MOLECULAR SIGNATURE TEST

Patient Report

PHYSICIAN

NAME Dr. Robert Jones

COLLECTION DATE 00/00/2020

COLLECTION TIME 00:00

SPECIMEN RECEIVED 05-June-2018

REPORT DATE 17-June-2018

CLINIC

CLINIC NAME

Community Rheumatology Clinic

ADDRESS 123 Main St. Ste 100

Anytown, US

PHONE NUMBER 888-111-2222

FAX NUMBER 444-555-6666

PATIENT

NAME Smith, Mary

DATE OF BIRTH 01-Jan-1955

SEX Female

REQUISITION NUMBER

R00036

MEDICAL RECORD NUMBER

1234567

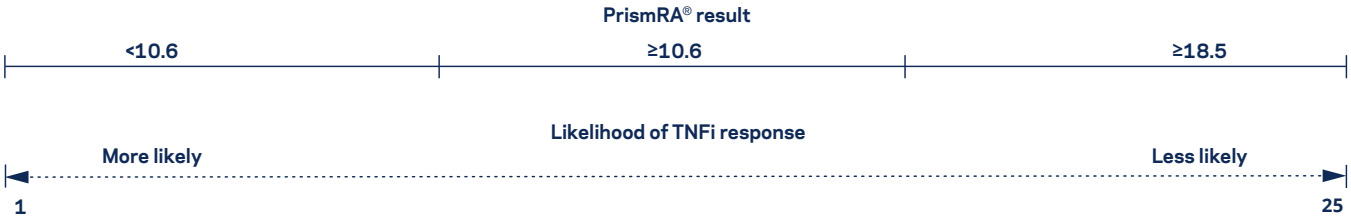
TEST DESCRIPTION

PrismRA® is a molecular signature test that uses RNA expression data, demographic variables, clinical metrics, and anti-cyclic citrullinated protein (CCP) antibody to detect a signal of non-response to tumor necrosis factor inhibitors (TNFi) for patients with rheumatoid arthritis. This signal is associated with a high or very high likelihood of inadequate response to TNFi therapies and indicates that the patient is unlikely to achieve low disease activity or remission with TNFi therapies. Response is defined as achieving ACR50 at 6 months.

YOUR PATIENT'S PrismRA® RESULTS

Result Value: **12.2**

Interpretation: **High Non-Response**



YOUR PATIENT IS IN THIS CATEGORY

Molecular signal of non-response not detected

PrismRA® result: **12.2**

HIGH non-response

High likelihood of inadequate response to TNFi therapies

Unlikely to achieve low disease activity or remission with TNFi therapies

VERY HIGH non-response

MOLECULAR SIGNATURE TEST

CLINICAL VALIDATION

The PrismRA® molecular signature test was validated in biologic-naïve and biologic-exposed patients who had moderate-to-severe RA.[1-4] The PrismRA results reflect the validation patient population cohorts and may differ between populations. The high category threshold corresponds to an approximate 90% chance of inadequate response to TNFi therapies, which means the patient has a 10% chance of responding. The very high category threshold corresponds to an approximate 95% chance of inadequate response to TNFi therapies, which means the patient has a 5% chance of responding.

METHODOLOGY

Total RNA was extracted from the blood sample and sequenced at Ambry Genetics utilizing validated methods.[5] Anti-CCP antibody measurements were performed at Scipher using validated methods.[6] Final algorithmic analysis was performed at Scipher.[6]

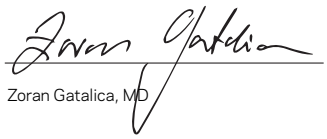
USE OF TEST RESULTS

The result is provided as an informational data point for the physician only, not a recommendation. Before making any treatment decision for your patient, the references should be consulted for more information along with the patient's medical history and clinical assessment. PrismRA scores are predictions of likelihood, not certainties. The test result is reported on a continuous 1-25 scale. The higher the score, the more likely the patient will have an inadequate response to TNFi therapies and be unable to reach low disease activity; the lower the score, the less likely the patient will have an inadequate response to TNFi therapies. However, a low score does not ensure a positive response to TNFi therapies. Although extremely rare, results could also be impacted by other factors not addressed above. For additional support, contact Scipher through the website or by calling **855-724-7437**.

DISCLAIMER

The clinical annotations provided by Scipher are intended solely for use by a medical professional and do not constitute medical advice by Scipher. The treating provider remains ultimately responsible for all diagnosis and treatment decisions for the patient. Scipher disclaims liability for any errors, omissions or ambiguities in any translation or interpretation of a report by a third party, including without limitation, direct, indirect, incidental, special, consequential or exemplary damages, whether such damages arise in contract, negligence, tort, under statute, in equity, at law or otherwise. Information included in this report is based upon scientific literature and does not take into account other genetic variants and environmental or social factors that may impact each patient. This test, and the interpretive content in this report, have not been reviewed, cleared or approved by the Food and Drug Administration (FDA). PrismRA was developed and its performance characteristics determined by Scipher. This laboratory is certified under the Clinical Laboratory Improvement Amendments (CLIA) as qualified to perform high complexity clinical laboratory testing. This test is used for clinical purposes. It should not be regarded as investigational or for research.

Laboratory CLIA number: 34D2180776
Laboratory Directors: Zoran Gatalica, MD,
Sarah Rapisardo, PhD, DABMGG



Zoran Gatalica, MD

Comments

Notes

1. Mellors T, et al. Clinical validation of a blood-based predictive test for stratification of response to tumor necrosis factor inhibitor therapies in rheumatoid arthritis patients. *Netw Syst Med.* 2020;3(1):91-104.
2. Cohen S, et al. A molecular signature response classifier to predict inadequate response to tumor necrosis factor-α inhibitors: the NETWORK-004 prospective observational study.
3. Data on file. Scipher Medicine Corporation. Analytical validation May 2021.
4. Zhang L, et al. A molecular signature response classifier predicts the likelihood of EULAR non-response to TNF inhibitor therapies in RA: Results from a retrospective cohort analysis. Scientific poster presented at EULAR 2021. Submitted for publication 2021.
5. Ambry Genetics 7 Argonaut, Aliso Viejo, CA 92656. Laboratory Director Chia-Ling Gau, Ph.D., DABMGG. Laboratory CLIA number 05D0981414. CAP 7154701.
6. Scipher Medicine Laboratory 4134 S. Alston Ave Suite #104, Durham, NC 27713. Laboratory Director Zoran Gatalica, MD. Laboratory CLIA number 34D2180776.

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