prism/RA®
MOLECULAR SIGNATURE TEST

Test Requisition Form

☐ Standard Draw ☐ Mobile Request

For mobile ONLY, has the patient received a PrismRA kit? ☐ Yes ☐ No

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 (At birth): ◯ Female ◯ Male **Date of Birth** (mm/dd/yyyy):

Weight: lbs **Height:** ft in

Address:

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

Email:

Phone:

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

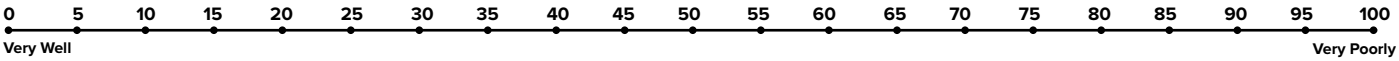
☐ M05.79 ☐ M05.9 ☐ M06.09 ☐ M06.00 ☐ Other _____

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

Is the patient naive to TNFi? ◯ **Yes** (NEVER been on TNFi) ◯ **No** (Been on TNFi)

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:

Please confirm the number you indicated below: _____



TEST ORDERED

☑ **PrismRA** The Scipher Medicine PrismRA, a molecular signature response classifier (MSRC) blood-based test, is used to determine a patient's likelihood of inadequate response to tumor necrosis factor-α inhibitor (TNFi) therapy. PrismRA is intended for use by advanced healthcare providers treating patients diagnosed with rheumatoid arthritis (RA) who are 18 years or older, have a history of failure, contraindication or intolerance to at least one csDMARD and are in moderate or high disease activity that are either: 1) naive to a biologic or targeted synthetic disease modifying antirheumatic drug (b/tsDMARD); OR 2) currently on a TNFi; and are considering adjusting the dose, starting or switching to a different b/tsDMARD.

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:

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**

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TEST DESCRIPTION

The Scipher Medicine PrismRA, a molecular signature response classifier (MSRC) blood-based test, is used to determine a patient's likelihood of inadequate response to tumor necrosis factor-α inhibitor (TNFi) therapy. PrismRA is intended for use by advanced healthcare providers treating patients diagnosed with rheumatoid arthritis (RA) who are 18 years or older, have a history of failure, contraindication or intolerance to at least one csDMARD and are in moderate or high disease activity that are either: 1) naïve to a biologic or targeted synthetic disease modifying antirheumatic drug (b/tsDMARD); OR 2) currently on a TNFi; and are considering adjusting the dose, starting or switching to a different b/tsDMARD.

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 **CHECK KIT EXPIRATION DATE PRIOR TO SAMPLE COLLECTION**

- **Ideally all specimen tubes are shipped the SAME DAY as the blood draw, but the NEXT MORNING is acceptable**
- **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)

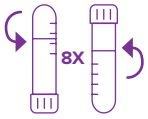
2 Complete TRF

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

3 Draw blood

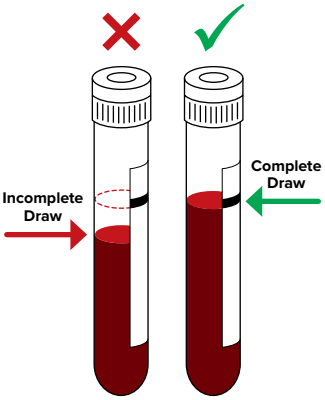
- Draw blood through the attachment of a 21g or 23g butterfly needle set
- Draw SST tube **FIRST** (tiger top) then draw PAXgene tubes **LAST** (red tops)
- If redraw is needed, you **MUST** use another needle and draw a discard tube prior to drawing the PAXgene tube
- If a new tube(s) is needed, use 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**

PAXgene Tube



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

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 shipping bag and seal

***Do NOT freeze or refrigerate the gel pack prior to shipping**

7 Ship

- Adhere one pre-paid shipping label of the preferred carrier (FedEx or UPS) to the shipping bag and ship to Scipher
- All specimen tubes must be shipped within 24 hours of the blood draw, but ideally the **SAME DAY OR NEXT MORNING** to avoid test failure
- Do **NOT** ship on Saturday
- Request a one-time pickup by calling FedEx or UPS at **1-800-GO-FedEx (1-800-463-3339)** or **1-800-PICK-UPS (1-800-742-5877)**

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scipher MEDICINE

PrismRA.com
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