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Title: The retrospective review of capillia MAC antibody ELISA

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Body: A morbidity of non-tuberculous mycobacterial infection (NTM) is increasing in japan yearly. Although the incidence was a person per 100,000 persons in 1975, it increased to over 5.7 person per 100,000 persons in 2007. In addition, the mortality is reported to be increasing. Because Mycobacterium avium complex (MAC) strains have been a major cause of NTM pulmonary diseases in non-HIV immunocompetent hosts in Japan, the diagnosis and treatment of MAC pulmonary diseases in those patients are essential. The aim of this study is to evaluate a newly-developed enzyme-linked immunosorbent assay to diagnose MAC disease, Capillia MAC antibody ELISA. Capillia MAC antibody ELISA was measured for all 106 patients who were suspicious of mycobacterial pulmonary disease and who had lung disease without suspicious cases of lung cancer between June 12, 2012 and December 11, 2012. We reviewed retrospectively 52 females (average age:61.17 y. o.) and 54 males (average age:70.39 y. o.).We adopted the cut off value of 0.7U/ml. The sensitivity and specificity of the test for a diagnosis of MAC pulmonary disease was determined based on clinical diagnosis. Forty-two cases showed positive results of Capillia MAC antibody ELISA : 25 females (M.avium - 16 cases, M.intracellulare - 9) and 17 males (M.avium - 9, M.intracellulare – 8).In comparison to clinical diagnosis, the sensitivity and specificity of the test for a diagnosis of MAC pulmonary disease is 67% and 94% (females 68% and 93%, males 65% and 95%), respectively. We concluded that Capillia MAC antibody ELISA might be a highly specific test. And so the laboratory test might be useful in ruling in bacteriologically-negative MAC pulmonary disease.