Central Reference Documentation for screening tests

The Central Reference Documentation contains summarizing data on each of the vitro diagnostic medical devices (IVD) used as screening tests in the manufacture of blood and stem cell preparations.

Content:

1) Manufacturer of the in vitro diagnostics and its distributor in Germany.
2) Test name, as declared on labels and Instructions for Use.
3) Description of the test principle
   a. Serological screening-tests: an informative description of the test principle in which the immunological components used are precisely mentioned.
   b. NAT-screening-tests: an informative description of extraction, amplification and detection procedure (optional procedures included).
4) A listing of the instruments for which the test was validated and for which it can be used.
5) Data on the studies for performance evaluation formatted according to the design dossier requirements of Annex IV directive 98/79/EC which have to document accordance with
   a. the "Imposition of conditions pursuant to Section 28 (3) c AMG (Arzneimittelgesetz, German Medicines Act) for the purpose of risk prevention to assure the safety of blood components for transfusion and of stem cell products for haematopoetic reconstitution: Testing for HIV, HBV and HCV",
   b. the Common Technical Specifications pursuant to Commission Decision 2009/886/EC, and
   c. the basic requirements pursuant to Annex I Section A Directive 98/79/EC.
6) A description of the batch tests containing
   a. Methodology
   b. Specimens to be tested and their specifications
   c. Accuracy (serological screening-tests)
   d. Precision (serological screening-tests)
7) A valid version of the Instructions for Use.

Paul-Ehrlich-Straße 51-59
63225 Langen
Deutschland / Germany

Telefon / Phone +49 (0) 6103 77 0
Fax +49 (0) 6103 77 1234
>> www.pei.de