

**EVALUATION OF PERFORMANCE AND ADHERENCE TO IFR 300
KIT FOR PREDICTING THE RESPONSE TO TNF α BLOCKERS
IN BIOLOGICS-NAIVE RHEUMATOID ARTHRITIS PATIENTS:
PROSPECTIVE COHORT STUDY FROM ISRAEL**

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Background

About 30-40% of Rheumatoid arthritis (RA) patients do not respond to TNF α blockers (TNF α B). GeneFrom Ltd has developed and validated a diagnostic kit (IFR 300) which predicts individual response to TNF α B. **Objectives:** To evaluate the performance of and adherence to IFR 300 kit in "real-world" Israeli healthcare setup. **Patients and methods:** Two cohorts were examined. Cohort 1 included biologics-naïve, active RA patients from Meuhedet HMO eligible for TNF α B therapy according to Israeli health basket who performed the IFR 300 test. Patients were clinically assessed for disease activity before initiating TNF α B (using DAS-28 score) and 3 months thereafter. The primary endpoint was the kit's prediction accuracy. Cohort 2 included community and hospital rheumatologists whose adherence to the kit's usage and results were qualitatively described. For patients in both cohorts, whole blood samples were withdrawn followed by RNA extraction and subsequent cDNA transcription. Qualitative real-time (qRT) PCR results were obtained using the IFR300 test for selected gene probes. In both cohorts, physicians were informed on the test results before initiating treatment. **Results:** Sixteen patients in Cohort1 were included. A significant decrease in DAS-28 was observed at 3 months (from 3.93 to 2.83, $p=0.0007$). Nine tests out of sixteen were predicted as responders (R) and seven as non-responders (NR). Six R patients achieved good response and two patients achieved moderate response to TNF α B according to EULAR response criteria. Two NR patients received TNF α B and did not respond. The remaining NRs were treated with other biologicals and three (60%) achieved good response. Overall, the kit correctly predicted the response in 10 of 11 patients, resulting in 90.9% accuracy and 93.3%

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adherence of physicians to the kit's results. In Cohort 2, sixteen physicians conducted 19 tests, of which 10 were predicted as R and 9 as NR. All Rs received TNF α B and 90% responded. 89% of physicians adhered to test's results, 20% used it repeatedly. **Conclusion:** In this prospective study, IFR 300 kit accurately predicted the response to TNF α B in a high percentage of patients. These results can serve as an established decision-making tool for rheumatologists in selecting a biological treatment for RA patients.

Keywords: Rheumatoid arthritis, TNF α blockers, Personalized medicine

