



ICBS Master Panels

Since its establishment ICBS planned to establish fully characterized Master Panels of plasma samples positive for HCV, HBV, HIV and normal negative plasma composed of 200 members each and, as possible, equally distributed among all major known genotypes and subtypes of each virus resourced from wide geographic origins. The purpose of establishing these panels is to evaluate and identify commercially available high-quality, affordable blood screening test kits.

ICBS HCV Panels

ICBS established the ICBS HCV Master Panel and Negative Master Panel in September 2002. The HCV Master Panel is composed of 200 members distributed among all major known genotypes. The 200 anti-HCV positive members of the HCV panel were selected from 1021 units that were initially anti-HCV reactive after local testing in the countries of origin. The 1021 units were resourced by ICBS from various geographic zones with the assistance of collaborators in Brazil, Egypt, Indonesia, Ivory Coast, South Africa, Vietnam and the United States. The Negative Master Panel is composed of 200 members tested negative for anti-HCV, HBsAg, and anti-HIV. Each unit was subsequently tested at the Division of Viral Hepatitis, Centers for Disease Control and Prevention (CDC), Atlanta, Georgia, USA for anti-HCV by HCV 3.0 (Ortho-Clinical Diagnostics, Raritan, New Jersey) and confirmed by RIBA 3.0 (Chiron Corp, Emeryville, California). All confirmed anti-HCV positive units were tested, in parallel at the CDC and Visible Genetics (VGI), NorCross, GA, USA, by PCR to quantitative HCV RNA (Amplicor HCV Monitor, Roche Molecular Systems, Roche Diagnostics Corporation, Indianapolis, Indiana). HCV genotype and subtype were determined by direct DNA sequencing using two different strategies. The 200 anti-HCV positive members were selected on the basis of the characterization results obtained by both institutions (CDC and VGI). Whenever possible, the samples were selected for use in the HCV Master Panel when positive by serology, PCR and show genotype concordance.

ICBS HBV Panels

The last phase in establishing the ICBS HBsAg Master Panel and its corresponding Negative Panel were accomplished in mid-March 2005. Seven-hundred and twenty HBsAg positive units were collected from diverse regions around the world: Brazil (Sao Paulo and Manaus), Egypt, Ivory Coast, Jordan, Tunisia, Vietnam and USA (New York and Atlanta). These units were fully-characterized at CDC as well as at the partnering laboratory, the Department of Medical Sciences in the Toshiba General Hospital in Japan. The HBsAg Master Panel is composed of 200 members and includes representation of worldwide genotypes A, B, C, D, E, F and their corresponding variety of subtypes. Of these 200 members, 146 individual members are included for the purposes of testing clinical sensitivity. The remaining 54 members comprise HBsAg Dilution series for the purposes of testing analytical sensitivity. (This series is created from nine carefully-selected members, in a series of dilutions. These members represent all of the aforementioned major genotypes as well as a full-range of corresponding HBV subtypes (adw2, adw4, ayw1, ayw2, adr,

ayw3, and ayw4). In addition, out of over 400 non-infectious plasma units received from the American Red Cross, Washington D.C. (U.S.A.), a corresponding Negative Panel composed of 200 members was also manufactured.

ICBS HIV Panels

The completion of the establishment of the ICBS HIV panels is pending availability of necessary funds. ICBS has already collected two hundred and fifty candidate units from the regions of Ivory Coast, Brazil and the United States. While testing continues, the initial units have already demonstrated results of HIV-1 and HIV-2. Further emphasis is being placed on the completion of testing of the remaining units, while looking forward to acquire units more units from other geographic regions, as soon as funds become available.