Chagas assay using recombinant antigens on a fully automated chemiluminescence immunoassay analyzer

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BACKGROUND: The Abbott PRISM® is a fully automated, chemiluminescence based immunoassay analyzer (ChLIA). It has been used to screen blood specimens for 5 different viral markers. A prototype assay is being developed on the PRISM analyzer for the detection of Chagas’ disease (American trypanosomiasis). The disease, caused by the protozoan T. cruzi, is endemic to most regions of Latin Americas. Of the estimated 18 million infected people, approximately 50,000 die from this disease yearly. The estimated seroprevalence of the disease in US blood donor populations was as high as 0.48% and the trend is increasing with the increase in the Hispanic population.

METHODS: The assay uses (a) microparticles coated with rAgs of T. cruzi to capture antibodies to T. cruzi, (b) a 9-N-sulfopropyl acridinium derivative labeled mouse anti-human IgG to tag the captured human Ab on the microparticles, and (c) alkaline peroxide to trigger the chemiluminescence. Samples from patients with anti-T. cruzi antibodies gave significant higher signal compared to normal control.

RESULTS: The sensitivity and specificity of the assay was evaluated by testing a number of T. cruzi positive specimens, random donor negative serum and plasma donations to set a provisional cutoff to differentiate positive and negative responses. Preliminary data showed 99.0% detection of confirmed T. cruzi positive specimens (n=203). Specificity was estimated to be 99.8% (n= 2,000; RR = 4). Further optimization of the assay is in progress.

CONCLUSIONS: A prototype Abbott PRISM Chagas assay based on rAg and Chemiluminescence detection was demonstrated. The assay has the potential to be developed into a product for blood screening for the prevention of transmitting Chagas’ disease through blood transfusion.