

Capture Lateral Flow Assay for a quantitative detection of neutralizing anti-drug Antibodies

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Technology

Anti-drug Antibodies (ADAs) are generated in patients by the response of the patient immune system against the biologic drug i.e. therapeutic proteins given. This immunity may result in reduced drug efficacy due to increasing its clearance from the body and/or blocking the personalized medicine tool to monitor the efficacy of drug in specific person and optimize the treatment given (different drug and/or change in dose). For example, it is estimated that ~30% of patients treated with the human anti-TNF- α antibody Humira developing ADA. Currently, if the treatment is inefficient, the physician changes the treatment to other optional drugs if exist. ADAs levels are usually being measured from regular blood sample in the laboratory using the common ELISA method. However, this measurement doesn't differentiate between neutralizing ADAs that reduce drug efficacy to non-neutralizing ones that only bind the biological drug (doesn't influence clearance or bind to other epitopes rather to the binding site). Moreover, current used methods, are time consuming and require experienced laboratory personnel and hence are not useful for point of care management. Here, Prof. Marks and Prof. Chowers used the capture flow immune-assay, a technology platform being developed by Prof. Marks to developed easy to use, point-of-care device. This device detect and quantify the ADAs using internal calibration technique that replace the need for calibration curve and additional reader devices. Most importantly, the device differentiates between neutralizing and non-neutralizing ADAs.

Application

Rapid point-of-care, easy to use, diagnostic device to monitor efficacy of treatment to biological drugs.

Advantages

- A rapid and sensitive assay, which will enable assessing the need for treatment adjustments.
- Easy differentiation between neutralizing and non-neutralizing ADAs
- Only one antibody required – enables hapten size detection
- Enables any cellphone reader thanks to internal calibration
- Proprietary capture layer
- Internal-calibration concept

Patent

[WO2021/260705A1](#); [WO2020/141525A1](#) (capture flow technology)