

PERiPLEX[®]

Instructions for Use

Infection test for Peritoneal Dialysis users

For self-testing

Please read in full



INTENDED USE

The PERiPLEX test is intended for the detection of two recognised markers of infection, in peritoneal dialysate taken from the waste bag. Detection of either, or both, of these markers indicates the potential presence of peritonitis, and you should seek urgent medical assistance. Early treatment is known to be more effective in treating peritonitis.

SUMMARY

Peritonitis, inflammation of the peritoneum, is a potentially life threatening condition. Suspected peritonitis must be addressed urgently. The PERiPLEX product is an in vitro diagnostic medical device, designed for use in the home, by peritoneal dialysis (PD) users, as a means of detecting peritonitis. Do not rely solely on the test result. If you feel unwell and are experiencing potential symptoms of peritonitis, seek medical assistance straight away. The PERiPLEX device is designed to be simple to use, and to generate clear, actionable results. It is intended for over-the-counter and for prescription use. Training will be offered at your PD clinic.

PRINCIPLE

The test detects two markers of infection, using a multiplexed lateral flow immunoassay system. Interleukin-6 (IL-6) and Matrix Metalloproteinase-8 (MMP-8) are recognised markers of infection. A shielded hypodermic needle is used to pierce the seal on a PD waste bag and obtain a sample of waste peritoneal dialysate. The sample of dialysate is transferred to the lateral flow test strip, which detects the infection markers. The control line (C) confirms that the PERiPLEX test has been performed correctly. If either (or both) of the infection markers is present, coloured test lines appear, indicating the presence of infection. You should seek urgent medical assistance to initiate suitable treatment. A positive test result may be obtained before physical symptoms are evident (such as feeling unwell, or cloudy dialysate).

STORAGE AND STABILITY








Keep dry and cool (2 to 30°C). Do not freeze.

MATERIALS

PERiPLEX devices individually pouched with a silica gel sachet. You will also need a 5 minute timer (not provided).



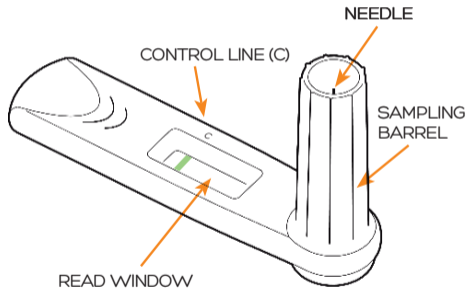
WARNINGS AND PRECAUTIONS

-  **Connect to outlet tube of waste PD bag only. (DO NOT attempt to connect to peritoneum outlet catheter).**
-  **Do not use if the silica gel sachet is GREEN. It should be ORANGE. Open another pouch.**
-  **For single use only.**
-  **Do not use beyond expiry date.**
-  **Do not use if the device packaging is punctured or not sealed.**
-  **Keep out of reach of children.**
-  **Dispose of safely.**

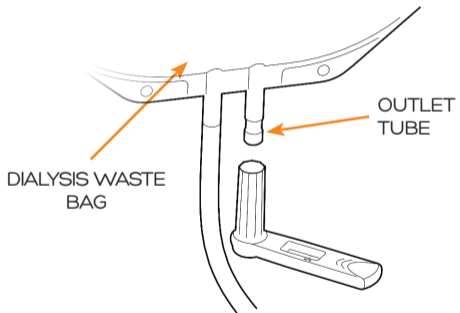
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THE DEVICE



THE DEVICE AND DIALYSIS WASTE BAG

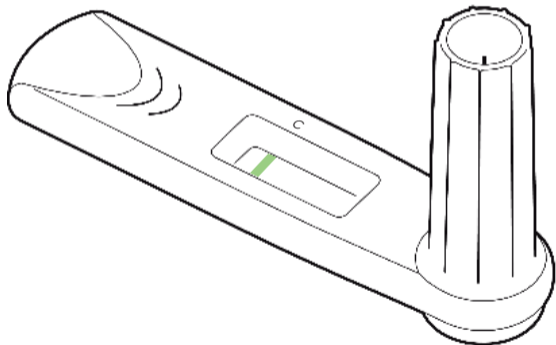


PERIPLEX TEST PROCEDURE

- Gently mix contents of waste bag. If there are air bubbles trapped in the outlet tube, then dislodge by flicking the end of the tube. Keep upright.
- The test should be performed daily, and takes approximately 5 minutes.
- Perform the test in a well lit area so you can easily view the test results.
- Do not touch the read window or get any substance on it, as results may be affected.
- Avoid distractions while running the test.
- Make sure you have a 5 minute timer ready.

1

Open the pouch and remove the PERiPLEX device. Discard silica gel sachet and pouch. Use device within 10 minutes of opening pouch.

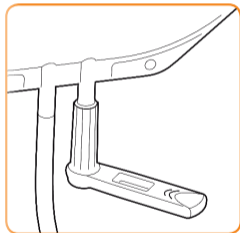
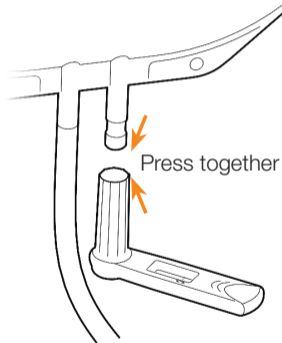


Do not use if the silica gel sachet is green. It should be orange.

2

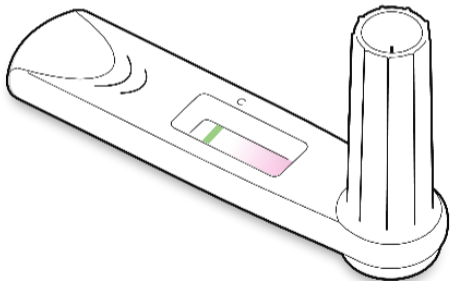
Gently insert needle into the outlet tube by pushing the sampling barrel of the test device onto the outlet tube.

As soon as the liquid appears in the window immediately remove the device from the bag - failure to do so may result in a failed test. If no liquid appears within 30 seconds - detach and re-run the test.



3

Place the device on a clean, dry surface, with the read window facing upwards.



4

Start the timer and wait for 5 minutes for the test to run.



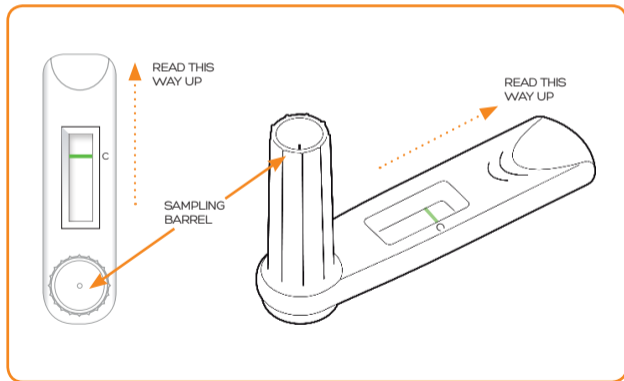
5

After 5 minutes examine the test results in the read window and interpret results.

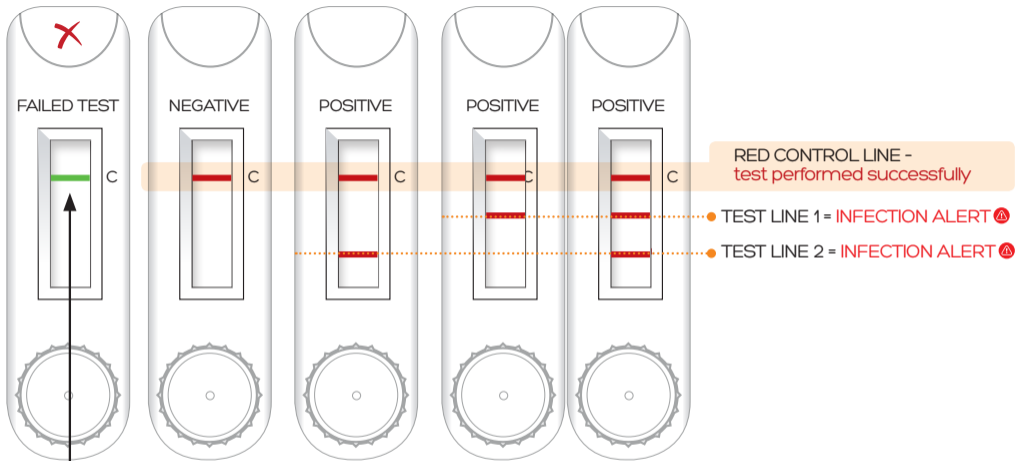
Dispose of used test device and packaging in general household waste.

INTERPRETATION OF RESULTS

If the test has been performed correctly the green control line (C) will turn red.



- If one or both TEST LINES appear, this indicates presence of peritonitis. **Seek urgent medical assistance.**
- If no TEST LINES appear, no further action required (check limitations).
- If no red control line, repeat test with a new device.



If control line stays green, the test has failed. **REPEAT TEST USING A NEW DEVICE** ⚠

PERFORMANCE CHARACTERISTICS

The performance of the PERiPLEX test was assessed using 121 frozen samples of waste dialysate from PD users:

- 66 samples from users clinically diagnosed with peritonitis.
- 55 samples from users without peritonitis.

The test gave a positive result for 65 of the 66 peritonitis samples (98.5% sensitivity), and a negative result for 52 of the 55 stable user samples (94.5% specificity).

LIMITATIONS

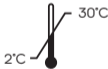
- Do not rely solely on the PERiPLEX test result. If you feel unwell and are experiencing potential symptoms of peritonitis, seek medical assistance straight away.
- If the CONTROL line does not appear, the test should be repeated using a new device.

- Only use with peritoneal dialysate samples. The performance of this test using other samples is not known.
- This test is a qualitative screening assay. It is not designed to determine the absolute concentration of the two infection markers, nor the severity of the infection.
- It is possible that technical or procedural errors, as well as other interfering substances in the specimen may cause erroneous results.
- A negative result does not confirm absence of infection. Negative results can be obtained when a marker is present, but below the detection threshold of the test.
- Reading the test results earlier than the recommended 5 minute time can cause false negative results. Reading after 5 minutes can cause false positive results.
- This is a screening test. If it indicates presence of infection, seek medical assistance urgently. Additional tests may be conducted.
- The presence of other infectious diseases may give rise to a positive result.
- Visually impaired/colour blind users may require assistance reading the device

PERiPLEX[®]

INFECTION TEST FOR PERITONEAL DIALYSIS USERS

VERSION 03, MAY 2017



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HELP LINE

If you have any questions, please call us at
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09:00 to 17:00, or email
technicalsupport@mologic.co.uk

Our professional staff will assist you.
To learn more, please visit us at
www.mologic.co.uk

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