BLOOD DONATION TESTING REAGENTS

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VERSION 1

LCBT-QUAL-003

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1- Preamble

This document concerns the supply of serological markers, used in automated (Enzyme immunoassay or Electro/Chemiluminescence immunoassay for Human Immunodeficiency virus, Hepatitis B virus, Hepatitis C virus and syphilis) or manual (only agglutination tests for syphilis) techniques, required for the testing of blood donations.

2- Conformity of products with the current legal and regulatory standards

The reagents, their analytical systems and additional supplies required for their use and/or automation as well as other consumables and accessories suggested by the manufacturers shall comply with the applicable standards of the European and/or North American markets. They are marked CE or FDA according to the regulations for in vitro diagnostic medical devices.

3- Nature and performance of reagents

The reagents related to the testing of blood donations are (Order N° 1873/1 of 20/11/2012):

- HBs Ag;
- Total anti-HBc;
- Anti HCV;
- Combined HIV (1/2) Ag/Ab test;
- Screening test for Syphilis: VDRL/RPR (optionally TPHA or immunoassay test)

For each of these reagents, the supplier shall provide in its proposal the following documentation:

- The reagent technical data sheet in English and French, specifying the pre-analytical conditions for samples;
- A summary of the technical file submitted for CE or FDA marking;
- The “safety data sheet” of the products, according to the European or North American regulations specific for hazardous substances;
- Publications and other quality assessment documents;
- Results of stress studies (extreme temperature, shelf life, stability);
- The main and any additional reagents along their solutions which must be preferably ready to use.

The supplier’s proposal shall specify for each biomarker the following performance results:

- The detection limit: it should be less than 0.1 ng/ml for HBs Ag and 2 UI/ml for P24Ag in HIV;
- The analytical and diagnostic sensitivity (representative panel of samples tested);
- The analytical (non-repeated initially reactive samples) and diagnostic (false positive samples) specificity;
- The repeatability and reproducibility;
- The analytical range (linearity zone) for anti-HBs;

The aforementioned analytical and diagnostic parameters have been assessed by the supplier (or manufacturer) in at least 2000 random blood donors, and if possible, on three different lot numbers. These assessments must be documented in his proposal.

When used as first-line tests, the analytical and diagnostic specificity for HBs Ag, HIV1/2 Ag/Ab, anti HCV and anti-syphilis must be greater than 99% and 99.7% respectively.

The supplier shall describe in his proposal all additional reagents or consumables needed for running the corresponding serological marker and also provide proof that they were adapted to use regardless of its lot number.

It is desirable that the supplier provide the exact parameters with which the reagent has been validated and must be used.

It is also desirable that the user have the possibility to define and establish a grey zone for each parameter.

4- Storage and use of products

4.1. Storage conditions

The supplier shall specify:

- The average size of a lot number;
- The average stability time of reagents after delivery;
- Reagent transport conditions (maximum transport time, optimum temperature range, maximum tolerated temperature);
- Storage conditions before opening the reagents;
- Storage conditions after opening the reagents;
- The stability time of reagents after opening and after reconstitution or dilution
- Results of the performed stress studies (extreme temperature, duration, stability).

4.2. Conditions of use

The supplier shall specify whether the reagent can be used on serum or plasma samples, 5 ml or 7 ml tubes, with or without separator (gel, beads…).

The supplier shall document:

- The conditions and duration of storage for samples before analysis (duration and temperature);
- The nature of the anticoagulant(s) that is (are) compatible with the reagent;
- Sample quality and acceptance criteria (hemolysis, lipemic, icteric...).

Furthermore, the supplier shall specify:

- The type, size and conditions of use for acceptable tubes (primary, secondary or micro tubes…);
- The nature and composition of the reaction materials and consumables;
- The means implemented to secure the different steps of the analysis (barcode identification of reagents, controls testing);
- The risks associated with the use of reagents, equipment, ancillary reagents or accessory consumables in the case of dangerous products (hazard pictogram). The safety data sheet shall be provided;
- Precautions to be taken by the BTC in order to ensure the operator safety;
- The nature and volume of the produced solid and/or liquid wastes and the preventive measures taken by the BTC to preserve the environment;
- The nature of antigens;
- If the technique is validated with post-mortem samples.

4.3. Methods of use

The supplier shall specify the following for each reagent:

- The duration and conditions of centrifugation for initial samples;

- The duration and conditions of centrifugation and preparation of frozen samples for analysis or control purposes, and the supplier shall provide all necessary assistance to implement these recommendations;
- The time required to prepare solutions that may need to be reconstituted;
- The total duration of the incubation and/or analysis;
- The daily output and the maximum capacity of the automated equipment that allow an optimal performance;
- The maximum number of samples that can be processed daily.

5- Product packaging and traceability

The supplier shall describe the size and packaging formats of reagents, reaction materials, ancillary reagents and accessory consumables.

The supplier shall deliver these products in the agreed upon formats. Each reagent kit shall include a leaflet and instructions to use written in English and French.

The lot number and expiry date are indicated on the kit.

The lot number and expiry date of its different components are stated on each. The expiry date indicated on the kit is the closest expiry date for any of its components.

Reaction materials, ancillary reagents and other consumables not included in the reagent kit are referred to as « supplementary items ». There are packaged separately and according to their nature. Their labeling follows the same rules for reagents.

6- Continuity of supply

The supplier shall maintain the continuity of supply of reagents, particularly in case of a breach in the medical device vigilance (or materiovigilance) system that prevents the use of the current lot number or a serious crisis/disaster that prevents their delivery.

7- Product changes or updates

The supplier shall allow the BTC to benefit from the updates regarding reagents, consumables, additional solutions, as well as software and automated equipment.

The supplier shall notify, in written form, the BTCs of any changes in the main reagent, reaction materials, ancillary reagents and accessory consumables, or in the packaging.

8- Associated services

8.1. Training of personnel

The supplier provides, for the BTC personnel, initial and/or ongoing training sessions on the handling of reagents and the use and maintenance of automated systems.

8.2. Provision of technical support

The supplier shall provide technical support, within the laboratory of the concerned establishment, regarding the implementation of automated system(s) and associated reagent (s) and their routine use in accordance with the terms and conditions specified in the proposal.

8.3. Notification

In the context of materiovigilance and achieving an optimal transfusion safety, the supplier shall notify as soon as possible, in written form, the concerned BTC of any confirmed event susceptible to have an impact on the quality of the products, the associated services, the activity of the laboratory (delivery date not respected or stock shortage) or involving the transfusion safety.

9- Quality Policy

The supplier shall engage in the following quality services:

- Adhere to a quality process;
- Act according to the applicable health and safety regulations;
- Respect the principles of confidentiality and rights;
- Conduct regular satisfaction surveys;
- Manage the procedures and technical documentation concerning analytical reagents/systems, and disseminate them in English and/or French.

The strategy for monitoring the analytical performance of reagents lots is based on conducting:

- A control at their receipt by the laboratories (validation of the transport);
- A control during their use according to the conditions set by regulation and internal standards.

Any detected non-compliance or decline in performance will be documented and reported to the supplier.

10- IT security obligations

The supplier shall respect and make sure that his personnel abides to the following:

- The pre-approval by the BTC is required:
    - For all copies of documents and supporting data entrusted to the supplier excluding those required for the provided service that figures in the contract;
    - For the use of documents and information for purposes other than those defined in the contract.

- The supplier shall respect the following confidentiality commitments:
    - Not to disclose any documents or information provided by the BTC to third parties;
    - To take all necessary security measures in order to avoid the misuse or fraudulent use of electronic files and ensure the retention and integrity of documents and information.

- At the end of the contract, the supplier must destroy all files, whether soft or hard copies, containing personal or medical information/data.

11- Manual Methods special features (VDRL, TPHA, RPR)

These agglutination tests detect the presence of specific antigens or antibodies in samples through the agglutination of particles coated with the complementary antibody or antigen, respectively. These particles are Red Blood Cells (hemagglutinin) or inert particles such as gelatin or latex;

These tests do not involve several steps nor washing equipment. Their results are read visually (subjective assessment) and cannot be permanently recorded.

Similarly, to the previous reagents, the supplier shall include in his proposal a validation file that contains technical (pre-analytical conditions, stress studies) and scientific documents in addition to the international certifications for use.

- The analytical and diagnostic sensitivity (representative panel of samples tested);
- The analytical (non-repeated initially reactive samples) and diagnostic (percentage of false positive samples) specificity which must be high (greater than 90%);

The aforementioned analytical and diagnostic parameters been assessed by the supplier (or manufacturer) in at least 2000 random blood donors, and if possible, on three different lot numbers.

The supplier shall document these assessments.