Abstract #3

High Throughput Donor Plasma NAT Screening Assay Applied to Acute HIV Detection in a Public Health Setting

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PROJECT

An HIV pooled specimen nucleic acid test (NAT) previously validated and FDA cleared for the screening of donated blood plasma was investigated for the utility to detect acute HIV in a public health setting.

ISSUES

A major challenge in the implementation of acute HIV screening programs is the availability of validated, cost-effective HIV NAT methods. National Genetics Institute has developed high throughput and cost-effective methods for pooled specimen NAT for broad-based screening of donated blood plasma. These methods are validated and cleared by FDA under a CBER biologics license. Here we describe the results of a demonstration project with the San Francisco Department of Public Health (SFDPH) to utilize these methods for the detection of acute HIV as part of routine public health activities.

RESULTS

The method utilizes a RT-PCR procedure combined with a proprietary three-dimensional pooling algorithm. It was optimized for a sensitivity of 2-3 copies/mL and an ability to detect a single HIV-infected plasma sample in a pool of up to 512 samples. Patient samples (n=1536) were collected from the SFDPH city clinics and community based services over a 5-month period. All samples were initially screened for HIV antibodies using either standard EIA (Vironostika) or rapid (Orasure Technologies) HIV antibody tests. Negative antibody samples were then pooled and subject to NAT. HIV antibody was positive in 43 individuals (2.8% positivity rate). Among the HIV-antibody negative samples for which an adequate sample was available (n=1444), pooled NAT testing identified 5 additional HIV-positive samples increasing the overall HIV detection rate by 12% to 3.1% (48/1536). NAT positive samples were identified in pools of 64 samples and confirmed by individual NAT. All patients identified as positive were counseled and referred for HIV care and follow-up.

LESSONS LEARNED

HIV pooled specimen NAT methods validated and FDA cleared for screening of donated blood plasma appear to detect acute HIV with a frequency consistent with other published studies. As this method is routinely used for screening millions of blood plasma donations per year using pools of 512 specimens, opportunities exist to implement broad-based acute HIV screening programs in a highly cost-effective fashion.