skyla Reagent Kit

PHBR (Phenobarbital)

PN：901-120

Rev：B1

For Veterinary Use Only

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1. Intended Use

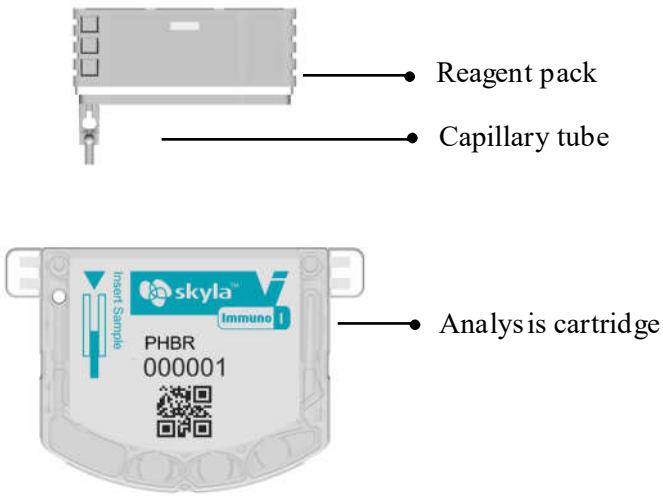
The skyla PHBR reagent kit used with skyla Analyzer, is intended to be used for the quantitative determination of Phenobarbital in animal's plasma and serum.

Precaution/Waring

1. This product is for in vitro diagnostic use only
2. The product must not be used individually for diagnostic purpose.
3. The Reagent kit should be stored at 2-8 °C (35.6-46.4 °F).
4. Please were the gloves when performing the test.
5. Do not re-use any part of the test kit.
6. Dispose all waste in accordance with applicable national and/or local regulations.

2. Test Component

The skyla PHBR reagent kit consists of analysis cartridge and reagent pack (including of capillary tip for specimen collection).



3. Principles

The skyla PHBR reagent kit is a turbidimetric immunoassay using monoclonal antibodies against Phenobarbital (PHBR) and allows to accurate determine the concentration of PHBR in the sample.

When a sample is mixed with Antibody Solution (R1) and Latex Reagent (R2), the PHBR conjugated latex particles are agglutinated with the anti-PHBR antibody. The agglutination reaction would be inhibited when the PHBR is presented in the sample at the meantime. Through the measurement of absorbance change caused by agglutination, the PHBR concentration can be determined. The measured absorbance change is inversely dependent upon the PHBR concentration of sample.

Clinical Significance:

Phenobarbital is used to control epilepsy in dogs and cats. It may be used alone or in conjunction with other drugs to reduce the number and severity of seizures. However, poor dose control would cause harmful side effects, such as liver damage, even result in total anesthesia. Hence, the regular monitoring of phenobarbital concentrations for careful dosing is important to ensure safe and effective treatment. Most veterinarians recommend that a phenobarbital level test be performed 2 to 4 weeks once receiving the medication. And additional tests may be required after any dose change and symptoms of toxic reaction occur.

4. Reagents

Major Composition:

R1: 150 μL

- Anti-PHBR antibody, Glycine buffer (pH 9.0) 50 mmol/L, Sodium azide 0.95 g/L.

R2: 90 μL

- PHBR conjugated latex particles, Glycine buffer (pH 7.4) 50 mmol/L, Sodium azide 0.95 g/L.

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 kit. Do not use if the kit has expired.

5. Sample Preparation

- Specimens suitable for skyla PHBR reagent kit include lithium heparinized plasma, serum and quality control materials. The requirement of sample volume for each test is 2 μL.
- If using a whole blood sample, the sample should be centrifuged with an appropriate centrifuge before the test.
- If applicable, local regulatory or standard operating procedures of your organization should be followed for the collection, preservation and handling of specimens.
- To analysis sample immediately after collection is recommended for good test result.

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.**
3. **The lipemic sample may affect result. For good test result, if the sample is cloudy obviously, the high speed centrifuge with force of 10,000 × g is recommended to remove the lipid layer from the supernatant before the test.**

6. Test Procedures

Reagent kit Preparation

1. Tear the foil pouch from the notch on the edge and take out the skyla reagent kit. (includes an analysis cartridge & a reagent pack)

   Note: Please retain the paper for sample collection purpose.

2. Take out the reagent pack from the analysis cartridge and remove the yellow cap on the capillary tube before using.

Sample Collection

3. Get the centrifugal sample.
4. Using a dropper or Pipette take up 1 drop of sample (> 5 μL) from the tube.

   Note: sample should be taken from the clear portion of the centrifuged sample.

5. Transfer the droplet onto the paper.
6. Within 3 min., use the reagent pack to collect the sample. Touch the sample with the capillary tube for about 3sec. Ensure that the capillary tube is fully-filled with the sample.

Performing a Testt

7. Insert the reagent pack into the analysis cartridge until the reagent pack cannot be pushed in further.
8. Place the analysis cartridge on the analysis carrier. Press “Start” button to eject the disc drawer.
9. Put the carrier on the tray. Press “OK” to begin the analysis.

Note:

1. **To operate the cartridge or instrument, please wear lab gloves and other protective gear to avoid contamination by specimen.**
2. **The used kit, tips, tissues should be discarded as biomedical waste, and treat according to the local legal requirements.**
3. **Please perform the test immediately once the reagent kit is taken out from storage.**
4. **Reagent kit retrieved from 2-8°C storage can be directly used without warming-up. 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 setting, please refer to “skyla Analyzer Operator’s Manual”.

7. Calibration

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

8. 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 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 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.

9. 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)
PHBR	Canine	15 - 45 μg/mL	65 - 194 μmol/L
	Feline	15 - 45 μg/mL	65 - 194 μmol/L

10. Limitation

Physiological interferences in blood include hemolysis, icterus, and lipemia. For every test item, 2 levels of control solution, 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	Intralipid
PHBR	600 mg/dL	49.6 mg/dL	0.4% (988 mg/dL TG)

11. Performance Characteristics

Dynamic range:

The dynamic range of PHBR reagent kit is as follows.

Test Item	Dynamic Range	Dynamic Range (SI Unit)
PHBR	5.0 - 60 μg/mL	21 - 258 μmol/L

Imprecision:

Precision studies adopt control solution of high and low concentrations as test samples. Tests are performed 3 repeats a day for a total of 5 days. Results are shown in the table below.

Test Item	PHBR	
Level	Control, Low	Control, High
Unit	μg/mL	μg/mL
Mean	11.7	54.8
Std.	0.702	0.932
%CV	6.0%	1.7%

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

Supplier : SKYLA CORPORATION HSINCHU SCIENCE PARK BRANCH

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