Cutting cost and time -
HCV immunoassay predicts clinical response rate to antiviral treatment

Reference No: B76124

CHALLENGE
Each year, 3-4 million people become infected with the hepatitis C virus (HCV). In 30% of cases, the virus clears within 6 months of infection without treatment. However, an estimated 71 million people globally develop a chronic course often resulting in cirrhosis or liver cancer. For these patients, the introduction of all-oral direct-acting antiviral (DAA) therapy has revolutionized treatment and life options with a 95% cure rate. However, response to DAA treatment can vary considerably between patients in terms of HCV RNA negativity. With the potential to identify the response outcome for patients before treatment, shorter and individualized courses of DAA therapy are made possible and possess a significant benefit toward reducing overall treatment costs.

INNOVATION
Here, we present a method to predict clinical response rate to DAA treatment of patients with chronic HCV infection by virtue of early viral control. DAA treatment is known to alter distribution of CD8+ memory T cell subsets. Prior to starting the cost-intense DAA treatment, analysis of peripheral blood by flow cytometry for frequency of CD8+ TEM lymphocytes divides patients into “fast” and “slow” responders to DAA therapy. Measured frequencies of CD3+ and naive CD8+ T cells correctly classified 82.6% of patients as “fast” (HCV RNA-negative by 4 weeks) or “slow”. With a false-positive rate to predict a fast response of only 9.1%, this method can reliably shorten treatment duration.

| PREDICTED RESPONSE | OBSERVED RESPONSE | (%)
|--------------------|-------------------|---
| SLOW               | 10                | 76.9|
| FAST               | 1                 | 90  |
| OVERALL CORRECT (%)| 82.6              |

COMMERCIAL OPPORTUNITIES
• Cost-effective approach to shorter treatment: under $100 in less than 4 h
• Highly standardized flow cytometry-based assay with commercially available kits
• Individually-tailored assay principle can be extend to other analytical methods or biomarkers

DEVELOPMENT STATUS
Proof-of-concept in vitro and in HCV patient group

REFERENCES:
1. https://www.who.int/news-room/fact-sheets/detail/hepatitis-c