skyla Single Assay Cartridge

SA23: UPC

PN：900-223

Rev：B

For Veterinary In Vitro Diagnostic Use Only

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1. Intended Use

The skyla UPC single assay cartridge used with skyla Analyzer, is intended to be used for the quantitative determination of Protein and Creatinine in urine in order to determine the urine protein:creatinine (UPC) ratio

2. Principles

The skyla UPC single assay cartridge contains dried reagent. The user only needs to put the cartridges on the single assay carrier, injects the diluted specimens into the sample ports of the cartridges, and then places the carrier into the analyzer. The test will be done automatically within 10 minutes. For the detail description of disc, please refer to “skyla Analyzer Operator’s Manual”.

Clinical Significance:

Urine Protein (UPRO):

Urinary protein is determined and compared to the concentration of creatinine in order to assess the level of renal protein (glomeruli and tubular) loss to determine the urine protein:creatinine (UPC) ratio.

Urine Creatinine (UCRE):

Urinary creatinine is determined and compared to the concentration of protein in order to assess the level of renal protein (glomeruli and tubular) loss to determine the urine protein:creatinine (UPC) ratio.

Urine protein:creatinine (UPC) ratio

Proteinuria indicating early renal failure, protein-losing nephropathy.

Method:

UPRO

UPRO is determined through the endpoint color reaction method. When Pyrocatechol violet–molybdate complex binds with protonated basic amino groups of proteins at an acidic pH, it forms a yellow-green complex. The absorbance at a wavelength of 650 nm can be measured. The color is

directly proportional to the protein concentration.

$$\text{Pyrocatechol violet + molybdate + Protein} \xrightarrow{H+} \text{Pyrogallol violet- molybdate-protein Complex}$$

UCRE

Urine creatinine is determined through the endpoint color reaction method. Creatinine complexes with 3,5-dinitrobenzoic acid at high pH to form a colored complex. The absorbance at a wavelength of 510 nm can be measured, and the color is directly proportional to the creatinine concentration.

$$\text{Creatinine + 3,5-dinitrobenzoic acid} \xrightarrow{\text{high pH}} \text{colored complex}$$

3. Reagents

Major Composition:

Composition	Quantity/Panel
Sodium Molybdate dihydrate	0.004 mg
Pyrocatechol Violet	0.003 mg
3,5-dinitrobenzoic acid	0.004 mg

Reagent Storage:

The cartridge should be stored at 2～8°C.

The expiry date of the reagent is printed on the outside of the sealed pouch of cartridge. Do not use if the cartridge has expired.

4. Specimen Collection and Preparation

Specimen Collection:

The urine sample requirement for UPRO and UCRE is 50 μL.

If applicable, local regulatory or standard operating procedures of your organization should be followed for the collection, preservation and handling of specimens.

Note:

1. Do not use hemolyzed specimens as hemoglobin increases UPRO results significantly. Intact red blood cells can be removed via centrifugation.

Specimen Preparation:

1. Before applying a sample to the cartridge, the specimen should be diluted with diluent. Please use the 50 μL pipette to transfer the 50 μL specimen (urine) into the

specified SingleAssay Dilution Tube. (skyla Product Code: 110-940)

2. After injecting the specimen, close the cap tightly and invert it 10 times to thoroughly mix the solution.

Note:

1. **Once the diluent spilled out from the dilution tube during handling or the insufficient liquid was observed, please don't use that dilution tube and change the new one.**
2. **Perform testing within 10 minutes after applying the sample to the cartridge (at room temperature).**

For further information in specimen collection and preparation, please refer to "skyla Analyzer Operator's Manual".

5. Test Procedures

Test Conditions:

Test should be carried out in an environment with temperatures of 10°C~32°C. Each test will take about 10 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 take the single assay cartridge out from the pouch.
2. Put the cartridge into a slot on the single assay carrier. (The single assay carrier can hold a maximum of three single assay cartridges.)
3. Put the dummy cartridges into other unused slots on the single assay carrier.
4. Use the 50 µL pipette to transfer the diluted specimen from the dilution tube to the single assay cartridge **twice**, totally 100 µL of the diluted specimen should be loaded into the sample port on the cartridge through 2 loads.
5. Use a lint-free tissue to clean any sample spilled on the outside of the single assay cartridge.
6. Press the "start" button on the screen to initiate testing.
7. Place the single assay carrier on the analyzer drawer, and press the "ok" button on the screen to analysis.

Note:

1. **To avoid errors in the system when reading data, never use a used single assay**

cartridge as a dummy cartridge.

2. **To operate the cartridge or instrument, please wear lab gloves and other protective gear to avoid contamination by specimen.**
3. **The used cartridge, tips, tissues should be discarded as biomedical waste, and treat according to the local legal requirements.**
4. **Testing should be performed within 20 minutes after the pouch is opened.**
5. **Avoid placing unopened reagent discs in places higher than 25°C (77℉) for more than 48 hours.**
6. **If the cartridge or its package is damaged or is over the expiry date, do not use it.**

For details on the operating steps and instrument settings, please refer to "skyla Analyzer Operator's Manual".

6. Calibration

The barcode on every manufactured cartridge 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, a confirmatory test is suggested to be carried out with the automated laboratory analyzer, or to contact our technical support.

External quality control materials can be used for the accuracy check 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)
UPC	Canine	<0.5	<0.5
	Feline	<0.5	<0.5

9. Limitation

Physiological interferences in blood include hemolysis and icterus. For every test item, 2 levels of urine 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.

Test Item	Substance concentration with interferences of less than 20%	
	Hemoglobin	Bilirubin (conjugated)
UPRO	100 mg/dL	6.3 mg/dL
UCRE	200 mg/dL	12.0 mg/dL

10. Performance Characteristics

Dynamic range:

The dynamic range for each test item showed is as follows.

Test Item	Dynamic Range	Dynamic Range (SI Unit)
UPRO	20.0-200 mg/dL	0.2-2.0 g/L
UCRE	10.0-700 mg/dL	0.1-7.0 g/L

Method Comparison:

IDEXX Catalyst One Chemistry Analyzer was used as comparative method in the study. The tests were performed with identical clinical urine samples for the comparison.

Marker		R^2	Slope	Intercept	Sample No.	Sample Range
UPRO	Canine	0.9758	1.0030	2.7899	30	<5-124 mg/dL
	Feline	0.9747	1.0044	1.4856	60	7-123 mg/dL
UCRE	Canine	0.9696	1.0076	12.029	7	11-514 mg/dL
	Feline	0.9968	0.9528	5.645	14	50-678 mg/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

Supplier	： SKYLA CORPORATION HSINCHU SCIENCE PARK BRANCH
Address	： 1F, No.8, Dusing Rd., Hsinchu Science Park, East Dist., Hsinchu City, Taiwan
Customer service/ Technical support	： +886-3-611-8511
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