

Patient Report Summary

PHYSICIAN

NAME Dr. Bob Jones
REQUISITION NUMBER R00036
COLLECTION DATE
COLLECTION TIME
SPECIMEN RECEIVED 05-June-2018
REPORT DATE 17-June-2018

CLINIC

Community Rheumatology Clinic
 123 Main Street, Ste 100 Anytown, US
 Phone number: 888-111-2222
 Fax number:

PATIENT

NAME Smith, Mary
DATE OF BIRTH 01-Jan-1955
SEX Female

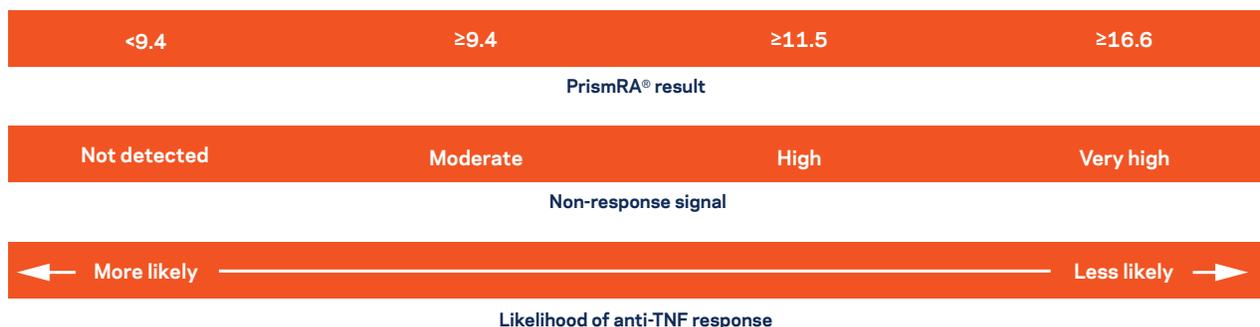
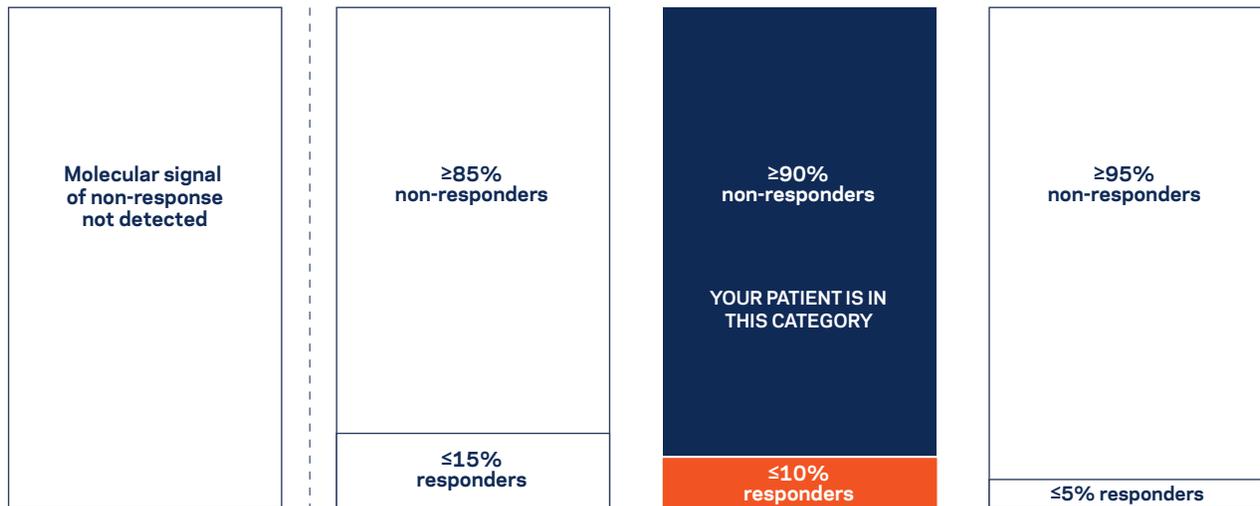
TEST DESCRIPTION

PrismRA[®] is a molecular signature test that uses RNA expression data, demographic variables, clinical metrics, C reactive protein (CRP) and anti-cyclic citrullinated protein (CCP) to detect a signal of non-response to tumor necrosis factor inhibitors (anti-TNF) for patients with rheumatoid arthritis. This signal predicts the patient's likelihood of not responding to all anti-TNF therapies before starting a biologic therapy. Response is defined as achieving ACR50 at 6 months.

YOUR PATIENT'S PrismRA[®] RESULTS

RESULTS INTERPRETATION

A patient with a high signal of non-response has a ≥90% likelihood of not responding adequately to anti-TNF therapies. Thus, your patient has a ≤10% likelihood of responding to anti-TNF therapies.



MOLECULAR SIGNATURE TEST

CLINICAL VALIDATION

The PrismRA® molecular signature test was validated in 175 biologic-naive patients who had moderate-to-severe RA.¹ The PrismRA® results and associated likelihoods shown on the first page of this report reflect the validation patient population and may differ between populations.

METHODOLOGY

Total RNA was extracted from the blood sample and sequenced at Ambry Genetics utilizing validated methods.² Plasma CRP and CCP measurements were performed at Scipher Medicine Corporation using validated methods.³ Final algorithmic analysis was performed at Scipher Medicine Corporation.³

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 lower the test score, the lower the likelihood of non-response. PrismRA® does not predict response to anti-TNF therapies. Test results and clinical interpretation may be inaccurate for individuals who have or are receiving anti-TNF therapies or other targeted drugs for the treatment of rheumatoid arthritis or another disease. Although extremely rare, results could also be impacted by other factors not addressed above. For additional support, contact Scipher Medicine through the website or by calling 855-724-7347.

DISCLAIMER

The clinical annotations provided by Scipher Medicine are intended solely for use by a medical professional and do not constitute medical advice by Scipher Medicine. The treating provider remains ultimately responsible for all diagnosis and treatment decisions for the patient. Scipher Medicine 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 Medicine. 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 Director: Zoran Gatalica, MD *Scipher Medicine Medical Director*

Zoran Gatalica, MD

Comments



Scipher Medicine Corporation
4134 S. Alston Ave Suite #104
Durham, NC 27713
855-724-7437
www.prismra.com

Notes

1. Mellors, T., et al. "Clinical validation of a blood-based predictive test for stratification of response to anti-TNF therapies in rheumatoid arthritis patients". Submitted. 2020
2. Ambry Genetics 7 Argonaut, Aliso Viejo, CA 92656. Laboratory Director Chia-Ling Gau, Ph.D., DABMGG. Laboratory CLIA number 05D0981414. CAP 7154701.
3. Scipher Medicine Laboratory 4134 S. Alston Ave Suite #104, Durham, NC 27713. Laboratory Director Zoran Gatalica, MD. Laboratory CLIA number 34D2180776.