</tbody>
</table>

#### Low-Dose Dexamethasone Suppression Test

<table>
<thead>
<tr>
<th>Concentration range</th>
<th>Accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.1-0.5 μg/dL</td>
<td>C &lt; 50% of Pre-Suppression</td>
</tr>
<tr>
<td>0.6-2.0 μg/dL</td>
<td></td>
</tr>
<tr>
<td>&gt;2.0 μg/dL</td>
<td></td>
</tr>
</tbody>
</table>

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.

#### High-Dose Dexamethasone Suppression Test

<table>
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<tr>
<td>1.0-6.0 μg/dL</td>
<td>C &lt; 50% of Pre-Suppression</td>
</tr>
<tr>
<td>&gt;6.0 μg/dL</td>
<td></td>
</tr>
</tbody>
</table>

#### Performance characteristics

1. **Dynamic range**
   - 1.0 - 6.0 μg/dL (27.6 - 828.0 nmol/L) (with dilution)
   - 1.0 - 6.0 μg/dL (27.6 - 1380.0 nmol/L) (with dilution)

   Conversion coefficient: 27.6 μg/dL = 1.0 ng/mL

2. **Accuracy**
   - Unit(A): μg/dL, Unit(B): nmol/L
   - Unit(B) = Unit(A) × Conversion coefficient

3. **Precision**
   - CV: 15%

4. **Correlation**
   - Correlation was evaluated between CLEIA method and FUJI DRI-CHEM IMMUNO AU CARTRIDGE v-COR using canine sera.

   This examination was carried out at the laboratory of FUJIFILM Corporation.

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

   - (2) Cross reactivity

<table>
<thead>
<tr>
<th>Compound</th>
<th>Concentration [μg/dL]</th>
<th>Cross reactivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prednisolone</td>
<td>10</td>
<td>27.8%</td>
</tr>
<tr>
<td>Prednisolone-16-glucuronide</td>
<td>10</td>
<td>27.8%</td>
</tr>
<tr>
<td>Prednisolone</td>
<td>10</td>
<td>27.8%</td>
</tr>
<tr>
<td>Corticosterone</td>
<td>100</td>
<td>6.3%</td>
</tr>
<tr>
<td>Cortisol</td>
<td>100</td>
<td>5.4%</td>
</tr>
<tr>
<td>11-Dehydropregnenolone</td>
<td>100</td>
<td>0.3%</td>
</tr>
<tr>
<td>Progesterone</td>
<td>1000</td>
<td>3.8%</td>
</tr>
<tr>
<td>Testosterone</td>
<td>1000</td>
<td>not detectable</td>
</tr>
<tr>
<td>11-Deoxycorticosterone</td>
<td>1000</td>
<td>0.2%</td>
</tr>
<tr>
<td>Aldosterone</td>
<td>1000</td>
<td>not detectable</td>
</tr>
</tbody>
</table>

(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. **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:** Expiry date is printed on the carton.
3. **Use immediately after opening the individual package.**

### [References]


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