Antagen Pharmaceuticals

Human Interleukin-8 XpressCard
(Cat. #: ATG-IL-8)

Intended Use

Antagen's hIL-8 XpressCard is an immunochromatographic rapid test for the detection of human interleukin-8 in biological fluids, such as urine, serum or plasma. The assay can be potentially used as an aid for diagnosis of primary and secondary infections (e.g., urinary tract infection and neonatal sepsis), as well as certain neoplastic conditions (e.g., bladder cancer), in conjunction with other criteria.

Introduction

IL-8 is also referred to as neutrophil chemotactic factor (NCF), neutrophil activating protein (NAP), monocyte derived neutrophil chemotactic factor (MDNCF), T lymphocyte chemotactic factor (TCF), granulocyte chemotactic protein (GCP) and leukocyte adhesion inhibitor (LAI), and is a chemotactic factor that attracts neutrophils, basophils, eosinophils and T-cells. Many cell types, including monocyte/macrophages, T cells, neutrophils, fibroblasts, endothelial cells, keratinocytes, hepatocytes, chondrocytes, and various tumor cell lines, can produce IL-8 in response to a wide variety of proinflammatory stimuli such as exposure to IL-1, TNF, LPS, and viruses. IL-8 has been reported to be a co-mitogen for keratinocytes and was also shown to be an autocrine growth factor for melanoma cells. It is reported to be angiogenic and plays a positive role in tumor metastasis. IL-8 is regarded as one of the earliest biomarkers for infection and inflammation. This assay takes only 5-10 minutes, compared to the conventional ELISA assay that takes several hours.

Test Principle

Antagen's hIL-8 XpressCard utilizes the principle of Immunochromatography (also called as lateral flow immunoassay, LFIA). A mouse anti-human IL-8 antibody is immobilized on the nitrocellulose membrane as the test line (T line) in the test window of the test device. As the test sample flows through the membrane assembly within the test device, IL-8 within the sample is bound by a sencond mouse anti-human IL-8 antibody conjugated with colloidal gold and released from the sample pad. This antigen-antibody complex moves further on the membrane to the test region where it is immobilized by the first anti-human IL-8 coated on the membrane, leading to the formation of a colored band, which confirms a positive test results. Absence of this colored band in the test window indicates a negative test result. A built-in control line (C line) will always appear in the test window, regardless of the presence or absence of hIL-8 in the specimen.

Specimen Collection

1. No prior special preparation of the patient is required before sample collection by approved techniques.
2. Fresh urine/serum/plasma is preferable. Urine/serum/plasma may be stored at 2-8°C up to 3 days in case of delay in testing. For long-term storage, freeze the specimen at -20°C for 3 months or -70°C for longer periods.
3. The test works best on fresh urine or blood samples. If testing cannot be done immediately, blood samples collected with a suitable anticoagulant such as EDTA or Heparin or Oxalate should be stored at 2-8°C up to 3 days. Blood samples should not be frozen.
4. Repeated freezing and thawing of the specimen should be avoided.
5. Do not use haemolysed, clotted, contaminated, lipamic and viscous/turbid specimen.
6. Specimen containing precipitates or particulate matter must be centrifuged and the clear supernatant only used for testing. Do not heat inactivate the sample.

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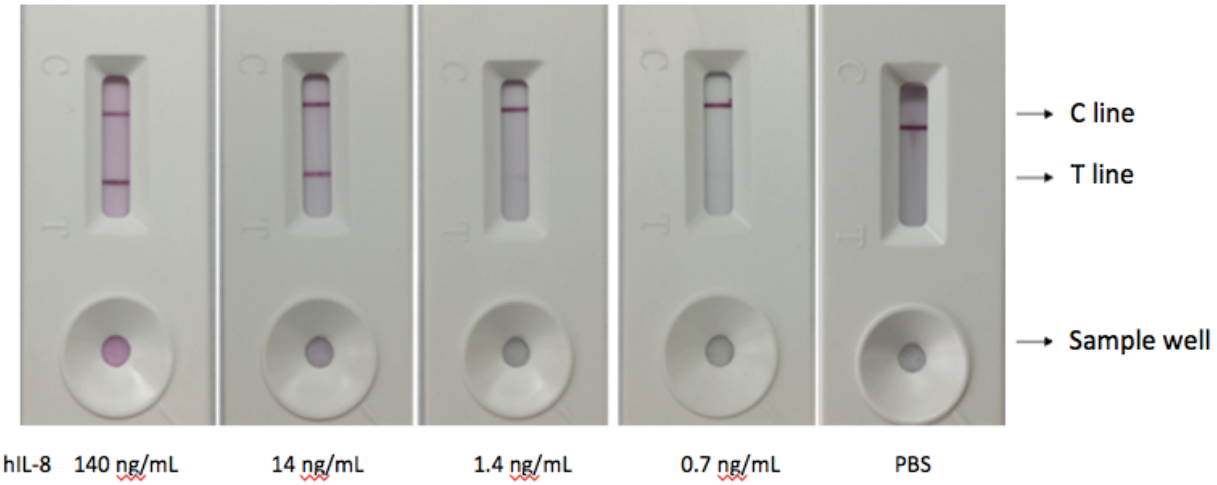
Test Protocol

1) Place the card horizontally.
2) Add 80 µL of biological fluids directly to the Sample Well.
3) Wait for 3-5 minutes.

Results

- **Negative:** Only the control C line appears.
- **Positive:** Both the C line and test T line appear, which indicates the presence of hIL-8.
- **Invalid:** If after 20 minutes no C line appears, the result is invalid. The test should be repeated with a new device.



Sensitivity

The assay has a sensitivity to detect hIL-8 down to **0.7 ng/mL**.

Storage

Store the cards in their original packaging at room temperature. This product is stable for up to 18 months from the certified date. Freezing the strips is not recommended.

Limitations of Procedure

1. The test is for qualitative detection of hIL-8 in human urine, serum, plasma or other biological fluids, but dose not indicate the quantity of hIL-8.
2. The test is for research use only, and should NOT be used for diagnosis.
3. As in case of all rapid tests, a definitive clinical diagnosis should not be based on the result of a single test but should rather be made after all the clinical findings have been evaluated.

Precautions

1. This kit is for *IN VITRO* research use and should be handled by *PROFESSIONALS*.
2. Read the instructions carefully before performing the test.
3. Follow standard lab procedure and biosafety guidelines, and handle all human specimens as potentially infectious. Wear gloves during the whole procedure.
4. When the assay procedure is complete, dispose specimens after autoclaving them at 121°C for at least 20 min. Alternatively, they can be treated with 0.5% Sodium Hypochlorite for 1-2 hours before disposal.

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