skyla

Diabetes Panel

PN：900-300

For Veterinary In Vitro Diagnostic Use Only **Rev：E**

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1. Intended Use

The skyla Diabetes Panel used with s skyla Analyzer, is intended to be used for the quantitative determination of Fructosamine (FRU), Glucose (GLU), Albumin (ALB), and Total Protein (TP) in animal whole blood, plasma, or serum. The calculated values of Globulin (GLOB) and Albumin/Globulin Ratio (A/G Ratio) can then be obtained.

2. Principles

The skyla Diabetes Panel contains a total of 4 types of dried reagents located in the respective detection wells of the reagent disc. The user only needs to inject the blood specimens into the sample port of the disc, and then places the disc into the analyzer. The test will be done automatically within 15 minutes. For the detail description of disc, please refer to “skyla Analyzer Operator’s Manual”.

Clinical Significance:

Fructosamine (FRU): FRU can be used for the diagnosis of diabetes and FRU concentration reflects relatively recent (1–2 week) changes in blood glucose.

Glucose (GLU): GLU can be used for the diagnosis of diabetes and diseases related to the carbohydrate metabolism.

Albumin (ALB): ALB is one of the indicators for kidney function, liver function and dehydration.

Total Protein (TP): TP is an indicator for function of liver synthesis and the degree of protein-losing caused by kidney diseases.

Globulin (GLOB): GLOB is calculated from TP and ALB and it is used to assess liver function.

Albumin/Globulin Ratio (A/G Ratio): The A/G Ratio is the ALB and GLOB ratio. It is used to assess liver function.

Method:

FRU

FRU is determined through the kinetic reaction approach. FRU reduces nitro blue tetrazolium chloride (NBT) to formazan in an alkaline solution. The absorbance at a wavelength of 546 nm can be measured in the presence of formazan. The rate of formation of formazan is directly proportional to the concentration of FRU.

GLU

GLU is determined through the endpoint enzymatic reaction approach. The Sucrose is catalyzed by Hexokinase to D-Glucose-6-Phosphate (G-6-P). In the presence of NAD, G-6-PD converts G-6-P into 6- Phosphogluconate and NADH. The absorbance at a wavelength of 340 nm can be measured in the presence of NADH. The absorbance is proportional to the GLU concentration.

ALB

ALB is determined through the endpoint chemical reaction method. When ALB binding to Bromocresol Green (BCG), it forms a yellow-green complex. The absorbance at a wavelength of 600 nm can be measured. The amount of ALB in the sample is proportional to the bound ALB.

TP

TP is determined by the Biuret method. The peptide bonds of the protein react with copper ions in an alkaline environment and form a purple compound. The color development is proportional to the original TP concentration and is measured at a wavelength of 546 nm.

Reaction pathway :

FRU

$$\text{Fructosamine} + \text{NBT} \xrightarrow{\text{Alkaline}} \text{Formazan dye}$$

GLU

$$\text{D-Glucose} + \text{ATP} \xrightarrow{\text{Hexokinase}} \text{D-Glucose-6-Phosphate} + \text{ADP}$$

$$\text{D-Glucose-6-Phosphate} + \text{NAD} \xrightarrow{\text{G-6-PDH}} \text{6- Phosphogluconate} + \text{NADH} + \text{H}^+$$

ALB

$$\text{Albumin} + \text{BCG} \longrightarrow \text{Albumin-BCG Complex}$$

TP

$$\text{Total protein} + \text{Cu}^{2+} \xrightarrow{\text{Alkali}} \text{Cu-Protein Complex}$$

3. Reagents

Included:

Each panel contains dried reagent beads, dried internal QC beads and the diluent.

Reagent Composition:

Composition	Quantity/Panel
NBT	0.03 mg
KOH	0.08 mg
Bromocresol Green Sodium Salt	5.4 μg
Copper Sulphate	0.1 mg
G6PDH	0.2 U
Hexokinase	0.1 U
NAD	0.1 mg
ATP	0.04 mg

Reagent Storage:

- The reagent disc should be stored at 2～8°C.
- The expiry date of the reagent is printed on the outside of the sealed pouch of reagent disc. Do not use if the reagent disc has expired.

4. Specimen Collection and Preparation

Specimen Collection:

- Specimens suitable for skyla Diabetes Panel include lithium heparinized whole blood, lithium heparinized plasma, serum and quality control materials. The sample requirement is 200 μL. (±10 μL tolerance are allowable)
- If applicable, local regulatory or standard operating procedures of your organization should be followed for the collection, preservation and handling of specimens.

Note: Do not use specimens containing other coagulants. That would cause an incorrect test results.

Specimen Preparation:

- Before applying a sample to the reagent disc, gently rotate the sample tube up and down several times, to confirm the sample is homogeneous (evenly mixed). If the sample is whole blood, do not shake the sample container vigorously to avoid occurrence of hemolysis.

Note:

1. Perform testing within 10 minutes after applying the sample to the reagent disc.
2. The use of whole blood specimens with hematocrits (Hct) higher than 60% may affect the test results.

Note: For further information in specimen collection and preparation, please refer to “skyla Analyzer Operator’s Manual”

5. Test Procedures

Material Preparation:

1 piece of the reagent disc of skyla Diabetes Panel

Required materials not included in the panel:

skyla Analyzer

Sample collection container

Micropipette / Tips

Test Conditions:

Test should be carried out in an environment with temperatures of 10°C~32°C. Each test will take about 15 minutes. During the test, chamber in the analyzer keeps the temperature at 37°C for stable assay.

Test Steps:

1. Open the aluminum pouch and remove the reagent disc.
2. Remove the diluent container sealing.
3. Using a micropipette to inject 200 μL of the sample into the reagent disc through the sample port.
4. Press the “start” button on the screen to initiate testing.
5. Place the reagent disc to the analyzer drawer, and press the “ok” button on the screen to analysis.

For details on the operating steps and instrument setting, please refer to “skyla Analyzer Operator’s Manual”.

Note:

1. To operate the reagent disc or instrument, please wear lab gloves and other protective gear to avoid contamination by specimen.

2. The used reagent disc and tips should be discarded as biomedical waste, and treat according to the local legal requirements.

3. Testing should be performed within 20 minutes after the pouch is opened.

4. Do not place the reagent disc at the environment more than 25°C and longer than 48 hours prior to use.

5. If the reagent disc or its package is damaged or is over the expiry date, do not use it.

6. Calibration

The barcode on every manufactured reagent disc contains all information required for calibration of the test items. The analyzer will automatically read the barcode information during testing.

7. Quality Control

- Please refer to the instruction manual for the preparation and use of quality control materials. For discrepancy results, the confirmatory test was suggested to carry out with the automated laboratory analyzer, or to contact with our technical support.
- External quality control materials can be used for the accuracy monitor of skyla system. The recommended frequency of QC testing is as follows, otherwise please follow local legal requirements or the standard operating procedures of your organization
  - At least every 30 days.
  - Before a new batch of reagents is used for testing.
  - When the analyzer was moved or the operating environment significantly changed.

8. Reference interval

The table below shows the reference interval for each test item. It is recommended that every laboratory or test site should establish its own reference interval from its patient population.

Test Item		Reference Interval		Reference Interval (SI Unit)	
FRU	Canine	200-375	µmol/L	200-375	µmol/L
	Feline	165-240	µmol/L	165-240	µmol/L
GLU	Canine	60 - 110	mg/dL	3.3 - 6.1	mmol/L
	Feline	53 - 150	mg/dL	2.9 - 8.3	mmol/L
ALB	Canine	2.6 - 4.6	g/dL	26-46	g/L

Test Item		Reference Interval		Reference Interval (SI Unit)	
	Feline	2.5 - 4.6	g/dL	25-46	g/L
TP	Canine	5.2 - 8.2	g/dL	52 - 82	g/L
	Feline	5.7 - 8.9	g/dL	57 - 89	g/L

9. Limitation

Physiological interferences in blood include hemolysis, icterus, and lipemia. For every test item, 2 Levels serum pool supplemented with known concentrations of the endogenous substances were used for the testing. Significant interference is defined as a >20% shift in the test result. (Note: Highest tested concentration for Hemoglobin: 600 mg/dL; Bilirubin (unconjugated): 62.5 mg/dL, Bilirubin (conjugated): 57.5 mg/dL; Intralipid: 0.55%)

Test Item	Substance concentration with interferences of less than 20%			
	Hemoglobin	Bilirubin (unconjugated)	Bilirubin (conjugated)	Intralipid
FRU	100 mg/dL	7.1 mg/dL	7.6 mg/dL	0.2%
GLU	600 mg/dL	62.5 mg/dL	57.5 mg/dL	0.3%
ALB	300 mg/dL	62.5 mg/dL	57.5 mg/dL	0.2%
TP	300 mg/dL	62.5 mg/dL	57.5 mg/dL	0.2%

10. Performance Characteristics

Dynamic range:

The dynamic range for each test item showed as below.

Test Item	Dynamic Range		Dynamic Range (SI Unit)	
FRU	100-1000	µmol/L	100-1000	µmol/L
GLU	30 - 550	mg/dL	1.7 - 30.5	mmol/L
ALB	1.0 - 6.0	g/dL	10 - 60	g/L
TP	1.5 - 10.0	g/dL	15 - 100	g/L

Method Comparison:

The SIMENS ADVIA 1800 and Arkray (for FRU) were used as comparative methods in the study. The tests are performed by using the same clinical serum sample for two methods.

Marker		R^2	Slope	Intercept	Sample No.	Sample Range
FRU	Canine	0.9721	1.000	0.0940	15	158-922 µmol/L
	Feline	0.9834	0.9995	0.1299	15	239-964 µmol/L
GLU	Canine	0.9953	1.0000	0.00892	43	78-558 mg/dL
	Feline	0.9957	0.9956	2.1761	44	93-549 mg/dL
ALB	Canine	0.9848	0.9999	0.0000	38	2.7-5.9 g/dL

Marker		R^2	Slope	Intercept	Sample No.	Sample Range
	Feline	0.9676	1.0000	0.0000	38	3.1-6.4 g/dL
TP	Canine	0.9603	0.9999	0.0000	38	5.2-9.5 g/dL
	Feline	0.9883	0.9999	0.0000	38	6.3-10.3 g/dL

Symbol Index			
REF	Catalogue number		Consult instruction for use
LOT	Batch code		Use by
	Manufacturer	CE	CE mark
	Temperature limitation		Caution
	Do not reuse	Σ	Sufficient for

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