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UK Biobank Limited

Procurement Name: Automated Large-Scale Ultra-Low Temperature Biological Sample Archive

Procurement Reference Number: UKBB017

Procurement Procedure: Open

Invitation to Tender (ITT): Specification

Contents

1. Introduction

1.1. Purpose of this document

1.1.1. This document sets out UK Biobank's requirements for a new Automated Large-Scale Ultra-Low Temperature Biological Sample Archive as part of a programme of infrastructure replacement, funding for which was recently announced by the UK Government (www.gov.uk/government/news/chancellor-reveals-life-sciences-growth-package-to-fire-up-economy).

1.1.2. In addition to UKB's requirements for such an Archive (Sections 2-5), this Specification includes briefing material on its storage and processing of biological samples (Section 1.2) and programme of infrastructure replacement (Section 1.3) to provide useful contextual information. UKB's requirements for Installation Services and ongoing Support Services are provided in Sections 6 and 7 respectively.

1.1.3. For the avoidance of doubt, UKB's minimum, mandatory requirements are highlighted using the term "must", e.g. 'the Archive [or Supplier] must […]', whilst desirable, enhanced performance and/or features are indicated by "should", e.g. 'the Archive [or Supplier] should […]'.

1.1.4. A comprehensive Glossary of terms used in this Specification is provided at the end of this document.

1.1.5. In addition to the terms defined in the Glossary, unless otherwise provided or the context otherwise requires, capitalised expressions in this Specification shall have the meaning set out in Schedule 1 (Definitions) of the Agreement.

1.2. Background to UKB and its storage and processing of biological samples

1.2.1. UKB (www.ukbiobank.ac.uk) is a company limited by guarantee and a registered UK charity established by its two founding funders: the Medical Research Council and Wellcome. It is a large-scale biomedical database and research resource containing genetic, lifestyle and health information from half a million UK participants. UKB is globally accessible to approved researchers who are undertaking health-related research that is in the public interest.

1.2.2. UKB recruited 500,000 people aged between 40-69 years in 2006-2010 from across Great Britain. At baseline, participants attended an assessment centre near their home where they completed consent and a detailed questionnaire about their lifestyle, environment and medical history. A number of physical measures were obtained (e.g. height, weight, lung function etc.) and samples of blood, saliva and urine were collected and stored for future analysis. Subsequent enhancements to the study have included repeat assessments, detailed imaging studies and assessments of diet and physical activity.

1.2.3. UKB has used the Sample resource to produce high quality, curated data on the entire cohort including genotyping, exome sequencing, whole genome sequencing and metabolomics. UKB has become a major contributor to the advancement of modern medicine and treatment, enabling better understanding of the causes, prevention, diagnosis and treatment of a wide range of serious and life-threatening illnesses – including cancer, heart disease and stroke. Over 30,000 researchers from more than 90 countries use UKB, and more than 7,000 peer-reviewed papers have been published as a result.

1.2.4. UKB is responsible for the safe preservation and scientific exploitation of this priceless collection of over 17 million Samples that are accessible for approved use by academic and industry researchers. About 11 million Samples are stored at -80 °C and include plasma, serum, buffy coat, extracted DNA, urine and saliva. Of these, 9 million are stored in an existing robotic archive at UKB's headquarters in Stockport, Greater Manchester. This archive ensures long-term stable cryostorage at -80 °C, with automated storage and access to Samples for processing and dispatch to

researchers. At present, a further 2 million Samples are stored in freestanding, non-automated -80 °C freezers. (The remaining 6 million Samples are stored in vapour phase liquid nitrogen offsite and are not relevant to this requirement.)

1.2.5. Typically, a (parent) Sample is retrieved from the archive, thawed and liquid handled to produce a (child) sub-sample (Aliquot) for dispatch using a controlled thawing protocol. Aliquots are produced in a format appropriate to the intended use. The parent Sample is then returned to -80 °C storage and the archive inventory (location) and Laboratory System (meta-data on the Sample) updated. As much of the Sample Handling as possible takes place at temperatures no warmer than -20 °C.

1.2.6. UKB undertakes the supply of Samples to support a range of different types of project:

1.2.6.1. handfuls to ca. 5,000 Cherry Picked Samples for piloting or case-control studies (where Samples are likely to be picked from across the whole collection);

1.2.6.2. vanguard projects involving ca. 50,000 Samples (with some degree of Cherry Picking);

1.2.6.3. longitudinal sets of Samples for the same participants over a number of time points; and

1.2.6.4. retrieval of whole cohort sets (ca. 500,000 Samples, with a higher density of Samples clustered together).

1.2.7. UKB often needs to deliver multiple Sample supply projects at the same time, requiring different Sample retrieval projects to be interleaved.

1.2.8. UKB is still actively collecting Samples from participants taking part in follow-on studies (for example, its imaging and repeat imaging projects), and has a requirement for regular (daily) loading of new Samples into cryopreservation. The requirement for daily loading in this Specification is designed to support an increase in future Sample collection, given the scientific benefit of conducting further follow-on studies at scale (e.g. inviting all participants for re-assessment, and recruiting first degree relatives).

1.2.9. As noted, a range of assays have already been undertaken successfully on Samples, including biochemistry measures, genotyping, whole exome and whole genome sequencing, and early metabolomics and proteomic analysis. These have produced a globally unique resource for research. As a result, UKB is experiencing increased demand for Samples from industry and academic-led studies and will need to support multiple whole cohort projects, including those requiring access to longitudinal Samples, including further metabolomics, proteomics, transcriptomics, and epigenetics.

1.2.10. UKB's Samples are universally held on 96-position SBS-format Racks, containing predominantly 1.2ml ABGene Tubes with split septum seals to optimise liquid handling on fixed-tip pipetting platforms (see Appendix A). A minority of Samples are held in other Labware, including 0.65ml ABGene and 0.3ml FluidX Tubes (see Table B). There are 2 important aspects relating to Sample storage that the Supplier should note:

1.2.10.1 The split septum seal bung can present challenges to automated Sample Handling. In certain circumstances, over-pressure in the Tube has led to the bung being raised, or ejected and becoming loose. It is anticipated that up to approximately 10% of Racks of ABGene Labware may have this characteristic, and each Rack may have one or many examples of raised or loose bungs. It is more common for particular Sample types (especially saliva).

1.2.10.2 Samples can also be expected to have some external frosting and icing (including from transport) that can obscure 2D Tube and 1D Rack barcodes.

It is anticipated that up to approximately 10% of Racks may have severe icing (with some overlap with the up to 10% of Racks that may have raised, loose or missing bungs). Occasionally, Sample Tubes will also be frozen to their Racks.

(See Appendix A for illustrations.)

1.2.11. UKB's existing robotic archive can hold up to 10 million Samples and is over 15 years old (see Appendix B). It is a bespoke designed, non-modular monolithic unit with a single aisle for Sample access, a single robot to retrieve Racks from a number of -80 °C storage compartments, and a single Tube-picking robot to pick Samples from Racks. This design has become rate-limiting to the number of projects UKB can support, and it does not offer the required resilience or throughput to meet UKB's future needs.

1.2.12. The existing archive has a number of other limitations:

1.2.12.1. **More frequent maintenance** issues which impact Sample access and increasingly risk impacting cryopreservation.

1.2.12.2. **Use of liquid nitrogen as a primary coolant** (with electrical backup cooling, which can only maintain -20 °C), which is costly to operate and carbon intensive.

1.2.12.3. **Integration between UKB's Laboratory System** and the existing archive cannot support continuous inventory reconciliation and flexible reporting.

1.2.12.4. **Insufficient Sample Handling throughput** to support Sample access and maintain efficient storage (i.e. insufficient capacity to consolidate or defragment free space whilst retrieving and loading Samples).

1.2.12.5. **Insufficient capacity** to store future Sample collections.

1.2.13. UKB's next phase of development will be characterised by increasing demand for access to Samples, and a number of new large-scale Sample collections. UKB therefore requires an Archive that has sufficient capacity, flexibility, resilience, handling speed, and energy efficiency to support the next 15 years of work and beyond, as set out in this Specification.

1.2.14. This Specification has been prepared by UKB to address such limitations, and prepare for the next phase of its development by supporting foreseeable operational requirements and potential future developments, including but not limited to:

1.2.14.1. **Extensive new Sample collections** from UKB participants (and potentially their relatives) at multiple future time points. *(In these requirements through storage capacity, Sample Handling throughput and loading rates.)*

1.2.14.2. **Prospective creation of additional whole cohort (child) Sample sets** whilst a particular (parent) Sample type is thawed for processing, stored on SBS-format Racks or Plates. *(In these requirements through Sample Handling throughput, storage capacity, and flexibility to store SBS-format Racks and other types of Labware, including Plates.)*

1.2.14.3. **Likely change to alternative Labware** for new Sample collections, and selective reformatting of existing Samples coincident with their next freeze-thaw cycle, or en-masse at some appropriate juncture. *(In these requirements through flexibility to store and process a range of Labware.)*

1.2.14.4. **Re-arraying of Samples** such that each 96-position SBS-format Rack contains a single Sample of the same type for 96 unique participants (at a particular collection time point). This will further enable whole cohort retrievals, as it will minimise the picking of Sample Tubes from Racks. (At

the baseline assessment, blood was collected into a variety of vacutainer Tubes. Each was processed into specified Aliquots into ABGene Tubes on dedicated automated systems. Hence, Aliquots from one participant are distributed across different individual SBS-format Racks such that each Rack contained Samples from between 16 and 48 participants. For example, one Rack will contain plasma Aliquots from about 24 different participants.) *(In these requirements through Sample Handling throughput, and Labware flexibility.)*

1.3. UKB infrastructure replacement

1.3.1. UKB requires a Supplier to provide a new Archive and be responsible for design, manufacture, installation, testing, commissioning and training ("Installation Services"), and ongoing Support Services over a period of at least five years from Operational Qualification ("OQ").

1.3.2. The Archive will be installed on the ground floor of a new purpose-built UKB facility in the City of Manchester in the North West of England, UK. The Developer plans to start main construction in early 2024, and to give UKB and the Supplier early access to the ground floor to enable installation of the Archive from 30 April 2025. Practical completion of the Facility is planned for March 2026, with transfer of UKB's Samples to the new Archive from November 2025 to April 2026 (see Table D for key dates). Such dates may change depending upon, for example, any delays to the Facility development timeline, but planning permission has been granted, a main contractor selected and enabling works have started on site. (See UK Biobank Delay and Works Delay provisions in clause 6 of the Agreement.)

1.3.3. Funding to support purchase of the Archive and development of the Facility has been budgeted by UKRI, and announced by both UKRI (https://www.ukri.org/what-we-offer/creating-world-class-research-and-innovation-infrastructure/funded-infrastructure-projects/) and HM Treasury (www.gov.uk/government/news/chancellor-reveals-life-sciences-growth-package-to-fire-up-economy). Under UK Government expenditure procedures, an outline business case has already been approved by UKRI, the UK Government Department of Science, Innovation and Technology, and HM Treasury. Release of funding will be subject to approval of a full business case by HM Treasury, which is expected in December 2023.

1.3.4. UKB will be responsible for the operational management of the Archive following Operational Qualification, noting this will occur before final sign-off of the Archive following Performance Qualification. After OQ, UKB will commence loading of its existing Sample collection of 11 million Samples on 96-position SBS-format Racks. About 9 million of the Samples will be extracted from the current automated archive (with the remainder from freezers). A logistics specialist will be engaged by UKB to safely unload en-masse (bypassing the current archive's robotic systems), pack and transport cryopreserved Samples from UKB's Stockport premises to the new Facility. UKB will be responsible for the loading of Samples into the new Archive.

1.3.5. UKB's objective will be to transfer existing Samples to the new Archive as quickly as possible whilst ensuring their safe transport and loading within a period of four to six months. After this period, UKB requires automated access to all Samples.

2. Design requirements

2.1. Overall architecture and modularity

2.1.1. The Archive must be able to store 20 million Samples in UKB's predominant current Labware (1.2 ml ABGene Tubes) on 96-position SBS-format Racks and allowing for an additional 5mm on top of the catalogue-specified Tube height to account for raised, loose or missing split septum seal bungs.

2.1.2. The Archive must have an expansion route to increase capacity to store a further 10 million Samples (i.e. 30 million in total), to the same specification as the 20 million

Sample requirement. This increased capacity must be offered as an Optional Deliverable under the Agreement.

2.1.3. Storage capacity may be divided across one or more separate modules. UKB has no specific requirement as to the number of such modules, provided that all requirements are met. The number of modules provided should be designed to offer UKB an optimised solution against this Specification, taking into consideration:

2.1.3.1. An Archive with more than one module may increase Sample Handling throughput and resilience by supporting parallel handling and greater levels of cooling redundancy;

2.1.3.2. An Archive with more than one module may support deliverability of UKB's requirements through phasing of installation (see Section 6.1.5);

2.1.3.3. An Archive with more than one module may support more straightforward incremental upgrade and replacement over time;

2.1.3.4. An Archive with more than one module may prove to be inefficient in terms of physical space (given requirements for operating and maintenance clearances around each);

2.1.3.5. An Archive with more than one module may prove to be environmentally less efficient in terms of electricity use and chilled water requirements if modules are all cooled simultaneously, yet may offer the opportunity to leave fallow capacity at ambient temperatures (provided resilience and throughput requirements are met);

2.1.3.6. An Archive with more than one module, by dividing UKB's Sample collection over a number of physical separate units, may lead to difficulties in providing fully randomised Sample selection as it may impede any single Sample from being picked and placed onto the same destination Rack as any other Sample.

2.2. Summary of physical characteristics

2.2.1. Table A below is a summary of the key physical characteristics, constraints and requirements for integration of the Archive into the new Facility. More detail is provided in subsequent sections.

2.2.2. The Developer will provide Supporting Plant and consumable services to meet the reasonable requirements of the Archive within the limits of this Specification, including but not limited to electricity, chilled water, liquid nitrogen and compressed air, with appropriate levels of resilience.

Characteristic	**Facility capability provided by Developer**	**Archive requirement placed on the Supplier**
Space	Space demarked in Appendix D is available for installation of the Archive: an area of 49m by 18m, in a grid pattern of 14 no. 7m by 9m bays demarked by structural columns, with an available height of 6.525m. Personnel circulation space is provided outside of the bounds of the space drawn in Appendix D on all four sides (top, bottom, left and right as drawn).	Must store 20 million Samples, and must accommodate expansion to 30 million Samples, whilst leaving sufficient fallow space for replacement programme. Should maximise the number of Samples stored per m^2 of the Sample Hall, using the height of the

		space (6.525m to the soffit) where possible.
Noise		Must be no more than 70dBA measured at a typical operator distance (~1.0m distance, 1.6m height).
Floor	Level cast concrete slab of thickness 250mm, Group 4 Flatness Specification as defined in Table 3 of DIN 18202. Rolled vinyl finished floor (e.g. Polysafe Verona or similar) if required. Vibration metric with a multiplying factor of better than 4.0 (per BS 6472).	Floor load must be no more than 20.0 kN/m^2 (fully loaded with Samples) and be compatible with the floor specification.
Electricity supply	Resilient supply for the maximum requirements indicated (UPS + backup generator).	Average power requirement must be no more than 90 kW (empty, excluding Supporting Plant), with a peak requirement of no more than 135 kW. Should be designed to minimise electricity use.
Chilled water	Resilient (dual redundant) chilled water supply at inlet temperature 6°C and outlet temperature of 12°C ('6-12') or inlet 14°C and outlet 24°C from Facility supply. Mains water backup (ambient temperature, 1.5 bar pressure).	Must require a chilled water flow rate of no more than 450 litres / minute. Should be designed to integrate with Facility supply if optimal for energy use and resilience. Should be designed to minimise chilled water requirements.
Liquid nitrogen	Resilient (dual redundant) liquid nitrogen supply with UPS backup for electrically-operated valves.	Must require a liquid nitrogen flow rate for backup cooling of no more than 320 litres / hour. Should be designed to minimise liquid nitrogen flow rates.
Ambient temperature and humidity in the Sample Hall	Sample Hall will be maintained by UKB at 20 ± 4°C; relative humidity of ≤ 60% with only short duration (1-2 hours) excursions above this level.	Must be installable and operate in the conditions specified in the Facility column.

Piped gases (if required by Archive)	Compressed air at 6 bar and -70°C dew point.	If compressed air is required, the Archive should be designed to be compatible with 6 bar and -70°C dew point supply.
Safety	Oxygen depletion and fire alarm, emergency extract, enhanced fire compartmentalisation around Sample Hall; gas fire suppression (subject to confirmation by UKB in Q4 2023).	Must have safety and security controls. Must either be fitted with oxygen depletion and fire sensors that can operate independently and are interfaceable with Facility systems, or have provision to fit such sensors during installation. Must be designed to minimise fire risk. Materials must comply with EN 13501-1: Fire classification of construction products and building elements rated to 'Class B' as a minimum, or by equivalent recognised international standard. Materials should be selected as far as possible that are rated to 'Class A2'.

Table A: Physical characteristics, constraints and requirements

2.3. Spatial efficiency, weight loadings and noise

2.3.1. The Archive must be physically accommodated within the Sample Hall of UKB's new Facility, as specified by the plans at Appendix D:

2.3.1.1. **including** appropriate clearances for operator and support personnel access between components, ventilation and maintenance;

2.3.1.2. **including** capacity for 20 million Samples, but with sufficient fallow, free space in the Sample Hall for upgrade to 30 million Samples;

2.3.1.3. **including** following upgrade to 30 million Samples, retention of sufficient fallow, free space to incrementally replace the Archive in-situ with parallel running to support Sample transfer when parts of the Archive reach end of life;

2.3.1.4. **excluding** personnel circulation space to the top, bottom, left and right of the Sample Hall as drawn (which is provided for outside of the bounds of the structural columns illustrated in Appendix D);

2.3.1.5. **excluding** equipment provided by the Developer to meet the integration requirements of the Archive (Supporting Plant e.g. chilled water supply), which will be located elsewhere in dedicated plant space.

2.3.2. The Archive should be designed to maximise the number of Samples stored per m^2 of the Sample Hall, for example using the height of the space (6.525m to the soffit) where possible.

2.3.3. The Supplier should populate the space preferentially from the bottom left-hand (i.e. South West) corner of the Sample Hall as drawn in Appendix D.

2.3.4. The Archive (including supporting interior components) must generate internal reverberant noise and external noise breakout of no more than 70dBA measured at a typical operator distance (~1.0m distance, 1.6m height).

2.3.5. The Supplier should consider the optimum placement of equipment so as to minimise noise for operators, and other personnel moving through the space, and working in processing laboratories to the North and East of the Sample Hall (top and right as drawn in Appendix D).

2.3.6. The Archive must be installable on a level cast concrete slab of thickness 250mm, with a maximum loading (when fully operational and filled with Labware) of no more than 20.0 kN/m^2, ground down and treated so that it is compliant with Group 4 Flatness Specification as defined in Table 3 of DIN 18202. If required, it can be finished with a rolled vinyl finished floor (e.g. Polysafe Verona or similar). The floor will have a vibration metric with a multiplying factor of better than 4.0 (per BS 6472).

2.4. Electrical power requirements

2.4.1. The Archive must draw an average power of no more than 90 kW (empty of Samples, excluding Supporting Plant), with a peak requirement of no more than 150% of this average (i.e. no more than 135 kW).

2.4.2. The Archive should be designed to support phasing of initial cool-down of the Sample storage areas to minimise peak loading.

2.4.3. The Archive should be designed to minimise direct energy use: for example, by using more efficient technology, and/or by allowing fallow areas within each component or module to be maintained at ambient temperature rather than actively cooled.

2.4.4. Electricity supply for the Archive (including control, monitoring systems, valves, compressors and automation, but excluding Supporting Plant) will be covered by a Facility uninterruptable power supply (UPS) and backup generator. However, Suppliers should consider as part of their proposed design that electrical consumption of the chilled water supply and other aspects of Supporting Plant may not be covered by the UPS and generator depending on the loading required.

2.4.5. The Archive should be designed to use the UPS provided by the Facility (as this will be housed in a fire suppressed space) in favour of internally-accommodated UPS provision.

2.5. Chilled water requirements

2.5.1. The Archive must require a chilled water supply of no more than 450 litres / minute.

2.5.2. The Archive should be designed to support phasing of the initial cool-down of the Sample storage areas to minimise peak chilled water requirements.

2.5.3. The Archive should be designed to minimise chilled water requirements (minimise required heat rejection and flow rate) and maximise resilience.

2.5.4. The Archive should be designed to minimise total energy use (being the sum of the direct electrical requirement for the Archive, and the indirect electrical requirement to provision chilled water by Supporting Plant), considering the optimum proposed balance of energy use and resilience.

2.5.5. The Supporting Plant is currently designed to deliver an efficient 2N resilient chilled water supply for the Archive alongside data centre cooling and hot water provision, and other Facility needs, through use of '4 pipe' and multiple '2 pipe' heat pumps. It can supply either:

2.5.5.1. inlet 6°C, outlet 12°C, i.e. '6-12'; or

2.5.5.2. inlet 14°C, outlet 24°C, i.e. an elevated temperature chilled water supply.

2.5.6. The Archive should be designed to integrate with the Facility's chilled water supply, minimise total energy use (direct Archive and indirect Supporting Plant) and maximise resilience.

2.5.7. The Archive should be designed to make use of ambient temperature mains water supply at 1.5 bar pressure to maintain contingency cooling.

2.6. Liquid nitrogen requirements

2.6.1. The Archive's backup cooling must require a liquid nitrogen flow rate of no more than 320 litres/hour to maintain Sample cryopreservation (flow rate assumes that the Archive has already been cooled to -80 °C and has subsequently risen to -70 °C before activation of backup cooling).

2.6.2. The Archive should be designed to minimise the liquid nitrogen flow rate required for backup cooling.

2.7. Other requirements

2.7.1. The Archive must be able to operate within a Sample Hall ambient temperature of 20 ± 4°C and Relative Humidity of less than or equal to 60%, with only short duration (1-2 hours) humidity excursions above this level.

2.7.2. To support troubleshooting and contingent access to Samples (and ultimately, decommissioning), authorised and trained UKB and Supplier personnel must be able to access storage areas and remove Labware manually.

2.7.3. The Archive must have a GUI management interface readily accessible to operator, UKB and Supplier support personnel, showing status and errors, and allowing control of the Archive including starting, stopping and reprioritising Sample Handling tasks.

2.7.4. All internal areas of the Archive must have closed-circuit television (CCTV) including loading and unloading buffers, picking, handling and transfer areas, all Sample storage areas and associated robotics.

2.7.5. CCTV images (and time-limited recordings) must be accessible through the Supplier IT System, via a programmatic interface (e.g. an API) or similar web-based service.

2.7.6. The Archive must have safety controls to allow for safe operation and maintenance including but not limited to interlocked access, machinery guarding and emergency stops.

2.7.7. The Archive must have security controls to prevent unauthorised access, and prevent access for untrained personnel to restricted areas (e.g. electrical components, control systems, Samples in storage).

2.7.8. The Archive must be designed to minimise fire risk: minimising sources of ignition, and maximising the protection given to Samples in the case of fire in the Sample Hall.

2.7.9. The Archive must either include oxygen depletion and fire sensors that can operate independently and are interfaceable with Facility systems, or have provision to incorporate such sensors provided by the Developer during installation.

2.7.10. All materials used to construct the Archive must comply with 'EN 13501-1: Fire classification of construction products and building elements' and be fire rated to 'Class B' as a minimum, or by reference to a recognised and equivalent international standard.

2.7.11. Materials should be selected as far as possible that are rated to 'Class A2' (or to a recognised and equivalent international standard).

2.7.12. The Archive should be designed to minimise embodied carbon, and seek to minimise environmental impact during use, by minimising energy consumption and through selection of refrigerant gases.

2.7.13. If compressed air is required, the Archive should be designed to be compatible with 6 bar and -70°C dew point supply.

3. Functional requirements: Sample storage

3.1. Capacity and Labware

3.1.1. As already stated in 2.1.1, the Archive must be able to store 20 million Samples predicated on them being held in UKB's predominant current Labware (1.2 ml ABGene Tubes) on 96-position SBS-format Racks and allowing for an additional 5mm on top of the catalogue-specified Tube height to account for raised or loose split septum seal bungs.

3.1.2. As already stated in 2.1.2, the Archive (and in particular, spatial efficiency and use of the Facility's Sample Hall) must be designed so that the Supplier can offer an Optional Deliverable for expansion to store a total of 30 million Samples.

3.1.3. The Archive must use 96-position SBS-format Racks for internal storage of UKB's Labware rather than any proprietary, or higher-density, storage. This requirement is based on maintaining compatibility with standard laboratory automation and reduce the need for Tube picking from Racks which only contain Samples of interest (which can simply be unloaded from the Archive for processing).

3.1.4. Suppliers should design the Archive to take into account the balance of benefits and dis-benefits of a modular approach against UKB's requirements (Section 2.1.3 above).

3.1.5. Table B provides the current disposition of UKB Labware and expectations for ongoing and future collections. As a minimum requirement, the Archive must be able to store and handle the different types of current UKB Labware.

3.1.6. Although newly-collected Samples for loading will be held in 1.2ml ABGene Tubes on 96-position SBS-format Racks for the foreseeable future, the Archive must be designed with flexibility to store different 96-position SBS-format Labware requiring different shelf pitches and handling requirements, together with Samples on Plates. Exemplars of other types of Labware are listed in Table B (see Appendix A for more details of each).

3.1.7. The Archive must be capable of handling different Labware types concurrently and identify them by a Rack (or Plate) barcode prefix.

3.1.8. The Archive should be designed to achieve this flexibility with minimal physical and electronic reconfiguration, and minimised requirements for additional or replacement hardware (e.g. changes of shelving or other internal fitments).

3.1.9. The Archive should be designed to accommodate other Labware identification methods (e.g. shape and size recognition).

	Total Racks (each storing up to 96 Samples)			
Current Labware	**Existing collection**	**Future collections**	**Working space**	**Total space**
1.2 ml AB Gene Tubes (56mm total height) Samples stored in these Tubes include urine, plasma, serum, saliva, RNA-stabilised blood	121,267 (~88% space utilised on Racks)	7,500	6,700	135,467
0.65 ml AB Gene Tubes (39mm total height) Samples stored in these Tubes are DNA only	5,260		700	5,960
0.26ml Azenta / FluidX 2D-coded Tube, 96-format, external thread Samples stored in these Tubes are plasma from COVID work	1,250		50	1,300
Future Labware exemplars	**Existing collection**	**Future collections**	**Working space**	**Total space**
Thermo Matrix™ 500µL ScrewTop Tubes Thermo Matrix™ 1.0mL ScrewTop Tubes Micronic 0.30ml Tubes External Thread Azenta 0.5ml Dual-coded Tube, 96-format, External Thread Thermo PCR Plate, 96-well, low profile, skirted Thermo Nunc™ 96 DeepWell™ Polystyrene Plates Samples planned to be stored in these Tubes include urine, plasma, serum, saliva, RNA-stabilised blood and skin-derived pluripotent stem cells. (Samples that may be stored in other Labware include stool and tissue)		62,500	3,106	65,606
TOTAL	**127,777**	**70,000**	**10,556**	**208,333**

Table B: UKB Labware for storage in the Archive

3.1.10. The Racks containing 1.2ml ABGene Tubes that will be transferred from UKB's existing archive are not stored with lids but will be lidded for transport. All Racks transferred from UKB's freezers (of any type of Labware) will be lidded. There is no expectation that the Archive will store Racks with lids.

3.1.11. The Archive must be fitted internally to store 135,500 96-position SBS-format Racks of 1.2 ml ABGene Tubes, 6,000 Racks of 0.65 ml ABGene Tubes and 1,300 Racks of 0.26ml Azenta / FluidX Tubes (figures from Table B above, rounded to the nearest 100). The specification of the remaining capacity (a further 65,500 Racks, or Plates) will be agreed with UKB at a later date.

3.1.12. As already stated in 2.1.1, the Archive must provide for an additional 5mm on top of the catalogue-specified Tube height for ABGene Tubes to accommodate raised, or loose, septum seal bungs, making a total height of 56mm (1.2ml ABGene Tubes) or 39mm (0.65ml ABGene Tubes), as per illustrations in Appendix A.

3.1.13. The Archive must be designed to store current and future Labware in the most spatially efficient way (e.g. by optimising shelf pitch to store lower height Labware in less space).

3.1.14. However, Suppliers should take into consideration whether (referring to Section 2.1.3) it would reduce throughput or resilience if a specific Labware type was concentrated in a specific part of the Archive as a result of optimisation of storage density.

3.1.15. Referring to Section 1.2.10, the Archive must be designed to successfully undertake Sample Handling with such ABGene Tubes with a raised, loose or missing septum seal bung, as per illustrations in Appendix A.

3.1.16. The Supplier should assume that raised septum seal bungs cannot simply be pushed down mechanically (owing to raised pressure within the Tube).

3.1.17. The Archive must allow UKB to configure in the Supplier IT System where each type of Labware can be stored.

3.1.18. The Archive must allow UKB to set up new Labware types in the Supplier IT System and configure fields including, but not be limited to: Rack height, Sample Tube height, Rack barcode prefix, position of Rack barcode, whether to expect 2D barcodes on Sample Tubes, whether to allow Sample Tube picking or loading and unloading only (e.g. in the case of Plate-based storage).

3.1.19. The Archive must allow UKB to monitor programmatically the total, used and unused Rack and Sample capacity by location, including empty spaces on Racks.

3.1.20. The Archive must allow operators to view via the GUI used and unused storage locations.

3.1.21. The Archive should be designed to allow UKB to monitor via the GUI the total, used and unused Rack and Sample capacity by location, including empty spaces on Racks.

3.1.22. The Archive should be designed to allow operators to view via the GUI the type of Labware and contents (e.g. Sample type) in each location.

3.2. Temperature and humidity regulation

3.2.1. The Archive must maintain stored Samples in long-term cryopreservation at a stable temperature of -80 °C, by maintaining a uniform air temperature within storage areas of -80 ± 5 °C and ensure that the temperature does not deviate outside of this range for more than 2 hours.

3.2.2. The Archive must be electrically cooled and offer 2N+1 resilience for cooling, with a minimum of dual redundancy of all key system components supporting long-term

cryopreservation of Samples (2N), with an additional contingency / backup cooling system (+1).

3.2.3. The Archive's additional contingency / backup cooling must be based on a supply of liquid nitrogen to mitigate against a prolonged failure in electrical cooling, or electrical supply, and be capable of maintaining air temperatures within storage areas of -80 ± 10°C (the wider deviation in temperature reflecting the potential difficulty of accurate climate control with contingency liquid nitrogen cooling). UKB considers that Samples exposed to temperatures warmer than -60 °C would be at risk of damage from ineffective cryopreservation.

3.2.4. Resilience in the Facility's Supporting Plant (e.g. UPS, backup electrical generator, dual redundancy in chilled water supply and ambient mains water supply) provides additional levels of resilience, but do not substitute for the requirement (see Section 3.2.2) to provide 2N+1 resilience within the Archive itself.

3.2.5. The Archive must maintain all Sample Handling areas at a stable temperature of -20 °C, by maintaining a uniform air temperature within these areas of -20 +2 /-5 °C.

3.2.6. The Archive must limit the time that Samples spend in any Sample Handling area to less than 8 hours, including in the case of a fault or Sample Handling error.

3.2.7. In the case of a fault or Sample Handling error, or cooling failure, the Archive must be designed to move Samples held outside of -80 °C back to storage at that temperature.

3.2.8. The Archive must store and handle Samples in conditions that are as dry as possible (no more than 10 ppm moisture, "Ultra-Dry Air") to minimise frosting and icing.

3.2.9. The Archive must be designed to control and minimise humidity introduced during Sample loading, unloading or maintenance.

3.2.10. The temperature and humidity of all areas of the Archive including loading and unloading buffers, picking, handling and transfer areas, and all Sample storage, must be monitored using independently calibrated probes that are traceable back to the National Institute of Standards and Technology ("NIST"), permanently logged and reportable to operators and support personnel.

3.2.11. There must be sufficient numbers of probes to provide dual redundancy and assurance that the temperature of all Sample storage areas, and the Samples stored within them, are maintained within the specified temperature ranges.

3.2.12. There must be measurement of both air temperature and the temperature of physical materials by connection to probes embedded within test Samples accommodated in Sample storage areas.

3.2.13. The Archive should be designed to accommodate the inclusion of separate temperature and humidity monitoring by UKB during installation.

3.2.14. The Archive must allow UKB to monitor (on-site and remotely) via the programmatic interface the current and longitudinal trends of temperature and humidity by location and probe.

3.2.15. The Archive must allow operators to view via the GUI the current temperature and humidity of each location and probe.

3.2.16. The Supplier IT System should be designed to record when temperature and humidity probes have been calibrated and when calibrations are due.

3.2.17. A climate KPI, which monitors deviations against temperature and humidity in Sample storage areas, is established in Schedule 3 (Performance Levels) of the Agreement.

4. Functional requirements: Sample Handling

4.1. General requirements for Sample Handling

4.1.1. The Archive must prevent error or failure of one task halting other types of Sample Handling, with a defined 'negative path' for each task to avoid the process halting due to an issue. For example, a failure to load a single Rack should not prevent other Racks loading, nor prevent Sample Tubes being picked.

4.1.2. The Archive must maintain a record of Sample Handling errors and other failures that require an operator intervention to resolve.

4.1.3. The Archive must be designed to record overall operational availability and performance metrics for each Sample Handling task sufficient to enable monitoring of the KPIs established in Schedule 3 (Performance Levels) of this Agreement.

4.1.4. With due consideration given to the issues stated in Section 1.2.10, the Archive should be designed to minimise the rate of Sample Handling errors that require operator intervention to rectify.

4.1.5. The Archive should be designed to maximise operational availability for Sample Handling (excluding Permitted Maintenance). An availability KPI, which measures the availability of the Archive for Sample Handling, is established in Schedule 3 (Performance Levels) of the Agreement.

4.1.6. The Archive should be designed to minimise 'hands on' operator time in favour of automation and support unattended Sample Handling.

4.1.7. The Archive should be designed to minimise errors when it encounters a raised, loose or missing septum seal bung (as described in Section 1.2.10 above).

4.1.8. The Archive should be designed to minimise errors when Sample Tubes are frozen to their Rack, have a thin layer of surface frost, or substantial ice-build up (as described in Section 1.2.10, and with reference to Appendix A).

4.1.9. Where a Sample Tube is frozen to a Rack, either because of icing, or in circumstances where a small amount of biological substance or system liquid from liquid handling has frozen between the Tube and the Rack, the Archive should be designed to detect and release frozen Tubes during handling (for example, by mechanically pushing Sample Tubes upwards in the Rack) to reduce Sample Handling errors that require manual intervention.

4.2. Sample loading

4.2.1. The Archive will be loaded initially with 127,777 96-position SBS-format Racks, containing 11 million Samples from UKB's existing archive and freezers. These will be predominantly 1.2ml ABGene Tubes, with 0.6m Samples in other Labware (see Table B above). UKB, through its logistics provider, will be responsible for transfer of Samples to the Sample Hall of the new Facility, and UKB operators will be responsible for loading on receipt.

4.2.2. During initial loading, the Archive must support a loading rate sufficient to complete loading within four to six months of OQ, and with an error rate requiring operator intervention of less than 1% of Racks loaded. Table E below illustrates a six month plan: a peak loading rate of approximately 1,400 Racks per day will be required to deliver this plan whilst providing some flexibility to accelerate loading to four months (assuming five Working Days per week, and that loading will be the near-exclusive Sample Handling task for the Archive to undertake).

4.2.3. After initial loading, the Archive must support the loading of 341 Racks per day, alongside UKB's other daily handling requirements, to account for the loading of new

SBS-format Racks, and return of Racks following laboratory processing of existing Samples (see Section 4.3 below).

4.2.4. During loading, the Archive:

4.2.4.1. must capture as a minimum the 2D barcode on the bottom of Sample Tubes, the Rack position and Rack barcode, and Archive storage position (e.g. Tube 1234 is in position A01 on Rack 5678). Rack barcodes are placed currently on the short left side of the Rack;

4.2.4.2. must allow UKB to configure, including via use of the GUI, which areas are available for loading Racks and where specific Rack types are stored, and whether to control locations automatically by reference to such parameters, or for an operator to manually assign locations;

4.2.4.3. must leave Labware ready to be picked once loading is complete;

4.2.4.4. should be designed to capture a photograph to accompany the scanning of each Rack loaded, retaining the photograph for a period configurable by UKB (that may be indefinite) and, in the case of an error state occurring, until the error state is cleared by an operator;

4.2.4.5. should be designed to store Samples as rapidly as possible in an Ultra-Dry -80°C environment so as to avoid exposure to humidity that would result in icing.

4.2.5. The Archive must be able to store partial Racks (i.e. less than 96 Sample Tubes in a SBS-format Rack) and distinguish accurately between 'no Sample Tube' and 'no read' scenarios to ensure all Labware entering the system is correctly recorded in the Inventory.

4.2.6. The Archive must be able to load existing ABGene Racks that have been stored long-term in a low humidity -80°C environment, unloaded and held on dry ice for up to several days for transport. Such Racks are likely to have a thin layer of frost on the 1D Rack barcode and 2D Tube barcode (see Appendix A).

4.2.7. The Archive must be able to load existing ABGene Racks that have been stored long-term in a higher humidity -80°C environment (e.g. an ultra-low temperature -80°C freezer). Such Racks may have a substantial ice build-up on the bottom of the Tubes and sides of the Rack that could obscure 2D and 1D barcodes (see Appendix A). Approximately 10% of existing Samples may be associated with substantial ice build-up.

4.2.8. The Archive must be able to scan and load Racks, Plates and Tubes containing Samples of any colour (i.e. colourless to very dark). There should be no discernible difference in the time it takes to scan based on the colour of the Sample.

4.2.9. The Archive must be able to detect and handle loading of a Rack in the incorrect orientation (e.g. rotated 180° horizontally), by rotating the Rack and checking for a barcode.

4.2.10. As already stated in 4.1.1, the Archive must prevent the encountering of a difficult to scan Rack or Sample Tube, or other loading Sample Handling error, from stopping loading of other Racks.

4.2.11. Where frost and ice prevents successful barcode scanning of Racks and / or Sample Tubes, the Archive should be designed to move the Rack to a -80°C Ultra-Dry buffer area for sublimation of the frost and ice ahead of re-scanning attempts and / or adopt other measures to successfully scan and load the Samples.

4.2.12. Where circumstances other than frost and ice prevent successful barcode scanning of Racks and / or Sample Tubes (including missing barcodes), the Archive should be designed to temporarily store the Rack in a buffer area (or similar) that maintains the Samples at a stable storage temperature of -80°C, until the problem is rectified by an operator.

4.2.13. The Archive must record the time taken to load each Rack (time from scanning of Rack barcode to storing at -80°C) and make this data available via the programmatic interface.

4.2.14. The GUI must allow the operator to view any Racks that have failed loading.

4.3. Sample Handling throughput

4.3.1. The Archive should be designed to have sufficient throughput to meet UKB's Sample Handling requirements, with an ability to interleave large-scale whole cohort Sample retrieval (500,000+ Samples) with smaller requests (handfuls to 50,000 Samples), daily loading of new Samples, return of retrieved Samples after processing, consolidation (defragmentation) of empty spaces, and downtime for Permitted Maintenance.

4.3.2. The Archive should be designed to, as far as possible, avoid single dependency on any particular automation component or robot for access to any Sample. Across the entire collection of Samples, the Archive should have an equivalent of 2N+1 resilience (at least dual redundant robotics to access any Sample, 2N), where the backup (+1) can be taken as manual access by Supplier or trained UKB support personnel.

4.3.3. Suppliers should design the Archive to meet this resilience requirement by considering whether Archive module(s) can be equipped with multiple robotic systems to provide the dual redundancy.

4.3.4. However, Suppliers may consider meeting this requirement by assuming Samples can be distributed across multiple modules where relevant for their Archive (so that Samples can still be accessed to meet throughput requirements from other modules should the robotics in any one module fail). In this case, the Archive should be designed to mitigate the disadvantages of modularity discussed in Section 2.1.3, and in particular, Section 2.1.3.6 (i.e. the challenge of picking any one Sample and placing onto the same destination Rack as any other Sample across the whole collection).

4.3.5. To express its throughput requirements, UKB has modelled an indicative scenario of Sample movements over a year. This comprises all of the tasks below over a year:

4.3.5.1. 2 x whole cohort Sample access projects, of 500,000 Samples each;

4.3.5.2. 2 x medium-sized Sample access projects, of 50,000 Samples each;

4.3.5.3. 1 x small project, of 5,000 Samples each;

4.3.5.4. re-loading of residual Samples from these projects after they have been processed;

4.3.5.5. consolidation (defragmentation) of free spaces on Racks created by the above; and

4.3.5.6. loading of new Samples from UKB enhancements, including imaging and repeat imaging (ongoing) and repeat assessments (prospective).

4.3.6. Table C below is the result of translating this indicative scenario to an implied 'typical' daily Sample Handling requirement in the form of Rack and Sample movements. The Supplier should note that the actual daily Sample Handling requirements will vary considerably depending on operational priorities: the 'typical' daily requirement is a way of expressing a balanced combination of loading and unloading, Rack retrieval and

Sample Tube picking speeds, given different Archives may be able deliver UKB's requirements through a different balance of these characteristics.

4.3.7. The Archive must be able to deliver the 'typical' daily Sample Handling requirement set out in Table C in any 24-hour period, giving due consideration to the expectation that the Archive might operate 24x7 but noting that any manual intervention needed will only take place when UKB operational personnel are available onsite between 7am and 5pm, 7 days per week.

4.3.8. The Archive should be designed to minimise the number of hours taken to deliver the 'typical' daily Sample Handling requirement.

4.3.9. The Archive must be designed to record, and make available via the programmatic interface and GUI, metadata relating to all Sample Handling activities performed (such as start time, end time, activity type) to allow UKB to monitor throughput for each activity type across a given period of time (e.g. average Tube pick time, average Rack load time, number of Tubes consolidated across a given period).

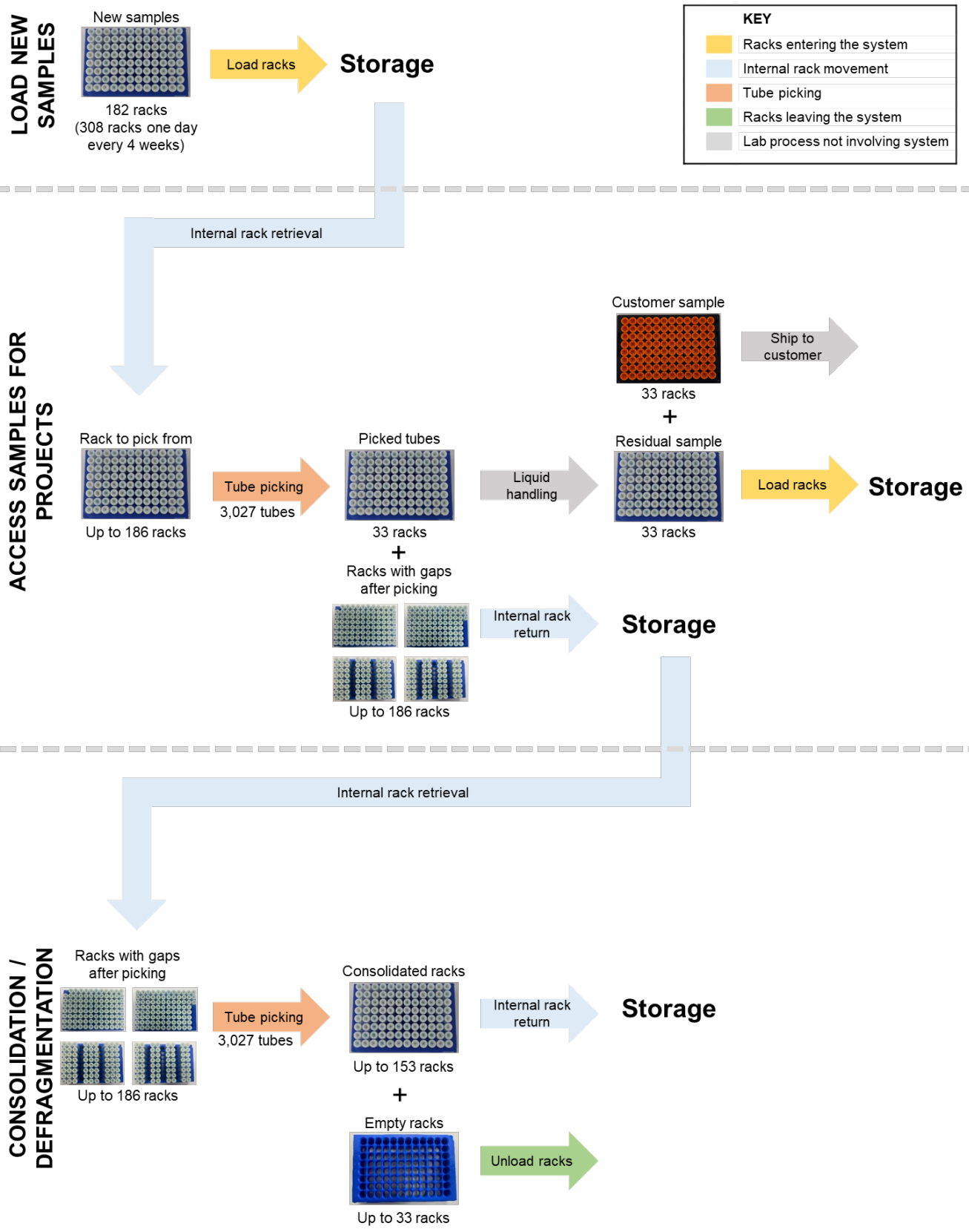
4.3.10. A throughput KPI, which measures the speed of all Sample Handling processes, is established in Schedule 3 (Performance Levels) of the Agreement.

4.3.11. To further illustrate UKB's throughput requirements, Figure 1 below provides a graphical illustration of the data in Table C.

Activity / process	Description	Load new Samples	Access Samples for projects	Consolidation / Defragmentation	Total
Loading Racks	Racks entering the Archive, scanned and entered into long-term storage	182 Racks / day (increasing to 308 Racks for one day every 4 weeks)	33 Racks /day (full Racks returned after laboratory processing)	0	215 Racks /day (increasing to 341 Racks for one day every 4 weeks)
Internal Rack retrieval and return	Retrieval of Racks within the Archive from storage to a Tube picking area, and their return	0	186 Racks /day (retrieval of Racks from which to select Samples for processing, and their return)	186 Racks /day (retrieval of Racks back from long-term storage to consolidate)	372 Racks /day
Tube picking	Movement of Tubes from one Rack to another in a Tube picking area	0	3,027 Tubes /day (selection to a destination Rack for laboratory processing)	3,027 Tubes /day (selection of Tubes to avoid any increase in empty spaces)	6,054 Tubes /day
Unloading Racks	Racks leaving the Archive	0	33 Racks /day (full, for laboratory processing)	33 Racks /day (empty, following consolidation)	66 Racks /day

Table C: UKB throughput requirements expressed daily – ALL activities must take place during the 'typical' day, irrespective of order

Figure 1: Graphical illustration of daily throughput requirement



4.4. Consolidation (defragmentation)

4.4.1. The existing 127,777 96-position SBS-format Racks (12.3 million Tube spaces) to be loaded from UKB's existing archive and freezers will contain 10.8 million Samples and 1.5 million empty spaces (i.e. 88% consolidation, 12% free spaces).

4.4.2. New Racks of Samples loaded may be assumed to be fully consolidated (i.e. almost no empty spaces).

4.4.3. Consolidation must be a separate Sample Handling task and defined process (separate to Tube picking) that ensures Samples are moved to full Racks and empty Racks unloaded, without the consolidated Racks leaving the Archive.

4.4.4. The Archive must allow UKB to control *which* Samples are consolidated together via the GUI and programmatic interface using fields held either in the Archive's Inventory or Laboratory System including but not limited to Sample type and time point relating to the participant visit.

4.4.5. The Archive must allow UKB to configure (through the GUI and programmatic interface) *when and how* consolidation happens including but not limited to: size of consolidation batches, maximum time per day to perform consolidation, starting and stopping, scheduling for specific times, or assigning it a priority relative to other tasks and running it automatically in the background.

4.4.6. The Archive must allow user- and role-based access control to protect the configuration of consolidation parameters.

4.4.7. Through the combination of configuration options and Sample Handling performance, the Archive should give UKB the capability to minimise the number of empty spaces on Racks.

4.4.8. The Archive should be designed without assuming that empty spaces can be controlled simply by returning Sample Tubes retrieved for processing to the Racks from which they were picked. (Given UKB may wish to manage consolidation to alter Sample co-location, and loading of processed Racks may take place at a different rate to unloading, depending on operational priorities.)

5. Functional requirements: Data and information systems

5.1. General requirements and support for certification to standards

5.1.1. The UKB Data & Technology environment is undergoing major transformation to modernise and implement future-proofed information systems and data services, which includes delivery of a new Laboratory System (comprising information technology to support laboratory operations for at least the next 15 years) of which the Supplier IT System will become a component part.

5.1.2. UKB Data & Technology guiding principles include:

5.1.2.1. Continuous evolution of software systems over time with no or little impact on other services, to deliver incremental functionality as the organisation evolves, and to maintain our compliance with various standards and certifications needed for our operations.

5.1.2.2. Implementation of loosely coupled services on virtualised or cloud platforms to allow for independent operation and management of these services.

5.1.2.3. Operation of a data-centric environment where disparate data sources can be combined for centralised high-quality reporting.

5.1.2.4. Deployment of independent services, comprising interface, business logic and often database services using open standards, and modular and extensible technology components.

5.1.2.5. Information security by design with continuous improvement of our Information Security posture.

5.1.3. The Archive should demonstrate alignment to the principles described in 5.1.2 above.

5.1.4. The Supplier must design, specify, source, install and manage all hardware and software components for the Supplier IT System required to operate and manage the Archive and provide ongoing support in respect of the Supplier IT System, including all:

5.1.4.1. software technology components (e.g. Supplier Software codebase, application server and/or database components, including New Releases and Updates);

5.1.4.2. hardware technology components (e.g. client and server infrastructure, networking switches and cabling); and

5.1.4.3. management components (e.g. configuration and testing tools, calibration tools, patching and endpoint management).

5.1.5. UKB is certified to ISO 9001, ISO 27001 and Cyber Essentials Plus standards and intends to attain accreditation for ISO 20387:2018 'General requirements for biobanking'.

5.1.6. The Supplier must maintain a demonstrable approach to quality management (for example, through certification to ISO 9001 or by reference to internal quality policies detailing their approach to an equivalent quality standard).

5.1.7. The Supplier must maintain a demonstrable approach to information security (for example, through certification to standards such as ISO 27001 or Cyber Essentials Plus, or by reference to internal information security policies detailing their approach to maintaining the confidentiality, integrity and availability of information systems).

5.1.8. The Supplier must be able to support UKB's continued certification to ISO 27001 throughout the period of the Agreement, and relating to the provision of Installation Services and Support Services, including demonstrable approaches to:

5.1.8.1. screening of Supplier staff engaged as part of this programme;

5.1.8.2. security awareness and training of such staff;

5.1.8.3. information security, malware protection and access control;

5.1.8.4. system audit logging and event management;

5.1.8.5. information storage, transfer and cryptographic controls;

5.1.8.6. information systems testing and validation;

5.1.8.7. management, patching and version control;

5.1.8.8. documentation of operating procedures; and

5.1.8.9. change and capacity management.

5.1.9. The Supplier IT System, through the lifetime of the Archive, must be able to support UKB's intent to attain accreditation to the ISO 20387 standard, with particular emphasis

on the requirements for the storage of biological material and sample traceability and management of information and data.

5.2. Access control and remote access

5.2.1 The Supplier IT System must provide fine grained access control for users and service accounts, supporting user- and role-based access control and user management configuration.

5.2.2 The Supplier IT System must have the ability for UKB to configure user roles including but not limited to those for reporting purposes, laboratory-based operators of varying levels, and UKB / Supplier support personnel, with configurable permissions for access to operational functionality, data and system administration functionality.

5.2.3 The Supplier IT System must provide for integration with UKB's Active Directory (AD) infrastructure (both on-premises or Microsoft Azure hosted) using Single Sign On (SSO) with Multi-Factor Authentication (MFA) enabled.

5.2.4 The Supplier IT System GUI must be securely accessible from both on-premise workstations and remotely by authorised users including Supplier support personnel.

5.2.5 The Supplier should note that access will be controlled by UKB with the MFA key controlled by UKB and provided to the Supplier as and when required.

5.2.6 The Supplier should note that UKB manages the provision of remote access to its internal systems by Supplier support personnel using secure remote management software provided by Bomgar (now called BeyondTrust).

5.3 Functionality and user experience

5.3.1 The Supplier IT System must provide the functionality for operation and management of the Archive by UKB laboratory and facilities staff with limited interaction from the Supplier (other than regular planned maintenance, such as Updates, delivered by the Supplier as part of Support Services).

5.3.2 The Supplier IT System must provide UKB (without the need for Supplier support) with the ability to configure, operate, manage, generate alerts, and report on all aspects of the Archive including:

5.3.2.1 any architectural functions (for example with respect to modularity, or regular maintenance activities);

5.3.2.2 environmental, such as temperature, power and cooling; and

5.3.2.3 sample storage, and all Sample Handling processes.

5.3.3 The Supplier IT System must be able to be controlled, managed and monitored via both the GUI and programmatically with support for integration with the Laboratory System through, for example, secure API based services.

5.3.4 The Supplier IT System programmatic interface must be accessible and usable remotely.

5.3.5 The GUI for general operation must be designed with user accessibility in mind (e.g. incorporating good practice guidelines, such as WCAG) with particular consideration given to human-readable reporting for operators, for example in a daily log of issues/faults.

5.3.6 The Supplier IT System must be capable of returning information (that is Timestamped and operator tagged) regarding the progress of any Sample Handling task, and allow an operator to shuffle priorities of tasks, delete picking orders and similar commands.

5.3.7 The Supplier IT System must include the ability to backup, export for version control, and restore configurations on an ad-hoc and scheduled basis for both resilience and experimental reproducibility purposes.

5.3.8 The Supplier IT System must maintain a precise, real-time Inventory of Labware (and by inference, Samples) stored at all times to document its current state, including Tube, Rack and Plate identifiers, Tube positions, and Rack and Plate storage locations.

5.3.9 The Supplier IT System must support flexible searching for specific Labware or groups of Labware within the Archive both via GUI and programmatically.

5.3.10 The Supplier IT System must support traceability of all Labware movements into, out of and within the Archive by notification of events (e.g. at each Rack scan, Sample Tube picking, or Rack movement or similar) via the programmatic interface with details of Labware, location, date and time sufficient to enable UKB to externally maintain a full record of how samples are managed. For example: notifications of “Rack XYZ loaded” followed by “Rack XYZ contents are ABCD” followed by “Rack XYZ location is HIJ” upon a Rack being loaded into the Archive.

5.3.11 The Supplier should note that UKB will maintain its own sample inventory separately as part of the Laboratory System to cover all storage systems including the Archive, other freezers and liquid nitrogen tanks.

5.3.12 Additionally, if manual work occurs (such as removing a Rack to address a Sample Handling error), the Supplier IT System must support means to update the Inventory and publish the changes associated with the Labware so they can be reflected in the Laboratory System and to keep other UKB Systems up-to-date.

5.4 Reporting, logging and alerting

5.4.1 The Supplier IT System must support the viewing of routine operational reports or dashboards within the GUI that are easily interpretable by the operators. For example:

5.4.1.1 reporting on Labware trends within the Archive (e.g. typical Rack density by storage location) to support decision making on management and consolidation;

5.4.1.2 daily error and fault reports, buffer utilisation, Archive throughput rates.

5.4.2 The Supplier should note that ‘in-depth’ reporting will typically be done by UKB against a separate data warehouse managed directly by UKB.

5.4.3 The Supplier IT System must produce detailed, Timestamped, auditable logs, recording all events pertaining to the Archive and its contents, all information & data changes, logins, environmental data and activity (e.g. user, administrative, Supplier, and automated system-initiated, activity), and associate each activity with specific user(s).

5.4.4 The Supplier IT System must be able to associate long-running processes with a change in operator identity part-way through a process: for example, for a long process where a shift change occurs before completion, or during rectification of an error state.

5.4.5 The Supplier IT System logs must be searchable via the GUI and exportable both in real-time (programmatically) and on-demand, in bulk (via some file transfer mechanism).

5.4.6 The Supplier IT System must maintain an unlimited, permanent longitudinal record of environmental and performance information, including but not limited to:

5.4.6.1 temperature and humidity in different locations across sample storage and handling areas with a configurable frequency of no less than one reading per 15 minutes;

5.4.6.2 electrical power requirements and cumulative energy usage with a configurable frequency of no less than one reading per 15 minutes;

5.4.6.3 automation efficiency including but not limited to Rack retrieval and Sample Tube picking rates, errors in Sample Handling and other faults; and

5.4.6.4 all measurements required to provide a monthly Performance Monitoring Report against the KPIs set out in Schedule 3 (Performance Indicators) of the Agreement.

5.4.7 The Supplier IT System must expose these records via the GUI, and programmatic interface with consideration made to the frequency of measurements.

5.4.8 To satisfy ISO 20387:2018 requirements, the Supplier IT System must support UKB's ability to maintain a longitudinal record of individual Sample history (including Sample movements and temperature, with consideration to 5.3.10 and 5.4.6 above).

5.4.9 The Supplier IT System must be able to integrate with internal or external monitoring solutions and alerting when thresholds (which must be configurable by UKB) are breached. UKB currently uses Realtime-Online provided by Haier Biomedical for monitoring for standalone freezers with audible alerts on temperature threshold breaches.

5.4.10 The Supplier must provide read access to any database schema with documentation to support reporting purposes. Reporting scenarios include, but are not limited to, all logs, store utilisation and breakdowns by storage locations, and fragmentation of Tubes across Racks.

5.4.11 Changes to the database schema must be communicated to UKB as soon as possible (but no less than 1-month in advance of implementation) to ensure the validity of UKB reporting.

5.4.12 UKB uses Microsoft Power BI for reporting. The Supplier IT System should be designed to support integration to Microsoft Power BI for reporting in addition to any standard, 'out-of-the-box' reports available within the GUI.

5.4.13 The Supplier IT System must provide UKB with the ability to configure alerts and notifications to groups and individuals via the GUI, via programmatic interface (e.g. API), email and/or telephone/SMS services. Alerting must be configurable with respect to (at least):

5.4.13.1 the ability to create alerting based on ANY event or action performed relating to the archive;

5.4.13.2 which groups or individual receive each alert;

5.4.13.3 the method by which each group or individual receives the alert (via the GUI, programmatic interface, email and phone/text messaging services or combination thereof);

5.4.13.4 what escalation path each alert needs to follow for example email > SMS text message > phone call > manager, and the timeframes between each escalation;

5.4.13.5 the ability to create templates for alerting;

5.4.13.6 include relevant management information formatted appropriately for the user (e.g. graphing of temperature) and include audit log entries.

5.4.14 The Supplier IT System must log all alerts and notifications and display them via the GUI and support programmatic interrogation.

5.5 Integration with the Laboratory System and other UKB Systems

5.5.1 With reference to 5.1.4, the Supplier must be responsible for development, provision and maintenance of the Supplier IT System (including New Releases and Updates) necessary to operate and manage the Archive, and for supplying a programmatic interface (e.g.: API) to support integration with the Laboratory System and other UK Biobank Systems, to support scenarios including, but not limited to, submission of Sample Handling tasks and receiving progress information, to notify regarding movements of Labware, or to query for the location of specific Labware, and querying of logs, environmental and performance information.

5.5.2 Communication between the Supplier IT System and the UK Biobank System should emphasise simple protocols such as HTTP resource APIs, gRPC, or messaging over a lightweight message bus.

5.5.3 Data transmitted to and from the Supplier IT System must be encrypted using TLS v1.2 or higher, using strong encryption cyphers.

5.5.4 The Supplier IT System must be programmatically accessible from services hosted either on-premises or in the cloud at UKB's discretion.

5.5.5 Any development of a programmatic interface must maintain adequate backward compatibility so that New Releases and Updates to the Supplier IT System can be applied without requiring changes to services consuming the interface.

5.6 Information systems and IT platforms

5.6.1 As already stated in 5.1.4, the Supplier must be responsible for specifying, sourcing, installing and managing all hardware and software components required to support the Supplier IT System used to operate the Archive.

5.6.2 The Supplier should note that UKB maintains hybrid on-premises and cloud infrastructure. The on-premises infrastructure typically consists of Intel based Dell servers running Windows 2022 Server Edition. Virtualised infrastructure is provided using VMware vSphere 8. The cloud-based infrastructure is hosted on Amazon Web Services in the London region with connectivity to this and the wider internet provided via a 10Gb Joint Academic Network link with Points of Presence on the Amazon Web Services backbone. The strategic direction for UKB is to be a cloud-first organisation and as such infrastructure and capabilities that the Supplier IT System will need to interact with (such as the Laboratory System and reporting) are likely to be cloud based.

5.6.3 UKB network services are provided using Cisco/Fortinet firewalls in High Availability mode providing services including Intrusion Prevention Services, Intrusion Detection Services, Access Control Lists, Secure Socket Layer Inspection, content filtering, anti-malware with Cisco switches providing end point network connectivity using 1/10G RJ45 or 1/10/25G-Gbps SFP+ and Windows servers provide Doman Name Services, Dynamic Host Configuration Protocol services.

5.6.4 The Supplier IT System must be:

5.6.4.1 suitably hardened to comply with the CIS Benchmark for the operating system and or database, or an equivalent standard;

5.6.4.2 offer only essential services to the network;

5.6.4.3 have the local firewall enabled restricting access to exposed services to a minimum;

5.6.4.4 be compatible with a modern, up to date commercial Anti-Virus / Endpoint Detection and Response solution which is capable of sending alerts to commercial Security Information and Event Management systems via common protocols such as Syslog; and

5.6.4.5 be configured to encrypt data at rest.

5.6.5 The Supplier IT System must be designed to be resilient, protecting against any potential component failure where possible and the loss of individual servers, appliances, components or other devices that host system software and data, supporting recovery of the Archive to a working state, whilst ensuring the integrity of the Inventory and logging, and minimising the risk of data loss.

6 Installation Services

6.1 Installation

6.1.1 The Archive must be installed on the ground floor of the new Facility (for location see Google Maps). Visualisations of the Facility are provided at Appendix C, and plans for the relevant area of the ground floor are provided at Appendix D.

6.1.2 Arrangements will be made with the Developer and their main construction contractor for access to the ground floor for installation of the Archive ahead of practical completion of the whole Facility. The Developer has agreed to deliver a ramp up of Facility access and services with three key dates ('Day 1, 2 and 3'). Details of the Day 1, 2 and 3 access areas, and services available are provided in Appendices E and F.

6.1.3 Installation access is planned from 30 April 2025 ('Day 1'), whilst handover of the early access area to UKB for operations is planned for 23 October 2025 ('Day 3'). 'Day 2' marks the availability of all relevant Facility services / Supporting Plant at full resilience. Practical completion of the entire Facility is planned for March 2026. These dates represent the current plan as of September 2023. Installation timing may be subject to a Works Delay, for example if the Facility development runs behind programme, or a UK Biobank Delay. Any such Works Delay Change or UK Biobank Delay (see Agreement for further details) will be promptly notified to the Supplier. The Supplier should refer to the Agreement and in particular clause 6 and Schedule 5 and its requirements with regard to compliance with the Project Plan and Achievement of Milestones by Milestone Dates.

6.1.4 All components of the Archive must be installable through a covered service yard, with a soffit height of 3100mm and two roller shutter openings, each of which will be 2500mm high by 2400mm wide (see Appendix D and E).

6.1.5 The Supplier must be able to commence installation of the Archive on Day 1, i.e. currently planned to be no later than 30 April 2025. Phased installation and commissioning is permitted provided that it does not involve disruption to the cooling and operation of previously installed phases and delivers Operationally Qualified capacity in accordance to the planned rate of transfer of Samples from UKB's existing site (Table E below), delivery of UKB's operational commitments, Facility access and commissioning of Supporting Plant.

6.1.6 The Supplier must take responsibility for the successful integration of the Archive with the Facility and its Supporting Plant, specifying to the Developer all connection points and requirements and working collaboratively with the Developer of the Facility, their main construction contractor and subcontractors, UKB and their appointed project and cost managers, Arcadis.

6.2 Project Plan and testing / qualification

6.2.1 Table D below summarises key dates.

Activity	Responsibility	Months after Effective Date	Current plan
Effective Date of Agreement with the Supplier	UKB	Month 0	January 2024
Factory Acceptance Test (FAT) *	Supplier to develop and conduct, UKB to agree and witness	TBA	TBA
Provide Supplier access to ground floor of the Facility ('Day 1')	Developer	Month 15	30 April 2025
Installation Services begins *	Supplier	Month 15	30 April 2025
Supporting Plant with full resilience available ('Day 2')	Developer	Month 19	4 August 2025
Installation qualification (IQ) test * / start of Site Acceptance Test (SAT)	Supplier to develop and conduct, UKB to agree and witness	Month 20	September 2025
Facility ground floor handed to UKB for operations ('Day 3')	Developer	Month 21	23 October 2025
Operational qualification (OQ) test *	Supplier to develop and conduct, UKB to agree and witness	Month 21	October 2025
Transfer of Samples commences	UKB and UKB's applicable Other Supplier	Month 22	November 2025
Practical completion of entire Facility	Developer	Month 26	March 2026
Transfer of Samples complete	UKB and UKB's applicable Other Supplier	Month 27	April 2026
Performance qualification test (PQ) * / completes Site Acceptance Test (SAT)	UKB to develop and conduct, Supplier to agree and witness	Month 29	June 2026
*Interpretable as multiple activities where a phased delivery is proposed.			

Table D: Key dates (plan as of September 2023)

6.2.2 Before delivery, the Supplier must develop, conduct and ensure the Archive passes a Factory Acceptance Test ('FAT'), agreed and witnessed in person by UKB, to meet the minimum requirements of the Test Plan provided at Schedule 6 (Testing Procedures) to the Agreement.

6.2.3 The Supplier must permit factory visits requested by UKB with reasonable notice at any point from the Effective Date of the Agreement to Archive delivery. From the Effective Date of the Agreement to completion of the SAT, the Supplier shall have the right to request site visits to UK Biobank Premises with reasonable notice, and dialogue with the Developer and their design team, main construction contractor and sub-contractors at any point via UKB or Arcadis.

6.2.4 After delivery and installation, the Supplier must develop, conduct and ensure the Archive passes a series of Qualification Testing agreed and witnessed in person by UKB including the IQ, OQ and PQ, which together will comprise UKB's Site Acceptance Test (SAT). The minimum requirements of the Qualification Testing/SAT are provided at Schedule 6 (Testing Procedures) to the Agreement.

6.2.5 The Archive, or any constituent phase, must pass IQ and OQ tests within six months of the start of its installation. No Samples will be transferred into the Archive, or any constituent phase, unless the IQ and OQ are passed. PQ will be conducted after the Archive has been successfully loaded by UKB with 127,777 96-position SBS Racks, to the planned schedule below, so that throughput performance can be tested and confirmed.

6.2.6 The Supplier must install sufficient Archive capacity and pass IQ and OQ on that capacity to meet the planned transfer schedule from the existing UKB archive provided in Table E. UKB's logistics' provider will be responsible for transfer of Samples to the Facility, and UKB operators will be responsible for loading into the Archive on receipt. The Supplier will be responsible for ensuring there is adequate on-site support in this period so that loading is not impeded.

6.2.7 UKB may, in its sole discretion, vary the Sample transfer schedule (dates and volumes) set out in Table E below provided that the variation maintains a 4-6 month window and the daily load rate does not exceed 1,400 Racks per day ("**Permitted Variance**"). The Sample transfer schedule may be varied outside of the Permitted Variance by prior agreement between UKB and the Supplier.

Transfer volume / Racks	**Peak daily load rate (5 days/week)**	**Cumulative transfer / Racks**	**Months after Effective Date**	**Current plan**
14,000	700	14,000	Month 22	November 2025
21,000	1,400	35,000	Month 23	December 2025
28,000	1,400	63,000	Month 24	January 2026
28,000	1,400	91,000	Month 25	February 2026
28,000	1,400	119,000	Month 26	March 2026
8,777	1,400	127,777	Month 27	April 2026

Table E: Planned Sample transfer schedule of existing collection (assuming 6 month transfer)

6.3 Project governance and responsibilities

6.3.1 The Supplier must provide a named project manager able to attend in-person meetings and visit UKB and the Facility site regularly from contract signature to successful PQ, who will develop, agree with UKB and maintain a Project Plan and provide regular written progress reports and risk registers as detailed in Schedule 5 (Project Plan) to the Agreement.

6.3.2 The Supplier must provide a named senior sponsor who can take part in a monthly Steering Group from the Effective Date to successful PQ alongside their project manager, UKB, the Developer, the main contractor for Facility construction and Arcadis.

6.3.3 UKB must have the right to review and veto any changes to the project manager and senior representative, as Key Personnel under clause 12 of the Agreement, to ensure proposed substitutions are with individuals with broadly equivalent seniority and expertise.

6.3.4 From the Effective Date of the Agreement through to the start of Installation Services, the Supplier's project manager must provide a written monthly project highlight report with an updated Project Plan and risk register in a format agreed with UKB. They will also attend the Steering Group monthly, and ad hoc project meetings at UKB's request.

6.3.5 After the start of installation, the Supplier's project manager must additionally attend a weekly update meeting to present a written weekly project highlight report, and any updates to the Project Plan and risk register.

6.3.6 The Steering Group shall be the forum where all Change Requests relating to the Archive, Supporting Plant and relevant areas of the Facility will be discussed, with reference to the relevant contracts. Steering Group meetings are expected to take place monthly. Urgent change requests will be handled electronically between meetings, or a special meeting convened. A change control process, and escalation process for any Dispute, is established within the Agreement.

7 Support Services

7.1 Ongoing services and support: maintenance, Spares and Supplier IT System

7.1.1 The Supplier must offer a minimum of five years of Support Services commencing at the point OQ is achieved.

7.1.2 At UKB's request, the Supplier must extend the availability of Support Services for such further periods as determined by UKB (of not less than 12 months) up to ten years (i.e. years 6-15). After year 15, UKB and the Supplier may choose to agree a further period of Support Services.

7.1.3 Support Services are services provided by the Supplier to maintain the Archive at the necessary level to meet the requirements set out in this Specification (and with associated Key Performance Indicators), and must include:

7.1.3.1 On-site engineering support personnel trained and engaged by the Supplier embedded within the Facility commencing no later than the OQ, to deliver an agreed programme of Permitted Maintenance and provide a timely response to Archive errors, faults and failures including those occurring during the initial load of Samples between Monday-Friday, 9am-5pm UK time, including cover for holiday, sickness and other absences. On-site engineering support personnel will be considered Key Personnel under clause 12 of the Agreement.

7.1.3.2 Second line support available to the on-site engineer and UKB support personnel across all Archive mechanical, electrical components and sub-systems and the Supplier IT System.

7.1.3.3 Agreement of up to 12 hours of Permitted Maintenance each month with UKB, inclusive of any Supplier IT System maintenance windows as referred to in Section 7.1.3.13 below, with a preference for, but not restriction to, maintenance work outside of 7am-7pm Monday-Sunday UK time as agreed with UKB.

7.1.3.4 Supply of Spare components (whether stored at the Facility or sourced off site), any shipping costs for parts and on-site and off-site labour to ensure the Archive remains operational and delivers to these requirements and associated KPIs.

7.1.3.5 A package of Spare components agreed with UKB stored at the Facility and re-stocked over the period of Support Services to minimise downtime, comprising all consumable, repairable, interchangeable and refurbishment parts for the Archive, including but not limited to all mechanical, electrical and pneumatic components such as wear and tear consumables/ connectors, all moving mechanical parts and fixed electrical components.

7.1.3.6 24/7 remote monitoring of the Archive by the Supplier to support timely intervention by the Supplier to ensure KPIs can be met, and including notification to UKB support personnel in the case of errors or failures.

7.1.3.7 Supplier responsibility to provide a Performance Monitoring Report for the Archive, including measurement against the KPIs set out in Schedule 3 (Performance Levels) of the Agreement.

7.1.3.8 Maintenance and support of the Supplier IT System (and associated programmatic interface), including application of Supplier IT System Updates and New Releases for the lifetime of the Archive to maintain UKB's expected business security posture and meet industry standard certifications (such as Cyber Essentials Plus), including operating system updates when current operating systems reach end-of-life.

7.1.3.9 Application of critical, high priority and security patches within 14 days from release, and all other patches within 30 days.

7.1.3.10 Protection of Archive operational availability from downtime or impact on production systems when installing hardware or software patches, unless agreed in writing with UKB.

7.1.3.11 Advance notice and approval from a UKB change advisory board of any plans to apply Updates or New Releases with a clear statement on how these are planned to be performed and any impact this might have on Archive availability to inform approval.

7.1.3.12 Documentation to demonstrate that sufficient Supplier IT System testing and validation has been performed.

7.1.3.13 Agreement of planned Supplier IT System maintenance windows with UKB as part of the Maintenance Schedule for the purposes of supporting New Releases, Updates and other Permitted Maintenance, no more than twice a month, no longer than 1.5 hours and performed outside of 7am-7pm Monday-Sunday UK time as agreed with UKB.

7.1.3.14 Advanced planning with UKB personnel, recording and auditing of Supplier access and interaction with the Supplier IT System.

7.1.3.15 A product lifecycle approach ensuring that all aspects of the Supplier IT System remain in full operational support (to the standards set by operating system, database and software providers) during the period of Support Services.

7.1.3.16 Full support for all IT hardware and software required for the Supplier IT System at all times during the period of Support Services and all costs and endeavours associated with doing so.

7.1.3.17 Management of all licences and Supplier's own relationships (e.g. 3rd party hardware suppliers and software such as operating systems and databases) and all costs and endeavours associated with doing so.

7.1.3.18 Maintenance of a documented Supplier IT System architecture including (at least) a high-level architecture diagram, a table of hardware and software components of the Supplier IT System with manufacturer, model, support/licence type and end date, demonstrating resilience and identifying areas of risk for incorporation into UKB's risk register.

7.1.3.19 A test environment, with consideration given to physical versus virtual representations of the Supplier IT System, to allow for any changes to be tested prior to deployment to the actual Supplier IT System, and to allow UKB to test its own systems that integrate with the Archive through the published programmatic interface (with such test environment provided and maintained during the period of provision of the Support Services).

7.1.4 Support Services should be designed to include:

7.1.4.1 Backup of the Supplier IT System using continuous data protection or incremental backups with snapshotting at no greater than 15-minute intervals, stored in more than one location and with weekly backup status reports provided to UKB.

7.1.4.2 Immediate reporting to UKB of any failed backups with a remediation plan and updates every 30 minutes until the issue has been resolved.

7.1.4.3 Regular Supplier IT System test restores from the backups to ensure data integrity, viability and availability, with regularity to be agreed with UKB.

7.1.4.4 "Live" Supplier IT System restore(s) achievable within a 4-hour time window, with details and status of these restore tests included in the backup status reports.

7.1.5 In the event that the agreement with the Supplier to support the Archive ends, the Supplier must provide UKB with a suitable handover of all Supplier IT System deployable artefacts (such as containers, executables, scripts and/or Source Code as appropriate), build configuration and tools, the test environment and training to ensure that UKB or their appointed resource is competent before the Supplier ceases providing the Support Services.

7.2 Design life

7.2.1 The Archive should have a design life of more than 15 years contingent on appropriate maintenance and component replacement.

7.2.2 The Archive should be designed to meet the requirements of this Specification for at least 15 years without requiring replacement of major components (e.g. whole-scale replacement of cooling units, robotics), or unloading of Samples from any part of the Archive in order to warm it to ambient temperature for maintenance.

7.2.3 The Archive should be designed to ensure there is an adequate supply chain of Spare components, which avoids, or otherwise mitigates single supplier and country dependencies for a minimum period of 15 years.

7.3 Documentation and training

7.3.1 The Archive must be provided with comprehensive documentation for all hardware and software components, including four paper copies and electronic media both in PDF and an editable format.

7.3.2 The Supplier must ensure UKB receives documentation updates including advisory notices, corrections, inclusion of new features and any other changes, in a timely manner.

7.3.3 The Supplier must provide a package of initial training for a range of UKB users, from laboratory personnel operating the Archive (ca. 20 No.), to laboratory leadership responsible for reporting and planning Archive utilisation (ca. 5 No.), to technical services (ca. 5 No.) and information technology personnel (ca. 5 No.) who will assist in its support, and integration with the Laboratory System.

7.3.4 The Supplier must provide additional ongoing training for new UKB personnel, and to reflect upgrades or availability of new features.

7.3.5 The Supplier must design the training and documentation to enable UKB to become self-sufficient in supporting the Archive if it chooses to do so at the end of any period of Support Services.

7.3.6 The Supplier should use the Transition period to undertake intensive training.

8. Technical Glossary

2N+1 resilience	Provision of dual redundancy plus a backup mechanism, as distinct from N+2 resilience: single redundancy plus two backups.
Aliquot	A proportion (sub-sample) of a parent Sample taken, typically to provide to a 3rd party academic or industry researcher for undertaking a biological assay.
API / HTTP resource API	Application Programming Interface; an HTTP API is an API that uses Hypertext Transfer Protocol as the communication protocol between the two systems.
CCTV	Closed-Circuit Television to monitor the internal workings of the Archive.
Cherry Picked/Picking	Highly selective retrieval of a limited number of Samples from a larger set, based on participant (or some other) specific characteristic. As opposed to whole cohort retrieval where one Sample is required for each participant. Associated with a low number of Sample selections from each SBS-format Rack, and puts greater emphasis on Rack retrieval speed rather than Sample picking speed.
CIS	Centre for Internet Security (www.cisecurity.org/cis-benchmarks)
Developer	The developer of the Facility, an experienced developer and operator of science estate.
Facility	UKB's new headquarters in a purpose-build facility developed by Bruntwood SciTech on the Manchester Science Park, in the City of Manchester in the North West of England, UK.
gRPC	A cross-platform open source high performance remote procedure call framework.
Inventory	An accurate catalogue of all the Labware in the Archive and their locations, thereby representing its current state and recording as a minimum the Tube identifier, Rack position, Rack / Plate identifier, and location.
Labware	Collective term for the range of products used by UKB to contain Samples, currently including blood and blood products including extracted DNA, urine and saliva. UKB's current Labware includes the following (see Table B for numbers, and Appendix A for specifications and photos): • 1.2ml ABGene Tube • 0.65ml ABGene Tube • 0.3ml FluidX Tube: 0.26ml 2D-coded Tube, 96-format, external thread (Azenta 68-0301-11). • The above Sample Tubes are held on a corresponding 96-position SBS-format Rack (defined below) • Plate: a range of 96-well PCR plates are used to store Samples plated for assay according to assay provider specifications. Where this Specification refers to Rack handling and storage, Suppliers should infer such requirements apply equally to storage of Plates.

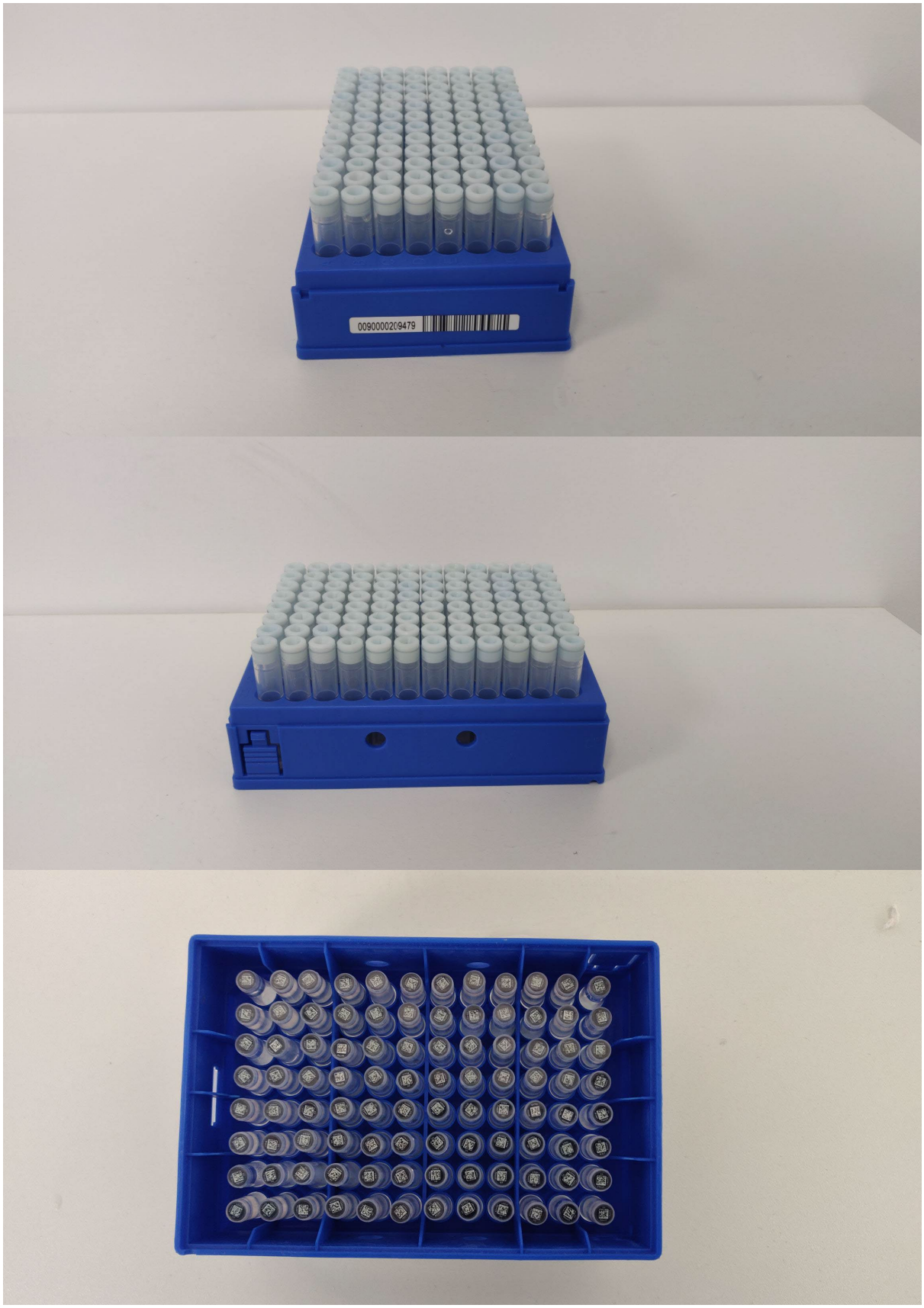
	Where this Specification refers to Sample Handling, selection or picking, it means handling, selection or picking of the Labware in which the Sample is contained.
Laboratory System	UKB's Laboratory Information Management System (LIMS). Currently: Thermo Fisher Nautilus. UKB has an ongoing project to replace its LIMS with a suite of software and supporting technology components to form the basis of a new Laboratory System to support laboratory functions during, and from, 2024.
NIST	National Institute of Standards and Technology, an agency of the US Department of Commerce and a recognised international standard-setting body.
Qualification Testing (IQ, OQ, PQ)	Tests of the Archive against the specified requirements including installation, operational and performance qualification ('IQ, OQ, PQ'). IQ and OQ are considered part of commissioning, and PQ will be linked to and represent the completion of the Site Acceptance Test. The Supplier will also conduct and demonstrate a Factory Acceptance Test.
Plate	Alternative storage format for Aliquots – typically a 96-well PCR plate used to store Samples plated for a specific customer / assay, but may in the future be created prospectively for future use, and stored. See Appendix A for examples.
Rack / SBS-format Rack	Carrier for Sample Tubes. UKB uses 96-position SBS-format Racks, standard laboratory format for storing Sample Tubes. UKB's SBS-format Racks were populated initially with multiple Samples attributed to between 16 and 48 different individuals, and thereby a whole-cohort Sample retrieval typically involves picking 24 Tubes from each SBS-format Rack. Where the term SBS-format is not specified, Suppliers should take the term to mean either SBS-format or any proposed alternative internal Rack storage format (e.g. higher density).
Sample Hall	The dedicated space for the Archive presented in the Facility, as set out in the plans at Appendix D.
Sample Handling	Archive tasks that involve moving Samples, including but not limited to: loading of Racks or Plates, Rack or Plate retrieval, Sample Tube picking, creation of new output Racks, Rack or Plate return to storage, consolidation, unloading of Racks or Plates, scanning of Racks, Plates and Sample Tubes.
Steering Group	UKB's Capital Infrastructure Steering Group, part of the formal governance of the infrastructure replacement programme and reporting to the Medical Research Council's Project Board. Consists of representatives from UKB, the Developer, the main contractor for Facility construction and Arcadis, UKB's project and cost managers, UKB's applicable Other Suppliers together with the Supplier. The forum where all Change Requests relating to the Archive, Supporting Plant and relevant areas of the Facility will be discussed, with reference to the relevant contracts.
Supporting Plant	Equipment provided by the Developer to meet the integration requirements of the Archive (e.g. chilled water supply, redundant power).

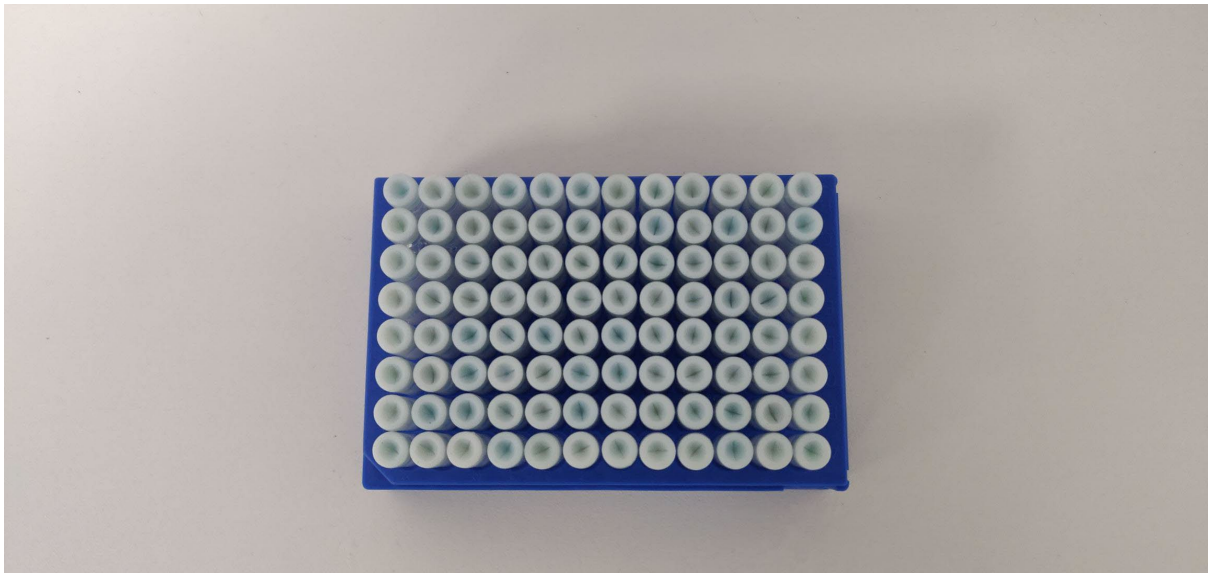
Timestamped	An unambiguous value for the point in time when an event of interest occurs. All representations of timestamps must satisfy the ISO 8601 standard for date and time formats.
TLS v1.2	Transport Layer Security is used by devices and applications to authenticate and encrypt data securely when transferred over a network. TLS protocol is a widely accepted standard.
Tube / Sample Tube	Component of UKB Labware that contains the Sample when the Sample is stored on a Rack (as opposed to a well on a Plate).
UKB	UK Biobank
User Interface (or GUI)	The physical interface of the Archive with which operators interact, specify tasks, and view alerts, status and task progress.

Appendix A: UK Biobank Labware specifications and photos

Current Labware: 1.2ml ABGene Rack and Sample Tube (representing the majority of UK Biobank's existing Sample collection)

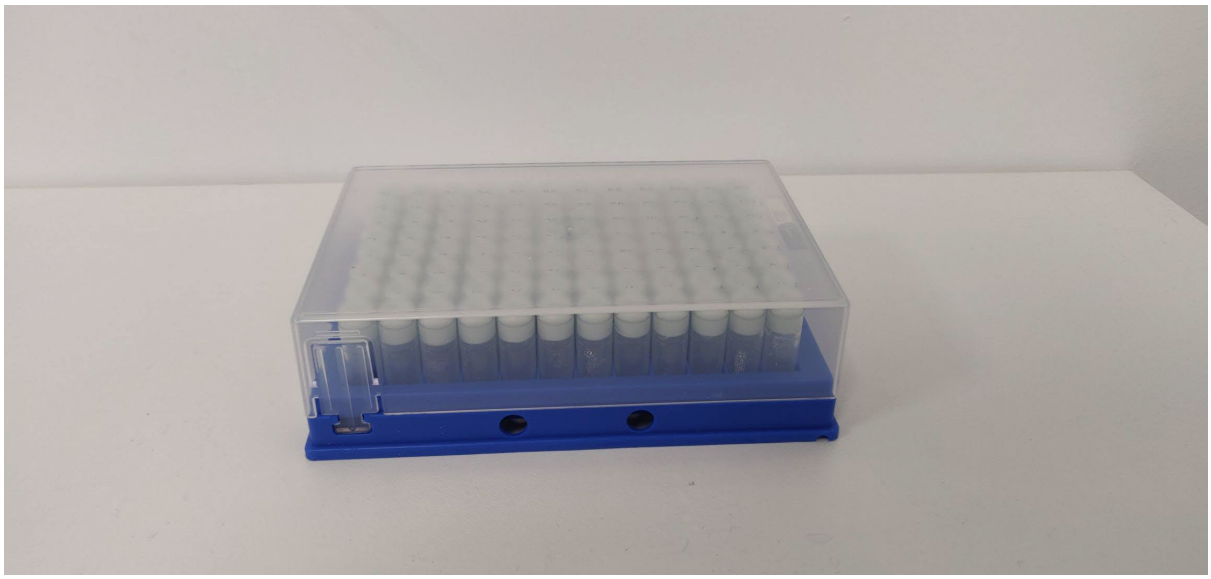
- Product code – AB-1180 (with custom barcoding on Racks and Tubes)
- Supplier – Thermo Fisher Scientific
- https://tools.thermofisher.com/content/sfs/brochures/D13099~.pdf
- https://www.fishersci.ie/webfiles/uk/web-docs/1244_LC.pdf
- *Note: the 1.2ml ABGene Racks that will be transferred from UKB's existing archive are not stored with lids as shown in the two photos below, but will be lidded for transport. All Racks transferred from UKB's freezers (of any type of Labware) will be lidded. There is no expectation that the Archive will store Racks with lids.*

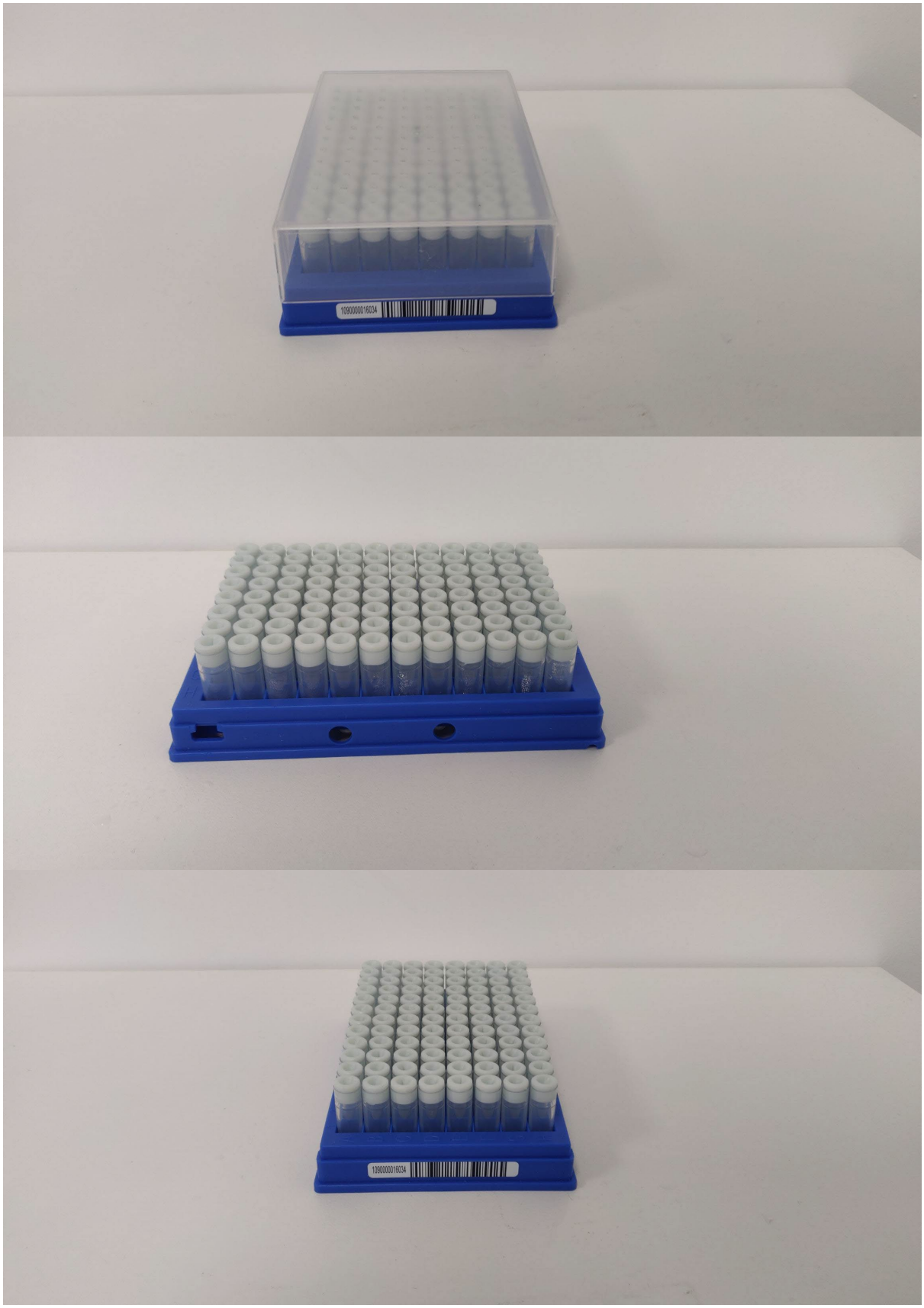

0090000209479

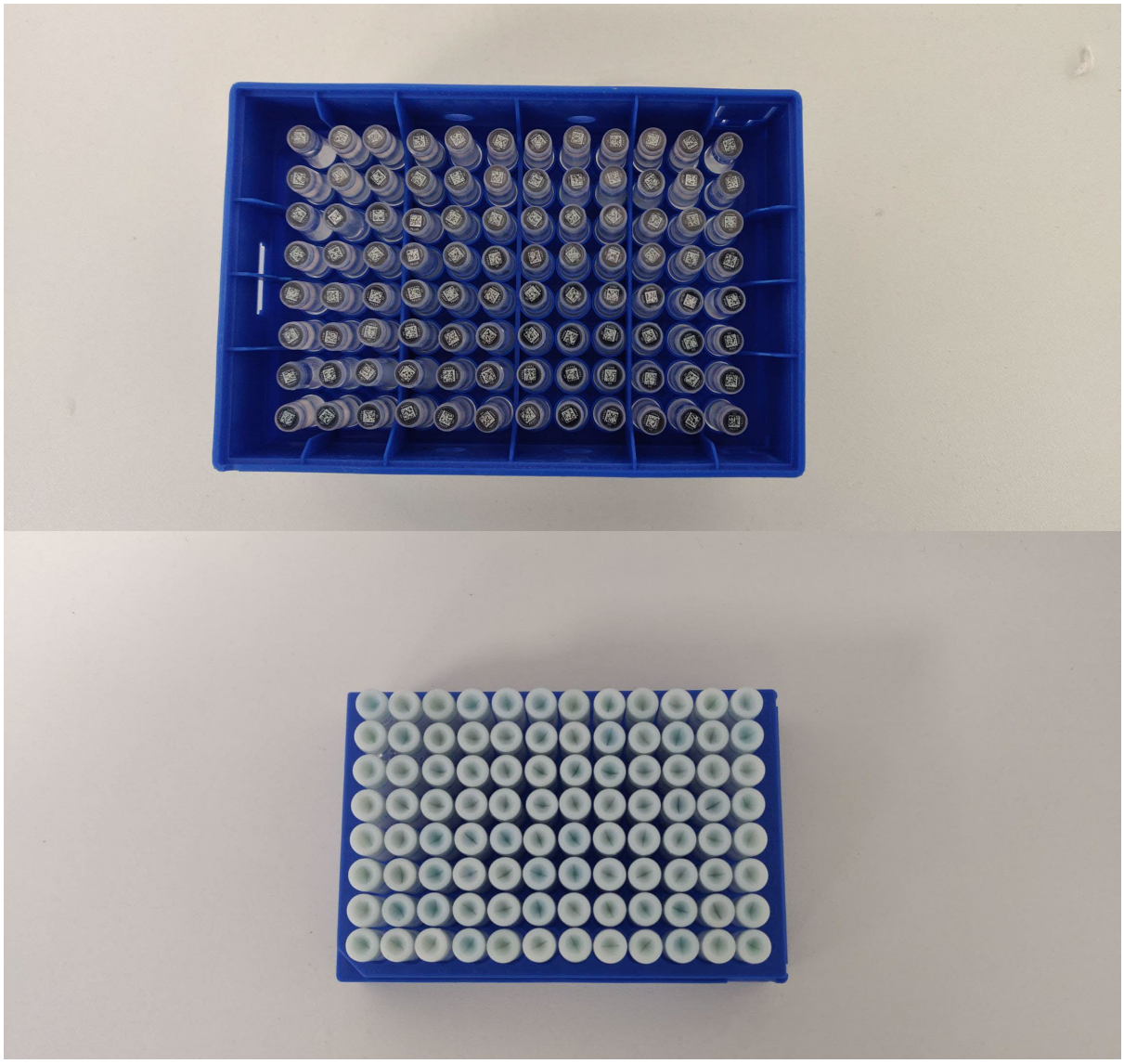


Current Labware: 0.65ml ABGene Rack and Sample Tubes

- Product code – AB-1186 (with custom barcoding on Racks and Tubes)
- Supplier – Thermo Fisher Scientific
- https://tools.thermofisher.com/content/sfs/brochures/D13099~.pdf
- https://www.fishersci.ie/webfiles/uk/web-docs/1244_LC.pdf

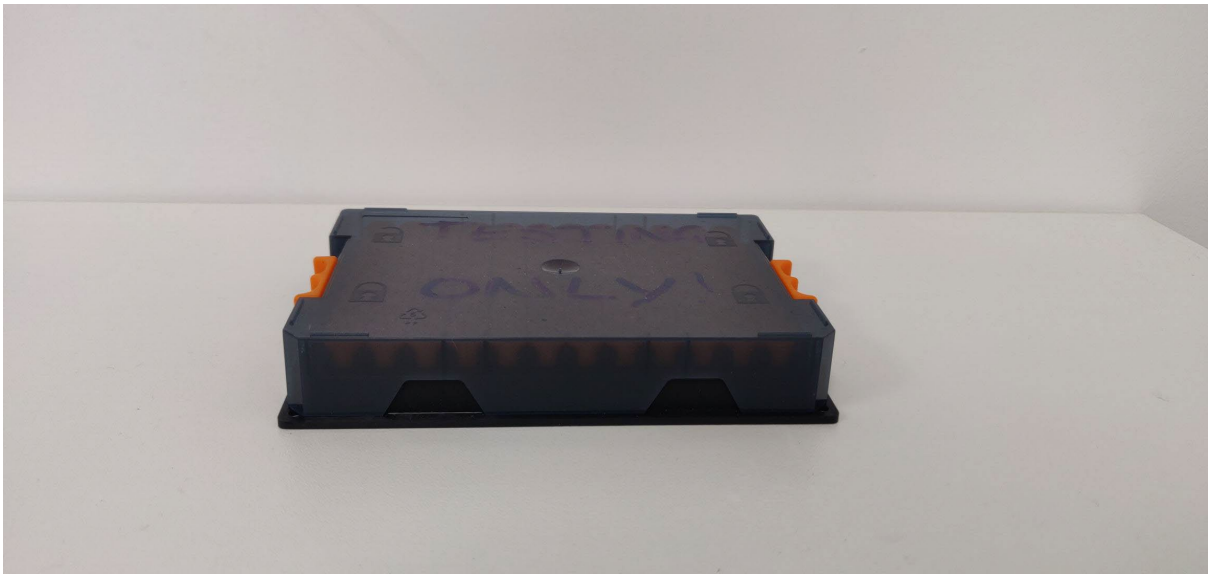


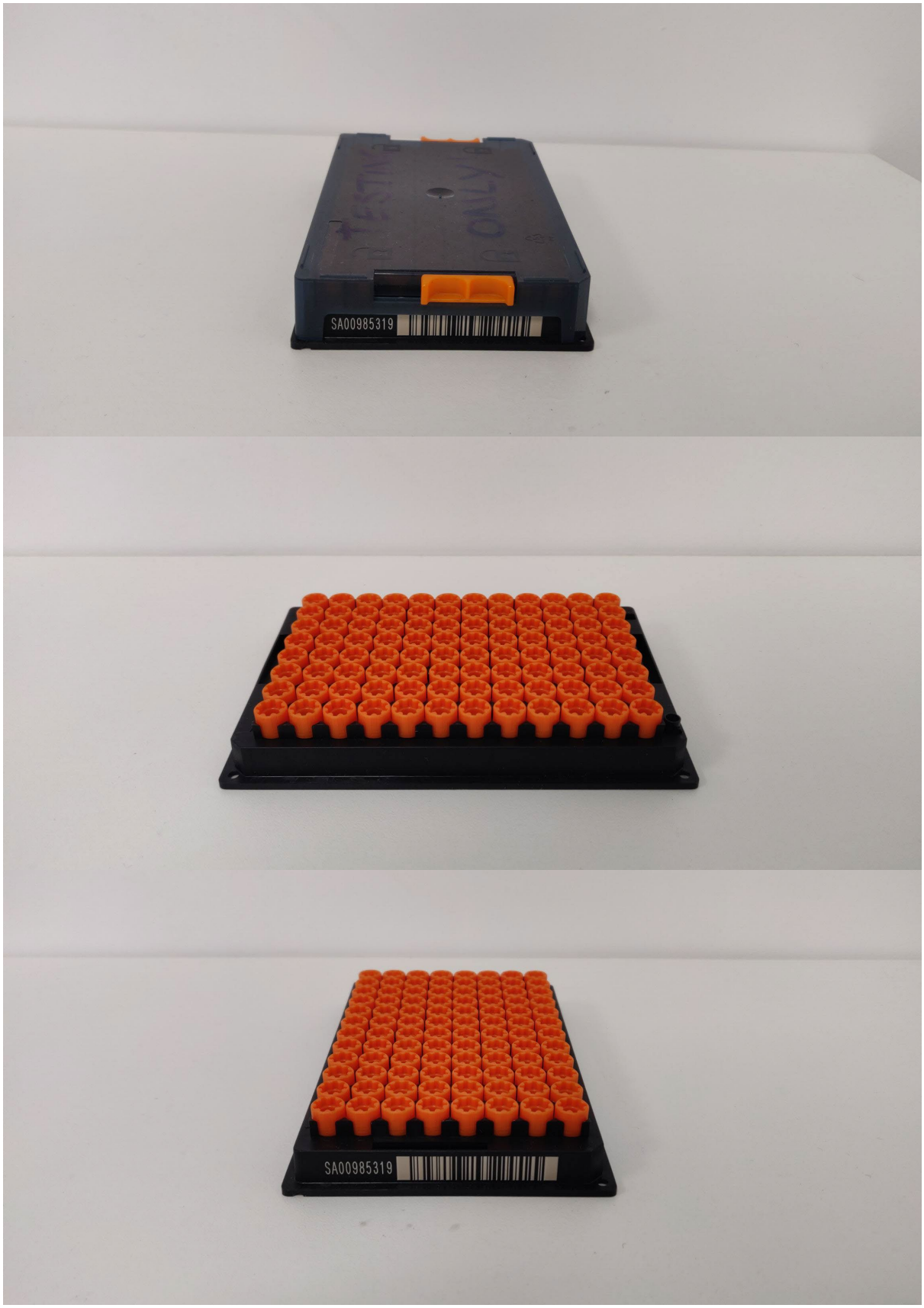




Current Labware: 0.26ml 2D-coded Tube, 96-format, external thread

- Product code – 68-0301-11
- Supplier – Azenta / FluidX
- https://www.azenta.com/products/0.26ml-2d-coded-tube-96-format-external-thread

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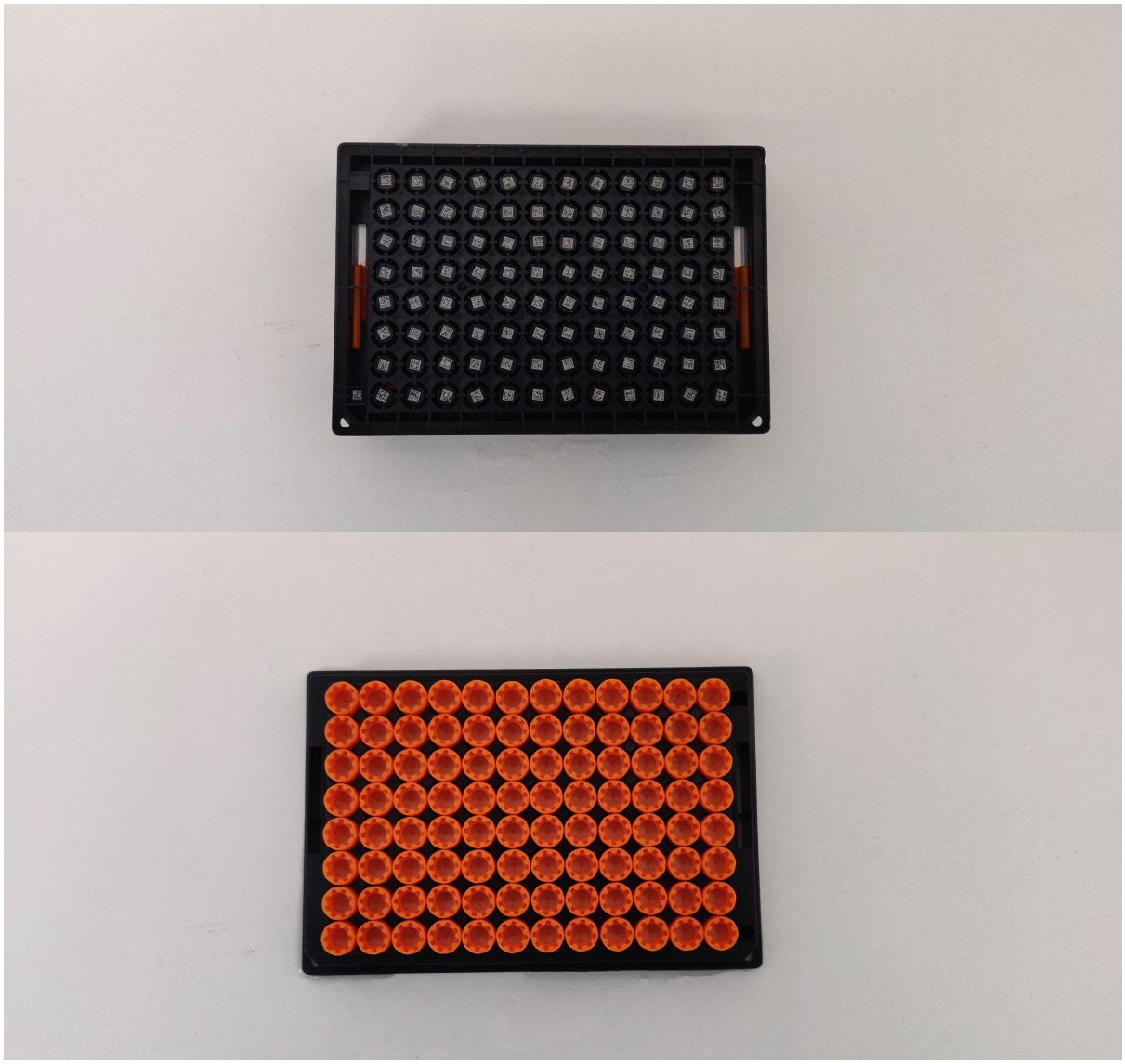


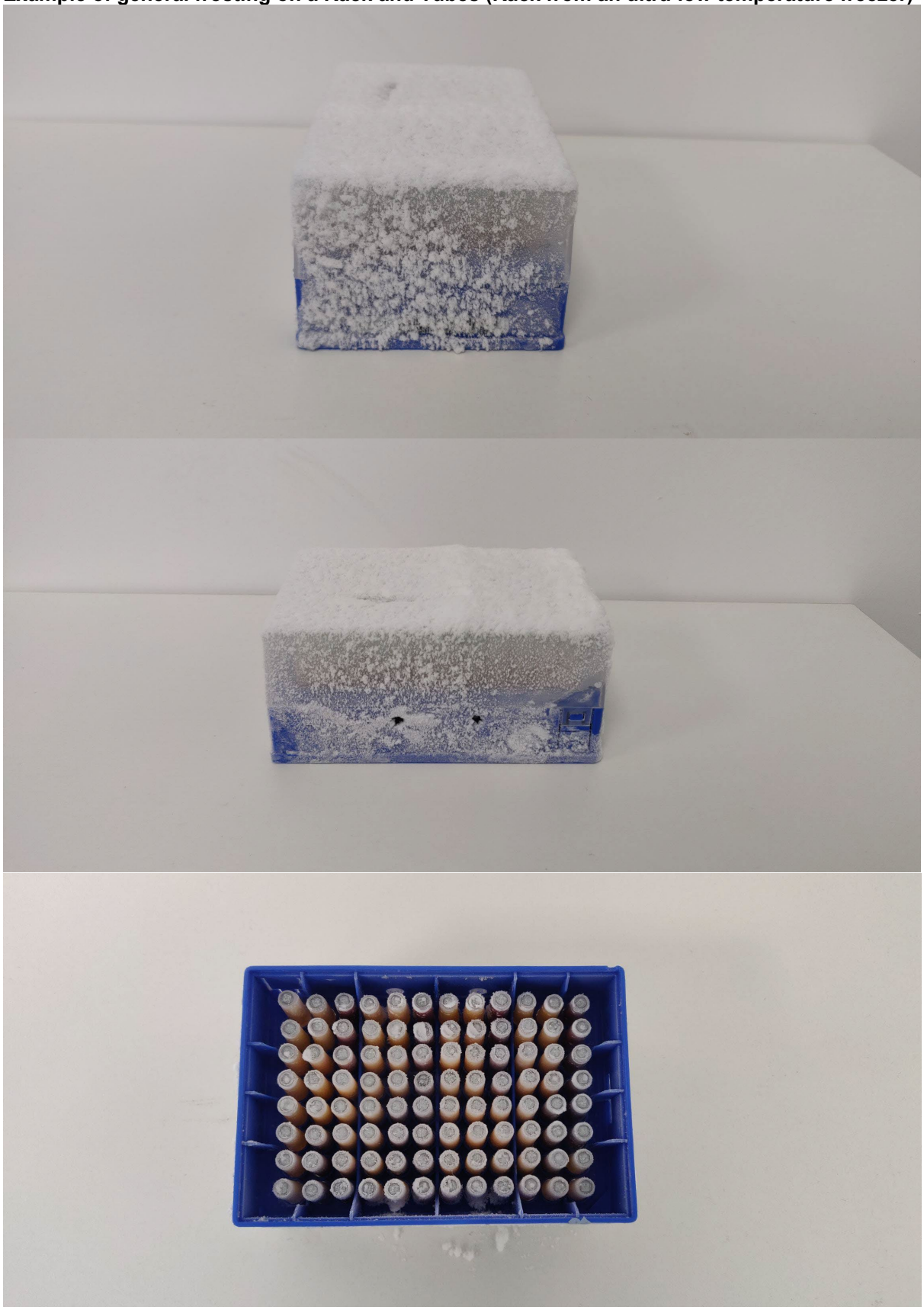
Exemplars of potential future Labware

For future Sample collections, and processed Samples created in the laboratory, UKB may wish to store in the Archive Plates or Tubes in Racks with capacity to hold between 100 to 1000 µl in each Plate well or Tube. Plates and Racks would be SBS-format and contain 48 to 96 positions. The Rack height would be unlikely to exceed the 56 mm required to store ABGene 1.2ml Racks, and may be considerably smaller.

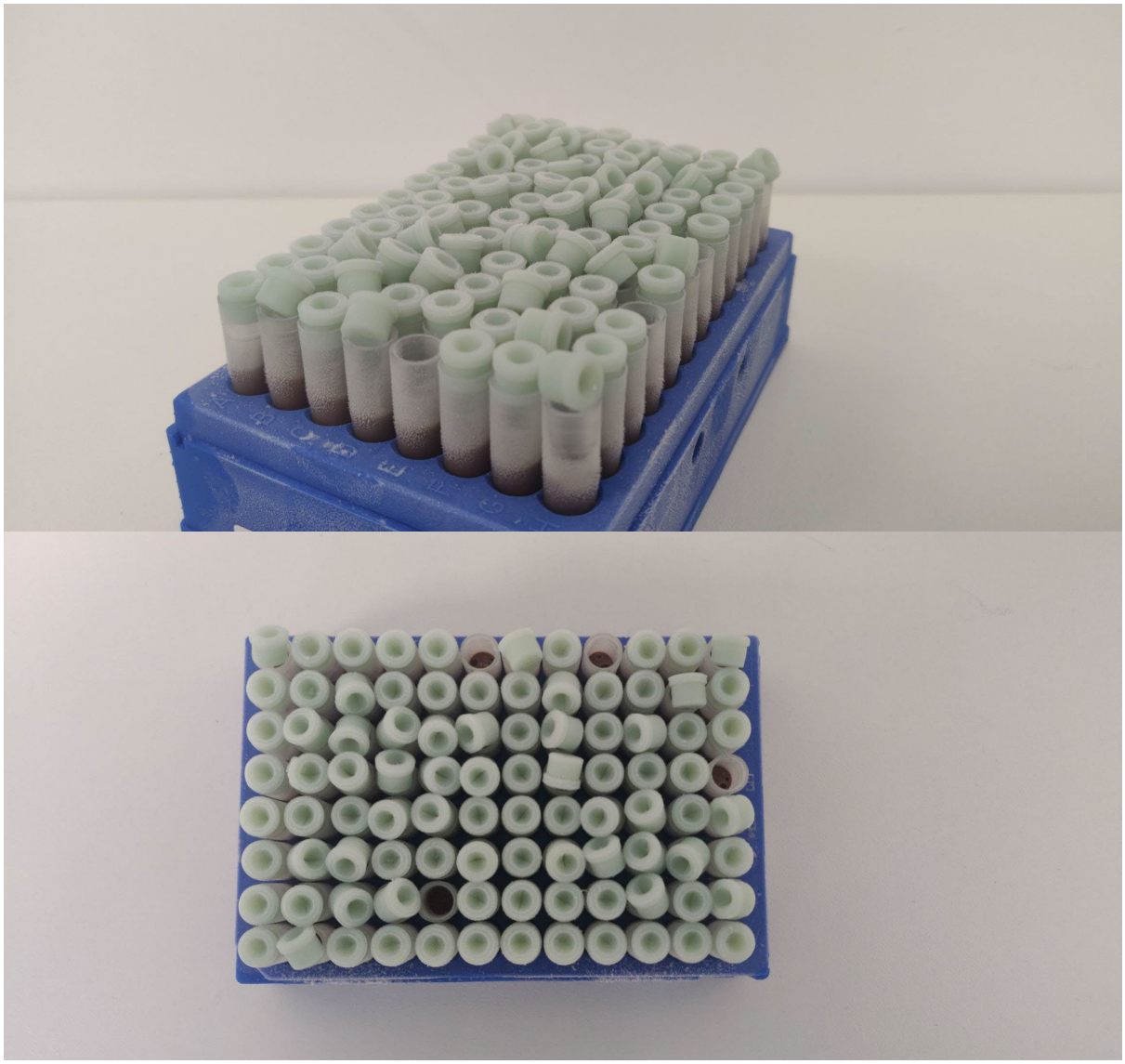
Details of exemplars of Tubes in Racks, and Plates are provided in the table below.

Type	Item	Product Number	Supplier	Maximum volume (µl)	Rack height without lid	Specification sheet
Rack with Tube (barcoded cryovial)	Matrix™ 500µL ScrewTop Tubes	3745	Thermo Scientific	500	41mm	https://www.thermofisher.com/document-connect/document-connect.html?url=https://assets.thermofisher.com/TFS-Assets%2FLSG%2FApplication-Notes%2FD13097.pdf
	Matrix™ 1.0mL ScrewTop Tubes	3741	Thermo Scientific	1000	55mm	https://www.thermofisher.com/document-connect/document-connect.html?url=https://assets.thermofisher.com/TFS-Assets%2FLSG%2FApplication-Notes%2FD13097.pdf
	0.30ml Tubes External Thread	MP52702	Micronic	320	27mm	https://micronic.com/product/030ml-tubes-external-thread/
	0.5ml Dual-coded Tube, 96-format, External Thread	68-0701-11	Azenta	550	33mm	https://www.azenta.com/products/0.5ml-dual-coded-tube-96-format-external-thread#specifications
Plate	PCR Plate, 96-well, low profile, skirted	AB0800	Thermo Fisher Scientific	100	16mm	https://www.thermofisher.com/document-connect/document-connect.html?url=https://assets.thermofisher.com/TFS-Assets%2FLSG%2Fmanuals%2FMAN0014518_96well_pcr_plate_skirted_low_profile_qr.pdf
	Nunc™ 96 DeepWell™ Polystyrene Plates	278606	Thermo Scientific	900	41mm	https://www.thermofisher.com/order/catalog/product/278605

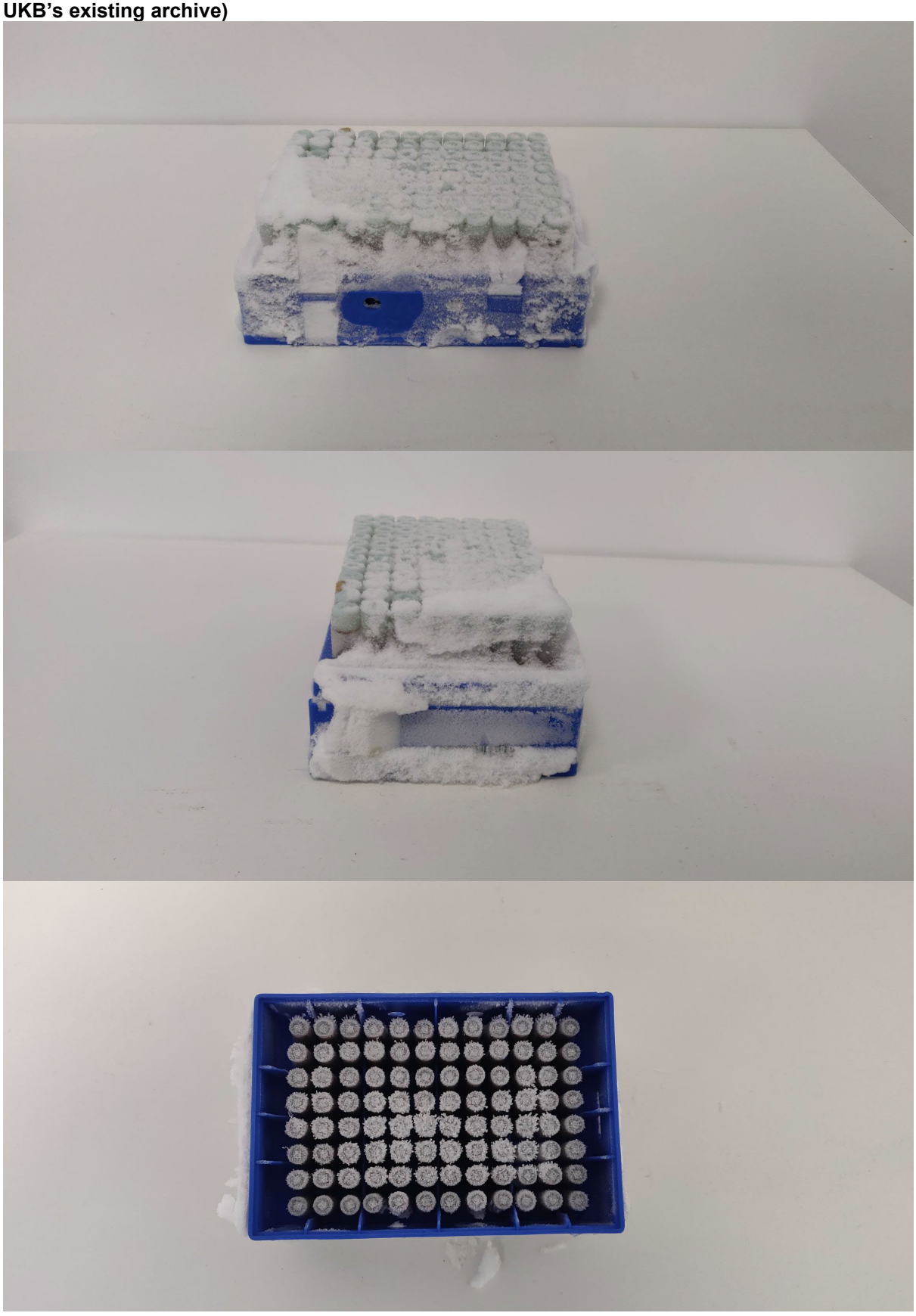
Example of general frosting on a Rack and Tubes (Rack from an ultra-low temperature freezer)

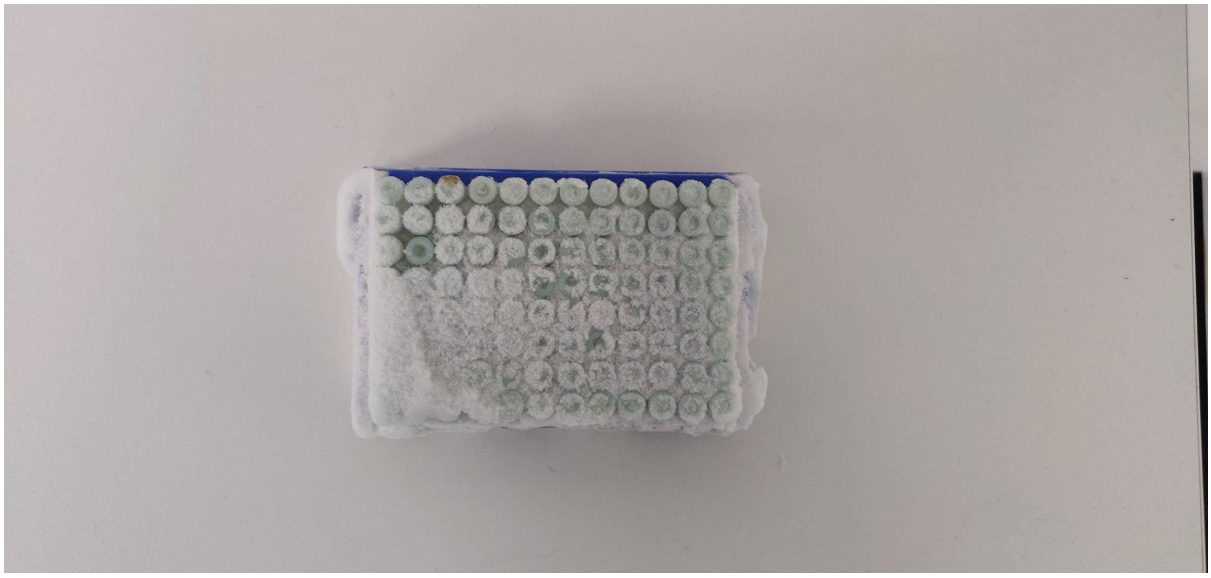


Example of an ABGene Rack with a particularly high density of raised and loose septum seal bungs (from UKB's existing archive)



Example of a Rack and Tubes with build-up on snow and ice from long-term storage (from UKB's existing archive)

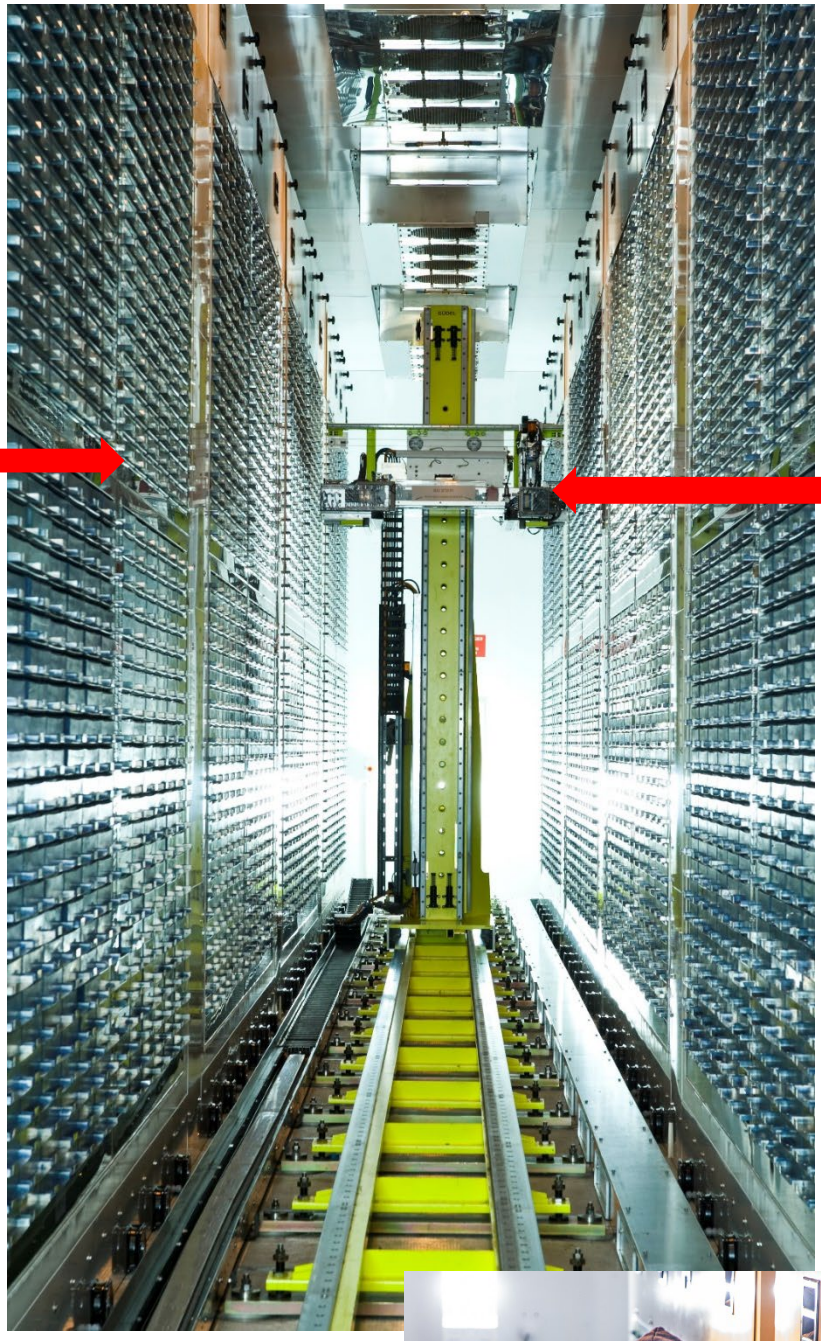




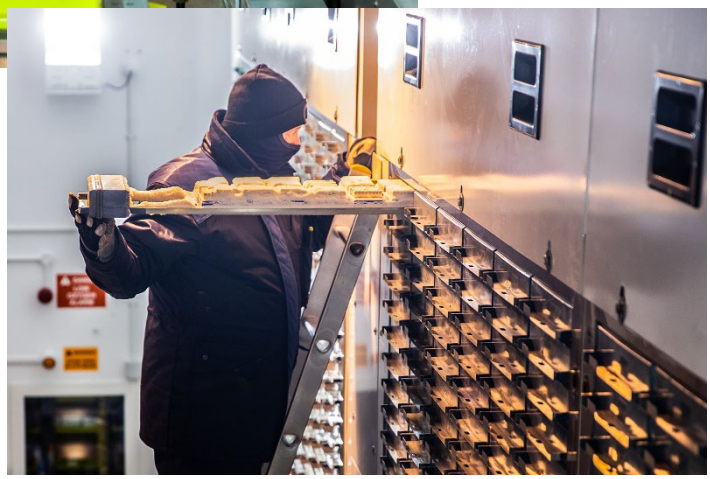
Appendix B: Current UK Biobank automated archive

5,000 sample trays slide in and out of drawers held at minus 80°C. Each tray contains 22 SBS-format racks holding 96 sample Tubes when fully populated. Typically, each Rack holds Samples for 24 unique individuals

The archive contains 9.2 million samples, and is over 90% full.



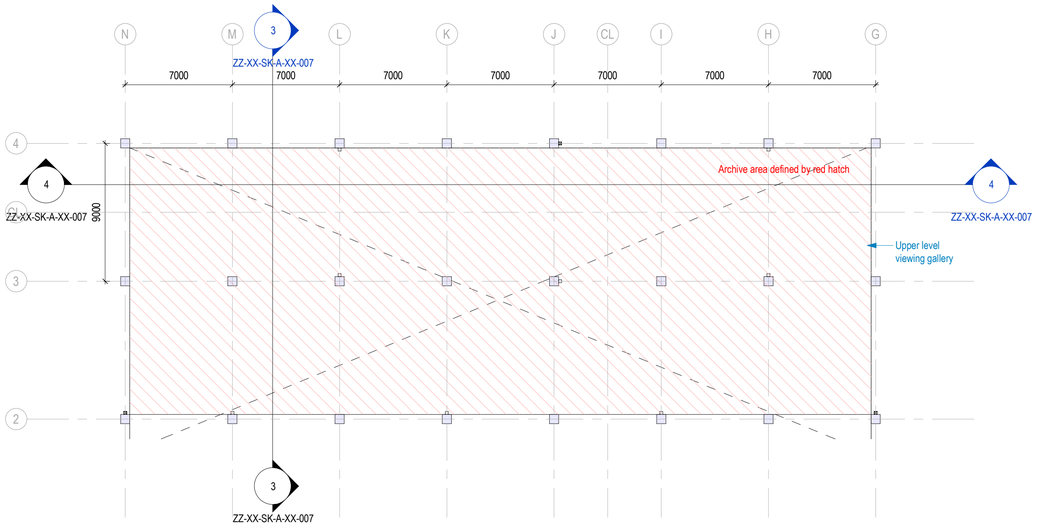
Access to Samples dependent on single robot (rate limiting speed, and single point of failure).



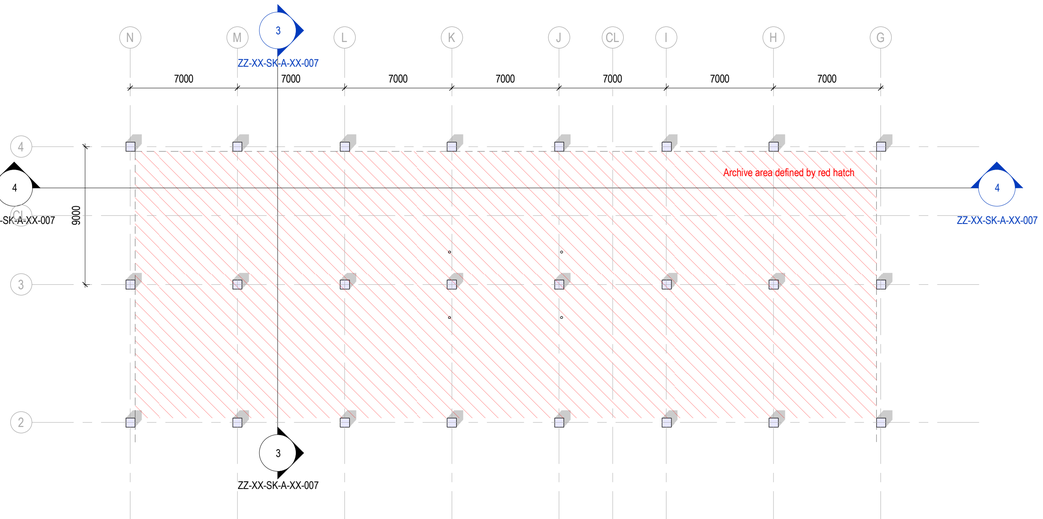
Appendix C: Visualisations of the new UK Biobank Facility in the City of Manchester

Interior visualisations of the Sample Hall

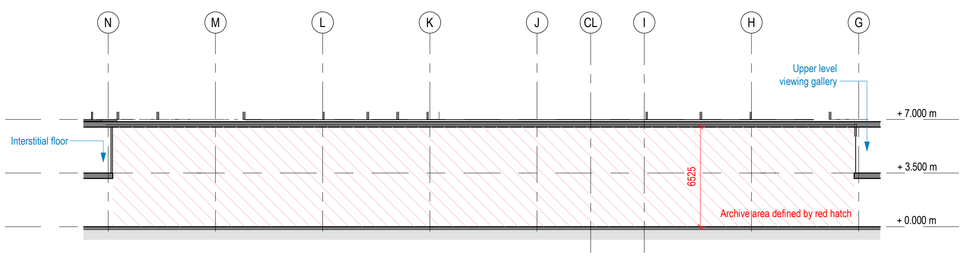
Appendix D: Plans for the ground floor Sample Hall



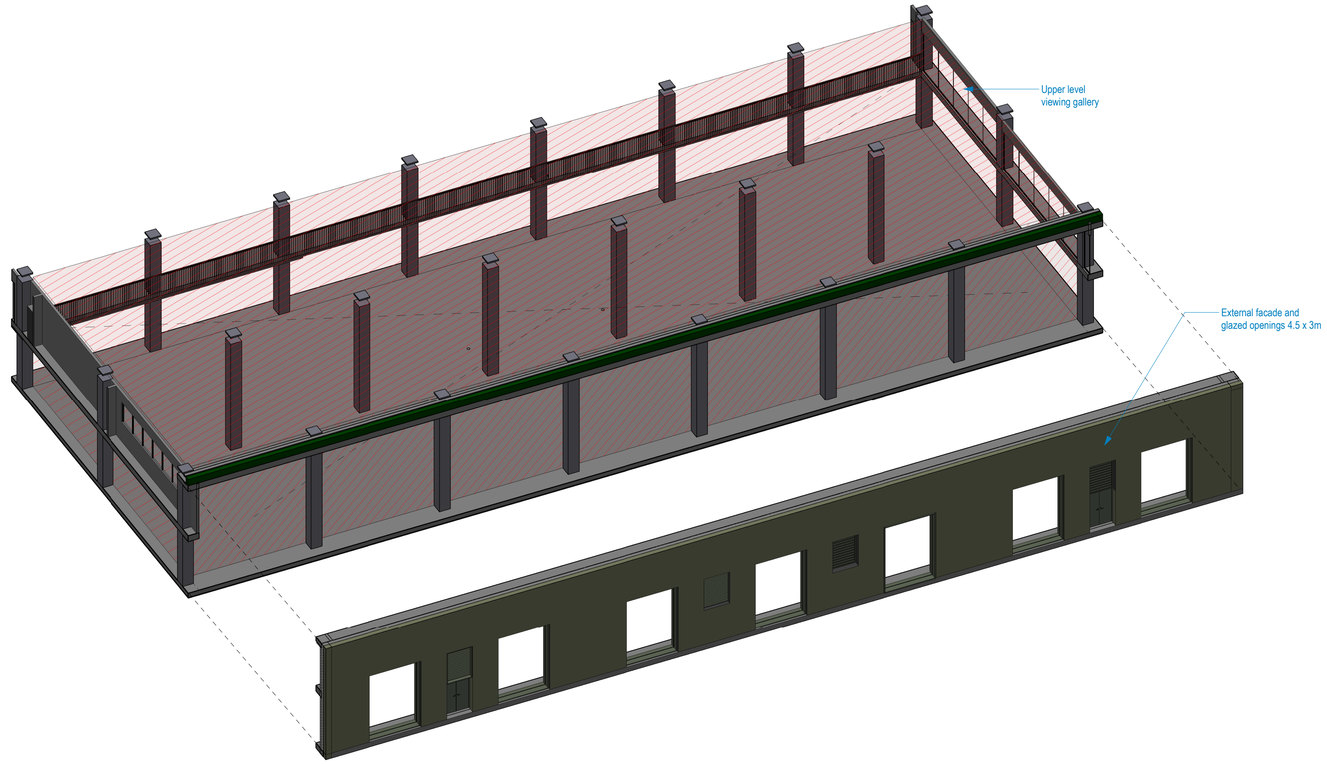
2 Proposed archive accommodation - Reflected Ceiling Plan
1 : 200



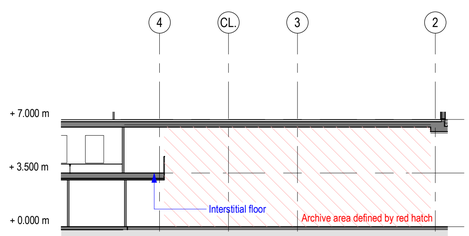
1 Proposed archive accommodation - Plan
1 : 200



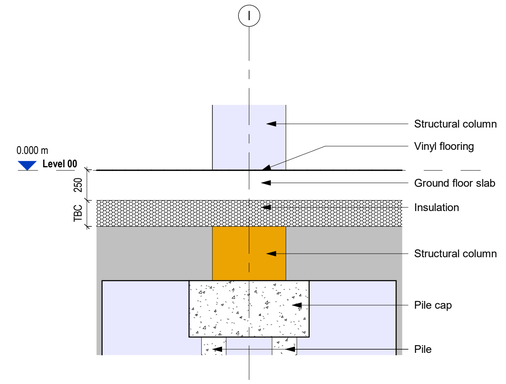
4 Proposed archive accommodation - Section A1
1 : 200



5 Cryostore parameters - Axo



3 Proposed archive accommodation - Section A
1 : 200



Indicative floor build up

ACCESS:
Access to the freezer storage area will be via a covered yard, with a soffit height of circa 3.1m and roller shutter openings, each of which will be 2500mm high by 2400mm wide.

To be read in conjuction with GRE-BDP-ZZ-XX-SK-A-XX-070, GRE-BDP-ZZ-XX-SK-A-XX-071 & GRE-BDP-ZZ-XX-SK-A-XX-072 (day, 1, 2 & 3)

PROJECT TITLE
MSP Greenheys (Private & Confidential)

BDP JOB NUMBER
P3001624

DATE
24.08.22

SKETCH TITLE
Proposed archive accommodation

Sketch No.
GRE-BDP-ZZ-XX-SK-A-XX-007

DRAWN BY
PE

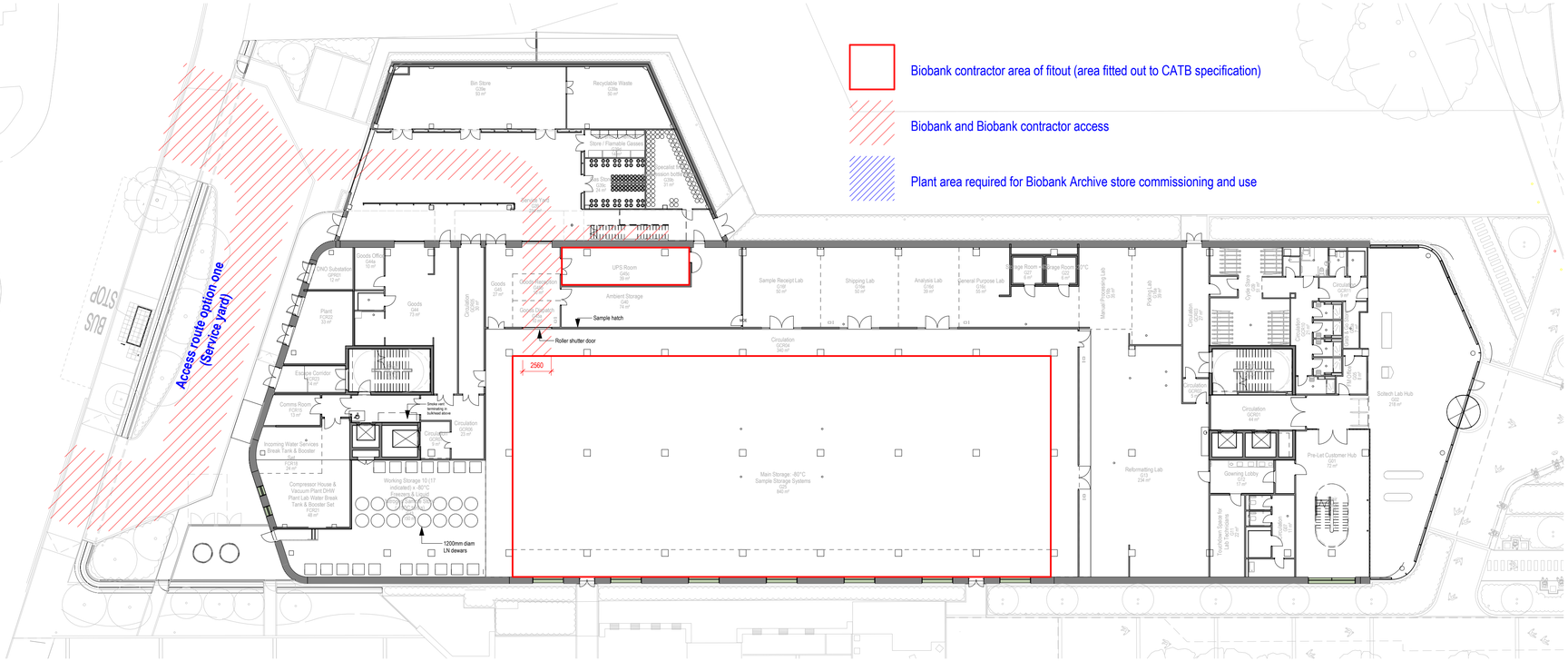
Revision
P08

BDP.

Appendix E: Supplier and UKB access areas for ‘Day 1-3’

2 Level 01 - Pre-let Customer Early access Day One

1 : 250



1 Level 00 - Pre-let Customer Early access Day One

1 : 250

NOTES

Subject to design development, survey, consultant input & statutory approval.

'G' Ground floor
'F' First floor
'S' Second floor
'T' Third floor
'H' Fourth floor
'E' Fifth floor
'X' Sixth floor

REVISION	DESCRIPTION	DRAWN	CHECKED	DATE
P09	General update	PE	PE	14.08.23
P08	General update	PE	PE	13.08.23
P07	General update	KK	PE	02.05.23
P06	General update	KK	GW	17.04.23
P05	General update	KK	PE	10.03.23
P04	General update	KK	PE	24.02.23
P03	General update	KK	PE	10.11.22
P02	General update	PE	PE	01.11.22
P01	First Issue	PE	PE	01.11.22

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BDP JOB NUMBER
P3001624

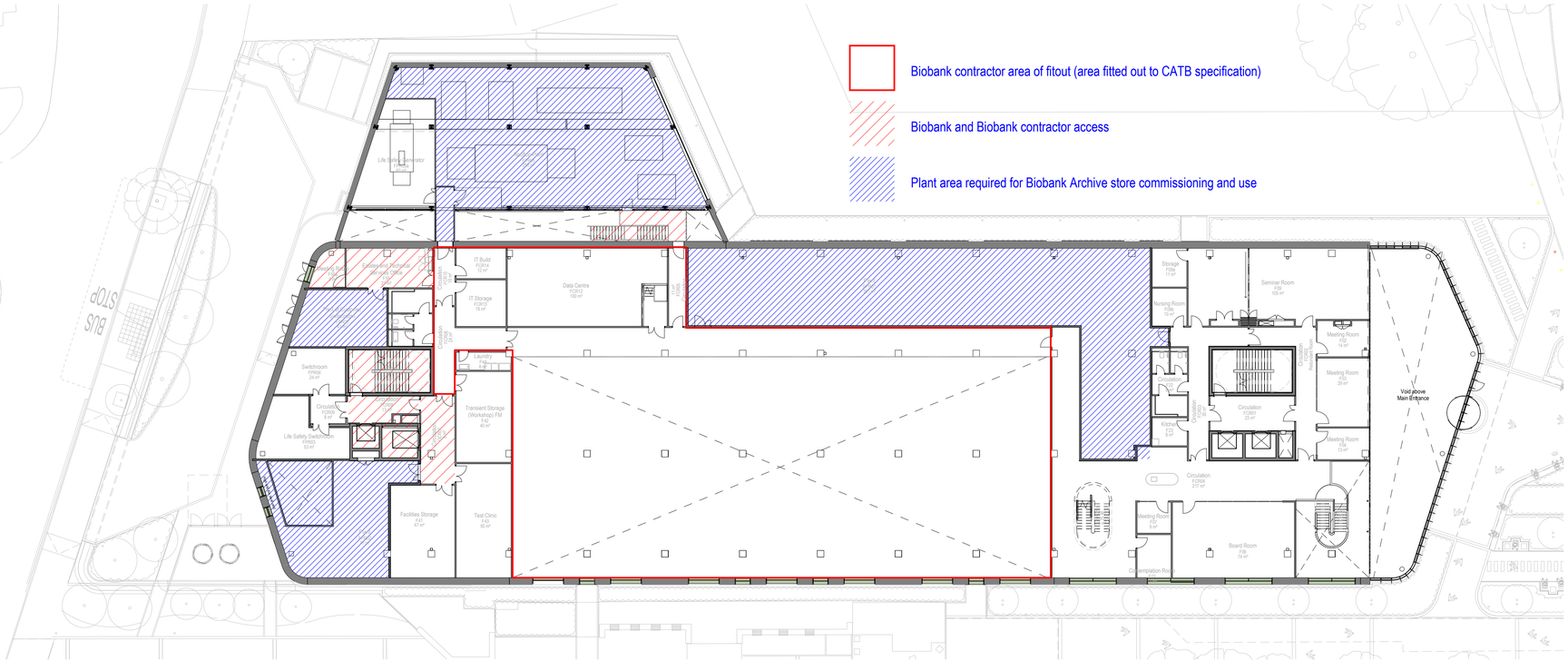
DRAWING TITLE
Pre-let Customer Early access Day One

SCALE @ A1
1 : 250

DATE FIRST ISSUED
01/11/22

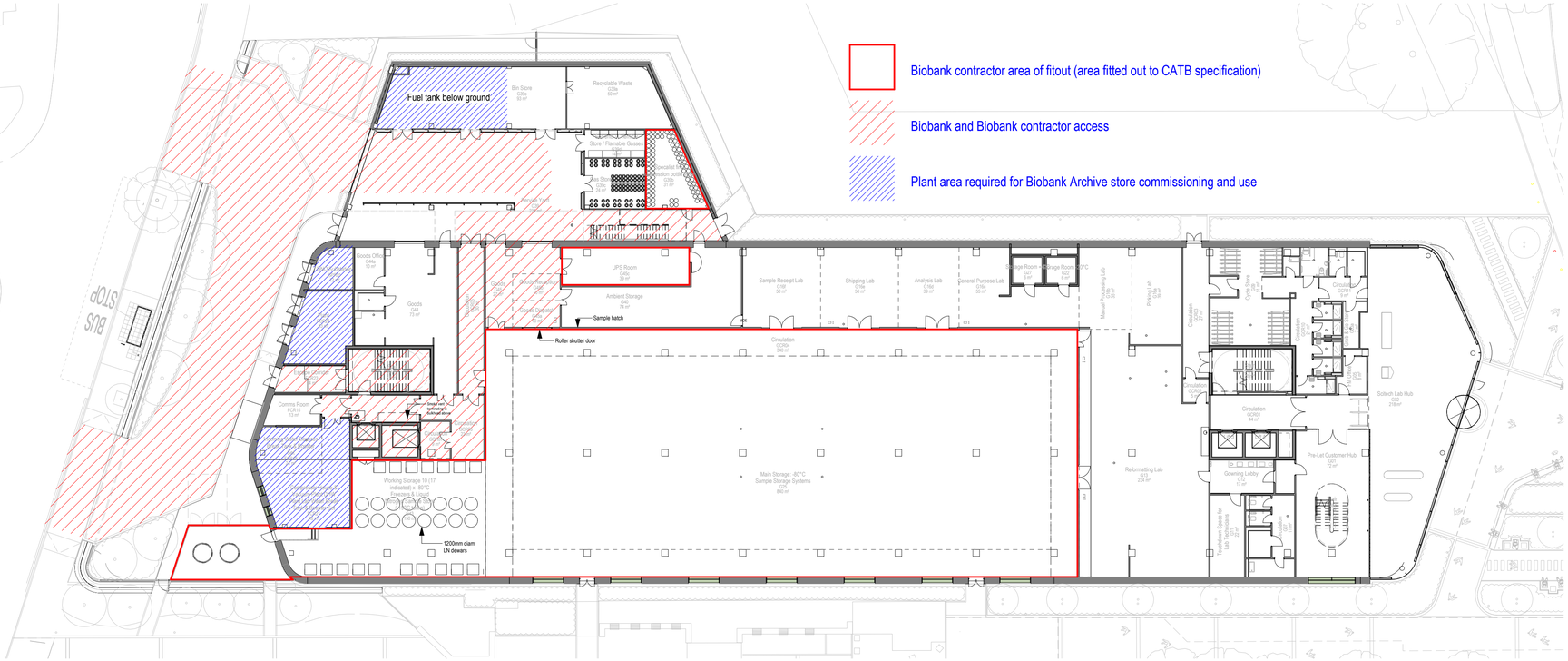
DRAWING No.
GRE-BDP-ZZ-XX-SK-A-XX-070

REVISION
P09



2 Level 01 - Pre-let Customer Early access Day Two

1 : 250



1 Level 00 - Pre-let Customer Early access Day Two

1 : 250

NOTES

Subject to design development, survey, consultant input & statutory approval.

'G' Ground floor
'F' First floor
'S' Second floor
'T' Third floor
'H' Fourth floor
'E' Fifth floor
'X' Sixth floor

REVISION	DESCRIPTION	DRAWN	CHECKED	DATE
P08	General update	PE	PE	13.08.23
P07	General update	KK	PE	02.05.23
P06	General update	KK	PE	02.05.23
P05	General update	KK	GW	17.04.23
P04	General update	KK	PE	10.03.23
P03	General update	KK	PE	24.02.23
P02	General update	KK	PE	11.11.22
P01	First Issue	PE	PE	01.11.22

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P3001624

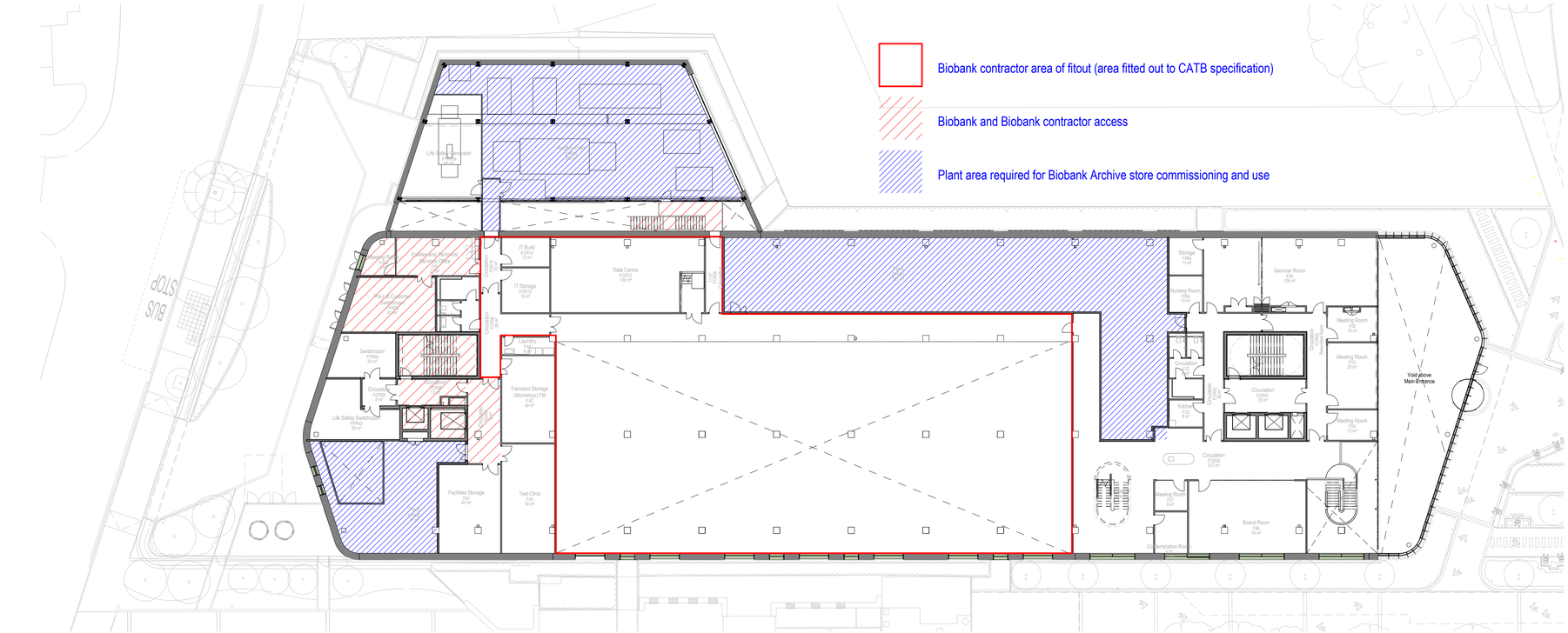
DRAWING TITLE
Pre-let Customer Early access Day Two

SCALE @ A1
1 : 250

DATE FIRST ISSUED
01/11/22

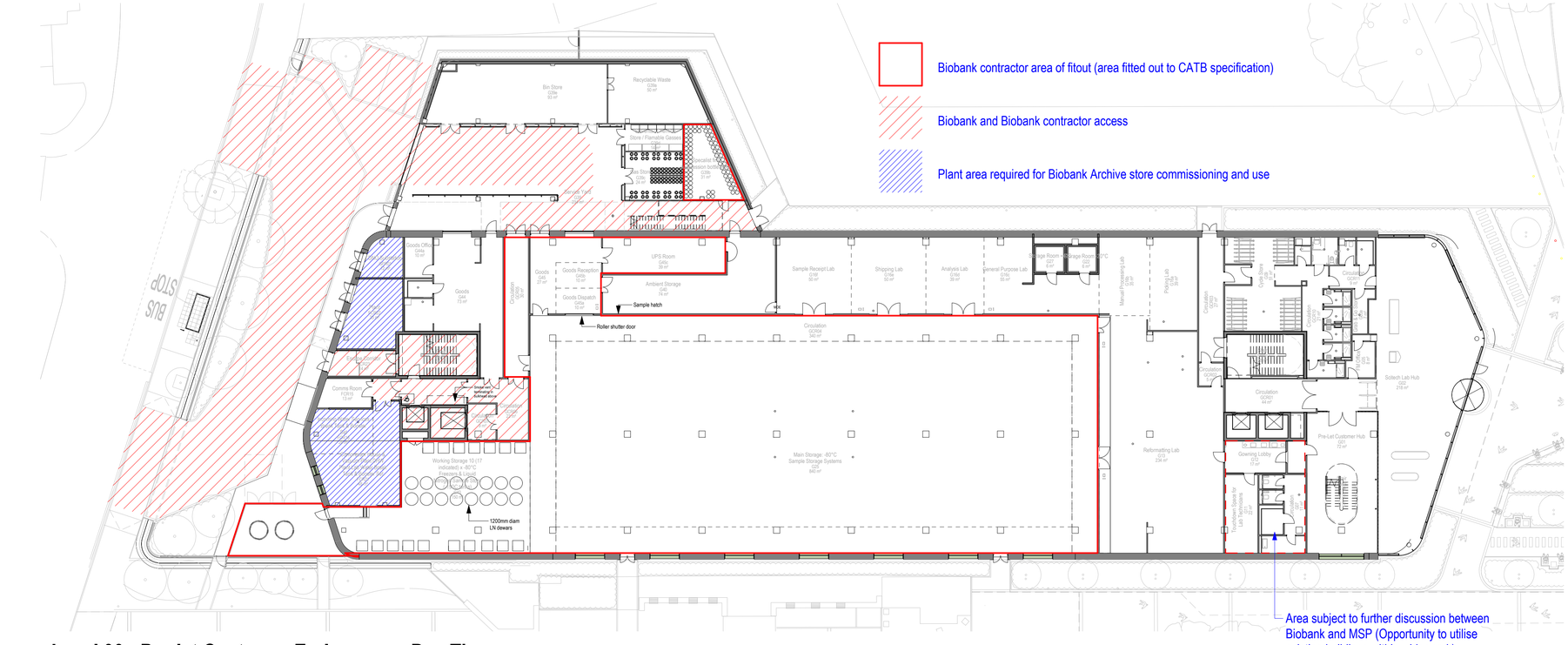
DRAWING No.
GRE-BDP-ZZ-XX-SK-A-XX-071

REVISION
P08



2 Level 01 - Pre-let Customer Early access Day Three

1 : 250



1 Level 00 - Pre-let Customer Early access Day Three

1 : 250

NOTES

Subject to design development, survey, consultant input & statutory approval.

'G' Ground floor
'F' First floor
'S' Second floor
'T' Third floor
'H' Fourth floor
'E' Fifth floor
'X' Sixth floor

REVISION	DESCRIPTION	DRAWN	CHECKED	DATE
P08	General update	PE	PE	13.08.23
P07	General update	KK	PE	02.05.23
P06	General update	KK	PE	02.05.23
P05	General update	KK	GW	17.04.23
P04	General update	KK	PE	10.03.23
P03	General update	KK	PE	24.02.23
P02	General update	KK	PE	11.11.22
P01	First Issue	PE	PE	01.11.22

KEYPLAN

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PROJECT TITLE
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P3001624

DRAWING TITLE
Pre-let Customer Early access Day Three

SCALE @ A1
1 : 250

DATE FIRST ISSUED
01/11/22

DRAWING No.
GRE-BDP-ZZ-XX-SK-A-XX-072

REVISION
P08

Appendix F: Matrix of Facility fabric, building services, access and logistics for 'Day 1-3'

Appendix F: UKB Facility fabric, building services, access and logistic arrangements for Day One-Three

Rev 2.1

	Fabric							Building Services									Access & Logistics
	Structure	**Facade**	**Floor**	**Walls**	**Ceilings**	**LN2 Compound & Service Yard**	**Other**	**Power**	**Lighting**	**Fire Alarm**	**Comms**	**Security**	**HVAC**	**Water**	**Waste**	**Gasses**	**Other**	
Day 1 Arrival of specialist equipment vendor (Archive Supplier) to site to commence on-site installation. Areas identified in the respective Day 1 diagram should be complete in full in respect of physical fit-out works (finishes, service installations, etc.) although commissioning of the permanent building services is not essential at this stage. Specialist equipment vendor to work under the main contractor's management during this phase.	Complete to ground, first and second floors and service yard.	Complete to ground, first and second floors as a minimum - to create a weathertight area (installation of living wall is not essential for this).	Structural slab, screeds and final floor finishes installed to all identified areas.	Book work and partition walls erected - within the early access boundary and the boundary walls themselves. It has been assumed at day once that there may be a temporary hoarding line to the outside face of the column line to the main archive hall (following the red line on Day One diagram), allowing the areas accessed from the perimeter circulation to the archive store area to still be constructed/finished. All final wall finishes within the identified areas to be complete along with any joinery items.	All final ceiling finishes and high level works complete - including but not limited to lighting, power, HVAC, acoustic treatment, fire treatment, concrete sealers, etc.	Complete LN2 base and enclosure in preparation of delivery of tank at Day 2. Service yard roof coverings and edge protection to be complete to facilitate the installation of plant and services.	The installation of all mechanical and electrical service media which passes through the Day 1 areas must be complete as a pre-requisite; this may require pre-testing of pipework, cabling, etc. which wouldn't otherwise be made live at this point in time.	Minimum - temporary power online to support construction, fit-out and installation activities. Preference - main, permenant power supply and LV systems commissioned to the identified Day 1 & 2 zones. Containment, cabling and outlets installed (i.e. all physical works within the Day 1 zones).	Minimum - temporary lighting. Preference - permanent lighting energised and in-use. Containment, cabling, controls and fittings installed (i.e. all physical works within the Day 1 zones).	Minimum - temporary linked construction fire alarm system. Preference - permanent fire alarm system installed and operational. Containment, cabling and devices installed (i.e. all physical works within the Day 1 zones).	Ducts for incoming comms lines to building complete and ready for cable pulling/connection by ISP's. Internal structured cabling to Day 1 and data centre (first floor) areas complete with end-to-end cable continuity tests undertaken. All physical installation works within identified Day 1 areas complete. First floor data centre and any other comms rooms involved in Day 1/2/3 activities to be constructed and fit-out in advanced stages.	All hardware - CCTV, access control readers, motion detectors, etc. - along with associated control devices, cabling, containment and other such ancillary items installed in full within identified Day 1 areas and cabled back to relevant servers/controllers/interfaces within data centre.	All physical installation works to Day 1 areas complete with only balancing and commissioning works outstanding. Including but not limited to ductwork, dampers, heating/cooling devices, fire collars, support brackettry, insulation, labelling, pipework, valves, controllers etc.	All water and other such pipework which passes through Day 1 zones to be physically installed in full (may require early pressure testing if Day 1 is ahead of the system commissioning). Main water system plant to be on-site and installation at an advanced stage.	All above ground drainage connected to below ground drainage within day 1 areas, and drainage system operational. Any foul or rainwater drainage pipework which passes through early access zones to be complete in full.	LN2 pipework installed in full with all associated valve set-ups, brackettry, pressure-controlling devices, etc. CO2 pipework installed in full with all associated valve set-ups, brackettry, pressure-controlling devices, etc. Compressed Air pipework installed in full with all associated valve set-ups, brackettry, pressure-controlling devices, etc. Any other lab gas pipework which passes through Day 1 zones to be complete in full (may require early pressure testing if Day 1 is ahead of system commissioning).	BMS field wiring to be complete or in advanced stages to ensure readiness for system activation by Day 2.	Unimpeded access will be required to the Day 1 areas for the specialist equipment vendor with minimum clearances along the full route equal to the dimensions of the external 'Goods' shutter. The main contractor's management team will be able to access the Day 1 bound areas to perform respective site and project management activities, however all physical construction and fit-out works should be complete. The specialist equipment vendor will be offered welfare facilities within the main contractor's cabins and must adhere to all site rules put in place by the main contractor. As far as CDM regulations are concerned, the main contractor is the site's Principal Contractor, whilst the specialist equipment vendor will be a Contractor and assume all such obligated duties.
Day 2 Specialist equipment vendor will have completed the equipment build-in the previous phase and now be looking to undertake system commissioning and validation, for which a stable environment and permanent commissioned building services are required to the identified areas. The specialist equipment vendor will continue to work under the main contractor's management during this phase. Archive Installation Qualification takes place	As above.	As above.	As above and extended to the areas identified in the Day 2 diagram.	As above and extended to the areas identified in the Day 2 diagram. All sealing of the building fabric to achieve air-tightness and/or pressure regimes (in support of building services commisioning) to be complete.	As above and extended to the areas identified in the Day 2 diagram.	All service yard roof plant installed, commissioned and put into use which serves Day 1/2/3 zones. Both LN2 compound and service yard to have active access control and lighting to enable unimpeded use.	As above and extended to the areas identified in the Day 2 diagram.	Abdolute requirement - permenant, commissioned HV and LV power to identified areas in Day 2 diagram, including back-up and resilience systems (generator and UPS). No power disruptions will be permitted post commencement of the Day 2 phase.	Commissioned lighting - general and emergency - systems to identified areas in Day 2 diagram.	Full permanent L2 fire alarm system commissioned and in-use to identified areas in Day 2 diagram, interfaced as required with the suppression and any other such system. Fire suppression system (TBC) installed and commissioned to suppressed zones (main storage hall, working storage area, data centre and UPS room).	Commissioned and certified structured cabling network. Comms rooms which serve Day 1/2/3 zones to be commissioned (in respect of power and HVAC).	CCTV, access control and any other electronic security devices made live - powered and networked.	HVAC and controls system online and commissioned. All specified air change rates, cooling outputs, etc. to be commissioned and certified. No disruption to HVAC systems permitted through Day 2 and afterwards due to specialist equipment dependency on environmental standards.	As above and extended to Day 2 areas identified in diagram. Installations which serve identified areas in Day 2 diagram complete in full and commissioned/in-use.	As above.	LN2, CO2 and compressed air systems commissioned and left ready for use. Oxygen depletion alarm and associated rapid extract ventilation system to be commissioned and put into use.	All BMS features which control or provide alarms for items of mechanical and electrical building services relevant to Day 1/2/3 uses to be commissioned and put into use, with access provided for control and manipulation by a third party (either Bruntwood or a nominated engineer from the incoming tenant). All cabling and infrastructure that traverses the Day One and Two zones shall be installed on the basis that no future access will be granted to contractors after Day Two. Cabling/infrastructure that serves upper levels (i.e. 6th floor plant) that may not be able to be terminated at Day Two shall be left in an appropriate position for installation to be concluded upon completion of the ongoing wider construction works.	As above, albeit with the equipment build process complete in the previous phase, access is expected to be limited to commissioning engineers from the specialist vendor. The main contractor's management team will be able to access the Day 2 bound areas to perform respective site and project management activities, however all physical construction and fit-out works should be complete. Welfare and CDM conditions are as per the above.
Day 3 Installation and commissioning of the specialist equipment will be complete. Supplier on-site engineering support present. The areas identified in the Day 3 diagram will be issued with sectional completion and subsequently handed over to the tenant to commence business operations. Unimpeded access to the completed areas will be required along with any necessary escape routes. Archive Operational Qualification takes place and following this, transfer of UKB samples commences.	As above.	As above.	As above and extended to the areas identified in the Day 3 diagram.	As above and extended to the areas identified in the Day 3 diagram.	As above and extended to the areas identified in the Day 3 diagram.	As above.	As above and extended to the areas identified in the Day 3 diagram. Escape routes for building occupants to be ready for use.	As above.	As above.	As above.	As above.	As above.	As above.	As above	As above.	As above.	As above.	Sectional completion and handover to tenant. Access through the area for construction team prohibited unless by exception and agreed with the occupying tenant.