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Comparison of electrochemiluminescence and ELISA methods in the detection of blood borne pathogens in Gabon

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ABSTRACT

Objective: To assess the performances of Cobas 6000 e601 and EVOLIS BioRad in the detection of HIV, HBV and HCV in blood donors in Libreville (Gabon).

Methods: A cross-sectional investigation was conducted in July 2017 in a total of 2 000 blood donors recruited at the National Blood transfusion Center (NBTC), Libreville Gabon. Among them, 363 donors were selected to compare the performances of COBAS 6000 e601 (electro-chemiluminescence) and EVOLIS BioRad in detecting HIV, HBV and HCV using Cohen's kappa coefficient.

Results: Both methods yielded similar results for the detection of HIV and HBsAg. A very good agreement of 93.39% and an excellent agreement of 98.90% were obtained for the detection of HIV and HbsAg, with kappa values of 0.80 and 0.98, respectively. The observed agreement of 91.86% was found for the detection of HCV, which gave a fair agreement between the two methods with kappa = 0.33.

Conclusions: The two evaluation methods showed a similar performance in the detection of HIV, HBV. However, given the high rate of intra and inter-genotypes recombination known for HIV and HBV, more robust techniques of detection such as polymerase chain reaction should be used to prevent post-transfusion contaminations.

1. Introduction

Each year, blood transfusion saves millions of lives worldwide. However, in Sub-Saharan Africa, it remains a major route of transmission of infectious diseases such as human immunodeficiency virus (HIV), hepatitis B and C (HBV and HCV), which are major public health problems [1]. To effectively reduce the burden of transmission of these infectious agents, their diagnosis is essential [2]. Currently, many screening tests are available, including automated tests using electrochemiluminescence and enzyme-linked immunosorbent assay (ELISA) technologies, which are used in many countries [2]. The choice of a particular serological test in the diagnosis of an infection is based on the epidemiological data, and genetics of the infectious agents which could affect the assay limit [3,4].

In Gabon, the routine diagnosis of transfusion-transmitted infections (TTI) in blood donors at the National Blood Transfusion Center (NBTC) in Libreville, is carried out mainly by EVOLIS BioRad, a 4th generation ELISA test (dual detection of antigens and antibodies of infectious entities) adapted for blood transfusion [3,5].

The NBTC has recently acquired a new ITT's diagnostic tool using an electro-chemiluminescence technique (Cobas 6000 e601), whose performance has been evaluated previously [6,7].

This study sought to assess the performance of Cobas 6000 e601, using electro-chemiluminescence technology and EVOLIS BioRad (4th generation ELISA) in the detection of HIV,

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HBV and HCV in voluntary non remunerated blood donors in Libreville (Gabon) Central Africa.

2. Materials and methods

2.1. Donors' recruitment

A cross-sectional study on blood donors in Libreville was conducted in July 2017. All volunteer and family donors who are apparently healthy were selected after responding to a panel of questions including their medical history. The age for inclusion in blood donation cluster was set from 18 to 57 years old and the weight $\geq$ 50 kg. Donors were consented and information on their health status was recorded into a questionnaire. Excluded donors were those who received transfusion, individuals with jaundice or signs of hepatitis, pregnant women and those who had sexual risk behavior during the six weeks prior to blood donation.

2.2. Selection of samples and anti-HIV, anti-HBsAg and anti-HCV serology

Out of the 2 000 samples tested by the 4th generation ELISA, only 363 samples were screened for serological markers by COBAS 600 e601. The selection criteria for the samples are described in detail in Figure 1. The detection of p24 antigen, anti-HIV-1&2 antibodies, hepatitis B surface antigen (HBsAg), anti-HCV antibodies and antigens was performed using the Genscreen ULTRA HIV Ag-Ab, MONOLISA HBsAg Ultra and Monolisa HCV Ag-Ab ULTRA (Bio-Rad, Marnes-la- Coquette, France). ElecsysHIV combi PT, Elecsys HBsAg II and Elecsys Anti-HCV II (Roche Diagnostics, Germany) were used for the screening of HIV, HBsAg and HCV. All reactive samples were confirmed by a second test using a different method. All donors with undetermined serological status were convened for a second screening after 2–3 months.

2.3. Statistical analysis

Data was analyzed with the Statistical Package for Social Sciences software (SPSS version 20.0). The Cohen's Kappa statistical test (http:graphpad.com/quickcalcs/kappa/) was used to compare the concordance of the two diagnostic methods in the detection of serological markers.

2.4. Ethical considerations

This study was approved by the NBTC Ethics Committee. Informed consent was obtained from adults and parents or guardians of individuals under 18 years old before blood collection.

3. Results

3.1. Detection of HIV, HBV and HCV by ELISA and electro-chemiluminescence

Of the 363 donors selected for the detection of HIV, HBV and HCV, 75 donors were reactive to HIV by both methods. Two hundred and eighty-four (284) and 288 donors were non-reactive for HIV by ELISA and electro-chemiluminescence, respectively, while 4 donors were undetermined for HIV by ELISA (Table 1). Both methods displayed identical results for the detection of HBsAg with 160 reactive and 203 non-reactive donors.

Thirty six (36) and 11 donors were reactive to HCV detected by EVOLIS Bio-Rad and COBAS 6000 e601, respectively; 323 and 352 non-reactive donors were detected by EVOLIS Bio-Rad and COBAS 6000 e601, respectively, while 5 indeterminate samples were obtained only by ELISA (Table 1).

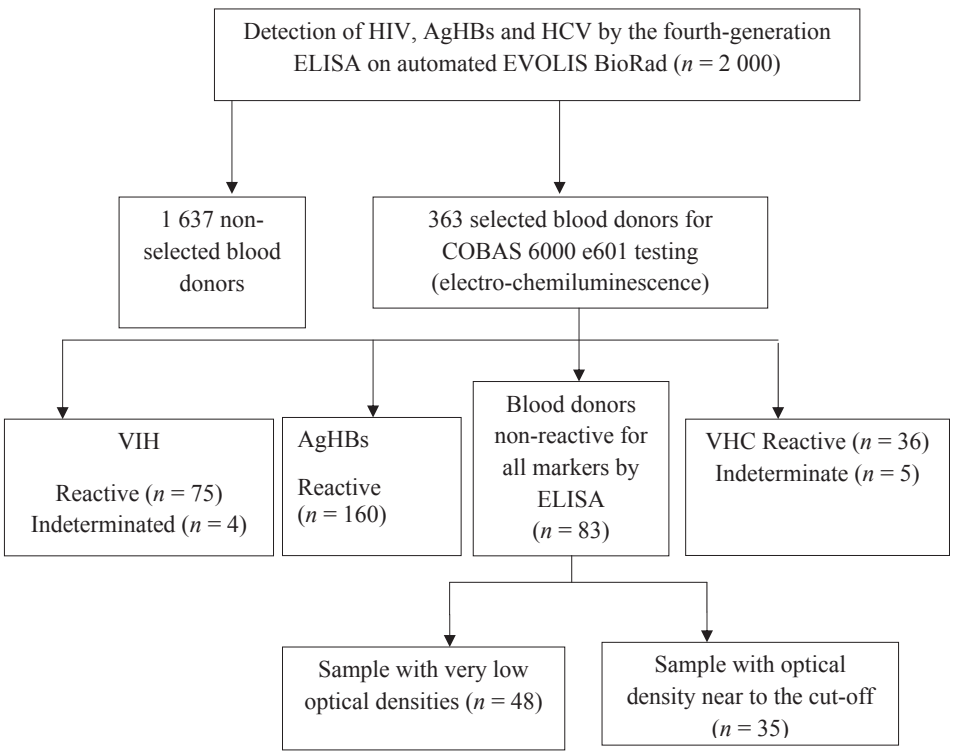

Figure 1. Diagram of selected samples tested with the two immunoassays.