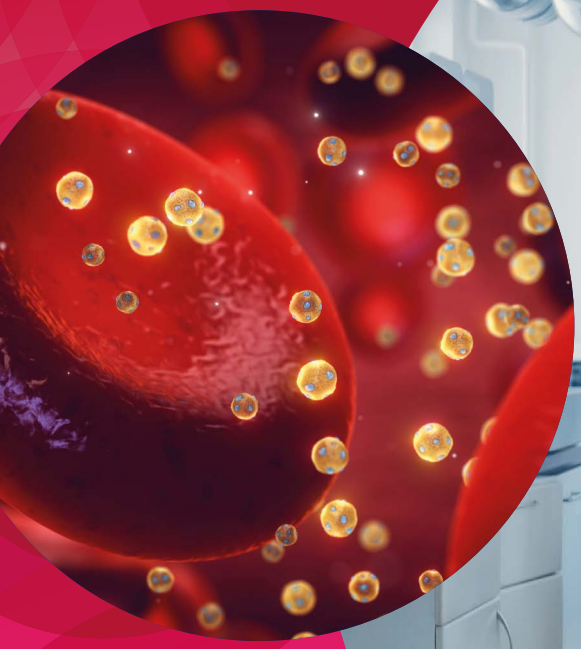
B-PTS – Blood Proficiency Testing Scheme Programme



B-PTS studies: assessing the performance of European blood testing laboratories in the field of substances of human origin

edqm
European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

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Background and objectives

The purpose of the Blood Proficiency Testing Scheme (or B-PTS) programme is to improve the safety of blood components, plasma-derived medicinal products, organs and tissues and cells, and therefore protect patients receiving blood transfusions, undergoing a transplant or benefitting from medically assisted reproduction. Set up and implemented by the European Directorate for the Quality of Medicines & HealthCare (EDQM), the Council of Europe directorate responsible for numerous essential healthcare programmes, this initiative has been assisting European blood establishments since 2010 and, since 2025, laboratories performing testing on living organ, tissue and cell donors. It is co-funded by the EDQM and the European Commission.

European Union legislation and the Good Practice Guidelines (GPG) in the Council of Europe's *Guide to the preparation, use and quality assurance of blood components* and *Guide to the quality and safety of tissues and cells for human application* require blood testing laboratories to participate in external quality assessment (EQA) initiatives such as PTS programmes, which are also recognised as an important aspect of any quality management system (QMS).

The EDQM designs and organises B-PTS studies according to the principles laid out in ISO/IEC 17043:2023 Conformity assessment – General requirements for the competence of proficiency testing providers.

Activities organised

• B-PTS studies

B-PTS studies are specifically designed for use in blood testing laboratories (blood establishment laboratories and laboratories performing testing on living organ, tissue and cell donors). Participating laboratories receive test panels consisting of real samples that a blood testing laboratory would typically receive and test them using their routine procedures and assays.

Studies are organised in the following fields:

Nucleic acid amplification technique (NAT)

NAT for hepatitis B and C virus (HBV and HCV), human immunodeficiency virus (HIV)

Serology immuno-haematology

Anti-HCV
Anti-HIV/p24
Anti-*Treponema*
HBsAg/Anti-HBc

Immuno-haematology

ABO, Rhesus, Kell, extended phenotyping and irregular antibodies

Microbiology

Bacterial testing of platelet components

Added value

Blood testing laboratories can count on B-PTS studies to provide objective means of assessing and demonstrating the reliability of their data. B-PTS study participants can evaluate the integrity of their entire testing process, identify potential sources of error and prevent erroneous results.

Comparing their results with other participating European blood testing laboratories also provides the opportunity to gain further insight into testing practices in use elsewhere and learn about state-of-the-art assays used in Europe in the fields of blood transfusion and organ, tissue and cell transplantation.

Participation

All European blood establishments and laboratories performing testing on living organ, tissue and cell donors from European Union and Council of Europe member states may participate in B-PTS studies.

Participation is entirely free.

Want to find out more? Visit the EDQM's dedicated website: https://go.edqm.eu/BPTS

Want to register for the programme? Visit: https://go.edqm.eu/BPTSregister

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