

REFERENCE VALUE CHANGE REFERRAL

NOTIFICATION DATE: September 20, 2011 **EFFECTIVE DATE:** October 24, 2011

BORDETELLA PERTUSSIS IGG ANTIBODIES, MAID #91869

EXPLANATION: Effective October 24, 2011, Bordetella Pertussis IgG Ab, referred to Focus Diagnostics, Inc., will be updated to reflect a Reference Value Change.

CURRENT REFERENCE VALUE:

Reference Ranges:

PT IgG <40 units/mL FHA IgG <84 units/mL

Levels of antibodies recognizing pertussis toxin (PT) and filamentous hemagglutinin antigen (FHA) are typically increased following either vaccination or natural exposure to Bordetella pertussis. Increased levels of FHA IgG alone may represent crossreactive antibodies induced by infection with other Bordetella species, Mycoplasma pneumoniae, Chlamydia pneumoniae, or nonencapsulated Haemophilus influenzae.

NEW REFERENCE VALUE:

REFERENCE RANGES:

PT IgG <45 IU/mL FHA IgG <90 IU/mL

Levels of antibodies recognizing pertussis toxin (PT) and filamentous hemagglutinin (FHA) are typically increased following vaccination or natural exposure to Bordetella pertussis. This assay is not appropriate for assessing immunity to pertussis because the specific antibodies and antibody levels that correlate with protection have not been well defined. The indicated reference range values reflect the 95th percentile of antibody levels from blood donors; thus, antibody levels above the reference range are highly suggestive of recent infection or vaccination. Increased levels of FHA antibodies alone may represent cross-reactive antibodies induced by infection with other Bordetella species, Mycoplasma pneumoniae, Chlamydophila pneumoniae, or nonencapsulated Haemophilus influenzae.

This assay was developed and its performance characteristics have been determined by Focus Diagnostics. Performance characteristics refer to the analytical performance of the test.

NOTE: This change may impact test set-up information and could require a change to file definition. Please review the Test Set-Up information for specifics at http://www.mayomedicallaboratories.com/test-notifications/index.html.

QUESTIONS: Contact Mary Erath, MML Laboratory Technologist Resource Coordinator Telephone: 800-533-1710