FUJIFILM

Use after reading this "Instructions for Use"

For veterinary use only

FUJI DRI-CHEM SLIDE Comprehensive S-Panel

Date of issue: 1/Sep/2013

(TP,ALB,ALP,GLU,TBIL,IP,TCHO,GGT,GPT/ALT,Ca,CRE,BUN)

[Warnings and precautions]

1. Only the required number of S-Panel packages should be taken out of the refrigerator and warmed up to room temperature before opening the individual packages.
2. Do not damage a package of dry silica gel and the binding tape, when you open the S-Panel package especially with scissors.
3. A new package must be used for each measurement. Do not reuse.
4. Use immediately after opening the S-panel package.
5. Do not use slides that fell on the floor as it could be contaminated.
6. Do not touch either the center part of the surface or the back of the slide.
7. Do not use the slide if the individual package is damaged.
8. Keep QC card away from magnetic materials.
9. Handle all patient specimens, control serum and used tips carefully as biohazardous samples. Wear proper gloves, glasses and other protective gear for your safety.
10. Used slides 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.
11. Make sure to dispose dry silica gel in accordance with the Waste Disposal Law and other related regulations.

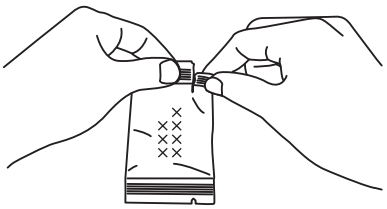
1910310

[Additional special equipment]

Analyzer: FUJI DRI-CHEM ANALYZER
Other implements: FUJI DRI-CHEM QC CARD (attached)
: FUJI AUTO TIPS
: FUJI HEPARIN/PLAIN TUBE or Blood collection tube specified in the "INSTRUCTION MANUAL" for FUJI DRI-CHEM ANALYZER

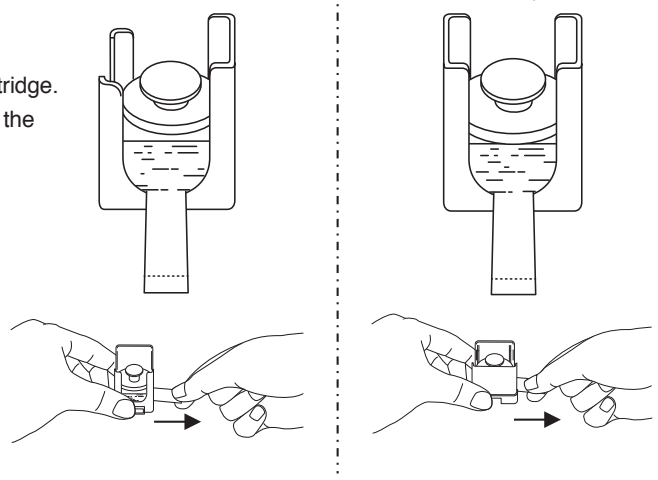
[Procedure]

1. Unwrap the package. Be sure to open gently from "V shaped" notch as shown in the figure. Do not rip the included pack of dry silica gel.



2. Take out slides from package. Do not touch either the center part of the surface or the back of the slide.
3. Place slides to be tested, barcode surface down, in the slide cartridge. Be sure to place an edge of the binding tape on the outside of the slide cartridge as shown in the figure.
4. Be sure to put the slide weight on top of the stacked slides.
5. Hold an edge of the binding tape. Pull out and remove the binding tape from the slide cartridge.

＜FDC7000＞ ＜FDC4000,NX500＞



6. Make sure the binding tape is removed completely from the slide cartridge.
7. Place the slide cartridge on the analyzer.
8. Read in the new QC-card when you switch to a new box of slides.
9. Set a sample tube in the specified sample rack.
10. Input a sequence No. and a sample ID if appropriate.
11. Press the "START" key to initiate testing. For further details of operation procedure, consult "INSTRUCTION MANUAL" for FUJI DRI-CHEM ANALYZER.

[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 and the individual packages.

[Contents]

Slide:	6 Panels/12 slides per Panel
QC card:	1
Desiccant:	1 silical gel pack per Panel

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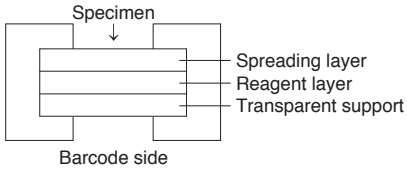
■TP

[Composition of the slide]

1. Multi-layered structure



2. Ingredients per slide

• Cupric sulfate pentahydrate 1.7 mg (6.9 µmol)

[Intended use]

Quantitative measurement of total protein concentration in plasma or serum.
For veterinary use only.

[Principle of the measurement]

10 µL of plasma or serum is deposited on a FUJI DRI-CHEM SLIDE TP-PIII. After depositing, the specimen spreads uniformly on the special spreading layer and reacts with the reactive reagent that was released from the reagent layer to form color. The slide is incubated at 37 °C for a fixed time in the FUJI DRI-CHEM ANALYZER and the optical reflection density is measured at 540 nm. The optical reflection density is then converted into the total protein concentration using a calibration curve preinstalled in the analyzer.

Protein + Cu^{2+} $\xrightarrow{\text{Alkaline}}$ Red purple color

[Specimen requirements]

1. After collecting the blood sample, immediate measurement is recommended.
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 monoiodoacetic acid.
3. Avoid using plasma or serum with precipitate such as fibrin.
4. Do not use hemolytic plasma or serum.
5. When the measured value exceeds the upper limit of the dynamic range, dilute the sample 2 times with distilled water or saline. Since the data obtained by dilution may deviate more widely than usual, the data should be treated as estimation.

[Performance characteristics]

1. Dynamic range 2.0–11.0 g/dL (20–110 g/L)

2. Accuracy

Concentration range	Accuracy
2.0–5.0 g/dL (20–50 g/L)	Within ±0.75 g/dL (Within ±7.5 g/L)
5.0–11.0 g/dL (50–110 g/L)	Within ±15 %

3. Precision

Concentration range	Precision
2.0–5.0 g/dL (20–50 g/L)	SD ≦ 0.25 g/dL (SD ≦ 2.5 g/L)
5.0–11.0 g/dL (50–110 g/L)	CV ≦ 5 %

4. Known interfering substances

The effects on the measured value were examined by adding substances as shown below to a serum sample obtained from a healthy volunteer or a control serum. No significant effect was observed to the following concentration for each substance.

Ascorbic acid	10 mg/dL (0.57 mmol/L)
Bilirubin	20 mg/dL (340 µmol/L)
Hemoglobin	1000 mg/L

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

[Internal quality control]

The accuracy and precision of this product can be evaluated with FUJI DRICHEM CONTROL QP-L and/or QP-H.

1. Select control level in accordance with your purpose.
2. Measure FUJI DRI-CHEM CONTROL QP-L and/or QP-H in the same way as patient specimens.
3. When the results obtained are outside the expected range shown in the sheet attached to FUJI DRI-CHEM CONTROL QP-L or QP-H, investigate the cause. For additional information, consult "Instructions for Use" for FUJI DRI-CHEM CONTROL QP-L or QP-H.

[Traceability of calibrators and control materials]

Total protein…NIST (SRM927)

Note: This reference material is applied to the reference method of FUJIFILM Corporation and is not directly applicable to FUJI DRI-CHEM SLIDE.

NIST: National Institute of Standards & Technology

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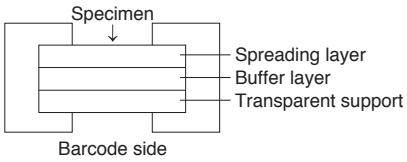
■ALB

[Composition of the slide]

1. Multi-layered structure



2. Ingredients per slide

• Bromcresol green 0.12 mg (0.18 μmol)

[Intended use]

Quantitative measurement of albumin concentration in plasma or serum.
For veterinary use only.

[Principle of the measurement]

10 μL of plasma or serum is deposited on a FUJI DRI-CHEM SLIDE ALB-P. After depositing, the specimen spreads uniformly on the spreading layer. In the process, albumin reacts with bromcresol green (BCG) to form an albumin-BCG complex.

The albumin-BCG complex diffuses onto the underlying layer. The slide is incubated at 37 °C for a fixed time in the FUJI DRI-CHEM ANALYZER and the optical reflection density is measured at 625 nm. The optical reflection density is then converted into the albumin concentration using calibration curve preinstalled in the analyzer.

Albumin + Bromcresol green ⟶ Blue color dye

[Specimen requirements]

1. After collection the blood sample, immediate measurement is recommended.
2. For plasma, heparin and EDTA salt can be used as the anticoagulant. When using heparin, less than 50 units of heparin should be used per 1 mL of whole blood. When using EDTA salt, less than 5 mg should be used per 1 mL of whole blood. Do not use sodium fluoride, citric acid, oxalic acid and monoiodoacetic acid.
3. Avoid using plasma or serum with precipitate such as fibrin.
4. Do not use hemolytic plasma or serum.

[Performance characteristics]

1. Dynamic range 1.0–6.0 g/dL (10–60 g/L)

2. Accuracy

Concentration range	Accuracy
1.0–6.0 g/dL (10–60 g/L)	Within ± 15 %

3. Precision

Concentration range	Precision
1.0–2.0 g/dL (10–20 g/L)	SD ≦ 0.1 g/dL (SD ≦ 1 g/L)
2.0–6.0 g/dL (20–60 g/L)	CV ≦ 5 %

4. Known interfering substances

(1) When albumin concentration is lower than the reference intervals and the A/G ratio is low, the result may have a plus bias.

(2) The effects on the measured value were examined by adding substances as shown below to a serum sample obtained from a healthy volunteer or a control serum. No significant effect was observed to the following concentration for each substance.

Ascorbic acid	10 mg/dL (0.57 mmol/L)
Bilirubin	20 mg/dL (340 μmol/L)
Hemoglobin	1000 mg/L

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

[Internal quality control]

The accuracy and precision of this product can be evaluated with FUJI DRICHEM CONTROL QP-L and/or QP-H.

1. Select control level in accordance with your purpose.
2. Measure FUJI DRI-CHEM CONTROL QP-L and/or QP-H in the same way as patient specimens.
3. When the results obtained are outside the expected range shown in the sheet attached to FUJI DRI-CHEM CONTROL QP-L or QP-H, investigate the cause. For additional information, consult "Instructions for Use" for FUJI DRI-CHEM CONTROL QP-L or QP-H.

[Traceability of calibrators and control materials]

Albumin…IRMM (CRM470)

Note: This reference material is applied to the reference method of FUJIFILM Corporation and is not directly applicable to FUJI DRI-CHEM SLIDE.

IRMM: Institute for Reference Materials and Measurement

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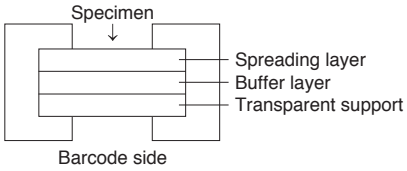
■ALP

[Composition of the slide]

1. Multi-layered structure



2. Ingredients per slide

• p-Nitrophenyl phosphate 0.075 mg (0.18 μmol)

[Intended use]

Quantitative measurement of alkaline phosphatase in plasma or serum.
For veterinary use only.

[Principle of the measurement]

10 μL of plasma or serum is deposited on a FUJI DRI-CHEM SLIDE ALP-PIII. The spotted specimen is incubated at 37 °C and catalyses the hydrolyzing reaction of co-existing p-nitrophenyl phosphate while spreading uniformly in the spreading layer. The p-nitrophenyl dye formed with the start of the reaction is diffused and collected in the buffer layer. Increase in absorption by the generated dye is measured from 2 min to 4 min at 400 nm by reflective spectrophotometry and the ALP activity is calculated according to the installed formula.

p-Nitrophenyl phosphate $\xrightarrow{\text{ALP}}$ p-Nitrophenyl dye + Phosphoric acid

[Specimen requirements]

1. After collecting the blood specimen, immediate measurement is recommended.
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 monoiodoacetic acid.
3. Avoid using plasma or serum with precipitate such as fibrin.
4. Do not use hemolytic plasma or serum.
5. When the specimen containing a high concentration (over 170 μmol/L (10 mg/dL)) of bilirubin is measured, error may occur in a low-concentration region. In such a case, dilute the specimen 5 times with the purified water and reanalyze. If you dilute specimen in the analyzer with auto-dilution function, the measured result is multiplied 5 times automatically.
6. When the measured value exceeds the upper limit of the dynamic range, dilute the sample with distilled water. Do not use saline. Since the data obtained by dilution may deviate more widely than usual, the data should be treated as estimation.
7. When the specimen containing high concentration of ALP5 (small intestine originated isozyme) is measured, the result may give minus bias compared to the JSCC Standard Method which uses the EAE buffer.

[Performance characteristics]

1. Dynamic range 50–3500 U/L (0.84–58.45 μkat/L)

2. Accuracy

Concentration range	Accuracy
50–120 U/L (0.84–2.00 μkat/L)	Within ± 24 U/L (Within ± 0.40 μkat/L)
120–3500 U/L (2.00–58.45 μkat/L)	Within ± 20 %

3. Precision

Concentration range	Precision
50–240 U/L (0.84–4.00 μkat/L)	SD ≦ 12 U/L (SD ≦ 0.20 μkat/L)
240–3500 U/L (4.00–58.45 μkat/L)	CV ≦ 5 %

4. Known interfering substances

(1) Theopylline gives minus bias.
(2) Increase of bilirubin gives plus bias.
(3) Lower protein concentration gives plus bias.
(4) The effects on the measured value were examined by adding substances as shown below to a serum sample obtained from a healthy volunteer or a control serum. No significant effect was observed to the following concentration for each substance.

Ascorbic acid 10 mg/dL (0.57 mmol/L)

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

[Internal quality control]

The accuracy and precision of this product can be evaluated with FUJI DRICHEM CONTROL QP-L and/or QP-H.

1. Select control level in accordance with your purpose.
2. Measure FUJI DRI-CHEM CONTROL QP-L and/or QP-H in the same way as patient specimens.
3. When the results obtained are outside the expected range shown in the sheet attached to FUJI DRI-CHEM CONTROL QP-L or QP-H, investigate the cause. For additional information, consult "Instructions for Use" for FUJI DRI-CHEM CONTROL QP-L or QP-H.

[Traceability of calibrators and control materials]

ALP...JCCLS (ERM)

Note: This reference material is applied to the reference method of FUJIFILM Corporation and is not directly applicable to FUJI DRI-CHEM SLIDE. The assigned value is traceable to the JSCC Standard Method.

JCCLS: Japanese Committee for Clinical Laboratory Standards

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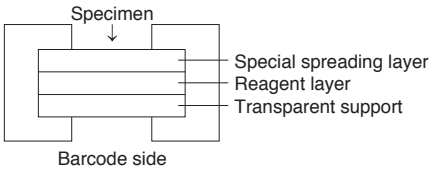
■GLU

[Composition of the slide]

1. Multi-layered structure



2. Ingredients per slide

• Glucose oxidase	0.95 U
• 1,7-Dihydroxynaphthalene	0.03 mg (0.19 µmol)
• 4-Aminoantipyrine	0.086 mg (0.42 µmol)
• Peroxidase	16 U

[Intended use]

Quantitative measurement of glucose concentration in plasma or serum.
For veterinary use only.

[Principle of the measurement]

10 µL of plasma or serum is deposited on a FUJI DRI-CHEM SLIDE GLU-PIII. After depositing, the specimen spreads uniformly on the spreading layer and diffuses into the underlying layer. As the process proceeds, large molecular components such as proteins or dye components are filtrated, and only small molecular components are able to permeate and diffuse into the reagent layer. Glucose oxidase (GOD) catalyzes the oxidization of sample glucose to generate hydrogen peroxide. In the presence of peroxidase (POD), hydrogen peroxide reacts with dye precursors and finally forms red dye. The slide is incubated at 37 °C for a fixed time in the FUJI DRI-CHEM ANALYZER and the optical reflection density is measured at 505 nm. The optical reflection density is then converted into the glucose concentration using a calibration curve preinstalled in the analyzer.

$$\text{Glucose} + O_2 + H_2O \xrightarrow{\text{GOD}} \text{Gluconic acid} + H_2O_2$$

$$\text{1,7-Dihydroxynaphthalene} + \text{4-Aminoantipyrine} + H_2O_2 \xrightarrow{\text{POD}} \text{Red dye}$$

[Specimen requirements]

1. (1) Blood collection tube containing sodium fluoride or monoiodoacetic acid as glycolytic inhibitor is acceptable. When sodium fluoride is used as glycolytic inhibitor, the amount of sodium fluoride should be 2.5 mg per 1 mL of whole blood or less.
   (2) Measurement of the specimen should be performed immediately because glycolysis will proceed gradually even when glycolytic inhibitor is added.
2. Avoid using plasma or serum with precipitate such as fibrin.
3. When the measured value exceeds the upper limit of the dynamic range, dilute the sample with distilled water or saline. Since the data obtained by dilution may deviate more widely than usual, the data should be treated as estimation.

[Performance characteristics]

1. Dynamic range 10–600 mg/dL (0.6–33.3 mmol/L)

2. Accuracy

Concentration range	Accuracy
10–100 mg/dL (0.6–5.6 mmol/L)	Within ± 15 mg/dL (Within ± 0.8 mmol/L)
100–600 mg/dL (5.6–33.3 mmol/L)	Within ± 15 %

3. Precision

Concentration range	Precision
10–100 mg/dL (0.6–5.6 mmol/L)	SD ≦ 5 mg/dL (SD ≦ 0.3 mmol/L)
100–600 mg/dL (5.6–33.3 mmol/L)	CV ≦ 5 %

4. Known interfering substances

(1) Increase of ascorbic acid gives minus bias.

(2) The effects on the measured value were examined by adding substances as shown below to a plasma specimen obtained from a healthy volunteer or a control serum. No significant effect was observed to the following concentration for each substance.

Bilirubin	20 mg/dL (340 µmol/L)
Hemoglobin	5000 mg/L
Total protein	50–90 g/L

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

[Internal quality control]

The accuracy and precision of this product can be evaluated with FUJI DRICHEM CONTROL QP-L and/or QP-H.

1. Select control level in accordance with your purpose.
2. Measure FUJI DRI-CHEM CONTROL QP-L and/or QP-H in the same way as patient specimens.
3. When the results obtained are outside the expected range shown in the sheet attached to FUJI DRI-CHEM CONTROL QP-L or QP-H, investigate the cause. For additional information, consult "Instructions for Use" for FUJI DRI-CHEM CONTROL QP-L or QP-H.

[Traceability of calibrators and control materials]

Glucose…NIST (SRM917)

Note: This reference material is applied to the reference method of FUJIFILM Corporation and is not directly applicable to FUJI DRI-CHEM SLIDE.

NIST: National Institute of Standards & Technology

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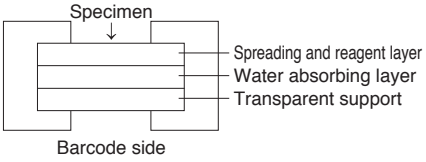
■TBIL

[Composition of the slide]

1. Multi-layered structure



2. Ingredients per slide

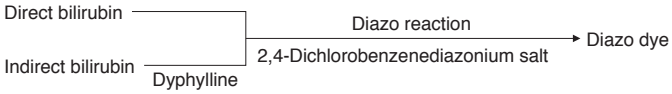
- 2,4-Dichlorobenzenediazonium salt 0.14 mg (0.36 µmol)
- Dyphylline 3.1 mg (12 µmol)

[Intended use]

Quantitative measurement of total bilirubin concentration in plasma or serum.
For veterinary use only.

[Principle of the measurement]

10 µL of plasma is deposited on a FUJI DRI-CHEM SLIDE TBIL-PIII. After depositing, the specimen spreads uniformly on the spreading and reagent layer and indirect bilirubin is dissociated with dyphylline and undergoes diazo reaction together with direct bilirubin by 2,4-dichlorobenzenediazonium salt to form diazo dye. The slide is incubated at 37 °C for a fixed time in the FUJI DRI-CHEM ANALYZER and the optical reflection density is measured at 540 nm. The optical reflection density is then converted into the total birilubin concentration using a calibration curve preinstalled in the analyzer.



[Specimen requirements]

1. After collecting the blood specimen, immediate measurement is recommended.
2. For plasma, heparin and EDTA·2Na can be used as the anticoagulant. When using heparin, less than 100 units of heparin should be used per 1 mL of whole blood. When using EDTA·2Na, less than 10 mg should be used per 1 mL of whole blood. Do not use EDTA·2K, sodium fluoride, citric acid, oxalic acid and monoiodoacetic acid.
3. Avoid using plasma with precipitate such as fibrin.
4. Do not use hemolyzed plasma or serum.
5. Bilirubin is known to deteriorate under light. Do not put the specimen under strong light, especially sunlight.
6. When the measured value exceeds the upper limit of the dynamic range, dilute the sample with distilled water or saline. Since the data obtained by dilution may deviate more widely than usual, the data should be treated as estimation.

[Performance characteristics]

1. Dynamic range 0.2–30.0 mg/dL (3–513 µmol/L)

2. Accuracy

Concentration range	Accuracy
0.2–3.0 mg/dL (3–51 µmol/L)	Within ± 0.4 mg/dL (Within ± 7 µmol/L)
3.0–30.0 mg/dL (51–513 µmol/L)	Within ± 20 %

3. Precision

Concentration range	Precision
0.2–3.0 mg/dL (3–51 µmol/L)	SD ≦ 0.15 mg/dL (SD ≦ 3 µmol/L)
3.0–30.0 mg/dL (51–513 µmol/L)	CV ≦ 5 %

4. Known interfering substances

(1) An antibiotics, cefotiam gives plus bias.
(2) Specimen of renal failure patient is known to have endogenous substance which effect the measurement.
(3) The effects on the measured value were examined by adding substances as shown below to a serum sample obtained from a healthy volunteer or a control serum. No significant effect was observed to the following concentration for each substance.

Ascorbic acid	10 mg/dL (0.57 mmol/L)
Hemoglobin	500 mg/L
Total protein	50–90 g/L*

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

*At the normal range of total bilirubin concentration.

[Internal quality control]

The accuracy and precision of this product can be evaluated with FUJI DRICHEM CONTROL QP-L and/or QP-H.

1. Select control level in accordance with your purpose.
2. Measure FUJI DRI-CHEM CONTROL QP-L and/or QP-H in the same way as patient specimens.
3. When the results obtained are outside the expected range shown in the sheet attached to FUJI DRI-CHEM CONTROL QP-L or QP-H, investigate the cause. For additional information, consult "Instructions for Use" for FUJI DRI-CHEM CONTROL QP-L or QP-H.

[Traceability of calibrators and control materials]

Total bilirubin…NIST (SRM916)
Note: This reference material is applied to the reference method of FUJIFILM Corporation and is not directly applicable to FUJI DRI-CHEM SLIDE.
NIST: National Institute of Standards & Technology

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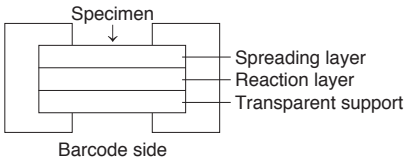
■IP

[Composition of the slide]

1. Multi-layered structure



2. Ingredients per slide

• Xanthosine	0.25 mg (0.87 μmol)
• Purine nucleoside phosphorylase	0.35 U
• Diarylimidazole leuco dye	0.044 mg (0.088 μmol)
• Xanthine oxidase	0.71 U
• Peroxidase	2.4 U

[Intended use]

Quantitative measurement of inorganic phosphorus concentration in plasma or serum.

For veterinary use only.

[Principle of the measurement]

10 μL of plasma or serum is deposited on a FUJI DRI-CHEM SLIDE IP-P. After depositing, the specimen spreads uniformly on the spreading layer and diffuses into the underlying reaction layer. As the process proceeds, large molecular components such as proteins or dye components are filtrated, and only small molecular components are able to permeate and diffuse into the reaction layer. The inorganic phosphorous in solution reacts with xanthosine by purine nucleoside phosphorylase (PNP), producing xanthine in the reaction layer. Xanthine then reacts with xanthine oxidase (XOD), producing hydrogen peroxide. With peroxidase (POD), hydrogen peroxide reacts with leuco-dye, producing imidazole blue color dye. The slide is incubated at 37 °C for a fixed time in the FUJI DRI-CHEM ANALYZER and the optical reflection density is measured at 650 nm. The optical reflection density is then converted into the inorganic phosphorus concentration using a calibration curve preinstalled in the analyzer.

$$\text{Xanthosine + Inorganic phosphorus } (H_2PO_4^-, HPO_4^{2-}) \xrightarrow{PNP} \text{Xanthine + Ribose 1-phosphate}$$

$$\text{Xanthine + } H_2O + O_2 \xrightarrow{XOD} \text{Uric acid + } H_2O_2$$

$$\text{Diarylimidazole leuco dye + } H_2O_2 \xrightarrow{POD} \text{Blue color dye + } 2H_2O$$

[Specimen requirements]

1. For plasma, heparin and EDTA salt can be used as the anticoagulant. When using heparin, less than 50 unit of heparin should be used per 1 mL of whole blood. When using EDTA salt, less than 5 mg should be used per 1 mL of whole blood. Do not use sodium fluoride, citric acid, oxalic acid and monoiodoacetic acid.
2. Avoid using plasma or serum with precipitate such as fibrin.
3. Do not use hemolytic plasma or serum.
4. When the measured value exceeds the upper limit of the dynamic range, dilute the sample with distilled water or saline. Since the data obtained by dilution may deviate more widely than usual, the data should be treated as estimation.

[Performance characteristics]

1. Dynamic range 0.5–15.0 mg/dL (0.16–4.84 mmol/L)

2. Accuracy

Concentration range	Accuracy
0.5–3.0 mg/dL (0.16–0.97 mmol/L)	Within ± 0.45 mg/dL (Within ± 0.15 mmol/L)
3.0–15.0 mg/dL (0.97–4.84 mmol/L)	Within ± 15 %

3. Precision

Concentration range	Precision
0.5–4.0 mg/dL (0.16–1.29 mmol/L)	SD ≦ 0.2 mg/dL (SD ≦ 0.06 mmol/L)
4.0–15.0 mg/dL (1.29–4.84 mmol/L)	CV ≦ 6 %

4. Known interfering substances

(1) Dobutamine hydrochloride (cardiotonic reagent) and dopamine hydrochloride (cardiotonic reagent) give minus bias.

(2) The effects on the measured value were examined by adding substances as shown below to a serum sample obtained from a healthy volunteer or a control serum. No significant effect was observed to the following concentration for each substance.

Ascorbic acid	10 mg/dL (0.57 mmol/L)
Bilirubin	20 mg/dL (340 μmol/L)
Hemoglobin	3000 mg/L
Total protein	40～95 g/L*
Uric Acid	20 mg/dL (1190 μmol/L)

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

* At the normal range of IP concentration.

[Internal quality control]

The accuracy and precision of this product can be evaluated with FUJI DRICHEM CONTROL QP-L and/or QP-H.

1. Select control level in accordance with your purpose.
2. Measure FUJI DRI-CHEM CONTROL QP-L and/or QP-H in the same way as patient specimens.
3. When the results obtained are outside the expected range shown in the sheet attached to FUJI DRI-CHEM CONTROL QP-L or QP-H, investigate the cause. For additional information, consult "Instructions for Use" for FUJI DRI-CHEM CONTROL QP-L or QP-H.

[Traceability of calibrators and control materials]

Inorganic Phosphorus…NIST (SRM200)

Note: This reference material is applied to the reference method of FUJIFILM Corporation and is not directly applicable to FUJI DRI-CHEM SLIDE.

NIST: National Institute of Standards & Technology

Comprehensive S-Panel

FUJIFILM

Use after reading this "Instructions for Use"

For veterinary use only

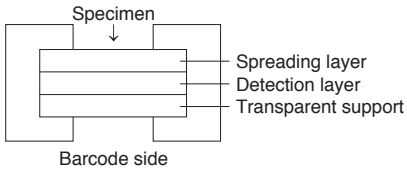
FUJI DRI-CHEM SLIDE Comprehensive S-Panel

Date of issue: 1/Sep/2013 **(TP, ALB, ALP, GLU, TBIL, IP, TCHO, GGT, GPT/ALT, Ca, CRE, BUN)**

■TCHO

[Composition of the slide]

1. Multi-layered structure



2. Ingredients per slide

- Cholesterol esterase 0.38 U
- Cholesterol oxidase 0.67 U
- Peroxidase 7.1 U
- Diarylimidazole leuco dye 0.075 mg (0.15 µmol)

3. Other Ingredients

- Surfactant
- Potassium ferrocyanide

[Intended use]

Quantitative measurement of total cholesterol concentration in plasma or serum.
For veterinary use only.

[Principle of the measurement]

10 µL of plasma or serum is deposited on a FUJI DRI-CHEM SLIDE TCHO-PIII. After depositing, the specimen spreads uniformly on the spreading layer and lipoproteins are dissociated to lipid (cholesterol) and protein by the action of surfactant. Following this, cholesterol ester is hydrolyzed to produce free form of the cholesterol by cholesterol esterase (CHE). This free cholesterol and endogenous cholesterol generate hydrogen peroxide by the reaction with cholesterol oxidase (COD). Hydrogen peroxide and peroxidase (POD) oxidize leuco-dye to form the blue color dye. The slide is incubated at 37 °C for a fixed time in the FUJI DRI-CHEM ANALYZER and the optical reflection density is measured at 505 nm. The change in optical reflection density is then converted into the total cholesterol concentration using a calibration curve preinstalled in the analyzer.

$$\text{Lipoprotein} \xrightarrow{\text{Surfactant}} \text{Cholesterol} + \text{Cholesterol ester} + \text{Protein}$$

$$\text{Cholesterol ester} + H_2O \xrightarrow{\text{CHE}} \text{Cholesterol (free)} + \text{Fatty acid}$$

$$\text{Cholesterol} + O_2 \xrightarrow{\text{COD}} H_2O_2 + \text{Cholestenon}$$

$$\text{Diarylimidazole leuco dye} + H_2O_2 \xrightarrow{\text{POD}} \text{Blue color dye} + 2H_2O$$

[Specimen requirements]

1. After collecting the blood specimen, immediate measurement is recommended.
2. For plasma, heparin or EDTA salt can be used as the anticoagulant. When using heparin, less than 50 units of heparin should be used per 1 mL of whole blood. When using EDTA salt, less than 5 mg should be used per 1 mL of whole blood. Do not use sodium fluoride, citric acid, oxalic acid and monoiodoacetic acid.
3. Avoid using plasma or serum with precipitate such as fibrin.
4. High concentration of triglycerides may cause minus bias to the measurement value.
5. When the measured value exceeds the upper limit of the dynamic range, dilute the sample with distilled water or saline. Since the data obtained by dilution may deviate more widely than usual, the data should be treated as estimation.

[Performance characteristics]

1. Dynamic range 50–450 mg/dL (1.29–11.64 mmol/L)

2. Accuracy

Concentration range	Accuracy
50–450 mg/dL (1.29–11.64 mmol/L)	Within ±15 %

3. Precision

Concentration range	Precision
50–450 mg/dL (1.29–11.64 mmol/L)	CV ≦ 5 %

4. Known interfering substances

(1) Dobutamine hydrochloride (cardiotonic reagent) gives minus bias.

(2) The effects on the measured value were examined by adding substances as shown below to a serum sample obtained from a healthy volunteer or a control serum. No significant effect was observed to the following concentration for each substance.

Ascorbic acid	10 mg/dL (0.57 mmol/L)
Bilirubin	10 mg/dL (170 µmol/L)
Hemoglobin	3000 mg/L
Total protein	45–85 g/L
Uric acid	2–9 mg/dL (119–536 µmol/L)

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

[Internal quality control]

The accuracy and precision of this product can be evaluated with FUJI DRICHEM CONTROL QP-L and/or QP-H.

1. Select control level in accordance with your purpose.
2. Measure FUJI DRI-CHEM CONTROL QP-L and/or QP-H in the same way as patient specimens.
3. When the results obtained are outside the expected range shown in the sheet attached to FUJI DRI-CHEM CONTROL QP-L or QP-H, investigate the cause. For additional information, consult "Instructions for Use" for FUJI DRI-CHEM CONTROL QP-L or QP-H.

[Traceability of calibrators and control materials]

Total cholesterol…NIST (SRM1951)

Note: This reference material is applied to the reference method of FUJIFILM Corporation and is not directly applicable to FUJI DRI-CHEM SLIDE.

NIST: National Institute of Standards & Technology

1910310

Comprehensive S-Panel

FUJIFILM

Use after reading this "Instructions for Use"

For veterinary use only

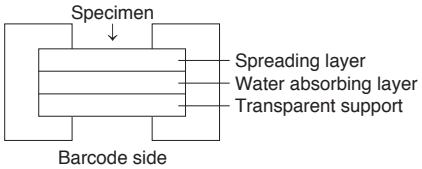
FUJI DRI-CHEM SLIDE Comprehensive S-Panel

Date of issue: 1/Sep/2013 **(TP, ALB, ALP, GLU, TBIL, IP, TCHO, GGT, GPT/ALT, Ca, CRE, BUN)**

■GGT(γ-GTP)

[Composition of the slide]

1. Multi-layered structure



2. Ingredients per slide

- L-γ-glutamyl-p-nitroanilide 0.078mg (0.27μmol)
- Glycilglycine 0.25mg (1.9μmol)

[Intended use]

Quantitative measurement of γ-glutamyltransferase activity in plasma or serum.
For veterinary use only.

[Principle of the measurement]

10 μL of plasma or serum is deposited on a FUJI DRI-CHEM SLIDE GGT-PIII. After depositing, the specimen spreads uniformly on the spreading layer. In the process, γ-GTP(GGT) in the specimen catalyses the amino-transition reaction with the substrate of L-γ-glutamyl-p-nitroanilide. Increase in absorption by the generated dye is measured from 2 min to 5 min at 400nm by reflective spectrophotometry and the γ-GTP(GGT) activity is calculated according to the installed formula.

L-γ-Glutamyl-p-nitroanilide + Glycylglycine $\xrightarrow{\gamma\text{-GTP}}$ L-Glutamylglycylglycine + p-Nitroaniline

[Specimen requirements]

1. After collecting the blood specimen, immediate measurement is recommended.
2. For plasma, heparin can be used as the anticoagulant. When using heparin, less than 40 units of heparin should be used per 1 mL of whole blood. Do not use EDTA salt, sodium fluoride, citric acid, oxalic acid and monoiodoacetic acid.
3. Avoid using plasma or serum with precipitate such as fibrin.
4. Do not use hemolytic plasma or serum.
5. When the measured value exceeds the upper limit of the dynamic range, dilute the sample with distilled water or saline. Since the data obtained by dilution may deviate more widely than usual, the data should be treated as estimation.

[Performance characteristics]

1. Dynamic range 10–1200 U/L (0.17–20.04 μkat/L)

2. Accuracy

Concentration range	Accuracy
10–50 U/L (0.17–0.84 μkat/L)	Within ± 10 U/L (Within ± 0.17 μkat/L)
50–1200 U/L (0.84–20.04 μkat/L)	Within ± 20%

3. Precision

Concentration range	Precision
10–60 U/L (0.17–1.00 μkat/L)	SD ≦ 3 U/L (SD ≦ 0.05 μkat/L)
60–1200 U/L (1.00–20.04 μkat/L)	CV ≦ 5 %

4. Known interfering substances

The effects on the measured value were examined by adding substances as shown below to a serum sample obtained from a healthy volunteer or a control serum. No significant effect was observed to the following concentration for each substance.

Ascorbic acid	10 mg/dL (0.57 mmol/L)
Bilirubin	10 mg/dL (170 μmol/L)
Total protein	40–95 g/L

These results are representative;

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

[Internal quality control]

The accuracy and precision of this product can be evaluated with FUJI DRICHEM CONTROL QP-L and/or QP-H.

1. Select control level in accordance with your purpose.
2. Measure FUJI DRI-CHEM CONTROL QP-L and/or QP-H in the same way as patient specimens.
3. When the results obtained are outside the expected range shown in the sheet attached to FUJI DRI-CHEM CONTROL QP-L or QP-H, investigate the cause. For additional information, consult "Instructions for Use" for FUJI DRI-CHEM CONTROL QP-L or QP-H.

[Traceability of calibrators and control materials]

γ-GTP…JCCLS (ERM)

Note: This reference material is applied to the reference method of FUJIFILM Corporation and is not directly applicable to FUJI DRI-CHEM SLIDE.

JCCLS: Japanese Committee for Clinical Laboratory Standards

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Comprehensive S-Panel

FUJIFILM

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For veterinary use only

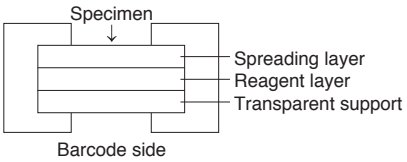
FUJI DRI-CHEM SLIDE Comprehensive S-Panel

Date of issue: 1/Sep/2013 **(TP, ALB, ALP, GLU, TBIL, IP, TCHO, GGT, GPT/ALT, Ca, CRE, BUN)**

■GPT/ALT

[Composition of the slide]

1. Multi-layered structure



2. Ingredients per slide

• L-Alanine	0.44 mg (4.9 µmol)
• α-Ketoglutaric acid disodium salt	0.064 mg (0.28 µmol)
• Potassium phosphate	0.072 mg (0.53 µmol)
• Pyruvate oxidase	0.54 U
• Peroxidase	2.4 U
• Diarylimidazole leuco dye	0.044 mg (0.09 µmol)

[Intended use]

Quantitative measurement of glutamic pyruvic transaminase (alanine aminotransferase) activity in plasma or serum.
For veterinary use only.

[Principle of the measurement]

10 µL of plasma or serum is deposited on a FUJI DRI-CHEM SLIDE GPT/ALTPIII. The slide is incubated at 37 °C and GPT in the sample catalyses the amino-transition reaction with the substrate of L-alanine after spreading uniformly in the spreading layer. Pyruvic acid produced by the reaction generates hydrogen peroxide by pyruvate oxidase (POP). Hydrogen peroxide oxidizes diarylimidazole leuco dye by the catalytic reaction of peroxidase (POD) and forms a blue color dye. The increase of absorbance by the generated dye is measured from 2.5 min to 4 min at 650 nm by reflective spectrophotometry and the GPT activity is calculated according to the installed formula.

$$\text{L-Alanine} + \alpha\text{-Ketoglutaric acid} \xrightarrow{\text{GPT}} \text{Pyruvic acid} + \text{L-Glutamic acid}$$

$$\text{Pyruvic acid} + O_2 + \text{Phosphoric acid} + H_2O \xrightarrow{\text{POP}} H_2O_2 + \text{Acetyl phosphate} + CO_2$$

$$\text{Diarylimidazole leuco dye} + H_2O_2 \xrightarrow{\text{POD}} \text{Blue color dye} + 2H_2O$$

[Specimen requirements]

1. After collecting the blood sample, immediate measurement is recommended.
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 monoiodoacetic acid.
3. Avoid using plasma or serum with precipitate such as fibrin.
4. Do not use hemolytic plasma or serum.
5. When the measured value exceeds the upper limit of the dynamic range, dilute the sample with distilled water or saline. Since the data obtained by dilution may deviate more widely than usual, the data should be treated as estimation.

[Performance characteristics]

1. Dynamic range 10–1000 U/L (0.17–16.70 µkat/L)

2. Accuracy

Concentration range	Accuracy
10–30 U/L (0.17–0.50 µkat/L)	Within ± 6 U/L (Within ± 0.10 µkat/L)
30–1000 U/L (0.50–16.70 µkat/L)	Within ± 20 %

3. Precision

Concentration range	Precision
10–60 U/L (0.17–1.00 µkat/L)	SD ≦ 3 U/L (SD ≦ 0.05 µkat/L)
60–1000 U/L (1.00–16.70 µkat/L)	CV ≦ 5 %

4. Known interfering substances

(1) Dobutamine hydrochloride (cardiotonic reagent) and dopamine hydrochloride (cardiotonic reagent) give minus bias.

(2) The effects on the measured value were examined by adding substances as shown below to a serum sample obtained from a healthy volunteer or a control serum. No significant effect was observed to the following concentration for each substance.

Ascorbic acid	10 mg/dL (0.57 mmol/L)
Bilirubin	20 mg/dL (340 µmol/L)
Pyruvic acid	2 mg/dL (0.23 mmol/L)
Total protein	40–95 g/L

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

[Internal quality control]

The accuracy and precision of this product can be evaluated with FUJI DRICHEM CONTROL QP-L and/or QP-H.

1. Select control level in accordance with your purpose.
2. Measure FUJI DRI-CHEM CONTROL QP-L and/or QP-H in the same way as patient specimens.
3. When the results obtained are outside the expected range shown in the sheet attached to FUJI DRI-CHEM CONTROL QP-L or QP-H, investigate the cause. For additional information, consult "Instructions for Use" for FUJI DRI-CHEM CONTROL QP-L or QP-H.

[Traceability of calibrators and control materials]

GPT...JCCLS (ERM)

Note: This reference material is applied to the reference method of FUJIFILM Corporation and is not directly applicable to FUJI DRI-CHEM SLIDE.

JCCLS: Japanese Committee for Clinical Laboratory Standards

FUJIFILM

Use after reading this "Instructions for Use"

For veterinary use only

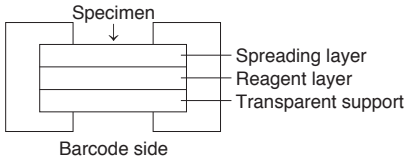
FUJI DRI-CHEM SLIDE Comprehensive S-Panel

Date of issue: 1/Sep/2013 **(TP, ALB, ALP, GLU, TBIL, IP, TCHO, GGT, GPT/ALT, Ca, CRE, BUN)**

■Ca

[Composition of the slide]

1. Multi-layered structure



2. Ingredients per slide

• Chlorophosphonazo III 0.058 mg (0.072 µmol)

[Intended use]

Quantitative measurement of calcium concentration in plasma or serum.
For veterinary use only.

[Principle of the measurement]

10 µL of plasma or serum is deposited on a FUJI DRI-CHEM SLIDE Ca-PIII. The deposited specimen spreads uniformly in the spreading layer, where bound type calcium is converted to free type calcium by the dissociation agent contained in the layer. The free calcium penetrates into the reagent layer and reacts with chlorophosphonazo III to form a dye. The slide is incubated at 37 °C for a fixed time in the FUJI DRI-CHEM ANALYZER and the optical reflection density is measured at 625 nm. The optical reflection density is then converted into the calcium concentration using a calibration curve preinstalled in the analyzer.

Ca^{2+} + Bound type Ca $\xrightarrow{\text{Dissociation agent}}$ Ca^{2+}

Ca^{2+} + Chlorophosphonazo III $\longrightarrow$ Ca-Chlorophosphonazo III

[Specimen requirements]

1. After collecting the blood specimen, immediate measurement is recommended.
2. For plasma, heparin is recommended to use as an anticoagulant.
3. The amount of heparin should be used less than 50 units per 1 mL of blood. EDTA salt should not be used because of serious interference for calcium determination (calcium concentration ≦ 1.00 mmol/L). Do not use sodium fluoride, citric acid, oxalic acid and monoiodoacetic acid.
4. Avoid using plasma or serum with precipitate such as fibrin.
5. When the measured value exceeds the upper limit of the dynamic range, dilute the sample with distilled water. Since the data obtained by dilution may deviate more widely than usual, the data should be treated as estimation. The saline should not be used because the error may become large.

[Performance characteristics]

1. Dynamic range 4.0–16.0 mg/dL (1.00–4.00 mmol/L)

2. Accuracy

Concentration range	Accuracy
4.0–7.0 mg/dL (1.00–1.75 mmol/L)	Within ± 1.0 mg/dL (Within ± 0.25 mmol/L)
7.0–16.0 mg/dL (1.75–4.00 mmol/L)	Within ± 15 %

3. Precision

Concentration range	Precision
4.0–7.0 mg/dL (1.00–1.75 mmol/L)	SD ≦ 0.35 mg/dL (SD ≦ 0.09 mmol/L)
7.0–16.0 mg/dL (1.75–4.00 mmol/L)	CV ≦ 5 %

4. Known interfering substances

The effects on the measured value were examined by adding substances as shown below to a serum sample obtained from a healthy volunteer or a control serum. No significant effect was observed to the following concentration for each substance.

Ascorbic acid	10 mg/dL (0.57 mmol/L)
Bilirubin	20 mg/dL (340 µmol/L)
Hemoglobin	3000 mg/L
Total protein	40–95 g/L
Magnesium	3 mg/dL (1.25 mmol/L)

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

[Internal quality control]

The accuracy and precision of this product can be evaluated with FUJI DRICHEM CONTROL QP-L and/or QP-H.

1. Select control level in accordance with your purpose.
2. Measure FUJI DRI-CHEM CONTROL QP-L and/or QP-H in the same way as patient specimens.
3. When the results obtained are outside the expected range shown in the sheet attached to FUJI DRI-CHEM CONTROL QP-L or QP-H, investigate the cause. For additional information, consult "Instructions for Use" for FUJI DRI-CHEM CONTROL QP-L or QP-H.

[Traceability of calibrators and control materials]

Calcium…HECTEF (CA-6)

Note: This reference material is applied to the reference method of FUJIFILM Corporation and is not directly applicable to FUJI DRI-CHEM SLIDE.

HECTEF: Health Care Technology Foundation

FUJIFILM

Use after reading this "Instructions for Use"

For veterinary use only

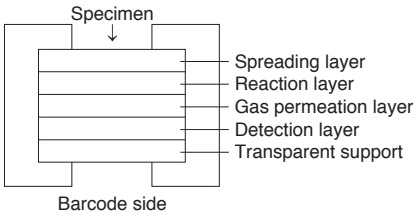
FUJI DRI-CHEM SLIDE Comprehensive S-Panel

Date of issue: 1/Sep/2013 **(TP, ALB, ALP, GLU, TBIL, IP, TCHO, GGT, GPT/ALT, Ca, CRE, BUN)**

■CRE

[Composition of the slide]

1. Multi-layered structure



2. Ingredients per slide

- Creatinine deiminase 0.28 U
- Bromphenol blue 0.018 mg (0.026 μmol)

3. Other ingredients

- α-Ketoglutaric acid disodium salt
- Glutamate dehydrogenase
- NADPH

[Intended use]

Quantitative measurement of creatinine concentration in plasma or serum.
For veterinary use only.

[Principle of the measurement]

10 μL of plasma or serum is deposited on a FUJI DRI-CHEM SLIDE CRE-PIII. The spotted specimen diffuses into the underlying layers after spreading uniformly in the spreading layer. The specimen diffuses and penetrates into the reaction layer. Endogenous ammonia is removed by the action of α-ketoglutaric acid, glutamate dehydrogenase (GLDH) and NADPH. Creatinine is decomposed by the action of creatinine deiminase (CD) in the reaction layer and ammonia gas is generated. The ammonia gas passes through the gas permeation layer and reaches detection layer.

The color of bromphenol blue contained in the detection layer changes from yellow to blue. The slide is incubated at 37 °C for a fixed time in the FUJI DRI-CHEM ANALYZER and the optical reflection density is measured at 600 nm. The optical reflection density is then converted into the creatinine concentration using a calibration curve preinstalled in the analyzer.

NH_3 (endogenous) + α-Ketoglutaric acid + NADPH $\xrightarrow{GLDH}$ L-Glutamic acid + $NADP^+$

Creatinine + $H_2O \xrightarrow{CD}$ N-Methylhydantoin + NH_3

Bromphenol blue + $NH_3 \longrightarrow$ Blue color dye

[Specimen requirements]

1. For plasma, heparin and EDTA salt can be used as the anticoagulant. The amount of heparin and EDTA salt should be used less than 100 units and 5 mg per 1 mL of whole blood, respectively. Do not use sodium fluoride, citric acid, oxalic acid and monoiodoacetic acid.
2. Avoid using plasma or serum with precipitate such as fibrin.
3. Positive bias may occur by increasing ammonia if the specimen is left for a long time at room temperature after sampling. Perform measurement soon after sampling. Note that specimens containing high concentration of ammonia such as control serums give positive bias.
4. When the measured value exceeds the upper limit of the dynamic range, dilute the sample with distilled water or saline. Since the data obtained by dilution may deviate more widely than usual, the data should be treated as estimation.

[Performance characteristics]

1. Dynamic range 0.2–24.0 mg/dL (18–2122 μmol/L)

2. Accuracy

Concentration range	Accuracy
0.2–1.33 mg/dL (18–118 μmol/L)	Within ±0.2 mg/dL (Within ±21 μmol/L)
1.33–24.0 mg/dL (118–2122 μmol/L)	Within ±15 %

3. Precision

Concentration range	Precision
0.2–4.0 mg/dL (18–354 μmol/L)	SD ≦ 0.2 mg/dL (SD ≦ 18 μmol/L)
4.0–24.0 mg/dL (354–2122 μmol/L)	CV ≦ 5 %

4. Known interfering substances

(1) When isopropyl amine is present in the blood, owing to pesticide poisoning, plus bias may occur.

(2) When the low molecular weight amines, such as dimethylamine, are present in the blood, owing to renal failure, plus bias may occur.

(3) The effects on the measured value were examined by adding substances as shown below to a serum sample obtained from a healthy volunteer or a control serum. No significant effect was observed to the following concentration for each substance.

Ascorbic acid	10 mg/dL (0.57 mmol/L)
Bilirubin	20 mg/dL (340 μmol/L)
Hemoglobin	3000 mg/L
Total protein	50–95 g/L
Ammonia (N amount)	600 μg/dL (428 μmol/L)

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

[Internal quality control]

The accuracy and precision of this product can be evaluated with FUJI DRICHEM CONTROL QP-L and/or QP-H.

1. Select control level in accordance with your purpose.
2. Measure FUJI DRI-CHEM CONTROL QP-L and/or QP-H in the same way as patient specimens.
3. When the results obtained are outside the expected range shown in the sheet attached to FUJI DRI-CHEM CONTROL QP-L or QP-H, investigate the cause. For additional information, consult "Instructions for Use" for FUJI DRI-CHEM CONTROL QP-L and/or QP-H.

[Traceability of calibrators and control materials]

Creatinine...NIST (SRM 914)

Note: This reference material is applied to the reference method of FUJIFILM Corporation and is not directly applicable to FUJI DRI-CHEM SLIDE.

NIST: National Institute of Standards & Technology

1910310

Comprehensive S-Panel

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For veterinary use only

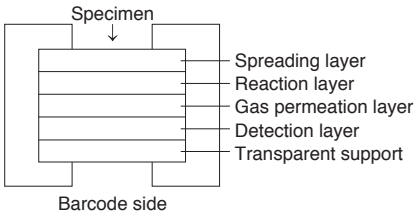
FUJI DRI-CHEM SLIDE Comprehensive S-Panel

Date of issue: 1/Sep/2013 **(TP, ALB, ALP, GLU, TBIL, IP, TCHO, GGT, GPT/ALT, Ca, CRE, BUN)**

■BUN

[Composition of the slide]

1. Multi-layered structure



2. Ingredients per slide

• Urease	4.86 U
• Bromcresol green	0.028 mg (0.040 μmol)

[Intended use]

Quantitative measurement of urea nitrogen concentration in plasma or serum.
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[Principle of the measurement]

10 μL of plasma or serum is deposited on a FUJI DRI-CHEM SLIDE BUN-PIII. After depositing, the specimen spreads uniformly on the spreading layer which filtrates large molecular components (protein and dye), and penetrates into the reaction layer. Urea is decomposed to ammonia and carbon dioxide by the reaction with urease. By alkalizing pH of the layer, ammonia gas is generated. The gas permeated through the gas permeation layer (porous layer) attains to the detection layer. Bromcresol green contained in the detection layer is changed from yellow to green by the ammonia gas. The color change is proportional to the urea nitrogen concentration. The slide is incubated at 37 °C for a fixed time in the FUJI DRI-CHEM ANALYZER and the optical reflection density is measured at 625 nm. The optical reflection density is then converted into the urea nitrogen concentration using a calibration curve preinstalled in the analyzer.

$$H_2NCONH_2 + H_2O \xrightarrow{\text{Urease}} 2NH_3 + CO_2$$

$$\text{Bromcresol green} + NH_3 \longrightarrow \text{Green dye}$$

[Specimen requirements]

1. For plasma, heparin and EDTA salt can be used as the anticoagulant. Heparin and EDTA salt should be used less than 50 units or 5 mg per 1 mL of whole blood, respectively. Do not use sodium fluoride, citric acid, oxalic acid and monoiodoacetic acid.
2. Avoid using plasma or serum with precipitate such as fibrin.
3. When the measured value exceeds the upper limit of the dynamic range, dilute the sample with distilled water or saline. Since the data obtained by dilution may deviate more widely than usual, the data should be treated as estimation.

[Performance characteristics]

1. Dynamic range 5.0–140.0 mg/dL (1.79–49.98 mmol/L)

2. Accuracy

Concentration range	Accuracy
5.0–140.0 mg/dL (1.79–49.98 mmol/L)	Within ±15 %

3. Precision

Concentration range	Precision
5.0–140.0 mg/dL (1.79–49.98 mmol/L)	CV ≦ 6 %

4. Known interfering substances

The effects on the measured value were examined by adding substances as shown below to a serum sample obtained from a healthy volunteer or a control serum. No significant effect was observed to the following concentration for each substance.

Ascorbic acid	10 mg/dL (0.57 mmol/L)
Bilirubin	20 mg/dL (340 μmol/L)
Hemoglobin	3000 mg/L
Total protein	50–90 g/L

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

[Internal quality control]

The accuracy and precision of this product can be evaluated with FUJI DRICHEM CONTROL QP-L and/or QP-H.

1. Select control level in accordance with your purpose.
2. Measure FUJI DRI-CHEM CONTROL QP-L and/or QP-H in the same way as patient specimens.
3. When the results obtained are outside the expected range shown in the sheet attached to FUJI DRI-CHEM CONTROL QP-L or QP-H, investigate the cause. For additional information, consult "Instructions for Use" for FUJI DRI-CHEM CONTROL QP-L or QP-H.

[Traceability of calibrators and control materials]

BUN...HECTEF (GN3-6)

Note: This reference material is applied to the reference method of FUJIFILM Corporation and is not directly applicable to FUJI DRI-CHEM SLIDE.

HECTEF: Health Care Technology Foundation

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

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