



Karubiotec™ the Human Biobank of Guadeloupe (French West Indies): A Driver Towards Caribbean Health Research

BIORESOURCE PAPER

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ABSTRACT

Karubiotec™ is a mono-site Biological Resources Center (BRC) and the only human biobank of Guadeloupe. It is an infrastructure of the University Hospital of Guadeloupe, which governed it. Located inside the hospital it is equipped with a molecular biology platform that allows all the processes from reception to preparation, storage and transfer of biological resources and their associated clinical data. These data are either part of specific research projects or of the BRC's own research programs. After studying requests, Karubiotec™ can provide samples from blood (serum, plasma, cells, DNA, RNA), secretions and tissues for most common diseases found in the Caribbean [1], in respect of ethics requirements according to the proposed use. Paraffin blocks and slides from pathology units are also collected for some cancer sites for research reuse.

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KEYWORDS:

Guadeloupe; biobanking; Caribbean; environmental diseases; infectious diseases

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(1) BIORESOURCE OVERVIEW

PROJECT DESCRIPTION

In 2009, European funds were granted to the University Hospital of Guadeloupe to build the biological resources center and a molecular biology platform. The scientific project was based on the combined effort of researchers, biologists, and clinicians to develop molecular biology and organize health research around a high-tech platform in the region.

In 2013, national directives led the University Hospital to undertake a certification process for this structure. Certification to the national NFS 96900 biobanking standards was obtained in January 2015. A dual certification to the NFS 96 900 and ISO 9001 standards obtained in 2018 rewarded the efforts made over the years.

The trademark *Karubiotec*TM was registered in November 2017. It defines *Karubiotec*TM as a biological resources center with a technical platform dedicated to research that provides samples from different sources: clinical research projects, clinical trials and routine patients' care after seeking for consent or non-objection. Non-objection is specified in the French law governing the use of body elements and allows the use for research of biological samples obtained for a different use provided the person from whom the samples were obtained is informed of the new use and does not express opposition to it. *Karubiotec*TM also provides technical support in molecular biology (genotyping, sequencing, immuno-assays, supplementary quality controls...).

All of *Karubiotec*TM collections are authorized by the French ministry of research and are part of one of its research programs.

*Karubiotec*TM was recently involved in clinical studies on epidemic diseases with the French consortium REacTING (Claude Bernard Hospital, Paris) in association with the Clinical Investigation Center of Antilles-Guyane (CIC) for the logistic management of biological resources. Thus, more than 30,000 samples from the ZIKA DFA FE cohort ([ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT02916732) Identifier: NCT02916732) implemented during the epidemic period of Zika Virus in the three regions of Guadeloupe, Martinique and French-Guyana are now centralized in the biobank [2–4].

Among other collaborations, *Karubiotec*TM participated in the vaccine trial led by the CDC/NIH (USA) in Guadeloupe on Chikungunya virus [5].

For the current COVID-19 pandemic, *Karubiotec*TM is also part of the biobanking set-up both for local and national projects like FRENCH-COVID cohort (NCT04262921), COVIDHIV cohort (NCT04361604) and EPICOV, a national epidemiological study on Covid-19 spread. In the Caribbean, collaborations are in progress between *Karubiotec*TM and Curaçao and in a new project framework with the African Caribbean Cancer Consortium (AC3).

CLASSIFICATION (1)

*Karubiotec*TM is a human biobank.

SPECIES

Homo sapiens

CLASSIFICATION (2)

Biological samples and associated data.

KEYWORDS

Guadeloupe, biobanking, Caribbean, environmental diseases, infectious diseases.

CONTEXT

Spatial coverage

- Western boundary: 061° 52' 30" W
- Eastern boundary: 060° 55' 30" W
- Northern boundary: 16° 34' 30" N
- Southern boundary: 15° 46' 30" N

All samples are collected in this Guadeloupe area, but samples can come from other Guadeloupe French West Indies Islands according to the project (e.g: Saint Martin in ZIKA DFA FE).

Temporal coverage

The collection period has started in 2011 with no termination date.

Temporal coverage for accessibility

All the collections of Karubiotec™ declared programs, mention in their declaration file “until depletion within the 30 years limit”

For remaining samples from studies, all are under embargo except for Zika-Dfa fe, Hepathochlord, Adiponectine and GSS studies.

(2) METHODS

STEPS

Samples are obtained from subjects enrolled in clinical research projects (for which the requester can provide a laboratory technical manual), or, according to the topic of Karubiotec™ declared collections, individuals can be enrolled during their care visit. All samples are sent to Karubiotec™ using professional shipment hospital internal devices (4°C shipment dedicated bag).

They are processed according to requester SOP (Standard Operating Procedures), or according to Karubiotec™ SOPs. All of Karubiotec™ SOPs have been elaborated using as standard, the Molecular Medicine Ireland Guidelines for standardized biobanking [6], and state of art according to the bibliographic survey transmitted by club 3CR, one of the most important national biobank networks. All data necessary to the bio collections, are pseudo-anonymized and integrated in the Karubiotec™ database using ModulBio® system software declared to the French national data protection authority (CNIL (Commission nationale informatique et liberté”)) under the reference n°1682116. Karubiotec™ has performed its Privacy Impact Assessment according to the General Data Protection Regulation (GDPR) of the data protection European legislation. The quality management system uses the dedicated software: Kalilab®.

STABILIZATION/PRESERVATION

Liquid samples are stored in 2 ml cryotubes with O-rings.

Whole blood in Heparin provides PBMC.

Whole blood in EDTA provides buffycoat or PBMC or cell clots for DNA/RNA extractions and plasma.

Whole blood in Citrate provides plasma.

Whole blood in dry tube after 30 minutes in vertical position provides serum.

The subsequent extraction of RNA is optimized by adding RNA Later or/RNA protect cell, to the cell pellet before freezing.

Cells are cryopreserved in a fetal calf serum/DMSO10% media at –80°C, after a minute-by-minute freezing procedure.

DNA is stored at –20°C.

Plasma and serum are preserved at –80°C and –20°C.

Formalin-fixed Paraffin Embedded blocks (FFPE) are obtained from the pathology laboratory and are stored in an air-conditioned room.

Fresh tissue is obtained from the operating room; the tissue is stored at –80°C in a 2 ml vial.

TYPE OF LONG-TERM PRESERVATION

Formalin-fixed Paraffin Embedded blocks are stored in an air-conditioned room.

Frozen samples are stored at –20°C or –80°C, or in liquid nitrogen.

STORAGE TEMPERATURE

An air-conditioned room is used (+25°C), and the samples are stored as described above at -20°C; -80°C; -196°C.

SHIPPING TEMPERATURE FROM PATIENT/SOURCE TO PRESERVATION OR RESEARCH USE

According to the sample type, shipment can be made at: +4°C, -20°C or in dry ice in dedicated normalized bags/boxes.

SHIPPING TEMPERATURE FROM STORAGE TO RESEARCH USE

Shipping temperature will be evaluated according to the sample storage temperature and the shipment will be made at: +4°C, -20°C, or in dry ice.

QUALITY ASSURANCE MEASURES

Karubiotec™ has a double certified quality management system (ISO 9001) and (NFS 96 900), the latter being specific to biobanks. Its goal for 2023 is to obtain the certification to ISO 20 387 standard.

Karubiotec™ employees follow IATA training for shipping management of samples (UN 3373, dry ice management).

SOURCE OF ASSOCIATED DATA

For collections from research projects, data from sample accompanying sheets are always recorded, and if requested for the project, supplementary data can be recorded.

Karubiotec™ has a specific form with a minimum set of data for each own authorized collection linked to research programs (age, gender, treatment information, inclusion criteria, previous story of the disease, name of prescriber, name of the person collecting the sample, time of collection, and name of the collection program).

For Cancer and neurodegenerative disease collections which are linked to local registries, specific data are recorded by Karubiotec™.

ETHICS STATEMENT

The Biological Resource Center Karubiotec™ is declared and authorized by the French Ministry of Education and Research (last authorization n°AC 2018-3313 and up-to-date declaration n°DC-2020-4212) for the activities of collection, processing, storage, transfer and use of human biological samples.

All consent forms of Karubiotec™ and information process (both prospective and retrospective) detailed in the collection declaration are approved by an institutional review board *Comité de Protection des Personnes Sud Ouest Outremer* (CPP SOOM III) under the reference number CEBH 2017/02.

There are different ethical circuits of samples:

- a) Samples prospectively processed for a research project, having their own authorizations, ethics approvals and informed consent forms. At the end of the study Karubiotec™ sends the collection to the requester laboratory, or proceeds to the destruction. If it has been mentioned in the patient informed consent, the requester can provide the remaining samples for scientific research use, by handing them to the management of Karubiotec™. After collective decision on the relevant aspects, Karubiotec™ can make a declaration to the Ministry of Education and Research for the storage prolongation.
- b) A retrospective pathway involving care samples that could become interesting for research in declared health program is also possible. To proceed for this, Karubiotec™ posts some information in the hospital information devices and media: a presentation of its activities is available on hospital communication screens (in the emergency service, and in the hospital hall). Postal information is sent to the donor or patient at home, to ensure its non-objection status. If an opposition is recorded, the sample(s) and their associated data are destroyed and erased from the database.

c) At last, samples can be prospectively processed in the framework of Karubiotec™ own research program bio collections, following information of the patient by the medical team during his/her clinical care. Its cannot depart from the requirements of the annex 2 of the bill order of 12 April 2018 establishing the list of research mentioned in 2° of Article L1121-1 of the Public Health Code, for Research Involving the Human subjects (RIPH). The consent form of Karubiotec™ is presented by the medical practitioner and signed by the patient and the doctor.

Karubiotec™ does not have a dedicated bio collection for healthy donors, as part of its declared programs. However, patients admitted within the establishment for a given illness may be included in one of the existing collections but subsequent examinations could reveal that the patient is indeed “healthy” (e.g.: no infectious disease after biological examinations).

In all cases, patients are informed that their decision will not have any impact on their healthcare. Particularly, the informed consent stipulates that the patient can inform the doctor of his/her choice about the possibility to be informed of an incidental finding of health relevance. It further documents whether the samples could be used for genetic studies (in the declared research program) only to better understand the physiopathology of the disease but never for purposes revealing the patient identity. This document informs the patient that studies can be realized with French or foreign organizations after obtaining export authorization.

CONSTRAINTS

Guadeloupe is nearly 7,000 km away from mainland France with a major concern being the cost of transportation.

Karubiotec™ reviews every year its export/import authorizations which are granted for 5 years.

(3) BIORESOURCE DESCRIPTION

BIORESOURCE NAME

Karubiotec™, the biological resources center of the University Hospital of Guadeloupe.

BIORESOURCE LOCATION

Karubiotec™ Centre Hospitalier Universitaire de la Guadeloupe

Site de RICOU

Bâtiment E niveau (-1)

97159 Pointe-à-Pitre

BIORESOURCE CONTACT

crb@chu-guadeloupe.fr

BIORESOURCE URL

<https://karubiotec.wixsite.com/crb-karubiotec>

IDENTIFIER USED

BRIF number: **KARUBIOTEC-GUA-00971**

BIORESOURCE TYPE

Karubiotec™, is an academic infrastructure working on Caribbean public health topics in virology, genetics, cancers, gynecology, neurology, immunology, cardiology, and endocrinology.

This biobank manages samples from the Guadeloupian population and is involved in both local/regional research and national/international projects.

TYPE OF SAMPLING

Karubiotec™ manages samples for numerous research projects, that need a quality sample processing before return to the sponsor (institution legally responsible for the project) at the end of the research.

Of special interest is the collection of 9,368 available serum samples from ZIKA DFA FE cohort from all pregnant subjects enrolled during Zika virus epidemic in Guadeloupe (four follow-up visits at 1, 2 and 3 trimesters, and one at the delivery date).

The samples that contribute to Karubiotec™ own collections, come from informed patients who give their consent for collecting once 4 tubes of blood in addition to the necessary blood sample for their clinical care.

Samples from the hospital virology or pathology laboratories, can also be included in the Karubiotec™ collection, after recording of the non-objection from the patients contacted by postal mail, email, or phone. The same patient can be sampled for a maximum of 4 times at different dates.

ANATOMICAL SITE

Whole blood

Tumoral zone (according to tissue locations)

Secretions (vaginal secretions, tears, saliva)

Swabs (vaginal, nasopharyngeal, buccal)

Urines

DISEASE STATUS OF PATIENTS/SOURCE

Emerging infectious disease collections available:

Arthropod-borne viruses of which *Flavivirus* (Zika virus): in Martinique and Guyana, in the **ZIKA DFA FE cohort project**.

Arthropod-borne viruses of which *Flavivirus* Dengue virus; Arthropod-borne viruses *Alphavirus* (*Togaviridae* like chikungunya); *Retroviridae* of which *Lentivirus* Human Immunodeficiency Virus (HIV): Samples from virology diagnostic laboratory processing (plasma, DNAc extract) Integrated in Karubiotec™ own collection **“emerging infectious diseases”**.

For *Coronaviridae* (*Coronavirus COVID-19*, positive and negative cases): Samples from virology diagnostic laboratory processing (nasopharyngeal sample and serum); and *Hepadnaviridae* (orthohepadnavirus, Hepatitis B Virus) of **HEPATOCHLORD** project, these samples have been retrospectively integrated in Karubiotec's own collection.

Cancer collections available:

Lymphomas including *Retroviridae*: Human T cell Lymphotropic Virus (HTLV), (PBMC/DNA/plasma/serum) samples of **“cancer biocollection”**, karubiotec's own declared biocollection

Cervix cancer including Human papillomavirus (*Papovaviridae*, HPV cases of CIN 2/3 cervix cancer): retrospectively integrated samples for the **“HPV COL study”** biocollection (FFPE, DNA)

Head and neck cancer project (salivary, buccal cell, frozen tumor) **VADS study**

Breast cancer (**GSS study**, healthy volunteer, and case) remain samples are included in the Karubiotec™ own biocollection

Immuno-hematologic disease collection available, in declared Karubiotec's own collection

Sickle cell disease (cases, available PBMC /DNA/plasma/serum)

Cardiometabolic collection available: in Karubiotec's own collection

Non-diabetic cohort (DNA, serum) from **ADIPONECTIN cohort** project retrospectively integrated in Karubiotec's own collection

Samples from patients who present hypertension, cardiac insufficiency are available: PBMC / buffy coat/plasma/serum.

CLINICAL CHARACTERISTICS OF PATIENTS/SOURCE

All clinical characteristics (inclusion criteria, disease...) are collected depending on sponsor request.

SIZE OF THE BIORESOURCE

Currently 14,145 patients have been enrolled, more than 60,000 samples are banked

For 18 ongoing projects, 1,568 subjects are already enrolled.

VITAL STATE OF PATIENTS/SOURCE

Alive or deceased.

PATHOLOGY DIAGNOSIS

The diagnosis is made by a virology expert and/or a pathology expert according to relevant recommendations, and by the other medical experts of the domain.

Data are available for the Karubiotec™ dedicated person (clinical study technician), who has specific access to the clinical data.

CONTROL SAMPLES

Control samples are only for technical purpose.

BIOSPECIMEN TYPE

Tissue size depends on requester's specificities

Blood 1 ml aliquot

Swab Cells (buccal) in 1 ml liquid media

DNA is aliquoted in 1 tube of 70-300µl (extraction method gives 50kb – 200kb fragments)

Plasma and serum are aliquoted by 500µL in 2mL cryotubes with O-rings

PBMC are stored in 1 ml aliquot (5×10^6 or more cell/ml)

Formalin-fixed Paraffin Embedded blocks (FFPE), or slide

SIZE OF THE BIORESOURCE

In 2020:

6 subjects were included in the breast cancer project (closed)

1,730 subjects were included in cardio-metabolic disease projects (Genantilles project: closed, Adiponectin project: closed, Karubiotec™ cardio-metabolic collection: on going))

241 subjects were included in the Cervix cancer project (closed)

942 subjects were included in the head and neck cancer project (closed) [7, 8]

14 subjects were included in the lymphoma and multiple myeloma project (on going)

9,368 subjects were included in infectious disease projects (ZIKA DFA FE: closed; Karubiotec™ infectious disease collection: on going)

431 subjects were included in neurodegenerative disease projects (Carpark project: closed, SLA Atypical parkinsonism project: on going)

272 subjects were included in the sickle cell disease projects (Karubiotec™ immune-hematological collection: on going)

RELEASE DATE

Samples of Karubiotec™ own collections are available for research as soon as their quality, and ethical check have been done, the time necessary, varies according to the requirements of the request. A minimal delay for a request is about 40 days. Shipping constraints, and Export authorization for foreign countries could be added and give a maximal duration of 4 months for fulfilling a request.

ACCESS CRITERIA

The requester sends an email to crb@chu-gadeloupe.fr or contacts Karubiotec™ from its website. Then a request form is sent to him/her to obtain some information on the request (the framework of the activity (scientific collaboration or not), the purpose of the reuse of samples (to verify the accordance with the declared collection, and informed consent), the composition of the teams using the collection (the user has to sign the form and to certify its reading and approval), the characteristics of the samples made available, the provision of associated data and usage or not of specific technics. Karubiotec™ is member of the scientific committee of the Research delegation that evaluates the relevance of the project if it has no other scientific committee.

If the project is validated, a document including intellectual property measures, financial conditions, responsibilities of each signatory, conditions for publication of the results of the work done using the biological resources made available, is submitted to the requester for approval.

(4) REUSE POTENTIAL

The patients/donors are informed of the reuse potential of their samples. Then the reuse is possible if the objective of the new project conforms to the global objectives of the collection program for which the patients/donors have been informed have given their consent. If not, the patient must be contacted to be informed, or in special cases, the institutional review board would be contacted to ask for an exemption to re-inform patients, according to Article L1211-2 of the French Public Health Code (CSP).

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COMPETING INTERESTS

The authors have no competing interests to declare.

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