Health Tradition has incorporated new policies for prior authorization of disease-modifying antirheumatic drugs—biologics and JAK kinase inhibitor for rheumatoid arthritis and updated the appropriate use criteria for anti-inflammatory biologics.

Through the work with state rheumatologists, Health Tradition has updated prior authorization criteria to require the following to consider starting a new biologic therapy in patients with rheumatoid arthritis.

1) Methotrexate polyglutamate blood levels in the therapeutic range ***(MTX PG level >60nmol/L)*** with evidence of moderate to severe disease activity, as evidenced by CDAI ***(>10)*** and Vectra® ***(>29)***, in order to have a biologic and JAK kinase inhibitor considered for coverage. This affects the following biologics and JAK kinase inhibitor used for rheumatoid arthritis—Humira, Rituximab (Rituxan), Enbrel, Xeljanz, Orencia, Actemra, Remicade (Renflexis). Orencia SQ requires prior TNFa inhibitor use since it is formulary non-preferred.

2) Hydroxychloroquine blood levels in the therapeutic range ***(level of 1000ng/ml)*** with evidence of moderate to severe disease activity, as evidenced by CDAI and Vectra, in order to have a biologic and JAK kinase inhibitor considered for coverage. This affects the following biologics and JAK kinase inhibitor used for rheumatoid arthritis—Humira, Rituximab (Rituxan), Enbrel, Xeljanz, Orencia, Actemra, Remicade (Renflexis). Orencia SQ requires prior TNFa inhibitor use since it is formulary non-preferred.

3) Vectra® (multi-biomarker of disease activity) is required as a marker of disease activity, as stated above, and required along with step-therapy and therapeutic blood levels of either/or MTX PG and/or HCQ.

The following provides an overview of the Vectra test as well as guidance on how to obtain and use the Vectra test. Contact your Myriad Autoimmune Clinical Science Liaison with any questions regarding Vectra testing in your practice. *Sara Holmblad* **phone:** 714-615-0564, **email:** sholmbla@myriad.com

Vectra®

Order Vectra® in 4 easy steps:

1

Obtain a test kit and test requisition form (TRF) by contacting the Vectra Customer Service Team by calling 1-877-RHEUMDX (1-877-743-8639), 8:00am to 6:30pm Eastern Time, Monday through Friday; or email Customer Service at customerservice@crescendobio.com

- Please include the physician name, institution name, address, phone, fax and quantity of test kits. The kit should be received within 1-3 business days
- If you need the kit sooner, please specify that this is an urgent request

2

Complete a Vectra test requisition form (TRF)

- The test requisition form (TRF) is attached. Please ensure that the test request form is completed in its entirety and sent with the patient's specimen.

3

Obtain patient blood sample per specimen collection and processing instructions (attached)

4

Ship Specimen and test requisition form to Crescendo Bioscience, Inc. a Myriad Genetics Lab within 7 days. For specimen pickup call FedEx at 1-800-463-3339*

Vectra test results will be available approximately 5-7 calendar days from shipment to Crescendo Bioscience Inc., a Myriad Genetics Lab. Results are returned by fax or via the VectraView portal.

Vectra® | Specimen Processing Instructions

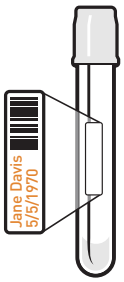
1. FREEZE

23˚F (-5˚C)

24 HOURS

Freeze PolarPack® FoamBricks (-5°C/23°F) for a minimum of 24 hours prior to use.

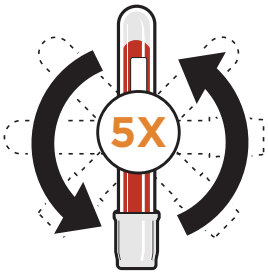
2a. LABEL



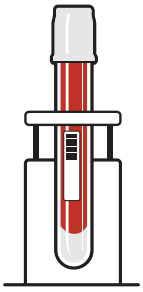
2a. FILL

Write the patient's DOB, first and last name on the Patient Specimen Barcode Label. Place the Patient Specimen Barcode Label lengthwise onto the Serum Separating Tube (SST). Fill the SST tube with 4 mL of blood.

3a. INVERT



3b. CLOT



68-77˚F (20-25˚C)

30 MIN TO **2** HRS

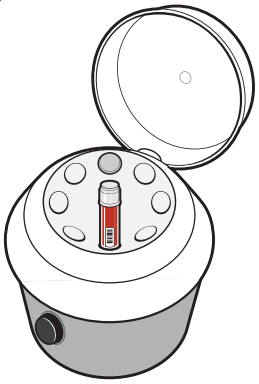
Gently mix the SST tube by inverting at least 5 times. Allow the SST tube to clot upright at room temperature (20-25°C) for no less than 30 minutes and no more than 2 hours.

4. CENTRIFUGE

68-77˚F (20-25˚C)

15 MIN

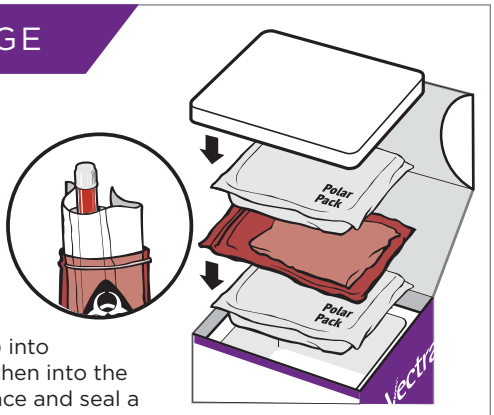
1100 TO **1300**



Centrifuge for 15 minutes (1100-1300 RCF at room temperature) in a swinging bucket or fixed angle centrifuge.

5. PACKAGE

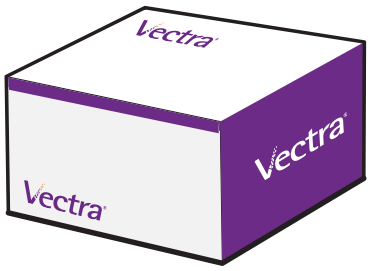
UP TO **5** SPECIMENS



Insert specimen(s) into protective sleeve then into the biohazard bag. Place and seal a test requisition form(s) into side pocket of bag. Up to 5 specimens may be packaged into a single cooler between frozen Polar Packs.

6. SHIP

7 DAYS



Specimens must be properly processed, refrigerated and received by Crescendo Bioscience, Inc. a Myriad Genetics Lab within 7 days. For specimen pickup call FedEx at 1-800-463-3339*

VectraDA.com / Vectra Customer Service: **1-877-743-8639**

VectraView®

VectraView® is an online analytical tool that enables you to draw insights from Vectra® results at the individual patient or practice level.

Request your account by following the steps below. Go to: vectra-view.com. Click on the "Request Account" tab. Account Information screen will appear. Complete all required fields in purple and click "submit". OR Contact customer service at 877-743-8639

***Note:** It is the shipper's responsibility to ensure that the package containing a diagnostic specimen conforms to FedEx guidelines along with all applicable local, state, federal and international regulations.

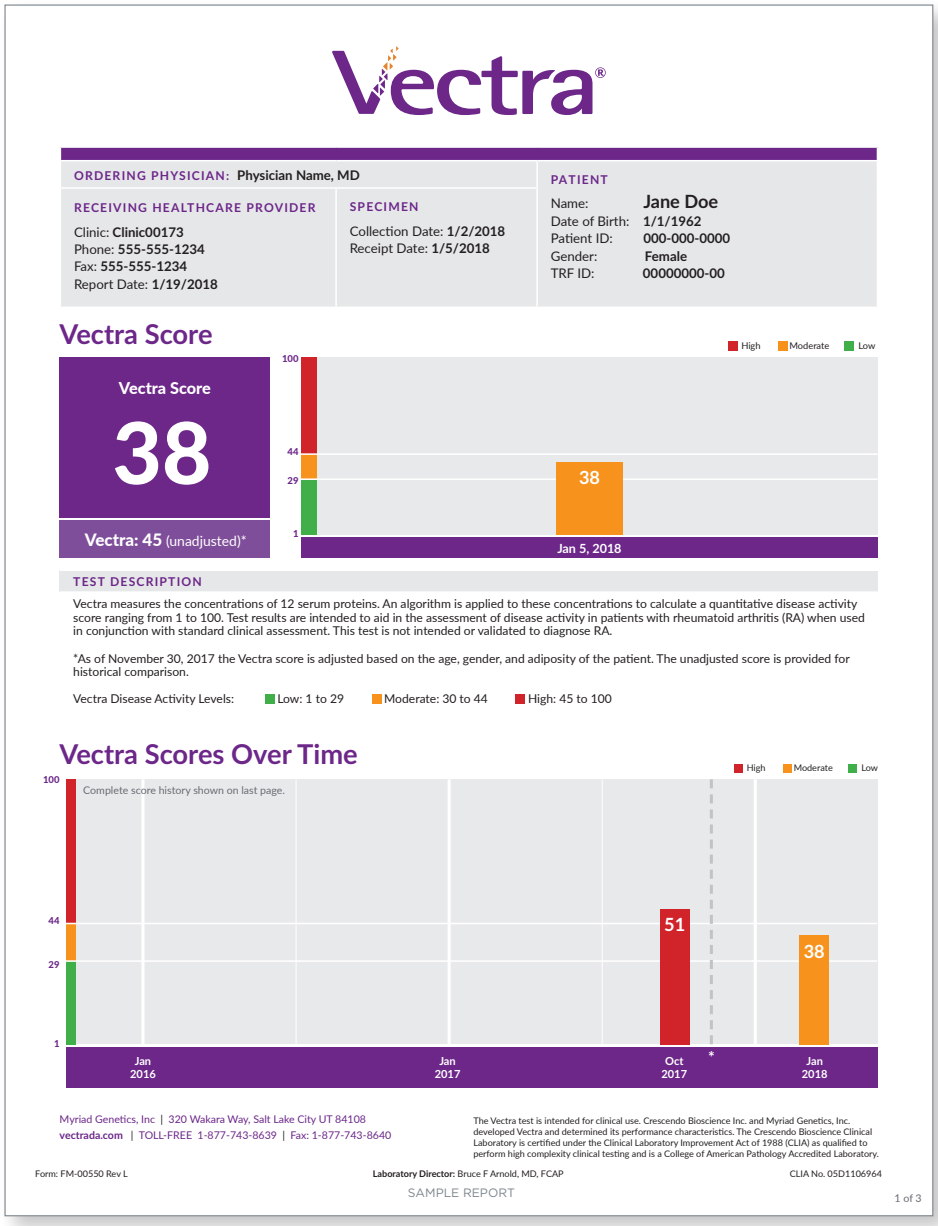
Vectra is validated for use in adults diagnosed with RA. Results are intended to aid in the assessment of disease activity in RA patients when used in conjunction with standard clinical assessment. This test is not intended or validated to diagnose RA.

Vectra® Report: A Personalized Precision Tool

Vectra is a multi-biomarker molecular blood test that provides an objective and personalized measure of inflammatory disease activity in patients with rheumatoid arthritis. Vectra demonstrates unsurpassed ability to predict radiographic progression and guides personalized medical management decisions to improve patient outcomes.

The Vectra score is reported on a scale of 1-100. Patients in the high and moderate categories are considered to have uncontrolled inflammation, and may require treatment modification.

Level of Disease Activity	LOW	MODERATE	HIGH
Vectra Score	1 to 29	30 to 44	45 to 100



Vectra®

ORDERING PHYSICIAN: Physician Name, MD

RECEIVING HEALTHCARE PROVIDER
Clinic: Clinic00173
Phone: 555-555-1234
Fax: 555-555-1234
Report Date: 1/19/2018

SPECIMEN
Collection Date: 1/2/2018
Receipt Date: 1/5/2018

PATIENT
Name: Jane Doe
Date of Birth: 1/1/1962
Patient ID: 000-000-0000
Gender: Female
TRF ID: 00000000-00

Vectra Score

Vectra Score
38
Vectra: 45 (unadjusted)*

High Moderate Low
100
44
29
1
38
Jan 5, 2018

TEST DESCRIPTION

Vectra measures the concentrations of 12 serum proteins. An algorithm is applied to these concentrations to calculate a quantitative disease activity score ranging from 1 to 100. Test results are intended to aid in the assessment of disease activity in patients with rheumatoid arthritis (RA) when used in conjunction with standard clinical assessment. This test is not intended or validated to diagnose RA.

*As of November 30, 2017 the Vectra score is adjusted based on the age, gender, and adiposity of the patient. The unadjusted score is provided for historical comparison.

Vectra Disease Activity Levels: Low: 1 to 29 Moderate: 30 to 44 High: 45 to 100

Vectra Scores Over Time

High Moderate Low
100
Complete score history shown on last page.
44
29
1
51
38
Jan 2016
Jan 2017
Oct 2017
Jan 2018

Myriad Genetics, Inc | 320 Wakara Way, Salt Lake City UT 84108
vectrada.com | TOLL-FREE 1-877-743-8639 | Fax: 1-877-743-8640

The Vectra test is intended for clinical use. Crescendo Bioscience Inc. and Myriad Genetics, Inc. developed Vectra and determined its performance characteristics. The Crescendo Bioscience Clinical Laboratory is certified under the Clinical Laboratory Improvement Act of 1988 (CLIA) as qualified to perform high complexity clinical testing and is a College of American Pathology Accredited Laboratory.

Form: FM-00550 Rev L

Laboratory Director: Bruce F Arnold, MD, FCAP

CLIA No. 05D1106964

SAMPLE REPORT

1 of 3

Test Requisition Form

Vectra®

SPECIMEN COLLECTION & PROCESSING DATE	TIME OF COLLECTION:
___ / ___ / ____ (MM / DD / YYYY)	___ : ___ ☐ AM ☐ PM

BLOOD DRAW LOCATION

☐ **OFFICE OF ORDERING PROVIDER**
No further information required

☐ **OTHER LAB:**
Laboratory Name / Site Code:

AFFIX ONE BARCODE HERE

Affix one barcode label to the specimen tube and one below to the test requisition form here.

Extra barcode labels have been provided.

1. Ordering Physician Account Information

Last Name	First Name	Email
NPI # (National Provider Number)	Clinic Name or Institution Name	
Account #	Phone	Fax
Address	City	State / Zip

2. Patient Information

Last Name	First Name	M.I.	Gender	Birth Date
			☐ Male ☐ Female	/ /
Email			Cell or Primary Phone	
Address	City		State	Zip

3. Billing Information

Reminder: Include a copy of BOTH SIDES of your insurance card(s). If you submit more than one card, indicate which is primary.

PATIENT'S INSURANCE INFORMATION (Please attach copy of group number)

Name of Policy Holder: _____ DOB: _____ Insurance ID#: _____

Patient Relation to Policy Holder: ☐ Self ☐ Spouse ☐ Other Group Number _____

Patient Financial Assistance & Resources:

☐ I would like to be considered for financial assistance through Crescendo Bioscience. ☐ I would like to receive information on resources associated with my test result.

SIGN HERE: PATIENT X _____ Date: _____

OTHER BILLING ☐ Bill our institutional account #_____. ☐ Established research project code#_____

4. ICD-10 Codes

Please provide the applicable ICD-10 code(s). For your reference, some of the ICD-10 codes that describe adult rheumatoid arthritis begin with M05 or M06.

Primary ICD-10 Code:				Secondary ICD-10 Code	
	☐ M06.09	☐ M06.89	☐ M05.841		**Regardless of whether listed herein,** you should refer to the ICD-10 Code Book when making your diagnosis and report only the diagnosis code(s) you have independently determined are appropriate based on documentation in your patient medical record.
	☐ M06.041	☐ M05.79	☐ M05.842		
	☐ M06.042	☐ M05.89	☐ Other: _____	_____	

5. Test Requested

☑ **Vectra®**

An order for Vectra DA includes and requires an order for 12 biomarkers: VCAM-1, EGF, VEGF-A, IL-6, TNF-RI, MMP-1, MMP-3, YKL-40, Leptin, Resistin, SAA, CRP. These 12 biomarkers are required to generate the Vectra DA test score. By ordering Vectra DA, you are ordering all 12 biomarkers and are acknowledging that we cannot provide a Vectra DA test result without these 12 biomarkers. Vectra DA was validated in adults with Rheumatoid Arthritis (RA). Test results are intended to aid in the assessment of disease activity in RA patients when used in conjunction with standard clinical assessment.

6. Statement of Medical Necessity

I affirm the following: My signature constitutes a certification of Medical Necessity; this test is medically necessary for the treatment and management of the patient. The findings of the test will be used in the patient's medical management and treatment decisions. The person listed as the Ordering Physician is authorized by law to order the test requested herein.

SIGN HERE ORDERING PHYSICIAN (required to process form) X _____ Date: _____

Crescendo Bioscience, Inc. a Myriad Genetics Company
320 Wakara Way, Salt Lake City, UT 84108
vectrada.com | Fax: 1-877-743-8640 | TOLL-FREE: 1-877-743-8639

Vectra®

IMPORTANT INFORMATION FOR PATIENT

FINANCIAL ASSISTANCE: Vectra Financial Assistance CARE Program

- Vectra Customer Service and Billing will work with your insurance provider to help you get the appropriate coverage. Your cost will depend on your health care plan and your ability to pay. Payment plans and financial assistance may be available through the CARE program.
- CARE Patient Certification:
  - If I do not have insurance, I certify I am not eligible for Medicare, Medicaid, or any other state or government health insurance and will not seek reimbursement from any insurance carrier or government agency for Vectra® fees waived.
- If I have insurance, I certify that I will not seek reimbursement from any insurance carrier or government agency for Vectra fees that are my financial responsibility.
- I certify that the information contained in this application is correct to the best of my knowledge. I understand this information will not be used for any other purpose unless I give written consent, or to the extent necessary to document my eligibility under the CARE program.
- I certify I will notify the Vectra Financial Assistance CARE Program within 30 days if there is any change in my eligibility status with regard to income and health care coverage. I will provide documentation, including but not limited to personal financial records, which are necessary to verify the information contained in this application.

TEST SUBMISSION INSTRUCTIONS

USE THESE TEST SUBMISSION GUIDELINES TO AVOID DELAYS AND TO ENSURE TIMELY SPECIMEN DELIVERY

SPECIMEN COLLECTION AND PROCESSING

- Ensure that the PolarPack® FoamBricks have been frozen (-5˚C/23˚F) for at least 24 hours.
- Ensure that the expiration date on the BD Serum Separator Transport™ (SST) tube* has not passed.
- Keep a copy of the test requisition form (TRF) for your records.
- Specimens must be received by Crescendo Bioscience Inc., a Myriad Genetics Lab within 7 days of collection.
- Place 1 Specimen Barcode Label in the designated area of the TRF.
- Write patient's DOB, first and last name on the Patient Specimen Barcode Label.
- Place the Patient Specimen Barcode Label lengthwise onto the SST tube.
- Fill the SST tube with at least 4mL of blood.
- Gently mix by inverting at least 5 times.
- Allow to clot at room temperature (20-25˚C) for 30-120 minutes.
- Centrifuge for 15 minutes (1100-1300 RCF at room temp) in a swinging bucket or fixed angle centrifuge.

STORING, PACKING AND SHIPPING

- Place the specimen and the TRF in the refrigerator until shipping pick up time.
- Specimen must remain in the refrigerator if not picked up the same day collected.
- Use another properly labeled Vectra kit box if the outer box doesn't have a pre-applied FedEx label.
- Place 1 frozen PolarPack FoamBrick in the bottom of the foam cooler.
- Each specimen should be in its own white absorbent tube sleeve and biohazard bag.
- The TRF(s) should be placed in the side pouch of the biohazard bag(s). Please provide a copy of the front and back of the patient's insurance or Medicare or Medicaid card(s).
- Up to 5 specimens can be shipped in the cooler.
- Place a 2nd frozen PolarPack FoamBrick on top of the specimen(s).
- Call for the specimen pick up.
- FedEx confirmation # _____

FOR SPECIMEN PICKUP, CALL FEDEX AT 1-800-463-3339 OR GO TO WWW.FEDEX.COM
and say, "Schedule a pick-up using a label."

FOR QUESTIONS REGARDING THE SPECIMEN, PLEASE CONTACT VECTRA CUSTOMER SERVICE AT 1-877-743-8639.

Vectra DA is validated for use in adults diagnosed with RA. Test results are intended to aid in the assessment of disease activity in RA patients when used in conjunction with standard clinical assessment. This test is not intended or validated to diagnose RA.