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Sponsor Novartis Vaccines and Diagnostics
Product Name(s) Assay for use in screening for the presence of HIV-1 RNA, HCV RNA, and HBV DNA in blood donations.
Study Number ULT-001-TW1-Amendment 1.1
Title Evaluation of A TMA Assay for the Screening of HIV-1 RNA, HCV RNA and HBV DNA in Human Blood Donor Plasma Specimens with an automated System.
Study Start / End Dates 08Aug2007 to 01 July 2008
Phase of Development **N/A**
Study Design / Methodology The study involved the use of an investigational device, a nucleic acid test (NAT) to detect the presence of transfusion transmittable viral infectious diseases, HBV, HCV, and HIV-1. This study compared the results from serologic blood screening methods for HBV, HCV, and HIV against NAT that detects viral nucleic acids for HBV, HCV, and HIV-1. A total of 10,290 normal

Taiwanese blood donors were screened. Of these, 4,210 donors were tested as individual specimens (IDT), and another 6,080 donors were tested in pools of four (P4) with the investigational device. The study also evaluated the performance of the NAT test in the following areas: analytical sensitivity, clinical sensitivity, analytical reproducibility, calibration reproducibility, and clinical specificity.

Centers

Taipei Blood Center (Taiwan Blood Services Foundation)
National Taiwan University Hospital (Taipei, Taiwan)
Tainan Municipal Hospital (Tainan, Taiwan)

Publication

2008 AABB Abstract: Evaluation of the PROCLEIX® ULTRIO® Assay on the PROCLEIX® TIGRIS® System for HBV/HCV/HIV Blood Screening in Taiwan.

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Objectives

Primary Objective(s)

To develop NAT data for screening blood donations for the presence of HBV, HCV, and HIV-1 viruses so that the testing device can be registered and licensed for use in Taiwan.

Secondary Objective(s)

1. To determine NAT yield cases for HBV, HCV, and HIV-1
2. Analytical sensitivity
3. Clinical sensitivity in serologic positive HBsAg, anti-HCV, and anti-HIV specimens
4. Clinical specificity
5. Reproducibility

Test Product(s)

PROCLEIX ULTRIO Assay

Reference Product(s)

Serological test methods for HBsAg, anti-HCV, and anti-HIV

Criteria for Evaluation

Sensitivity
Specificity
Other ☒
☒

Statistical Methods

1. Estimation of analytical sensitivity by Probit analysis at the 95% confidence interval
2. Estimation of reproducibility using standard calculations for mean, standard deviation, and percent coefficient of variation for calibration and controls.
3. Estimation of clinical sensitivity
4. Estimation of clinical specificity

Study Population: Inclusion/Exclusion Criteria and Demographics

10,290 Healthy Taiwanese blood donors, and 494 seronegative volunteers obtained at two hospitals for clinical specificity testing.

Number of Subjects/Samples

10,290 blood donors
494 seronegative volunteers
64 anti-HIV seropositive samples
102 anti-HCV seropositive samples
92 HBsAg positive samples

Primary Result(s)

ULTRIO assay specificity in blood donors (IDT n=4,210 / P4 n=6080 testing) = 99.95% / 100%
ULTRIO assay specificity in seronegative volunteers = 100%

Secondary Result(s)

1. There were 11 HBV yield cases observed in the donor population. Eight cases (0.19%) were observed with IDT testing, and 3 cases (0.049%) were observed during P4 testing. Ten of the eleven were occult hepatitis B infections, and one was a window period HBV infection.
2. Analytical sensitivity met the performance characteristics when using the WHO standards (Mean 95% Limits of Detection): HBV 6.3 IU/mL; HCV 4.4 IU/mL; HIV 18 IU/mL
3. Clinical sensitivity in confirmed seropositive samples: anti-HIV = 100%; anti-HCV = 98.6%; HBsAg = 86.8%
4. Reproducibility= across two master lots of reagents (calibrators and controls): Lot 3413523 3.5% to 9.0% CV; Lot 3413527 3.9% to 6.9% CV. Acceptable levels of precision and reproducibility for an assay of this type. There was no difference in performance between lots.

Safety Results

N/A

Serious Adverse Events and Deaths

N/A

Other Relevant Findings

N/A

Date of Clinical Trial Report

12 Sept. 2008