Technical procedures for implementing the infectious disease screening tests

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1 – Objective and Scope

The objective of this document is to define the technical procedures for implementing the mandatory screening tests for infectious diseases, according to the guidelines related to the testing of blood donations and the Principles of Good Transfusion Practices released In October 2012 by the Lebanese Ministry of Public Health.

This document applies to the BTC personnel performing infectious diseases screening activities.

2 - Abbreviations

BTC……: Blood Transfusion Center
HIV …… : Human Immunodeficiency virus
HCV ……: Hepatitis C virus
Anti-HIV 1/2 +P24……: Antibodies against HIV types 1 and 2 and P24 antigen
Anti-HCV …... ……..: Antibodies against HCV
HBs Ag ……: Hepatitis B virus (HBV) surface antigen
T anti-HBc ……: Total (IgM+IgG) Hepatitis B core antibodies
Anti-HBs ……: Hepatitis B surface antibody
IgM anti-HBc……: IgM antibodies to Hepatitis B core
HBe Ag……..: Hepatitis B e antigen
Anti-HBe……..: Hepatitis B e antibodies
VDRL …… : Venereal Disease Research Laboratory; anti-treponema antibody
RPR ……: Rapid Plasma Reagin; anti-treponema antibody
TPHA …… : Treponema Pallidum Hemagglutination Assay; anti-treponema antibody
FTA-ABS……: Fluorescent Treponemal Antibody Absorption; anti-treponema antibody

3 – General procedure

The testing of blood donations.is performed on venous blood samples collected from the same phlebotomy site as the donation. Only tubes labelled with the donation ID (primary tubes) are accepted by the laboratory to enter the qualification process.

The technical procedures for implementing the qualification are based on the decisional algorithms for the microbiological markers (check procedures).

3.1. Screening

3.1.1. Initial screening

The initial screening performed on each donation consists of using a chosen and validated procedure and reagent in order to detect a given marker in accordance with the applicable regulation.

The result is either:

- negative,
- or initial reactive: reaction signal above the supplier threshold.

In case of an initially negative result and if there is no discrepancy with the donor's previous history for this marker, the donation is considered negative.

In case of an initially reactive result, the validation of the involved blood component is blocked (impossibility of labelling).

3.1.2. Management of initial reactive samples: Repeatability

All initially reactive samples should be repeated in duplicate using the same assay as the initial screening and the same automatically pipetted tube (primary identification) in order to check for the repeatability.

If both results are negatives, the result of the initial screening is considered non-repeat-reactive.

If one or both results are reactive(s), the sample is considered as repeat reactive.

3.1.3. Non-repeat-reactive samples

These samples are considered negative if there is no discrepancy with the previous donations for a given marker.

3.1.4. Repeat reactive samples

If the screening test result is repeatedly reactive, the sample is considered positive for that marker (except for the VDRL) in accordance with the diagnostic approach defined by the attached algorithms.

3.2. Additional tests

Repeatedly reactive samples for a given marker are subject to further analysis according to the available capabilities and procedures specific to each laboratory. In all cases, an orientation support is provided to the donor by the BTC director (check procedure: course of action for abnormal test results in blood donors).

3.3. Importance of the donation history in the testing of blood donations

The donation is qualified based on the following test results: the initial screening, the biological qualification of the previous donation and, if necessary, the additional analyses.

The **« Decisional algorithms for the testing of blood donations »** describe the steps required for the testing of blood donations.

4 – Specific procedures

For each marker, a procedure specific to each BTC describes the additional confirmatory tests that can be suggested to the donor, even if these are not performed on site.

4.1. HBs Antigen

Additional tests include the neutralization test, a second different HBs Ag screening test and molecular studies.

Other tests may be performed to complete the laboratory work-up in case of a confirmed positive HBs Ag.

4.2. Anti-HIV 1/2 +P24

Additional tests include at least one of the following:

- A second different anti-HIV1/2 and p24 screening test
- HIV 1/2 immunoblot (Dot Blot or Western Blot)
- Molecular test

4.3. Anti-HCV

Additional tests include at least one of the following:

- A second different anti-HCV screening test
- HCV immunoblot,
- Molecular test.

4.4. T anti-HBc

Additional tests include, in addition to the HBs Ag, at least one of the following:

- Anti-HBs titer
- HBc IgM
- HBe Ag
- Anti-HBe

4.5. Syphilis serology

Syphilis screening involves VDRL/RPR or enzyme immunoassay test (IgM+IgG). Additional tests include at least one other screening assay: TPHA, FTA abs. An immunoblot test may be performed to confirm the result.