

mi**PROTECT**[®] Plague

Rapid test for the detection of *Yersinia pestis*

Product: #221
Lot: #221-AHWA-04-18
Storage: +4° to +30°C
Exp. Date: 2013-04-31

Intended use

mi**PROTECT**[®] is an easy-to-use rapid test for testing of environmental samples. The test is suitable for a visual read-out. In addition, tests can be measured with a portable reader provided by miprolab. This reader allows a semi-quantification of the test signals. The test is intended for screening of environmental samples and NOT for any medical use.

Test principles

After applying the diluted sample onto the sample port (S) of the test cartridge, the solution migrates via capillary forces through the test cassette. After less than a few minutes, a red line appears in the control zone (C) in the result window. This line confirms that the test is working correctly. Another red line appearing in the test zone (T) shows a positive signal and the presence of the biological threat agent in the sample. A negative test consists of a red line appearing solely in the control zone (C).

Storage and stability

Test cartridge should be stored cooled or at room temperature (+4°C to +30°C). During storage, frequent changes in temperature should be avoided. Test cartridge must not be frozen. It must remain in foil pouch until use. Sampling device as well as test cartridge must not be used after the expiration date printed on the foil pouch (test cartridge).

Sample preparation

Samples have to be diluted with sample buffer provided with the kit. It is recommended to use a dilution factor of 2.

Test procedure and interpretation of results

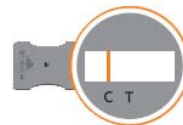
1. In case of not using sampling devices, an aliquot of 100 µl of the diluted sample has to be applied onto the sample port of the test cartridge. Do not add more than 100 µl onto the sample port of the test cartridge.



2. Read results in the result window after exactly 20 minutes. Read-out can be done visually by naked eye or tests can be measured with the mi**PROTECT** reader (for more details, please read “Manual for the mi**PROTECT** Reader” and “Manual for Lateral Flow Control Software”). Do not interpret results after 25 minutes.

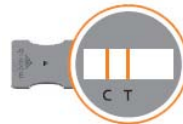


Negative



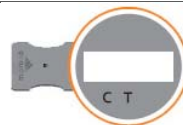
The appearance of one color line (control line) in the result window indicates a negative result.

Positive



The test is positive if two colored lines appear. One line appears in the control zone (C) and another line appears in the test zone (T).

Invalid



The test is invalid if no colored line appears.



The test is invalid if a test line appears in the test zone (T), only.

Normalized results (Ratio) should be calculated using following formula:

$$\text{Ratio} = \frac{\text{Peak Area Test [mV]}}{\text{Peak Area Control [mV]}}$$

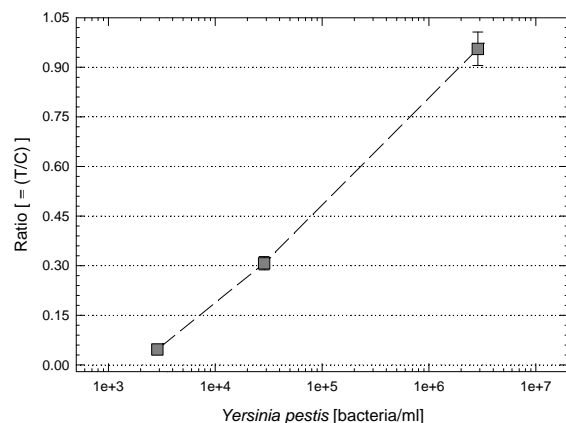


Fig. 1: Results obtained from the determination of the intra- and inter-assay precision (5 replicates on 5 days).