**skyla Single Assay Cartridge**

# SA03: BUN

**For Veterinary In Vitro Diagnostic Use Only**

**PN：900-203**
**Rev：E**

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## 1. Intended Use

The skyla BUN single assay cartridge used with skyla Analyzer, is intended to be used for the quantitative determination of Blood Urea Nitrogen, (BUN) in animal plasma or serum. The calculated values of UREA can then be obtained.

## 2. Principles

The skyla BUN single assay cartridge contains a 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:*

BUN is one of the important markers for diagnosis and prognosis tracking of kidney diseases.

*UREA*：UREA is synthesized in the liver and secreted by the kidneys. Urea is the end product of protein nitrogen metabolism and is the primary vehicle for removing toxic ammonia from the body. The analysis of urea is an important clinical test for renal disease and dysfunction.

### Method:

BUN is enzymatically determined. Urea undergoes an Urease catalyzed hydrolysis, thus producing Ammonia and Carbon Dioxide. In a Glutamate Dehydrogenase (GLDH) catalyzed reaction, Ammonia reacts with 2-Oxoglutarate yielding L-Glutamate. In the process of this reaction, β-Nicotinamide Adenine Dinucleotide (NADH) is oxidized to β-Nicotinamide Adenine Dinucleotide ($NAD^+$) which in turn undergoes a color reaction. The rate of change of absorbance at a wavelength of 340 nm is measured and proportional to the BUN concentration.

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

$$NH_3 + \text{2-Oxoglutarate} + \text{NADH} \xrightarrow{\text{GLDH}} \text{L-Glutamate} + H_2O + NAD^+$$

# 3. Reagents

## Major Composition:

| Composition | Quantity/Panel |
|---|---|
| Glutamate Dehydrogenase | 0.05 U |
| NADH | 0.03 mg |
| Urease | 0.03 U |
| α-Ketoglutaric Acid | 0.05 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:

- Specimens suitable for skyla BUN single assay cartridge include lithium heparinized plasma, serum and quality control materials. The plasma or serum sample requirement 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. **The centrifugation of whole blood sample should be done within 60 minutes (at room temperature) in order to prevent cellulose precipitation in the blood.**
2. **Do not use specimens containing other coagulants. That would cause an incorrect test results.**

## Specimen Preparation:

- Before applying a sample to the cartridge, the specimen should be diluted with diluent. Please use the blue 50 μL pipette to transfer the 50 μL specimen (plasma or serum) into the dilution tube.
- 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 blue 50μL pipette to transfer the diluted specimen from the dilution tube to the single assay cartridge **twice**, totally 100μL 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 treated 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°F) 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 follow, 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 particular patient population.

| Test Item | | Reference Interval | | Reference Interval (SI Unit) | |
|---|---|---|---|---|---|
| BUN | Canine | 6.0 - 26.0 | mg/dL | 2.1 - 9.3 | mmol urea/L |
| | Feline | 13.0 - 37.0 | mg/dL | 4.6 - 13.2 | mmol urea/L |

# 9. Limitation

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

| Test Item | Substance concentration with interferences of less than 20% | | | |
|---|---|---|---|---|
| | Hemoglobin | Bilirubin (unconjugated) | Bilirubin (conjugated) | Intralipid |
| BUN | 600 mg/dL | 53.9 mg/dL | 51.3 mg/dL | 0.3% |

# 10. Performance Characteristics

## Dynamic range:

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

| Test Item | Dynamic Range | | Dynamic Range (SI Unit) | |
|---|---|---|---|---|
| BUN | 2.0 - 140 | mg/dL | 0.7 - 50.0 | mmol urea/L |

## Method Comparison:

SIMENS ADVIA 1800 was used as comparative method in the study. The tests were performed with identical clinical samples for the comparison.

| Marker | | $R^2$ | Slope | Intercept | Sample No. | Sample Range |
|---|---|---|---|---|---|---|
| BUN | Canine | 0.9936 | 1.0048 | -0.4669 | 56 | 35.7-133 mg/dL |
| | Feline | 0.9907 | 0.9987 | 2.3037 | 30 | 36-149.3 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 |


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