Yersinia Pestis (F1) SMART™ II

Yersinia Pestis (plague)  Lateral Flow Screening Assay

Reorder No. 89-120202

For Environmental Use Only. Not for Human Use.

INTENDED USE:
This test is designed to detect *Yersinia pestis* from environmental samples. It is not intended to be used in the diagnosis of plague or any other human/animal disease.

CAUTION: This test is a rapid, screening assay. No known rapid screening assay is 100% sensitive or 100% specific, therefore results should be confirmed by an alternative method.

MATERIALS INCLUDED PER POUCH:
1. Lateral Flow Test Devices
2. Plastic Dippers
3. Chase Buffer

COLLECTION KITS NOT INCLUDED:
(To collect sample, you should use one of the following kits or their equivalent.)
1. Large Surface Sample Collection Kit, (SWIPE-1), Reorder No. 87-130001
2. Powder/Small Surface Sample Collection Kit, (SWIPE-2), Reorder No. 87-130002
3. Liquid Sample Collection Kit, (SWIPE-3), Reorder No. 87-130003
4. Air Sampler Sample Collection Kit, (SWIPE-4), Reorder No. 87-130004

If the sample has debris or large particles, it may require use of the SPK:
1. Sample Processing Kit: SWIPE-SPK, Reorder No. 87-130100

ASSAY PROCEDURE:
CAUTION: For assay to function properly, NHD’s SWIPE or a validated collection system must be utilized to properly collect and process the sample. Failure to utilize a proper collection system may cause false negative or false positive results.

1. Collect samples and follow dilution guidelines to ensure sample is in a liquid form.
2. Open pouch of lateral flow device. Remove contents.
3. Place three drops (or 100μl) of liquid sample into sample well of a lateral flow device using plastic dropper provided.
4. Wait three (3) minutes for the sample to be absorbed into the sample well. Then place two (2) free falling drops of Chase buffer from the dropper bottle.
5. Read results at 15 minutes (no longer than 30 minutes). Observe the development of color on the Control (C) and Test Line (T) and record result. See table to interpret test.
RESULTS:

<table>
<thead>
<tr>
<th>POSITIVE TEST</th>
<th>Appearance of a distinct red line on both CONTROL and TEST Lines.</th>
</tr>
</thead>
<tbody>
<tr>
<td>NEGATIVE TEST</td>
<td>Appearance of a red line only at the CONTROL Line and absence of a red line on the TEST Line.</td>
</tr>
<tr>
<td>INVALID</td>
<td>Appearance of red line at the TEST Line and absence of a red line on the CONTROL Line.</td>
</tr>
<tr>
<td>INVALID</td>
<td>No lines appeared. Sample did not flow.</td>
</tr>
</tbody>
</table>

ILLUSTRATION:

Sample

<table>
<thead>
<tr>
<th>S</th>
<th>T</th>
<th>C</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>![Positive Image]</td>
<td>![Negative Image]</td>
<td>![Invalid Image]</td>
</tr>
</tbody>
</table>

Yersinia Pestis Screening Assay  Manufactured by:
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