

PERiPLEX[®]

PERITONEAL DIALYSIS
INFECTION DIAGNOSTIC

FOR SELF TESTING



WHAT IS PERiPLEX?

PERiPLEX is a simple, 5 minute point-of-care test for home use as an aid to diagnosis of infection in patients receiving Peritoneal Dialysis (PD) treatment. The test detects two recognised markers of host immune response to bacteria in a lateral flow assay.

THE CLINICAL ISSUE

Kidney disease is on the rise, and peritoneal dialysis usage around the world is increasing slowly, driven by the benefits of lower cost, increased patient mobility and independence.

Peritonitis is a serious potential complication of PD which can lead to the need for line replacement, emergency treatment with antibiotics and potentially peritoneal lining damage or scarring that prevents the long-term use of this technique.

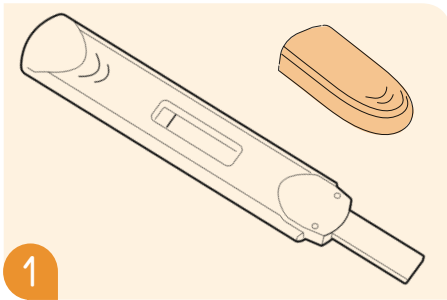
PERiPLEX is a simple to use product designed for use in the home, allowing waste dialysate to be tested immediately before disposal. A positive result indicates that infection is present, and medical help should be sought. A negative result provides reassurance that the patient is well.

PERiPLEX can be used in a variety of situations such as:

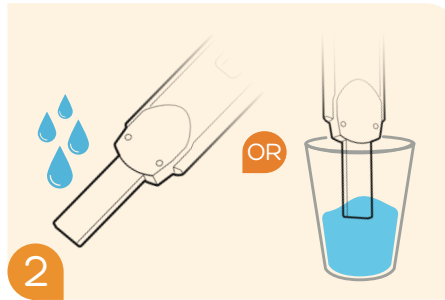
- To provide surety to regular PD users when suffering from abdominal pain or feeling unwell
- To provide reassurance for new users in their first few months on PD
- For routine monitoring of high risk patients
- For monitoring patients for a period immediately post-infection
- To provide reassurance to carers of assisted PD patients

PERIPLEX ASSAY PROCEDURE

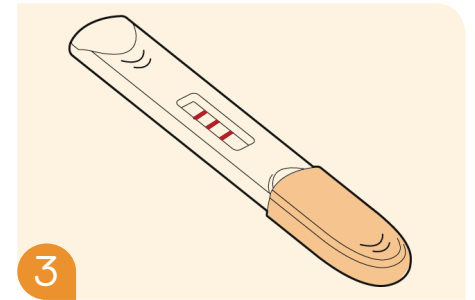
PERIPLEX is quick and simple to use, needing only three steps to give a result in five minutes.



1 Remove test device from foil pouch, and remove cap from the device

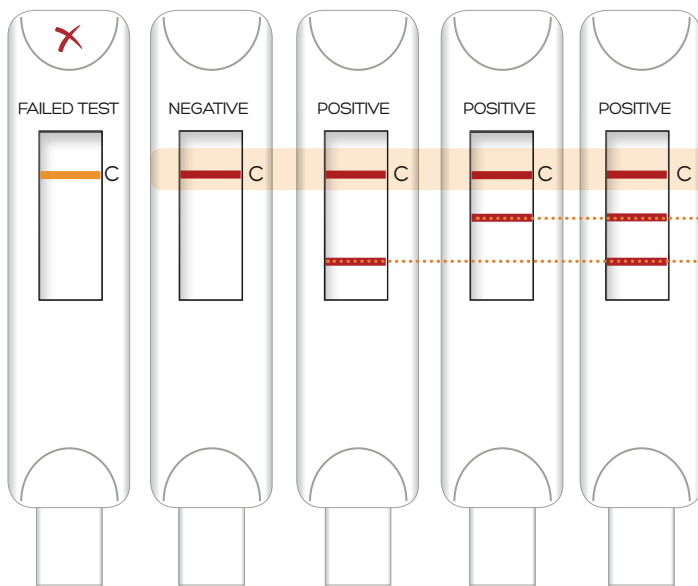


2 Expose the wick to the waste dialysate solution until a pink wash appears in the read window



3 Remove the device from the fluid and replace cap. Place device on a flat surface and read after 5 minutes

INTERPRETATION OF RESULTS



RED CONTROL LINE - test performed successfully

- TEST LINE 1 = INFECTION ALERT ⚠
- TEST LINE 2 = INFECTION ALERT ⚠

Results are easy to interpret. An infection is indicated by the presence of either 2 or 3 lines in the device window. A single control line indicates no infection is present

PRODUCT INFORMATION

Product code	11011203 - 3 tests 11011235 - 35 tests
Sample type	Peritoneal dialysis effluent
Assay running time	5 minutes
Assay format	Lateral flow
Storage	2° - 25°C
Shelf life	Minimum 12 months

PERFORMANCE INFORMATION

- 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.

To place an order, Contact sales@mologic.co.uk
Call +44(0)1234 780020 or Visit www.mologic.co.uk

Mologic Ltd, Bedford Technology Park, Thurleigh, Bedford MK44 2YA
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