

Patient Name TEST,IMPLEMENTATION TESTING	Patient ID 321	Age 56	Gender M	Order # X100029007
Ordering Phys TESTING				DOB 05/23/1955
Client Order # X100029007	Account Information			Report Notes
Collected 04/20/2012 16:10	C7028846-DLMP ROCHESTER 3050 SUPERIOR DRIVE ROCHESTER,MN 55901			
Printed 04/24/2012 10:48				

Test	Flag	Results	Unit	Reference Value	Perform Site*
Lyme Disease Ab (IgG, IgM) Panel			REPORTED	04/23/2012 12:35	
Lyme Disease Ab (IgG), IFA		<1:80			Y03 8
Lyme Disease Ab (IgM), IFA		<1:10			Y03 8
Interpretation					Y03 8
<p>ANTIBODY NOT DETECTED</p> <p>REFERENCE RANGES: IgG <1:80 IgM <1:10</p> <p>Borrelia burgdorferi is the causative agent of Lyme Disease. Specific antibody titers are measured using an indirect immunofluorescence assay (IFA). IgM-specific titers usually peak 4 to 6 weeks after onset of infection and may persist in the presence of disease. IgG levels begin to rise above background levels about 2 to 3 weeks after infection, and may stay elevated in cases of prolonged disease. Seronegative cases of Lyme Disease have been reported and alternate laboratory tests may be necessary to make a diagnosis (e.g., culture, PCR). Crossreactivity is shown with other Borrelia and Treponema species.</p> <p>As recommended by the Food and Drug Administration (FDA Public Health Advisory, July 7, 1997), all samples with positive or equivocal results in the Lyme Disease C6 Antibody EIA (Screening) should be tested by Western Blot/Immunoblot. Positive or equivocal screening test results should not be interpreted as truly positive until verified as such using a confirmatory assay [e.g., Lyme Disease Antibodies (IgG, IgM), IBL (serum)]. The screening test and/or immunoblot for Lyme Disease antibodies may be falsely negative in early stages of Lyme Disease, including the period when erythema migrans is apparent.</p> <p>This assay was developed and its performance characteristics have been determined by Focus Diagnostics. It has not been cleared or approved</p>					

Performing Site Legend on Last Page of Report

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* Report times for Mayo performed tests are CST/CDT

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by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary. Performance characteristics refer to the analytical performance of the test.

* Performing Site:

Y038	Focus Diagnostics, Inc. 5785 Corporate Avenue Cypress, CA 90630-4750	Lab Director:
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