

PERiPLEX[®]

Instructions for Use

Infection test for Peritoneal Dialysis users

For self-testing

Please read in full



APR 2018

REF 11011203
11011235

INTENDED USE

The PERiPLEX test, intended for self-testing, detects two recognised markers of infection, Matrix MetalloProteinase-8 (MMP-8) and Interleukin-6 (IL-6), 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. Training may be offered at your PD clinic.

PRINCIPLE

The test detects two recognised markers of infection, Interleukin-6 (IL-6) and Matrix Metalloproteinase-8 (MMP-8), using a multiplexed lateral flow immunoassay system. A sample of waste peritoneal dialysate is transferred to the lateral flow test strip, which

detects the infection markers, by either dipping the sample wick into a container of dialysate, or by holding the sample wick in the dialysate stream as the waste bag is emptied. The control line confirms that the PERiPLEX test has been performed correctly. If either (or both) of the infection markers is present, coloured test lines appear in the read window, indicating the presence of infection and 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 25°C). Do not freeze.

MATERIALS

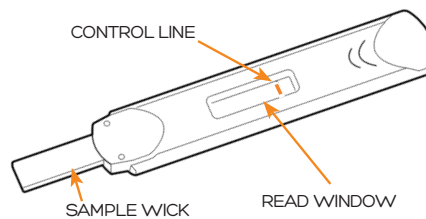
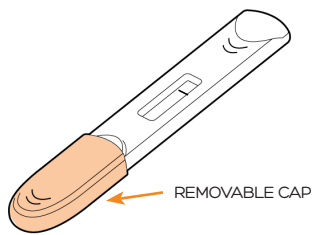
PERiPLEX devices individually pouched with a silica gel sachet. You will also need a 5 minute timer (not provided).



WARNINGS AND PRECAUTIONS

- 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.**

THE DEVICE



PERIPLEX TEST PROCEDURE

- Peritoneal dialysate waste fluid should be tested immediately after draining from the waste bag
- Gently mix contents of waste bag by inverting or shaking.
- Perform the test in a well lit area so you can easily

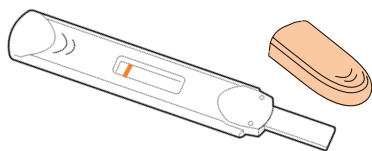
view the test results.

- Do not touch the read window or allow the waste dialysate to splash 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. Remove the cap from the device. An orange line should be visible when the device is removed from the pouch.

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



2

Hold the device with the absorbent sample wick pointing downwards in EITHER the waste dialysate stream as the bag is emptied, OR in waste dialysate fluid collected into a clean dry container, until a pink wash starts to appear in the read window.



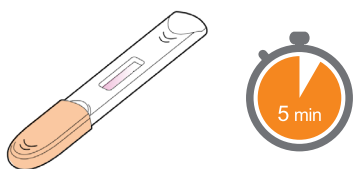
OR



Only immerse the sample wick in the liquid

3

Remove the device from the fluid and replace cap. Place the device on a clean, dry surface with the read window facing upwards. Start the timer and wait for 5 minutes for the test to run.

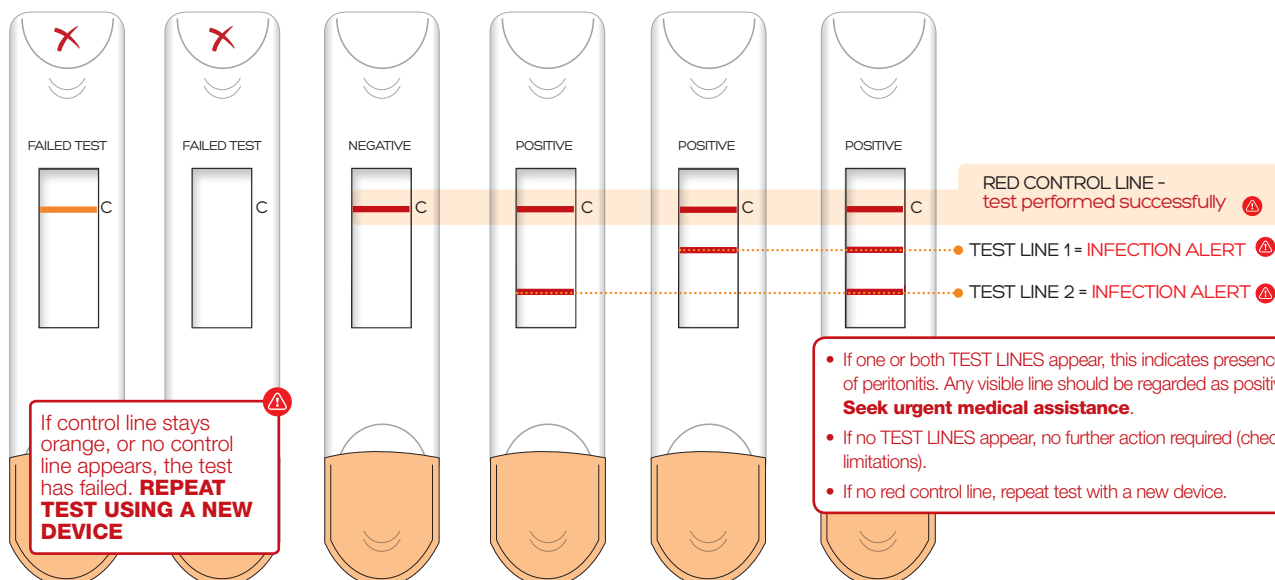


4

After 5 minutes examine the read window for the presence of any coloured lines. Interpret results as shown overleaf. Dispose of used test device and packaging in general household waste.

INTERPRETATION OF RESULTS

If the test has been performed correctly the orange control line will turn red.



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).

The data above was generated using Version 1 of the PERiPLEX test. A further study has been performed to demonstrate performance equivalence between Version 1 and Version 2. This additional data is available on request.

LIMITATIONS

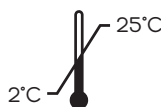
- Do not rely solely on the PERiPLEX test result. If you feel unwell and are experiencing potential symptoms of peritonitis, seek medical assistance straight away.
- If the CONTROL line does not appear, or does not change from orange to red, the test should be repeated using a new device.
- Only use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

The PERiPLEX technology was developed following a collaborative project with Cardiff University Medical School, funded by the National Institute of Health Research (NIHR).

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INFECTION TEST FOR PERITONEAL DIALYSIS USERS

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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