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British Bone Marrow Registry (BBMR) & NHS Cord Blood Bank (NHS CBB) Supplier Qualification Summary

BBMR and NHS CBB together form a division of NHS Blood and Transplant (NHSBT). As such, all internal and external suppliers of BBMR and NHS CBB including cellular product collection, processing and testing facilities are subject to stringent Quality Management System controls. Contractual and / or procedural requirements include:

All entities providing UK regulated services (collection and processing of tissue, related IDM testing) on behalf of BBMR must continually hold a suitable Human Tissue Authority (HTA – UK competent authority in relation to the European Union Tissue & Cells Directive) license. Collection Centres providing services to BBMR must additionally hold FACT-JACIE accreditation. As part of HTA requirements, all supplier IDM testing laboratories are required to utilise only Conformité Européene (CE) marked or suitably validated testing kits/devices, according to manufacturer's instructions.

Detailed service level agreements are in place to ensure these entities also abide by pertinent World Marrow Donor Association (WMDA) accreditation standards.

Any laboratory performing HLA typing services to BBMR or NHS CBB must hold European Federation of Immunogenetics (EFI) accreditation.

Both internal and external service providers are additionally subject to periodic assessment. During these assessments, all pertinent licensing and accreditation statuses are checked and verified to ensure continual pertinent compliance.

On 31st January 2020, Britain left the European Union. There is now a transition period until the end of 2020 while the UK and EU negotiate additional arrangements.

The current rules on trade, travel, and business for the UK and EU will continue to apply during the transition period.

On the following pages there is a compilation of information to assist registries based within the European Union, that may aid with the import of stem cell products from NHSBT after the end of the current transition period (i.e. from 1st January 2021).

The following was compiled with reference to EU Directive [2015/566](#) as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells.

BBMR and the NHS CBB remains World Marrow Donor Association [accredited](#), with the NHS Cord Blood Bank also Netcord-FACT [accredited](#). Both the registry and the cord blood bank are located at the NHSBT Filton, Bristol (site HTA inspection reports available [here](#)).

BBMR utilises four collection centres for the procurement of stem cells and donor lymphocytes. If you require further information about these collection centres and are unable to access information on these tissue establishments on the [EU Coding Platform](#); the UK tissue and cell competent authority; the Human Tissue Authority maintains all relevant information on its own website as follows. Also included are hyperlinks to testing laboratories ISO15189 schedules of accreditation, where relevant.

1. The London Clinic:
 - <https://www.hta.gov.uk/establishments/london-clinic-11052>
 - https://www.ukas.com/wp-content/uploads/schedule_uploads/00007/8166%20Medical%20Single.pdf
2. NHSBT SCI Oxford
 - <https://www.hta.gov.uk/establishments/sci-oxford-11042>
3. NHSBT SCI Sheffield / Sheffield Teaching Hospitals NHS Foundation Trust
 - <https://www.hta.gov.uk/establishments/sci-sheffield-11036>
 - <https://www.hta.gov.uk/establishments/sheffield-teaching-hospitals-nhs-foundation-trust-22620>
4. NHSBT Bristol
 - <https://www.hta.gov.uk/establishments/nhsbt-bristol-22518>
(Also includes information about BBMR and the NHS Cord Blood Bank)

The infectious disease marker screening laboratory utilised by the SCI/NHSBT sites (2,3, and 4 above) is NHSBT Manchester which is a satellite site of the HTA licensed NHSBT Liverpool site

- <https://www.hta.gov.uk/establishments/nhsbt-liverpool-11018>

🏠 Related licences

Main licence:

NHSBT Liverpool

Satellites:

Basildon SHU

Epsom Hospital

NHSBT Manchester

Royal Liverpool University Hospital

The Horder Centre for Arthritis

A list of donor infectious disease marker tests routinely performed on our donors can be found [here](#)

- Relevant screening test results detected at NHSBT Manchester are confirmed at the NHSBT Transfusion Microbiology Reference Laboratory in London <https://www.hta.gov.uk/establishments/nhsbt-colindale-22600>
- https://www.ukas.com/wp-content/uploads/schedule_uploads/00007/8783%20Medical%20Single.pdf

Any other information is available on request. This letter will be revised annually and hosted on the NHSBT website [here](#).

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