

REQUEST FOR PROPOSAL (RFP)
FIND SPECIMEN BANK
BIOREPOSITORY AND ASSOCIATED SERVICES

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1. LIST OF ACRONYMS AND DEFINITIONS:

ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
BSL	Biosafety Level (2 or 3)
CDA	Confidentiality Disclosure Agreement
FIND	Foundation for Innovative New Diagnostics
IATA	International Air Transport Association
LN2	Liquid Nitrogen
Open Specimen	Biobanking Database
PBMC	Peripheral Blood Mononuclear Cell
QC	Quality Control
RFP	Request for Proposal
SOP	Standard Operating Procedure

2. BACKGROUND INFORMATION:

FIND, the global alliance for diagnostics, seeks to ensure equitable access to reliable diagnosis around the world. We connect countries and communities, funders, decision-makers, healthcare providers and developers to spur diagnostic innovation and make testing an integral part of sustainable, resilient health systems.

As part of its worldwide operations FIND maintains in storage various collections of human biological samples which it distributes to partners worldwide for research, development, testing and quality control of diagnostic tests in line with its mission (the “Collections”).

FIND’s biorepository operations are subcontracted.

FIND will transfer its Collections from its current biorepository services vendor in N. America to a new vendor (the subject of this RFP) at the end of 2022.

The biorepository operations are coordinated and managed by the Biobanking department of FIND.

More about FIND and its programmes can be found on www.finddx.org.

3. STATEMENT OF PURPOSE:

FIND is looking for a long-term partnership with a vendor with whom it can grow its operations.

This RFP covers the transfer of the current Collections to the selected vendor, reception of new samples, inventory, sample processing and aliquoting, storage, picking, quality control, packing and shipping, and tracking of samples and associated data, as further set out in this document.

Vendor should have extensive experience shipping biological material and reagents to various countries as depicted in Appendix F: Specimen Bank Annual Report 2021.

4. SCOPE OF WORK AND DELIVERABLES:

4.1. INITIAL TRANSFER OF COLLECTIONS

- 4.1.1. Agree with FIND on shipping method, cost and timing of transfer.
- 4.1.2. Coordinate transfer with current vendor.

- 4.1.3. Place received Collections in new vendor freezers.
- 4.1.4. As necessary return transport material/freezers to current vendor.
- 4.1.5. Perform inventory to sample level of received Collections.
- 4.1.6. Set up database for FIND Collections in new vendor tracking system.
- 4.1.7. Ensure export from new vendor tracking system to FIND database, OpenSpecimen.

4.2. RECEPTION (AFTER INITIAL TRANSFER)

- 4.2.1. Coordinate with incoming shipping courier.
- 4.2.2. Verify received material against manifest.
- 4.2.3. Communicate possible discrepancies to FIND.
- 4.2.4. Place in long-term storage, passing via quarantine, temporary storage, or laboratory processing, as required.

4.3. STORAGE AT -80°C

- 4.3.1. Store samples in -80°C freezers.
- 4.3.2. Ensure availability at all times of back-up freezers at temperature ready for immediate transfer of samples in case of freezer failure.
- 4.3.3. Ensure continuous temperature monitoring and recording of freezers with full historic data available to FIND on request per freezer.
- 4.3.4. Ensure dual independent alarm systems (e.g., dry contact alarms and vendor installed probes connected to temperature monitoring system with alarms).

4.4. STORAGE IN LN2

- 4.4.1. Store samples in LN2 freezer tanks.
- 4.4.2. Ensure availability at all times of back-up tanks at temperature ready for immediate transfer of samples in case of tank failure.
- 4.4.3. Ensure continuous temperature monitoring and recording of tanks with full historic data available to FIND on request both per tank and per sample.
- 4.4.4. Ensure dual independent alarm systems (e.g., temperature alarm and probe for liquid nitrogen level alarm).

4.5. LABORATORY OPERATIONS

- 4.5.1. Aliquoting of biological fluids under BSL1 or BSL2 conditions.
- 4.5.2. DNA extraction from whole blood, biological fluids including swab media, faecal material, skin biopsies.
- 4.5.3. RNA extraction from whole blood, biological fluids including swab media, faecal material, skin biopsies.
- 4.5.4. Isolation and cryopreservation of viable PBMC.
- 4.5.5. Isolation of bacterial strains under BSL2 or BSL3 conditions.
- 4.5.6. Inactivation of samples prior to distribution based on demand of material recipient.
- 4.5.7. Antimicrobial resistance characterization (specify by which methods).
- 4.5.8. Bacterial strain identification (specify by which methods).
- 4.5.9. Whole genome sequencing of pathogens (virus, bacteria, parasites).
- 4.5.10. Quality Control assays on any of the above-mentioned types of specimens, including viable specimens (specify by which methods).

4.6. SAMPLE TRACKING AND INFORMATION

- 4.6.1. Use OpenSpecimen to capture sample information and track position of FIND samples or at least provide FIND with an updated inventory list to be uploaded into OpenSpecimen.
- 4.6.2. Ensure continuous access for FIND, to FIND's inventory stored at vendor facilities, either by direct access or automated periodic database extract transfer.
- 4.6.3. Maintain database throughout storage duration.

4.7. PICKING, PACKING

- 4.7.1. On instructions from FIND, pick specified samples from storage, pack in suitable (IATA, ADR, etc) transport packaging and prepare paperwork for shipping out,
- 4.7.2. Coordinate collection with courier / shipping partner.
- 4.7.3. Communicate suitably with the material recipient until samples are delivered (e.g. reply to potential questions, share expected date of delivery).

4.8. SHIPMENTS

- 4.8.1. Unless otherwise agreed to by the parties, outgoing shipping shall be door-to-door and vendor shall use FIND's FedEx, World Courier or Biocair account as a last resort, and use the FedEx, World Courier or Biocair account of the ship-to addressee/material recipient when possible.
- 4.8.2. Note: FIND shall be responsible for all incoming and outgoing shipping costs, including, but not limited to, freight, duty tax, and cost of customs formalities related to export and import of related to shipping Material. Courier may be paid by FIND or by one of its partners direct or by vendor and charged to FIND or third party as a pass-through cost.
- 4.8.3. For outgoing shipments, coordinate collections with couriers and notify FIND when samples have been collected from the storage facility in response to FIND instruction, and when samples have been delivered at destination.
- 4.8.4. For incoming shipments, notify FIND when shipments arrive at storage facility, scan samples into OpenSpecimen within 2-3 working days, updating the FIND Specimen Inventory List. When necessary, print and relabel the samples prior to scanning in.

4.9. AUDITS

- 4.9.1. Cooperate with audits by FIND or FIND's selected third-party partners or funding agencies or competent authorities, whether for cause or periodic.

5. PERFORMANCE STANDARDS:

The applicant must comply to all applicable national and international standards.

Turnaround time guaranteed on outgoing shipments responding to distribution instructions from FIND should be within 3 working days from receipt of instruction or as otherwise agreed between FIND and new vendor on a case-by-case basis.

Database of sample location and annotations maintained and updated never later than 3 working days after receiving samples.

Significant temperature excursions during storage to be added as annotations to samples.

Accredited laboratory services is an advantage.

Certification to ISO9001 or equivalent, for the scope of operations, is a basic requirement. Accreditation to ISO20387 for biobanking operations and/or to ISO17025 for laboratory analyses is a plus.

Demonstratable risk mitigation and contingency plans to ensure the continuous quality of FIND specimen.

6. APPLICATION GUIDELINES:

Applicant should structure their bid in three sections following the templates in the appendices to this RFP:

- applicant qualification and competence to perform the intended contract, including:
 - a. history
 - b. certifications and accreditations
 - c. training policy
 - d. client references
- technical response
 - e. facilities and equipment available
 - f. technical explanations behind proposed service offer e.g., alarm systems & 24/7 call-out
 - g. selected SOPs related to storage conditions and QC
 - h. methods and instruments used for laboratory services
 - i. turnaround times
- financial response
 - j. unit prices for specific deliverables
 - k. answers to specific questions posed

7. AWARD CONDITIONS:

1. An applicant that is selected for final award is required to: Be legally permitted to perform work in the country where the work shall be carried out.
2. Commit to and follow FIND Code of Conduct and Ethics (Appendix D)

Exclusion criteria include:

An applicant shall not be selected for final award, if they:

- a) are bankrupt, being wound up or ceasing their activities, are having their activities administered by courts, have entered into receivership, or are in any analogous situation;
- b) have been convicted by a final judgement or a final administrative decision or subject to financial sanctions by the United Nations, the European Union and/or Germany for involvement in a criminal organisation, money laundering, terrorist-related offences, child labour or trafficking in human beings; this criterion of exclusion is also applicable to legal Persons, whose majority of shares are held or factually controlled by natural or legal Persons which themselves are subject to such convictions or sanctions;
- c) have been convicted by a final court decision or a final administrative decision by a court, the European Union or national authorities in the Partner Country or in Germany for Sanctionable Practise during any Tender Process or the performance of any Contract or for an irregularity

affecting the EU's financial interests, unless they provide supporting information together with their Declaration of Undertaking which shows that this conviction is not relevant in the context of the respective financed Contract;

- d) have been subject, within the last five years to a Contract termination fully settled against them for significant or persistent failure to comply with their contractual obligations during Contract performance, unless (i) this termination was challenged and (ii) dispute resolution is still pending or has not confirmed a full settlement against them;
- e) have not fulfilled applicable fiscal obligations regarding payments of taxes either the country where they are constituted or in Switzerland;
- f) are subject to an exclusion decision of the World Bank or any other multilateral development bank and are listed in the respective table with debarred and cross-debarred firms and individuals available on the World Bank's website or any other multilateral development bank, and cannot demonstrate with supporting information along with their Declaration of Undertaking that the exclusion is not relevant in the context of the relevant financed Contract;
- g) have misrepresented information requested by FIND during the Tender Process for the relevant Contract.

8. HOW TO APPLY

Applicants interested in bidding should communicate their interest to RFP_Biobanking@finddx.org to receive copies of all questions submitted by potential applicants and FIND's corresponding answers.

Application dossier to be sent electronically to RFP_Biobanking@finddx.org for the attention of procurement before the closing date. Reference of the RFP + Name of Organisation to be mentioned in the subject line of the email correspondence and submission for easy tracking.

9. EVALUATION AND AWARD PROCESS:

Dimensions below with different weighting as captured in appendix B will be utilised to score shortlisted candidates.

1. Relevant Certifications/Accreditation and Established QMS.
2. Demonstrated ability to provide services of a high quality.
3. Range of services corresponding to FIND's needs.
4. Pricing.
5. Referees.

The profile of the review committee comprises of the Specimen Bank Manager, Logistics Manager / Procurement Officer, Biobanking Consultants and FIND Biobank Coordinator.

10. CONTRACTUAL TERMS AND CONDITIONS:

The contract shall be awarded under FIND's standard purchasing terms and conditions attached in Appendix G to this RFP.

11. TERM OF CONTRACT:

The contract shall start at a date to be determined, expected to be in 4Q2022 or 1Q2023. The contract shall be for a period of 12 months renewed automatically for further periods of 12 months unless terminated with 6 months' notice by either side. The contract may be terminated for cause in accordance with the provisions of the terms and conditions of the contract.

12. CONFIDENTIALITY:

FIND considers any proposal received under the RFP as confidential. If required, FIND can sign a Confidentiality Disclosure Agreement (CDA) with interested applicants/bidders prior to proposal submission. Review of proposals will be carried out by an internal FIND team as well as a team of external experts (which may or may not include members of FIND's independent Scientific Advisory Committee), all of whom are under confidentiality and are recused if found to have a potential conflict of interest (which they are obliged to disclose). Any specific questions concerning confidentiality should be addressed to the FIND team.

13. TIMELINES:

	Activity	Expected date
1	Publication of RFP	25 th April 2022
2	Closing for submission of written queries	13 th May 2022
3	Closing of RFP	24 th May 2022
4	Start of interviews	24 th June 2022
5	Close of interviews	25 th July 2022
6	Communication on Award/s of Contract	12 th September 2022
7	Contract/s signed with selected Contractors	30 th September 2022
8	Public announcement of Award/s of Contract	31 st October 2022
9	Project kick-off meeting/s completed	15 th November 2022

14. QUESTIONS AND COMMUNICATIONS PROTOCOL:

Please email questions to: RFP_Biobanking@finddx.org. Questions will be accepted and responded to expediently until 13 May 2022 Submitted questions (and corresponding answers) will be sent to all bidders having expressed an interest in the RFP.

15. APPENDIX/ICES:

- 15.1. APPENDIX A – ELIGIBILITY CRITERIA**
- 15.2. APPENDIX B – VENDOR EVALUATION CRITERIA**
- 15.3. APPENDIX C – TEMPLATE PRESENTATION IN RESPONSE TO RFP**
- 15.4. APPENDIX D – FIND GLOBAL ACCESS POLICY**
- 15.5. APPENDIX E – FIND SPECIMEN BANK – SAMPLE INVENTORY ON 31 MARCH 2022**
- 15.6. APPENDIX F – SPECIMEN BANK ANNUAL REPORT 2021**
- 15.7. APPENDIX G – FIND STANDARD T&CS**