

## REQUESTING PHYSICIAN

Example Physician, M.D.  
St. John's Hospital  
1234 Main Street  
San Diego, CA 92121

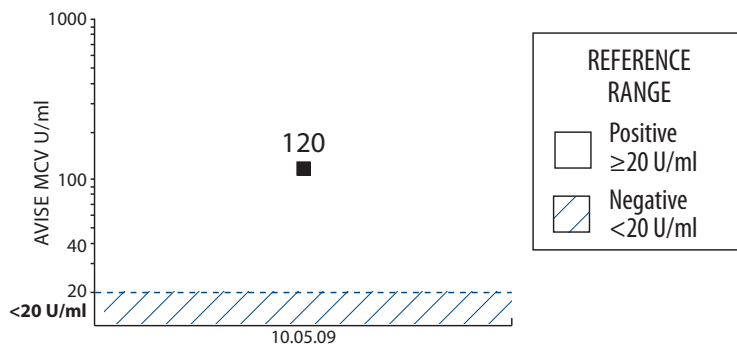
phone: 999.999.9999 fax: 777.777.7777

## PATIENT AND ORDER INFORMATION

Order ID: 99999999A  
Patient Name: Susan S. Sample  
DOB: 01.01.60 Gender: Female  
Patient ID / Medical Record #: 7777777B  
Sample ID: 3333333C  
Date of Collection: Date Received: Date Reported:  
10.05.09 10.07.09 10.09.09

## AVISE MCV TEST RESULTS

DATE COLLECTED	RESULT (U/ml)	RESULT ASSESSMENT
10/05/09	120	<b>POSITIVE</b>



- Avise MCV measures IgG antibodies to mutated citrullinated vimentin (MCV).
- A negative result (<20 U/ml) indicates a reduced likelihood of rheumatoid arthritis. However, a negative result does not exclude the presence of rheumatoid arthritis.<sup>1-8</sup>
- A **positive** result (≥20 U/ml) indicates a high likelihood of rheumatoid arthritis.<sup>1-8</sup>
- **Elevated** levels of anti-MCV (≥ 20 U/ml) are associated with more severe rheumatoid arthritis and disease progression.<sup>1-3</sup>
- Clinical Sensitivity 76.9%  
Clinical Specificity 93.2%  
Overall Accuracy 82.9%  
(Data on file, Cypress Bioscience, Inc.)

## ADDITIONAL INFORMATION

### REFERENCES

1) Bang H, Egerer K, et al. *Arthritis Rheum.* 2007; 56(8):2503-11. 2) Innala L, Kokkonen, et al. *J Rheumatol.* 2008;35(6):1002-8. 3) Mathsson L, Mullazehi M, et al. *Arthritis Rheum.* 2008; 8(1):36-45. 4) Ursum J, Nielsen M, et al. *Arthritis Res Ther.* 2008; 10(1):R12. 5) Soós L, Szekanez Z, et al. *J Rheumatol.* 2007;34(8):1658-63. 6) Bizzaro N, Tonutt E, et al. *Clin Chem.* 2007;53(8):1527-33. 7) Coenen D, Verschueren P, et al. *Clin Chem.* 2007;53(3):498-504. 8) Dejaco C, Klotz W, et al. *Arthritis Res Ther.* 2006;8(4):R119.

### ASSAY DESCRIPTION AND METHODOLOGY

Results were obtained by indirect solid phase enzyme immunoassay (ELISA) for the quantitative measurement of IgG antibodies against MCV.

### INTENDED USE

Avise MCV, in conjunction with other laboratory and clinical findings, is an aid in the diagnosis and prognosis of rheumatoid arthritis.

### CLINICAL LABORATORY INFORMATION

Cypress Bioscience, Inc. Laboratory Director: Curtis McGuyer, M.D. CLIA# 05D1075048 CAP# 7201051 CA# CLF334804

Diagnostic testing should be interpreted in the context of additional clinical findings. How this information is used to guide patient care is the responsibility of the physician. This test was developed and its performance characteristics determined by Cypress Bioscience. It has not been approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes. It should not be regarded as investigational or for research. This laboratory is certified under CLIA-88 as qualified to perform high complexity clinical laboratory testing.

© Cypress Bioscience, Inc. 2008-2010. All rights reserved. Avise MCV, the Avise MCV logo are service marks of Cypress Bioscience, Inc. The Cypress Bioscience, Inc. logo is a registered trademark of Cypress Bioscience, Inc.