

Summary of Product Characteristics

Mycoplasma Gallisepticum antigen for rapid agglutination test

1. Name of product

Mycoplasma Gallisepticum antigen for rapid agglutination test

2. Pharmaceutical form

Liquid (Diagnostic agent)

3. Main components

- Inactivated *Mycoplasma gallisepticum* S6 strain
- Crystal violet

4. Purpose of use

Detection of agglutinating antibodies against *Mycoplasma gallisepticum*.

5. Methods to use

(1) Usage

In the whole blood method using chicken blood as the test material, mix two drops (about 0.06 mL) of the bacterial fluid and one drop (about 0.03 mL) of blood, and in the serum method using serum as the test material, mix each drop (about 0.03 mL) of the bacterial fluid and serum on the test glass plate, and observe the reaction while tilting the glass plate anteroposteriorly and laterally.

(2) Judgement

The judgment is positive if purple aggregated granules appear within one minute after mixing the bacterial fluid with blood or serum. The judgment is pseudo-positive if the appearance of aggregated granules appear in one to two minutes. The absence of a reaction after two minutes of observation is considered negative.

6. Pharmaceutical particulars

a Shelf life;

See the package insert.

b Storage condition;

See the package insert.

c Nature and packing size of package

5 mL per one vial

This product has precipitant at the stable condition, and turns into homogenous violet suspension by shaking.

7. Name and address of manufacturer

Nisseiken Co., Ltd.

9-2221-1 shin-machi, Ome, Tokyo 198-0024, JAPAN

All information are as of February, 2023