Instructions for Use

380290-A

English For Veterinary Research Use Only **Store at 2-10°C**

VET-SAA 'Eiken' Reagent

REF V-SZ51
REF G-SZ52

INTENDED USE
For measurement of Serum Amyloid A (SAA) in animal serum or plasma.

INTRODUCTION
Serum amyloid A (SAA) is an apolipoprotein associated in HDL. It has 11.4 kDa molecular weight and its amino acid sequence has high homology between animals. SAA has been considered as one of the most sensitive acute-phase protein as CRP. Serum SAA level rises dramatically by bacterial infection, viral infection, stress, trauma, inflammation, surgery, tumors, autoimmune diseases and tissue necrosis. Also, the level of SAA is considered to reflect healing of the inflammation. The increase occurs within 12hrs after induction and the level may increase 1000 times of normal concentration.
This measurement utilizes a latex agglutination reaction, and the change in turbidity caused by the reaction measured optically to determine SAA concentration.

PRINCIPLE OF THE METHOD
This method is an optical measurement method by using the latex agglutination reaction and automated analyzer.
The latex reagent is prepared by binding anti SAA antibodies to the surface of the latex particles. When this reagent is mixed in a react cell with the sample, SAA antibodies which are bounded to the latex particles react with SAA in the sample, and cause agglutination. This reaction is measured as a change in the turbidity, with the amount of the change increasing in proportion to SAA concentration in the sample.
Measurement using VET-SAA applies this principle to find a calibration curve from calibrators of known concentration. The amount of SAA in the sample is then found relative to this calibrator.

CONTENTS OF THE KIT
1. Reagent-1 ·····20mL, 2 vial
   (Contains 50mmol/L of Good's Buffer)
2. Reagent-2 ····· 20mL, 2 vial
   (Contains latex sensitized with anti SAA monoclonal antibodies)

WARNINGS AND PRECAUTIONS
1. For veterinary research use only.
2. Use the fresh animal serum or plasma. When samples are stored, they should be kept at -20°C. Repeated freezing and thawing of sample should be avoided.
3. Be sure to store the reagents under the designated conditions(2-10°C). Do not use reagents that have passed their expiration date.
4. Mix the latex reagent before using by gently inverting the vial several times.
5. Measurement errors may result if bubbles are present on the surface of the sample after it is dispensed into the sample cup. Therefore remove all bubbles. If fibrin is present in the sample cup, remove it. Fibrin can cause clogging of the sample nozzle.
6. Create a calibration curve for each day of measurement. Also be sure to create a new calibration curve when a reagent from a different vial or lot is used.
7. The test sample may be contaminated with pathogens. Therefore use caution when handling.
8. If the sample antigen concentration exceeds the measurement range, dilute with a normal saline solution or similar solution and perform measurement again.
9. Use the reagents as quickly as possible after they are opened. If they are to be stored, be sure to close the caps and store them using the prescribed method.
10. There is the danger of infection from all tools, reagents, and reagent containers that contact the sample. Disinfect them using an autoclave or other means, or soak them in hypochlorous acid or other disinfectant solution.
    Example of treatment: Soak for 60 minutes or longer in a sodium hypochlorite solution (available chlorine concentration 1000 ppm or greater). (Neutralize any substances that contain acids before soaking.) Alternatively, treat in an autoclave at 121°C for 20 minutes. (Do not treat in this way any items to which sodium hypochlorite has adhered.)
11. Dispose of used reagents and containers as infectious waste in accordance with applicable regulations.
12. If the product is used in any way other than that specified here, the reliability of measurement results cannot be guaranteed. Be sure to follow the procedure.
13. The product contains Guanidinium chloride (CAS No.50-01-1), Lithium chloride (CAS No.7447-41-8), and ProClin 300 (CAS No.55965-84-9) which are classified by applicable 'The Classification, Labelling and Packaging (CLP) Regulation' as Skin and Eye Irritant and Acute toxicity by Oral.
    If the reagent contacts with eyes, mouth or skin, rinse it out with large volumes of running water, and perform other required first aid. If necessary, seek medical attention.

Warning

H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P264	Wash hands thoroughly after handling.
P270	Do not eat, drink, or smoke when using this product.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves/protective clothing/eye protection/ face protection.
P301+P312	IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell.
P330	Rinse mouth.
P302+P352	IF ON SKIN: Wash with plenty of soap and water.
P305+P351 +P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P321	Specific treatment.
P332+P313	If skin irritation occurs: Get medical advice/attention.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P337+P313	If eye irritation persists: Get medical advice/ attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
P501	Dispose of contents/container in accordance with local disposal regulations.

SAMPLE COLLECTION
1. Use animal serum or plasma as test sample (specimen).
2. Collect samples in usual manner and test them while fresh.
3. If test samples are to be stored over a long period of time, preserve them frozen at -20°C or lower (avoid repeated freezing and thawing).
4. If a frozen stored test sample is to be used, thaw it at room temperature and then mix it by inversions before running the test.
5. Dialyzed blood-derived serum samples, in which fibrin is likely to be separated, should be defibrinated before used in the test.

TEST PROCEDURE
1.Preparation of reagents
   1) Reagent-1: Use the Reagent-1 as-is.
   2) Reagent-2: Use the Reagent-2 as-is.
   3) Calibrators: Separately obtain the VET-SAA Calibrator Set (REF V-SZ90) as the calibrators.

2. Measurement procedure
   1) Follow the instructions in the instruction manual to operate the automated analyzer.
   2) Dispense the sample and calibrators into sample cups, and set them in the designated positions.
   3) Set Reagent-1 and Reagent-2 in the designated positions.
   4) Enter the parameters into the analyzer.
   5) Press the analyzer "Start" key to begin analysis and output the measurement results (by printout or other means).

INTERFERING SUBSTANCES
Almost no effect on the measurement value was found from conjugated bilirubin (20mg/dL), free bilirubin (20mg/dL), hemoglobin (500mg/dL), chyle (2,000 formazine turbidity units), and rheumatoid factor (RF positive sample 500 IU/mL). As an anticoagulant almost no effect on the measurement value was found from EDTA・2Na (500mg/dL), sodium citrate (1,000mg/dL) and heparin sodium (40mg/dL).

INTERNAL QUALITY CONTROL
A quality control program to monitor the performance of VET-SAA is recommended to each laboratory. The following relevant products are being recommended for the quality control program.
VET-SAA-QC-Low (REF V-SZ91)
VET-SAA-QC-High (REF V-SZ92)

PERFORMANCE CHARACTERISTICS
1. Sensitivity
   When measuring SAA calibrators of 0 mg/L and 7 mg/L, the average value –2.6SD of the absorbance change amount of 7 mg/L is larger than the average value +2.6SD of the absorbance change amount of 0 mg/L.
2. Accuracy
   When control samples of known concentration were measured, the value obtained was within ±15% of indicated value.
3. Within-run reproducibility
   When the same sample was measured 10 times within the same run, the coefficient of variation (CV) for the values obtained was 10% or less.
4. Measurement range
   5 – 200 mg/L

PRODUCT CODE, PRODUCT NAME & STORAGE

Product code	Product name	Contents	Storage
V-SZ51	VET-SAA 'Eiken' Reagent	2 × 20mL 2 × 20mL	2-10°C
V-SZ90	VET-SAA Calibrator Set	5 × 1mL	2-8°C
V-SZ91	VET-SAA-QC-Low	5 × 1mL	2-8°C
V-SZ92	VET-SAA-QC-High	5 × 1mL	2-8°C

REFERENCE
1. Sack GH Jr.: Mol Med. ,24(1):46, 2018.

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(Date of issuance: 2019-10-01)