SCIPHER MEDICINE

Service Guide

ScipherMedicine.com / 1-855-724-7437

About Scipher

A Precision Immunology Company

THE CHALLENGE

Matching patients suffering from autoimmune diseases with effective medications is one of the greatest challenges in health care today.

Despite drug therapies that improve and extend lives, tens of millions of patients annually are still subjected to drug therapy “trial and error” because until recently it was not possible to personalize treatment using a patient’s unique molecular profile.

Medicines that patients do not respond to cost the health care system billions of dollars annually and the largest contributor is autoimmune diseases.

THE SOLUTION

Scipher Medicine’s approach benefits nearly every health care stakeholder:

- **Patients** benefit from better clinical outcomes and more rapid advances in effective medications to treat their conditions.
- **Payers** benefit from lower costs and better clinical outcomes.
- **Health care providers** benefit from helping more patients, more efficiently.
- **Drug companies** benefit from shorter drug development cycles.

OUR MISSION

Scipher Medicine is a precision immunology company on a mission to match each patient with their most effective therapy to improve health outcomes.

OUR VALUES

- Hard working
- Risk tolerant
- Accountable
- Transparent

QUALITY POLICY

Scipher's Quality Policy strives to deliver innovative, high-quality products and services that lead to more effective treatment selections and ultimately better outcomes, for patients with autoimmune disease. Scipher is committed to maintaining a Quality Management System that complies with all applicable regulatory requirements, strives towards continuous process improvement, and provides high value to our customers with good professional practice. This is achieved through the commitment of management and the participation of ALL of those engaged in the operation of Scipher Medicine.

LICENSURE & CERTIFICATION

Important: For any compliance or licensing inquiries please do not hesitate to contact Scipher Medicine at (855) 724-7437.

To view all licenses please visit our website at: https://www.prismra.com/certifications/

CLIA	34D2180776
CAP	8821838
California	COS-90003223
New York	9631
Pennsylvania	38401
Rhode Island	LCO01390
Maryland	3210

CLIENT SERVICES

Phone: 855-724-7437 Opt. 2

Fax: 833-520-5128

Email: support@scipher.com

Hours: 9:00 AM – 5:00 PM EST

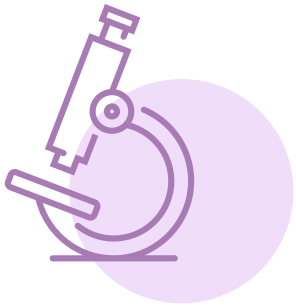
BILLING

Phone: 855-724-7437 Opt. 1

Fax: 833-643-1004

Email: billing@scipher.com

Hours: 9:00 AM – 5:00 PM EST



SCIPHER LABORATORY

Scipher Medicine
8 Davis Dr. Ste. 200, Durham, NC 27709

Mon-Fri: 8:30 AM – 5:00 PM EST

Sat: 8:30 AM – 1:00 PM EST

prism/RA®

MOLECULAR SIGNATURE TEST

PrismRA is a molecular signature response classifier (MSRC) that uses gene expression features, clinical features and anti-cyclic citrullinated protein (anti-CCP) antibody to detect a signature of non-response to tumor necrosis factor-α inhibitors (TNFi) for patients with rheumatoid arthritis.

PrismRA predicts the patient's likelihood of inadequately responding to all TNFi therapies. Response is defined as achieving ACR50 at 6 months. The PrismRA result is reported on a continuous 1 to 25 scale. The higher the score, the more likely the patient will have an inadequate response to TNFi therapies; 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.

PRISMRA® REPEAT TESTING POLICY:

1. Given that PrismRA inadequate response predictions are stable, patients are not eligible to repeat a PrismRA test. Changes in non-b/tsDMARD treatments, including but not limited to conventional synthetic disease modifying antirheumatic drugs (csDMARDs) and prednisone, do not warrant additional PrismRA testing.
2. Since PrismRA is clinically validated in patients who are TNFi-naïve and TNFi-exposed, treatment decisions made after PrismRA testing do not warrant additional PrismRA testing. This includes but is not limited to 1) making no change to treatment, 2) switching or starting a new TNFi therapy, or 3) dose escalating a current TNFi therapy.
3. Patients who have received a PrismRA test result and were subsequently prescribed a b/tsDMARD with a non-TNFi MOA are not eligible for repeat testing. PrismRA has not been clinically validated in such patients.

TURNAROUND TIMES

PrismRA turnaround time is 5-7 business days from when the patient sample is received.

Current validation evidence supports the use of PrismRA once per patient according to the following intended use statement:

PrismRA is intended for use in adult (18 years of age or older) rheumatoid arthritis (RA) patients with moderate or high disease activity who are 1) on csDMARDs and considering starting a b/tsDMARD or 2) on TNFi therapies and are considering a targeted therapy change (including dose escalation or cycling to another TNFi).

The PrismRA algorithm assesses blood gene expression features and clinical features to predict inadequate response to TNFi therapies, including adalimumab, certolizumab pegol, etanercept, golimumab and infliximab. Results are reported on a continuous 25-point scale and categorize a patient as having a molecular signature of inadequate response detected or not detected. When samples satisfy technical and quality control requirements, the molecular signature detection status of a patient is never reported as indeterminate.

SPECIMEN REQUIREMENTS & HANDLING PROCEDURES

Clients are responsible for submitting specimens which are properly labelled with patient's name, date of birth, and collection date, in addition to meeting the submission requirements for all testing requested. The quality of laboratory results is highly dependent upon proper specimen collection and handling. Please see below for specimen requirements and handling procedures for tests performed by Scipher Medicine.

Test Requested	Specimen Type	Tube Types	Collection and Handling	Storage and Transportation
PrismRA	Peripheral Blood	(1) Serum Separator Tube (SST)	Draw SST tube first. Slowly invert the tube 8-10 times immediately. Place the SST tube upright in a test tube rack at ambient temperature for a minimum of 30 minutes. If possible after the waiting period, spin the SST tube at a speed of 1000 to 1300 RCF for 10 minutes in swinging bucket centrifuge or 15 minutes in a fixed-angle centrifuge.	Package according to collection instructions. Use cool pack during transport. Ship same day as drawn whenever possible; specimens received >72 hours after collection will be rejected.
		(2) PAXgene™ Blood RNA Tubes	Draw PAXgene™ tubes last. Minimal amount of blood is 2 mL. Slowly invert the tubes 8-10 times immediately. Place PAXgene™ tubes upright in a test tube rack at ambient temperature for a minimum of 2 hours; do NOT spin the PAXgene™ tubes.	

Please note that Scipher Medicine cannot accept Category A infectious substances as defined by IATA (Dangerous Goods Regulations 3.6.2.1.1 Definition –Infectious Substances).

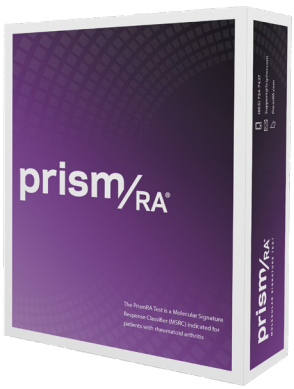
SPECIMEN KITS GUIDE

Note: Scipher Medicine kit components and test requisition forms are subject to change. Please communicate with your account manager for the most up-to-date versions.

Each test requisition form must contain complete patient demographic information including the patient's full legal name, date of birth ("DOB") and all additional highlighted information on the test requisition form (TRF). Please note that if any required information is missing on a TRF, it may impact turnaround time for the test results while we gather the missing information.

Kit components:

- 1 SST tube
- 2 PAXgene™ tubes
- Absorbent sleeve
- 3 oz. gel pack
- 5 labels for sample tubes
- Insulated foil envelope
- Biohazard zip poly bag
- Pre-paid clin-pak shipping bag
- Test requisition form (TRF)
- 1 label for the TRF



1. PrismRA® Technical Specifications. Scipher Medicine Corporation. 2021. **2.** Cohen S, Wells AF, Curtis JR, et al. A Molecular Signature Response Classifier to Predict Inadequate Response to TumorNecrosis Factor-α Inhibitors: The NETWORK-004 Prospective Observational Study. *Rheumatol Ther.* 2021;8(3):1159-1176. doi:10.1007/s40744-021-00330-y.

PRISMRA TEST REQUISITION FORM

prism/RA®
MOLECULAR SIGNATURE TEST

PrismRA Test Requisition Form

Please attach QR code label here

Required Fields (Patient sex, height, weight, and global assessment scores are used in the PrismRA classifier. Incorrect inputs in those fields could result in inaccurate test results.)

Client Services Team **Phone:** 855-724-7437 | **Fax:** 833-520-5128 | **Email:** Support@Scipher.com

PATIENT INFORMATION

Patient Name:

Sex: ☐ Female ☐ Male **Date of Birth** (mm/dd/yyyy): / /

Weight: lbs **Height:** ft in

Address:

City: **State:** **Zip:**

Email:

Phone:

Patient Global Assessment: On a scale from 0 to 100, where 0 represents VERY WELL and 100 represents VERY POORLY, rate how well you are doing:

0 5 10 15 20 25 30 35 40 45
Very Well

50 55 60 65 70 75 80 85 90 95 100
Very Poorly

Please confirm the number you indicated above: _____

ICD-10 CODE(S) (list all that apply):

☐ M05.79 ☐ M05.9 ☐ M06.09 ☐ M06.9 ☐ Other _____

Ordering practitioners should report diagnosis code(s) that best describes the reason for performing the test.

Is the patient naïve to TNFi? ☐ Yes ☐ No ☐ Unknown

TEST ORDERED

☑ PrismRA

The PrismRA Test is intended for use in adult patients with moderate to severe rheumatoid arthritis who are (1) naïve to b/tsDMARD and considering starting their first b/tsDMARD or (2) TNFi-exposed who are considering switching to another TNFi therapy or escalating their TNFi dose.

TO BE COMPLETED BY PHLEBOTOMIST

Phlebotomist Name:

Collection Date (mm/dd/yyyy): **Collection Time:**

PROVIDER INFORMATION

Provider Name:

Practice Name:

NPI:

Scipher Account Number:

Clinic Address:

City: **State:** **Zip:**

Clinic Phone: **Clinic Fax:**

Clinic/Provider Email:

PROGRAM OR STUDY TYPE

Program or Study Code:

Medical Record Number (if available):

BILLING INFORMATION

Required Documents

- ✓ Insurance Card - Front
- ✓ Insurance Card - Back
- ✓ Patient Demographic Sheet

Fill out the following fields ONLY if you are unable to attach all required documents.

☐ Bill Insurance ☐ Bill Self Pay

Insurance Plan Name:

Insurance ID Number: **Insurance Group Number:**

Insurance Phone Number: **Insurance Email:**

Place completed form in the PrismRA collection kit to be returned to Scipher Medicine with the three blood tubes.

Certificate of Medical Necessity and Informed Consent: My signature certifies that a) the PrismRA Test is medically necessary for the patient, b) the test information will inform the patient's ongoing treatment plan, and c) I am the patient's treating provider. I have explained to the patient the nature and purpose of the test and have obtained the patient's informed consent, to the extent legally required, to permit Scipher Medicine to a) perform the PrismRA Test, b) retain the test results and samples for an indefinite period of time for internal quality assurance and operations purposes, c) remove information that directly identifies the patient from the test results and genetic material, and use or disclose such information and materials for future unspecified research or other purposes, and d) release the test results and related patient information to the patient's third-party payer as needed for reimbursement purposes.

_____ _____

Provider Signature and Credentials **Date**

PRISMRA TEST REQUISITION FORM REQUIREMENTS

prism/RA MOLECULAR SIGNATURE TEST

PrismRA Test Requisition Form

TEST DESCRIPTION

PrismRA is a blood-based, precision medicine, molecular signature response classifier (MSRC) test that predicts non-response to TNFi therapy in rheumatoid arthritis so that patients with a molecular signature of non-response can be directed to a treatment with an alternative mechanism of action.

SCIPHER MEDICINE BILLING POLICY

- Scipher is committed to never surprise bill any patient.
- The majority of patients tested will have an out-of-pocket expense less than $75.
- If we estimate a patient's out-of-pocket expense to be greater than $75, a Scipher representative will reach out directly to the patient to discuss prior to performing their PrismRA testing.

PHLEBOTOMY INSTRUCTIONS

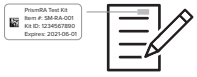
IMPORTANT

- **Ideally all specimen tubes are shipped the SAME DAY as the blood draw to avoid test failure**
- **All sample collection tubes must be stored at room temperature prior to use**
- **Discard the PrismRA kit and use a new one if any of the contents are expired or broken**
- **Do NOT freeze or refrigerate the gel pack prior to shipping**

1 Label tubes

- Write patient's name, DOB, and date on provided labels
- Label two PAXgene™ tubes (red tops) and one SST tube (tiger top)

2 Complete TRF

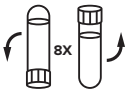


- Place QR code label at top right of TRF where indicated
- Complete required fields

3 Draw blood

- Draw SST tube **FIRST** (tiger top) then draw PAXgene tubes **LAST** (red tops)
- If redraw is needed, you **MUST** use another needle and draw a discard tube prior to drawing the PAXgene tube
- If a new tube(s) is needed, use contents from an additional PrismRA kit
- Ensure all tubes are labeled with labels from the original kit
- Minimum amount of blood in PAXgene tubes is 2 mL or the sample will be rejected
- Allow the tubes to completely fill as the flow will diminish to a drip at the end of the process
- Be sure to complete the draw for the first PAXgene tube before drawing the second to avoid test failure in case the blood draw volume is insufficient

4 Invert sample tubes



- Slowly invert the two PAXgene tubes and the SST tube 8-10 times **IMMEDIATELY**
- Blood must be completely mixed with the reagent so the final color of the sample is uniform
- **DO NOT SHAKE THE TUBES**

5

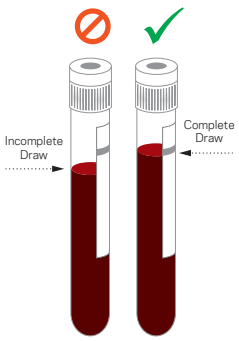
PAXgene waiting period

- Place the PAXgene tubes upright in a test tube rack at ambient temperature for a minimum of 2 hours
- Do **NOT** spin the PAXgene tubes

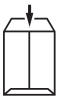
SST waiting period

- Place the SST tube upright in a test tube rack at ambient temperature for a minimum of 30 minutes
- If possible after the waiting period, **SPIN JUST THE SST TUBE** at a speed of 1000 to 1300 RCF for 10 minutes in a swinging bucket centrifuge or 15 minutes in a fixed-angle centrifuge

PAXgene Tube



6 Package



After the waiting period, package tubes in the following order:

1. Place three tubes in white sleeve
2. Place sleeve in foil envelope and add gel pack
3. Place envelope in biohazard bag and seal
4. Place biohazard bag into kit box
5. Add TRF and patient's insurance info to the kit and close
6. Place kit box in pre-paid shipping bag

7 Ship

- Ship to Scipher Medicine using pre-paid shipping bag
- All specimen tubes must be shipped within 24 hours of the blood draw, but ideally the **SAME DAY** to avoid test failure
- Do **NOT** ship on Saturday

scipher MEDICINE

PrismRA.com
ScipherMedicine.com

Client Services
P: 855-724-7437
F: 833-520-5128
E: Support@Scipher.com

Billing Questions
P: 855-724-7437
E: Billing@Scipher.com

 RA-LB0002-005-220520

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