



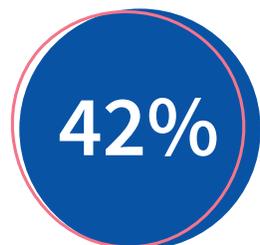
**A HEALTHCARE PROVIDER'S GUIDE**

# Vectra<sup>®</sup> by Labcorp Guided Care

Evaluate success of controlling rheumatoid arthritis inflammation by using Vectra at initiation, change in drug therapy, and repeating to monitor response to therapy.



# Vectra<sup>®</sup> by Labcorp Can Help Guide Personalized Medical Management Decisions to Improve Patient Outcomes



of patients thought to be in low or moderate disease activity by traditional disease activity measure were in high disease activity measured by Vectra and thus were at risk for joint damage progression.

In a combined analysis of patients from three studies, 42% of those with low or moderate disease activity by DAS28-CRP had a high Vectra Score<sup>1</sup>

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## Vectra Guided Care provides quantitative personalized insight to help guide disease management plan:



Vectra is a **validated prognostic test** for radiographic progression<sup>2</sup>



Provides scores ranging from 1 to 100 to categorize RA disease activity into low, moderate or high to **help guide medical management**



The Vectra Score Interpretation found on the report **provides guidance to physicians**



**Changes in the Vectra Score of 8 or more** in high and moderate patients represent a meaningful change in RA inflammation

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## The benefits of using Vectra in your office



Objective Insight  
into Inflammation

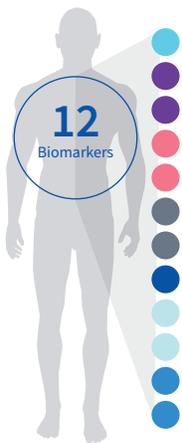


Improved  
Efficiency



Patient  
Affordability

# Vectra® Provides Molecular Insights on the Inflammatory State of RA That Can Help Inform Your Medical Management Decisions

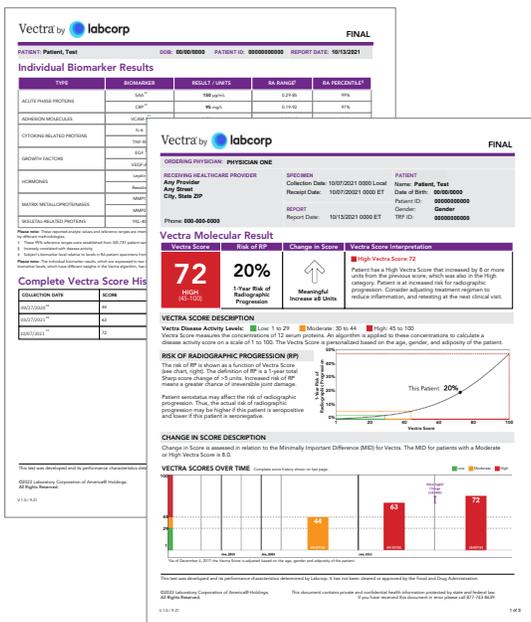


Vectra® by **labcorp**

- Vectra measures 12 biomarkers and combines them into a single score thus allowing providers to incorporate molecular insight from various inflammatory pathways driving RA disease activity
- Vectra incorporates information on age, gender and adiposity to provide a score that reflects a patient's personalized disease activity and inflammation level
- Vectra is an unsurpassed predictor of radiographic progression compared to CDAI, SDAI, DAS28-CRP and CRP

## Vectra is a molecular measurement of disease activity and RA inflammation

Adhesion Molecules	Growth Factors	Cytokines/ Receptors	Matrix Metalloproteinases	Skeletal-Related Proteins	Hormones	Acute-Phase Proteins
VCAM-1	EGF	IL-6	MMP-1	YKL-40	Leptin	SAA
	VEGF-A	TNF-RI	MMP-3		Resistin	CRP



## Report Highlights

- Vectra provides a personalized measure of disease activity
- Vectra provides the risk of rapid radiographic progression within one year<sup>2</sup>
- Change in Vectra Score is assessed in relation to the Minimally Important Difference (MID). MID of 8 reflects the smallest absolute change in Vectra Score that likely reflects a change in disease activity and is not due only to random variation.<sup>3</sup>
- Vectra Score Interpretation calls out considerations for treatment decisions
- Patient Vectra Scores for the past three years are presented in one easy-to-read graph

# The Vectra® Report Gives Clear Perspective of RA Inflammation



## Vectra Helps Identify a Patient's Future Risk of Radiographic Progression

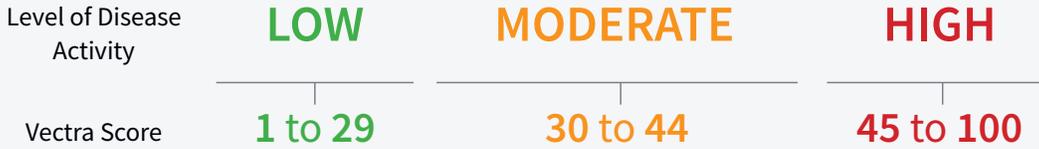
PATIENT INFORMATION		VISIT NOTES	Vectra Score
Age	49	<ul style="list-style-type: none"><li>• Patient is 5'2", 178 lbs.</li><li>• Patient reports feeling okay and is resistant to changing therapy</li><li>• Patient has had RA for five years</li></ul>	<b>72</b> HIGH (45-100)
Gender	Female		
Diagnosis	RA		
Drug Therapy	MTX, Etanercept		



Scores over time will show a trend and can **provide insight into a meaningful change** in the patient's disease activity

# Vectra® Report: A Personalized Precision Tool

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.



## REPORT PAGE 1

**Vectra Score** factors in age, gender and adiposity of the patient to provide personalized measurement of inflammation

**Risk of RP** patient's risk of rapid radiographic progression within one year

**Change in Score** will show the difference between multiple scores and indicate if there has been a meaningful change, or no change in disease activity

**Vectra Scores Over Time** is a rolling 3.5 year date range plus initial score consisting of 7 half-year periods

**FINAL**

**Vectra** by **labcorp**

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**ORDERING PHYSICIAN: PHYSICIAN ONE**

<b>RECEIVING HEALTHCARE PROVIDER</b> Any Provider Any Street City, State ZIP  Phone: 000-000-0000	<b>SPECIMEN</b> Collection Date: 10/07/2021 0000 Local Receipt Date: 10/07/2021 0000 ET	<b>PATIENT</b> Name: Patient, Test Date of Birth: 00/00/0000 Patient ID: 0000000000 Gender: Gender TRF ID: 0000000000
<b>REPORT</b> Report Date: 10/13/2021 0000 ET		

**Vectra Molecular Result**

Vectra Score	Risk of RP	Change in Score	Vectra Score Interpretation
<b>72</b> HIGH (45-100)	<b>20%</b> 1-Year Risk of Radiographic Progression	↑ Meaningful Increase ≥8 Units	<div style="background-color: red; color: white; padding: 2px; display: inline-block;">High Vectra Score: 72</div> Patient has a High Vectra Score that increased by 8 or more units from the previous score, which was also in the High category. Patient is at increased risk for radiographic progression. Consider adjusting treatment regimen to reduce inflammation, and retesting at the next clinical visit.

**VECTRA SCORE DESCRIPTION**

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

Vectra Score measures the concentrations of 12 serum proteins. An algorithm is applied to these concentrations to calculate a disease activity score on a scale of 1 to 100. The Vectra Score is personalized based on the age, gender, and adiposity of the patient.

**RISK OF RADIOGRAPHIC PROGRESSION (RP)**

The risk of RP is shown as a function of Vectra Score (see chart, right). The definition of RP is a 1-year total Sharp score change of >5 units. Increased risk of RP means a greater chance of irreversible joint damage.

Patient serostatus may affect the risk of radiographic progression. Thus, the actual risk of radiographic progression may be higher if this patient is seropositive and lower if this patient is seronegative.

**CHANGE IN SCORE DESCRIPTION**

Change in Score is assessed in relation to the Minimally Important Difference (MID) for Vectra. The MID for patients with a Moderate or High Vectra Score is 8.0.

**VECTRA SCORES OVER TIME** Complete score history shown on last page.

\*As of December 4, 2017 the Vectra Score is adjusted based on the age, gender and adiposity of the patient.

This test was developed and its performance characteristics determined by Labcorp. It has not been cleared or approved by the Food and Drug Administration.

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**Vectra Score Interpretation** provides a more detailed explanation of the Vectra Score, disease activity category, risk of radiographic progression and treatment plan consideration

**Risk of RP Graph** gives a patient's future risk of radiographic progression based on their Vectra Score

As of 12/4/2017 Vectra Score has been adjusted based on **age, gender and adiposity** of the patient\*

**Meaningful Change:** MID of 8 is the smallest absolute change in the Vectra Score that is likely to reflect change in disease activity

## REPORT PAGE 2

The Vectra Score is calculated from the concentrations of the 12 biomarkers shown on this page, which represent different biological pathways involved in RA pathophysiology. The clinical application of individual biomarker values, which have different weighting in the Vectra algorithm, has not been established

Includes the leptin range for all RA patients

Result/Units:  
Concentrations of the individual biomarkers



**FINAL**

**PATIENT:** Patient, Test    **DOB:** 00/00/0000    **PATIENT ID:** 0000000000    **REPORT DATE:** 10/13/2021

### Individual Biomarker Results

TYPE	BIOMARKER	RESULT / UNITS	RA RANGE <sup>†</sup>	RA PERCENTILE <sup>‡</sup>
ACUTE PHASE PROTEINS	SAA <sup>§</sup>	150 µg/mL	0.29-85	99%
	CRP <sup>§</sup>	95 mg/L	0.19-92	97%
ADHESION MOLECULES	VCAM-1 <sup>§</sup>	0.58 µg/mL	0.39-1.2	34%
CYTOKINE-RELATED PROTEINS	IL-6 <sup>§</sup>	74 pg/mL	2.5-200	91%
	TNF-α <sup>§</sup>	0.94 ng/mL	0.8-3.9	7%
GROWTH FACTORS	EGF <sup>§</sup>	410 pg/mL	12-410	97%
	VEGF-A <sup>§</sup>	770 pg/mL	75-790	97%
HORMONES	Leptin <sup>§</sup>	13 ng/mL	1.5-120	33%
	Resistin <sup>§</sup>	9.4 ng/mL	3.5-21	66%
MATRIX METALLOPROTEINASES	MMP1 <sup>§</sup>	11 ng/mL	1.3-23	80%
	MMP3 <sup>§</sup>	160 ng/mL	7.9-160	97%
SKELETAL-RELATED PROTEINS	YKL-40 <sup>§</sup>	87 ng/mL	22-540	56%

**Please note:** These reported analytic values and reference ranges are intended for use in the generation of the Vectra score only. These results should not be used interchangeably with results generated by different methodologies.

<sup>†</sup> These 95% reference ranges were established from 325,781 patient samples tested at Crescendo Bioscience Clinical Laboratory.

<sup>§</sup> Inversely correlated with disease activity.

<sup>‡</sup> Subject's biomarker level relative to levels in RA patient specimens from which the RA ranges were determined.

**Please note:** The individual biomarker results, which are expressed to two significant figures, are required inputs into the algorithm used to calculate the Vectra Score. Clinical interpretation of individual biomarker levels, which have different weights in the Vectra algorithm, has not been established.

### Complete Vectra Score History

COLLECTION DATE	SCORE	NOTES
09/27/2020 <sup>§</sup>	44	
03/27/2021 <sup>§</sup>	63	
10/07/2021 <sup>§</sup>	72	

This test was developed and its performance characteristics determined by Labcorp. It has not been cleared or approved by the Food and Drug Administration.

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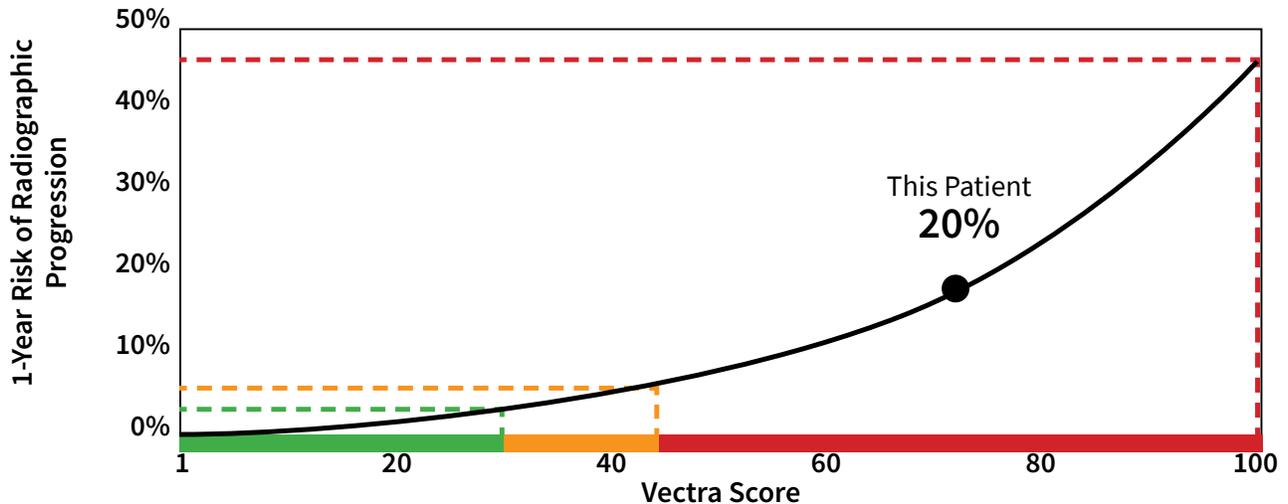
The RA range refers to the reference range for each biomarker based on a reference set of RA patients. This is the concentration range that contains the central 95% of results for that biomarker

Patient biomarker level relative to levels in all patients in the RA reference set

Includes a complete list of your patient's historical Vectra Scores

## Vectra® by Labcorp Guided Care

Vectra Is a Validated Prognostic Test for Radiographic Progression<sup>2</sup>



The Vectra Score correlates to the risk of radiographic progression (RP), which leads to permanent joint damage. As the Vectra Score increases, the risk of RP increases. Sharp Score is used to evaluate radiographic progression. A Sharp Score change of 5 or more within one year is considered rapid radiographic progression.<sup>2</sup>

Patient serostatus may affect the risk of radiographic progression. The actual risk of radiographic progression may be higher if this patient is seropositive and lower if this patient is seronegative.

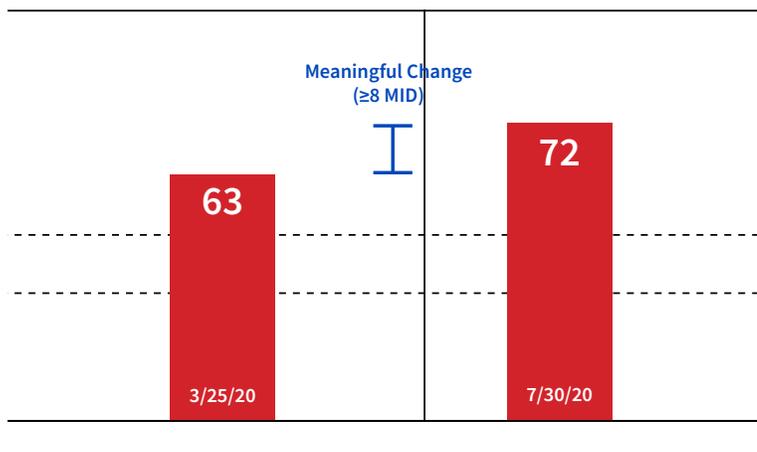
### How was the Radiographic Progression Risk developed?

The risk of RP was determined by combining data from four cohorts (OPERA, BRASS, SWEFOT, and Leiden) to evaluate the ability of the Vectra Score to predict radiographic progression and to compare this ability with those of DAS28-CRP and CRP. Vectra was three times better at predicting RP in one year than DAS28-CRP.<sup>2</sup>

An increased risk of radiographic progression means **greater chance of irreversible joint damage**

# Vectra® by Labcorp Guided Care

## Minimally Important Difference (MID) Can Help Guide Your Decision Making



**Changes of Vectra Scores of 8 or more help guide medical management decisions** by representing meaningful changes in rheumatoid arthritis inflammation.

**How was the Minimally Important Difference established?** The minimally important difference (MID) was determined by conducting a clinical study. This clinical study evaluated daily and diurnal variation in Vectra Scores in order to determine the minimally important change in score that is clinically meaningful. Having this information will help aid in your ability to make treatment decisions.

## Vectra Score Interpretation

VECTRA SCORE	MEDICAL MANAGEMENT RECOMMENDATION <sup>†</sup>
<b>Low</b> (<30)	<p><b>CONSIDER ONE OF THE FOLLOWING:</b></p> <ul style="list-style-type: none"> <li>• <b>No treatment change</b> (re-test in 6-12 months or sooner if indicated)</li> <li>• <b>Reduce treatment if Vectra Score is low at two consecutive measures</b> (re-test in 6-12 months or sooner if indicated)*</li> </ul> <p><small>*See ACR Guidelines for therapy reduction in clinically well controlled patients</small></p>
<b>Moderate</b> (30-44)	<p><b>CONSIDER ONE OF THE FOLLOWING:</b></p> <ul style="list-style-type: none"> <li>• <b>Change or intensify treatment</b> <ul style="list-style-type: none"> <li>• If the Vectra Score has increased by <math>\geq 8</math> units since previous Vectra (re-test in 3 months)</li> <li>• If the Vectra Score has decreased by <math>&lt;8</math> units since the most recent RA treatment change use clinical judgment (re-test when indicated)</li> </ul> </li> <li>• <b>No treatment change</b> <ul style="list-style-type: none"> <li>• If the Vectra Score has decreased by <math>&gt;8</math> units since baseline or the most recent RA treatment change (re-test when indicated)</li> <li>• If therapy was recently changed but no previous Vectra Score is available (re-test in 3 months)</li> </ul> </li> </ul>
<b>High</b> (>44)	<p><b>CONSIDER ONE OF THE FOLLOWING:</b></p> <ul style="list-style-type: none"> <li>• <b>Change or intensify treatment</b> (re-test in 3 months)</li> <li>• <b>No treatment change if the Vectra Score has decreased by <math>&gt;8</math> units when a change in therapy has recently occurred</b> (re-test in 3 months)</li> </ul>

This medical management guidance provides recommendations only. The treatment management decisions can only be done by a medical professional with the full information of patient's medical status and medical history. These recommendations are currently being tested in clinical trial "VIVID" listed on [clintrials.gov \(NCT03810144\)](https://clinicaltrials.gov/ct2/show/study/NCT03810144).

Test Name	Test No.	Specimen	Container	Storage
Vectra	504965	2 mL Serum	Gel-barrier tube, red-top tube or serum transfer	Frozen (preferred) or refrigerated
Vectra CV Risk	504980			

## Intended Use

### MANAGEMENT DECISION

Patient and provider agree to make a treatment change



## Baseline at time of treatment change decision



**Therapy Initiation or Change:** Until the desired treatment target is reached, drug therapy should be adjusted every 3-6 months

### THERAPY MONITORING

Evaluate if treatment is working



## Test at 3-6 months after treatment change to evaluate if treatment is working



Achieving a state of disease remission in RA is considered a primary treatment goal

### LOW DISEASE ACTIVITY MONITORING

Evaluate that patient remains within disease goal



## Continue to test patient two times a year, once in low activity



Monitor that patient is remaining in treatment goal

# Provider Resources

## VectraView®

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

- Access all of your patients' Vectra results in one place through a convenient online portal
- Store and access disease activity measurements alongside Vectra results
- View Vectra Scores displayed in the context of your patients' medications
- View Vectra results for all tested patients in one view and filter to identify patients for follow-up

## labcorp | Link™

A secure, mobile optimized web application that lets you:

- Order tests and receive result reports
- Order supplies
- View on-screen visual cues with specimen collection instructions (AccuDraw)
- Pay a bill and access billing forms

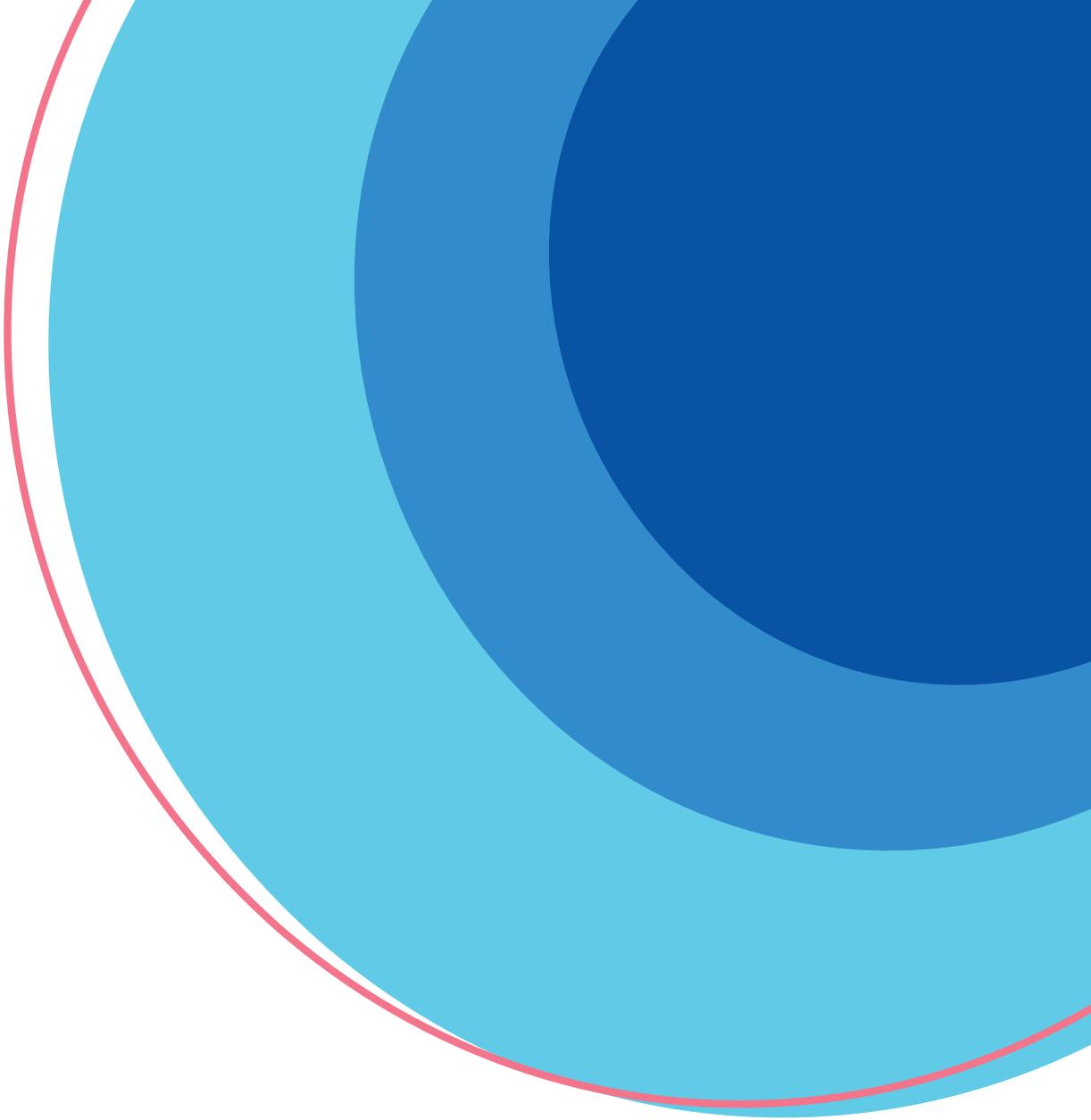
## Provider Support



A team of highly-trained medical liaisons is available for consultation. For questions associated with the Vectra Test, please contact Customer Service.

**Phone: 1-877-743-8639**





#### References

**1.** Curtis JR, Brahe CH, Ostergaard M, et al. Predicting risk for radiographic damage in rheumatoid arthritis: comparative analysis of the multi-biomarker disease activity score and conventional measures of disease activity in multiple studies. *Current Medical Research and Opinion*. 2019; 35(9):1483-1493. **2.** Curtis JR, Weinblatt ME, Shadick NA, et al. Validation of the adjusted multi-biomarker disease activity score as a prognostic test for radiographic progression in rheumatoid arthritis: a combined analysis of multiple studies. *Arthritis Research & Therapy*. 2021; 23(1). **3.** Chernoff D, Eastman PS, Hwang CC, et al. Determination of the minimally important difference (MID) in multi-biomarker disease activity (MBDA) test scores: impact of diurnal and daily biomarker variation patterns on MBDA scores. *Clin Rheum*. 2019;38:437-445. **4.** Curtis JR, Xie F, Yang S, Danila MI, et al. Uptake and clinical utility of multibiomarker disease activity testing in the United States. *J Rheum*. 2019;46:3.