skyla Single Assay Cartridge

SA19: NH_3

For Veterinary In Vitro Diagnostic Use Only

PN：900-219
Rev：B

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1. Intended Use

The skyla NH_3 single assay cartridge used with skyla Analyzer, is intended to be used for the quantitative determination of Ammonia (NH_3) in animal plasma.

2. Principles

The skyla NH_3 single assay cartridge contains dried reagents. The user only needs to put the cartridges on the single assay carrier, injects the 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:

Ammonia (NH_3): NH_3 is a reliable marker in diagnosis of hepatic encephalopathy.

Method:

NH_3

NH_3 is enzymatically determined. 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 NH_3 concentration.

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

3. Reagents

Major Composition:

Composition	Quantity/Panel
Glutamate Dehydrogenase	1 U
α-Ketoglutaric acid disodium salt dehydrate	0.2 mg

Composition	Quantity/Panel
NADH	0.03 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 NH_3 single assay cartridge include lithium heparinized plasma and quality control materials. The plasma sample requirement is 100 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.**

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. 100 μL of the specimen should be loaded into the sample port on the cartridge.

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 cartridges, 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 patient population.

Test Item		Reference Interval		Reference Interval (SI Unit)	
NH_3	Canine	0-98	μmol/L	0-98	μmol/L
	Feline	0-95	μmol/L	0-95	μmol/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
NH_3	100 mg/dL	30 mg/dL	20 mg/dL	0.2%

10. Performance Characteristics

Dynamic range:

The dynamic range for each test item is as follows.

Test Item	Dynamic Range		Dynamic Range (SI Unit)	
NH_3	10-500	μmol/L	10-500	μmol/L

Method Comparison:

IDEXX catalyst one was used as comparative method for NH_3, separately in the study. The tests were performed with identical clinical samples for the comparison.

Marker		R^2	Slope	Intercept	Sample No.	Sample Range
NH_3	Canine	0.9798	1.0000	0.0000	24	34 – 438μmol/L
	Feline	0.9799	1.0092	4.9942	12	34 – 404μmol/L

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

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