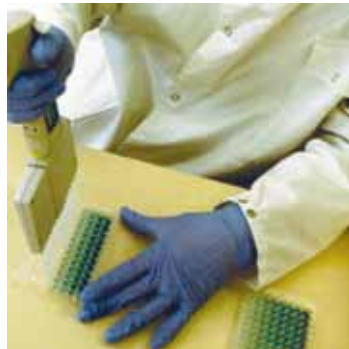
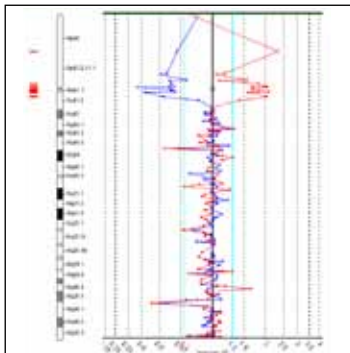


Genetic reference materials from experts in biological standardisation



Genetic reference materials from experts in biological standardisation



Genetic Reference Materials

The National Institute for Biological Standards and Control (NIBSC) is the global leader in the field of biological medicine standardisation and is responsible for producing over 90% of World Health Organisation (WHO) International Standards which are used in laboratories around the world to assure the quality of biological medicines.

NIBSC also produces reference materials for nucleic acid based diagnostics both for infectious disease and genetic disorders. Reference materials for human genetic diagnostic tests are of particular importance in improving assay performance and therefore diagnosis of genetic disorders which are of major clinical impact. Such reference materials are available either as WHO International Standards or as CE-marked *in-vitro* diagnostic materials (IVDs)

In the last 5 years NIBSC has produced several WHO International Standard panels of reference materials for human genetic diagnostics. These panels are produced by extracting human genomic DNA from patient-derived cell lines which is then freeze-dried in glass ampoules for long term stability. These panels are considered 'Higher Order' materials which are suitable for *in-vitro* diagnostic use. They are not intended as routine 'run-controls', but as materials to occasionally verify reagents, equipment and staff, as well as to act as calibrants for in-house local controls. These panels are supplied to laboratories worldwide upon request and can be ordered through the NIBSC website www.nibsc.ac.uk/science/diagnostics/human_genetic_diagnostics.aspx

NIBSC has also produced a panel of routine 'run-controls' for the typing of the HLA-A gene which is CE-marked and therefore appropriate for use as a component of diagnostic tests in most countries.

In order to expand our range of genetic reference materials we are constantly seeking appropriately consented, ethically approved patient blood samples for cell line generation. The genetic reference materials team at NIBSC have built up excellent working relationships with the National Genetic Reference Laboratories, UK NEQAS and the national blood transfusion services as well as the WHO, and seek to develop additional relationships where possible. If you are able to assist with this please contact us via our website www.nibsc.ac.uk/science/diagnostics/human_genetic_diagnostics.aspx

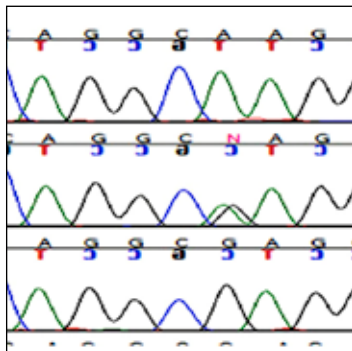
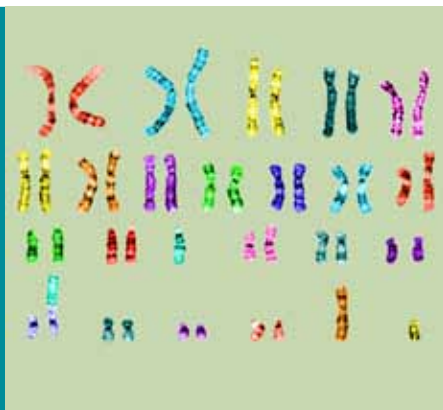
How the process works





NIBSC's reference materials include:

- WHO International Standards
- Secondary biological reference materials
- *In vitro* diagnostic working reagents
- Customised reference materials
- Human embryonic stem cells
- Research reagents
- Cell lines for use in quality assurance



Panels Available	NIBSC Order Code	Certification	Disorder
Factor V Leiden	04/224	WHO	Thrombosis
Prothrombin	05/130	WHO	Thrombosis
HLA-A	05/208	CE	(Transplantation)
Haemophilia A	08/160	WHO	Haemophilia, intron 22 inversion
Fragile X syndrome	08/158	WHO	Fragile X syndrome
Prader Willi & Angelman syndromes	09/140	WHO	Prader Willi & Angelman syndromes
BCR/ABL fusion gene quantitation	09/138	WHO	Chronic Myeloid Leukemia
Fetal RhD status for non-invasive maternal screening	07/222	WHO	Haemolytic Disease of the Newborn

Panels in Development	Expected completion	Certification	Disorder
HLA-DRB1	end 2010	CE	(Transplantation)
Hereditary Haemochromatosis	end 2011	CE	Iron overload
Hereditary Non-Polyposis Colorectal Cancer (HNPCC)	2011	CE	Colon Cancer
Red cell antigen genotyping	end 2011	WHO	Allo-immunisation
Platelet antigen genotyping	end 2011		Allo-immunisation



International validation study



Approval by WHO as international reference panel

To find out more...

Further information about our International Standards, reference reagents and biological materials can be found on our website.

Please see www.nibsc.ac.uk or contact us at: business@nibsc.hpa.org.uk.

About NIBSC

The National Institute for Biological Standards and Control (NIBSC) is a world renowned scientific Institute. Operating at the interface between scientific research, biopharmaceutical quality control and government regulation, our role is to protect public health through assuring the quality of biological medicines. NIBSC is a centre of the Health Protection Agency, a UK public body whose role is to protect the public from health threats.

World Health Organisation (WHO) International Laboratory

NIBSC is the leading WHO International Laboratory for Biological Standardisation and is responsible for producing and distributing over 90% of all WHO International Standards introduced for the quality assurance of biological medicines. The WHO International Standards serve as the primary 'gold standards' against which regional and national laboratories, manufacturers and others calibrate their working standards.

Quality

NIBSC has an excellent international reputation, established over many years, reflecting its commitment to developing robust, fit-for-purpose and efficient processes in all areas of its activities. In addition to an in-built culture of best practice, the Institute holds accreditation and certification to a number of external formal quality systems including:

- ISO/IEC 17025 for compliance testing of biological medicines
- ISO 13485 for design/production of CE marked in vitro diagnostic reference materials
- ISO 9001 for the production, storage and dispatch of our reference materials

NIBSC is a centre of the Health Protection Agency, a UK public body whose role is to protect the public from health threats.

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