skyla Reagent Kit

SAA (Serum Amyloid A)

For Veterinary Use Only

PN：901-110
Rev：B

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1. Intended Use

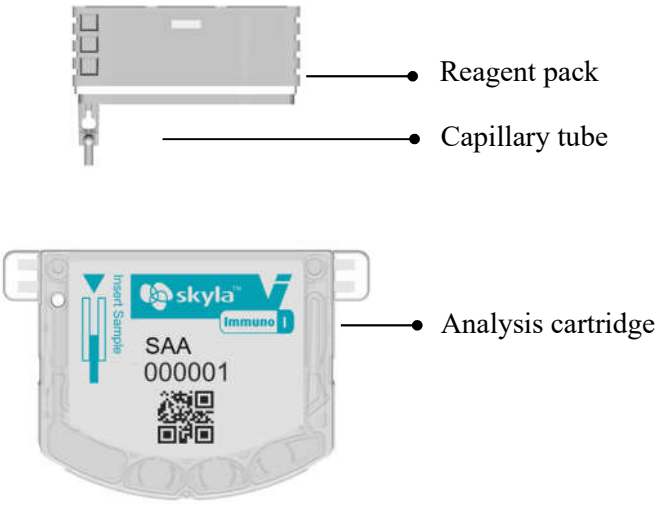
The skyla SAA reagent kit used with skyla Analyzer, is intended to be used for the quantitative determination of Serum Amyloid A in plasma and serum.

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** SAA reagent kit consists of analysis cartridge and reagent pack (including of capillary tip for specimen collection).



3. Principles

The skyla SAA reagent kit is a turbidimetric immunoassay using polyclonal antibodies against Serum Amyloid A (SAA) and allows to accurate determine the concentration.

When a sample is mixed with Buffer (R1) and Latex Reagent (R2), SAA in the sample combines specifically with the anti-SAA antibody bound to the latex particles in the Latex Reagent to yield an insoluble aggregate which causes increased turbidity in the solution. The degree of turbidity of solution can be measured optically and is proportional to the concentration of SAA in the patient's sample.

Clinical Significance:

Serum amyloid A (SAA) is a major acute phase protein in many species including human beings, dogs, cats and horses. The level of SAA proteins in blood increases within just a few hours following the onset of various inflammatory stimuli. These include infection, trauma and surgery.

Especially, SAA is an excellent acute phase biomarker in cats and horses, its level can increase several hundred-fold than the normal as the result of infection, disease, or cancer.

4. Reagents

Major Composition:

R1: 75 μL

- Phosphate buffer (pH 7.4) 80 mmol/L, Sodium chloride 150 mmol/L, Sodium azide 0.95 g/L.

R2: 85 μL

- Latex particles coated with anti-SAA antibody, Glycine buffer (pH 8.2) 20 mmol/L, Sodium chloride 150 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 SAA reagent kit include lithium heparinized plasma, serum and quality control materials. The requirement of sample volume for each test is 5 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 (> 10 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 Test

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.

   The correct way to place the analysis cartridge on the analysis carrier:
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)
SAA	Feline	< 10 μg/mL	< 10 mg/L
	Equine	< 20 μg/mL	< 20 mg/L

10. 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	Intralipid
SAA	600 mg/dL	42.2 mg/dL	0.21% (527 mg/dL TG)

11. Performance Characteristics

Dynamic range:

The dynamic range of SAA reagent kit is as follows.

Test Item	Dynamic Range	Dynamic Range (SI Unit)
SAA	5.0 - 150 μg/mL	5.0 - 150 mg/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	SAA	
Level	Control, Low	Control, High
Unit	μg/mL	μg/mL
Mean	39.1	128.4
Std.	1.846	3.680
%CV	4.7%	2.9%

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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