

## Innate immune response biomarkers in peritoneal dialysis effluent as reliable diagnostic indicators of peritonitis - evaluation of a rapid diagnostic test device

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### Introduction:

Peritoneal dialysis patients often present with a “cloudy bag”. The diagnosis of peritonitis is easy if the patient has clear symptoms and signs, but patients who present with hazy fluid and atypical or no symptoms may be asked to wait for a four hour dwell and white cell count (WCC). This is inconvenient and has resource use implications if the patient is allocated a medical bed.

We used the Periplex<sup>®</sup> rapid diagnostic test from Mologic alongside our usual clinical protocols in over 90 patients presenting with various indications for PD fluid examination, to assess whether this could reliably exclude or diagnose peritonitis.

### Method:

The Periplex<sup>®</sup> test arose from research undertaken by Mologic Ltd. in collaboration with Cardiff University as part of an i4i (NHS NIHR Invention for Innovation) grant. It is a point of care single-use test-system which is dipped into the effluent dialysate. A positive test manifests at 5 minutes as one or two lines appearing in a “read window” next to a control line. It detects MMP-8, a marker of neutrophil activity not usually found in effluent dialysate, and IL6, present in dialysate at elevated levels during peritonitis episodes. Indications for fluid examination included: hazy fluid, abdominal pain, as part of a septic screen, an exit site infection or line contamination episode, bloody dialysate and post peritonitis.

### Results:

Of 96 samples, 48 had a positive Periplex<sup>®</sup> test result. 43 required treatment for peritonitis. Of five false positive results, four had sepsis – one with C.Difficile, one with an infected intra-abdominal lymphocele, and two had severe urosepsis. In one patient a Strep Oralis was grown but the WCC was 15 and no treatment was needed. 48 patients had a negative Periplex<sup>®</sup> result. There were two false negative results. One patient had a dialysate WCC of 20; fluid grew S Epidermidis and within 48 hours he had clinical peritonitis with WCC of 340. Another patient post-treatment for peritonitis had a dialysate lymphocytosis with likely ongoing infection (fluid white cell count 175, cultures negative).

The positive predictive value of the test in this sample was 89.5%, and the negative predictive value was 95.8%.

### Conclusions:

The Periplex<sup>®</sup> was easy for PD nursing staff to use. Peritonitis can be excluded on the basis of a rapid test result, which allows the team to reassure the patient who is clinically well and to focus on finding other causes of illness in a patient who is unwell. All patients who had a positive Periplex<sup>®</sup> test but not PD peritonitis had alternative causes of infection and were clinically unwell.

The Periplex<sup>®</sup> test had a high negative predictive value. Testing carried out too early may be negative and the test might not detect partially treated peritonitis reliably.