22. A RAPID, SENSITIVE, AND SPECIFIC IMMUNOCHROMATOGRAPHIC LATERAL FLOW ASSAY FOR ANTHRAX PROTECTIVE ANTIGEN IMMUNITY STATUS: DEVELOPMENT AND EVALUATION

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Evidence from animals suggests that anti-protective antigen (PA) IgG from vaccination with Anthrax Vaccine Adsorbed (AVA) is protective against B. anthracis infection. Measurement of anti-PA IgG in human sera can be performed using either Enzyme-Linked Immunosorbent Assay (ELISA) or Fluorescent Covalent Microsphere Immunoassay (FCMIA, Clin Lab Diagnostic Immunol 11:50-55, 2004). Both these methods are laboratory based. We describe the development of a rapid lateral flow immunochromatograhic assay (LFIA) test kit for the measurement of anti-PA IgG in serum or whole blood (50 µl sample) using colloidal gold nanoparticles as the detection reagent and an internal control. Using sera from 19 AVA vaccinees (anti-PA IgG range, 2.4 – 267 µg/ml), 10 controls and PA-supplemented whole blood, we demonstrated the LFIA had a sensitivity of ~2 µg/ml anti-PA IgG in sera and ~14 µg/ml anti-PA IgG in whole blood. Pre-adsorption of sera with PA yielded negative anti-PA LFIAs. Internal controls were positive for all tests. The diagnostic sensitivity and specificity of the assay (for human sera) were 100% using FCMIA anti-PA IgG as standard. This kit has utility for determining the immune status of individuals (military personnel, decontamination workers) vaccinated with AVA or possibly exposed to sub-clinical levels of B. anthracis.

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