FLORIDA AGRICULTURAL AND MECHANICAL UNIVERSITY

SOLE SOURCE CERTIFICATION

Requisition Number: _000203449_____ **Bid #** _____

In accordance with authority granted under Florida A & M University Regulation 6.005(10) (b). the following documentation is submitted in support of a request to purchase the items(s) listed below that are only available from one vendor.

Vendor: BioIVT

Account Number: **Cost $** _10,605_____

Item(s): BioIVT will perform immunohistochemical staining for detection of midasin in in formalin-fixed paraffin-embedded (FFPE) histopathological tissue sections and perform analyses

Justification: (Describe efforts made. vendors contacted. prices quoted. specifications required, availability. compatibility. decision/reason for selection). See attached for justification.

I, the undersigned, certify the above to be true and correct to the best of my knowledge and belief.

Associate Professor 05/13/2020

Signature **Title** **Date**

I, the undersigned designee of the Florida A & M University Purchasing Office, as delegated in Regulation 6.005(10) (b). (or a designee delegated the authority as described in, **hereby concur { } do not concur { }** with the above justification and **recommend { } do not recommend { }** the procurement of the above as a sole source. If applicable, the reason(s) for disapproval are:

Mattie Ford 5/26/2020

Director of Procurement Services **Date**

I, the undersigned designee, acting for and on behalf of the University President pursuant to the delegation authority **approve { }, disapprove { }** the procurement of the above as a sole source. If applicable, the reason(s) for disapproval are:

Alan D. Roberts 5/26/20

VP, Administrative and Financial Services **Date**

POSTED FROM 5/27/2020 **TO** 1:00p.m. 6/1/2020 1:00pm

DATE **TIME** **DATE** **TIME**

FAILURE TO FILE A PROTEST WITHIN THE TIME PRESCRIBED IN REGULATION 6.005(9) (K), SHALL CONSTITUTE A WAIVER OF THE RIGHT TO PROCEEDINGS.

Revised 08-12 sf

BIOIVT

ELEVATING SCIENCE™

2A Orchard Rd
Royston, Hertfordshire, SG8 5HD, U.K.

Syreeta L. Tilghman
Florida Agricultural & Mechanical University
1601 S. Martin L. King Jr. Blvd
Tallahassee
Florida 32307
United States

Re: Project Proposal # 180471

Dear Syreeta,

This letter is in response to your institution's request for a Sole Source letter from our company.

BioIVT has exclusive rights and access to our breast tumor biorepository and database. As such, we are the sole proprietor of the unique samples selected to support your project # 180471 and are therefore the only organization with the technical competence, expertise, experience and proprietary knowledge to perform the work using these samples that is detailed in the aforementioned project proposal.

With best wishes,

AJWoodrooffe

Amanda J. Woodrooffe, PhD
VP & General Manager

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Immunohistochemical analysis of the expression of midasin in human breast tumor

PROJECT OUTLINE & PRICE ESTIMATE

Florida A&M University

PROJECT CODE: 180471

PROPOSAL DATE: 28-Apr-2020

REVIEWED BY: Amanda Woodrooffe

Client Contact Information

Name: Syreeta Tilghman
Phone: (410) 302 0843
Email: syreeta.tilghman@famu.edu

BioIVT Contact Information

Name: Rebecca Houliston
Phone: +44 (0) 1763 211614
Email: rhouliston@bioivt.com

Corporate Address

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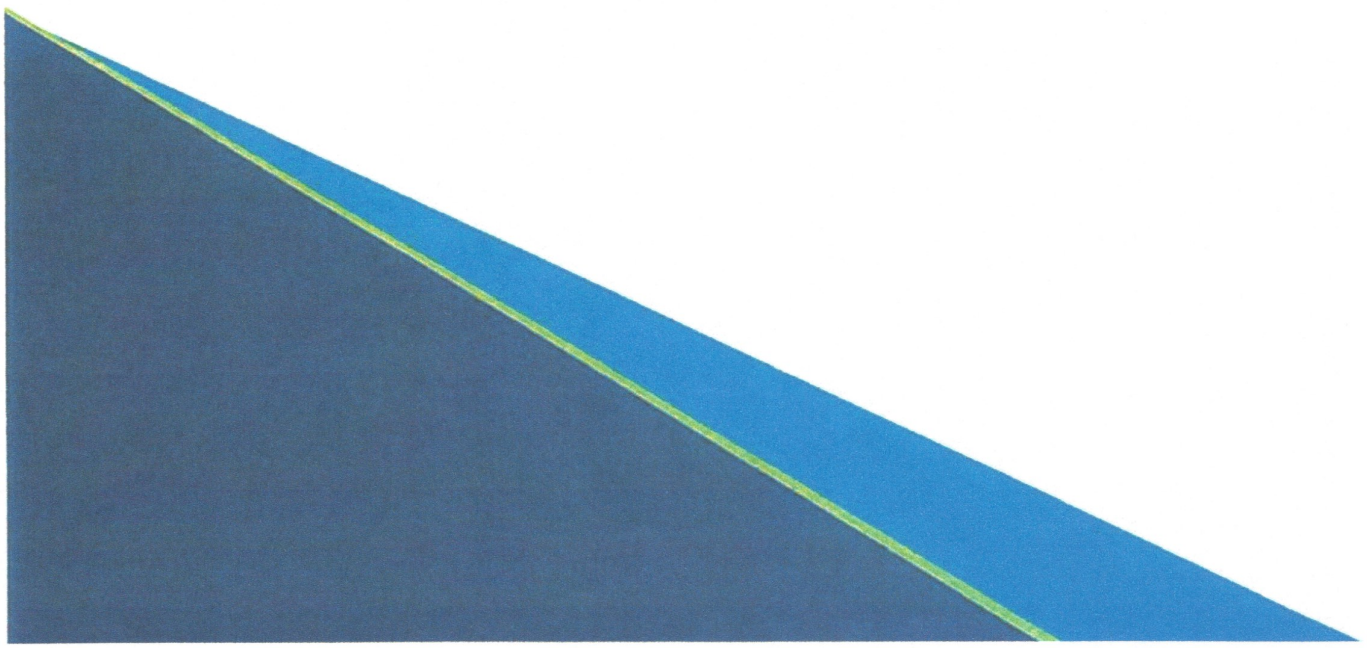

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SYNOPSIS

Florida Agricultural and Mechanical University (FAMU) has requested that BioIVT provide a Project Outline & Price Estimate for the immunohistochemical detection and analysis of one target, midasin, in human breast tumor tissue.

The analysis of midasin will be carried out in two Stages:

Stage 1: BioIVT will determine the optimal assay conditions for the immunohistochemical detection of midasin in formalin-fixed paraffin-embedded (FFPE) sections of one positive and one negative control tissue.

If the Stage 1 assay fails to demonstrate specific antibody binding in the expected cellular compartment additional rounds of optimization may be required using alternative antibodies and/or reagents. Any additional work will affect timelines and incur additional research fees. Any additional work required will be discussed and agreed by FAMU and BioIVT ahead of initiation.

Stage 2: BioIVT will use the optimal IHC assay conditions determined in Stage 1 to analyze the expression of midasin in four samples of human breast tumor.

EXPERIMENTAL OUTCOME SUCCESS CRITERIA

A successful experiment will be defined as one where experimental conditions suitable for IHC have been established, as determined by the successful detection of an assay control antibody (e.g. anti-von Willebrand Factor) in the appropriate cellular location within a control tissue (e.g. vascular endothelium).

HUMAN BIOMATERIALS

All human samples used by BioIVT are obtained with appropriate ethical approval and informed consent for research use.

All human tissue sections will be provided by BioIVT. The most suitable positive and negative control samples for use in Stage 1 will be discussed and agreed prior to initiation of the project. FAMU has selected the following four samples of human breast tumor for use in Stage 2:

Case ID	Specimen ID	Clinical Diagnosis of Specimen
73893	290177A3	Infiltrating lobular carcinoma of the breast
73938	290199A4	Infiltrating ductal carcinoma of the breast
73991	308344B1FS	Infiltrating ductal carcinoma of the breast
74011	308363A10	Infiltrating ductal carcinoma of the breast

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RESEARCH FEES AND ESTIMATED TIMELINES

PROJECT CODE	PROJECT TITLE
180471	Immunohistochemical analysis of the expression of midasin in human breast tumor

STAGE 1

DELIVERABLE(S)
- Access to digital images
- Electronic report that will include details of the tissues used, a description of the methods, images of the immunostained tissues and will recommend the conditions for use in Stage 2.

ESTIMATED STAGE TIMELINE
2-3 weeks

STAGE DETAILS
Single round of assay optimization consisting of
- Sectioning of two control samples
- Two antigen retrieval techniques
- One midasin antibody tested at three concentrations
- Appropriate control incubations (non-immune IgG, antibody diluent alone, assay control)
- Analysis and reporting

STAGE 1 RESEARCH FEES	$ 5,040

STAGE 2

DELIVERABLE(S)
- Access to digital images
- Stage 2 Report in electronic format that will include either
  full details of the tissues used and a description of the methods (no analysis by BioIVT)
  OR
  full details of the tissues used, a description of the methods, midasin expression data and selected, representative images of the immunostained tissue sections.

ESTIMATED STAGE TIMELINE
3-4 weeks

STAGE DETAILS
Analysis of midasin expression consisting of
- Sectioning of four breast tumor samples
- One antigen retrieval technique
- One midasin antibody, used at a single concentration
- Appropriate control incubations (non-immune IgG, antibody diluent alone, assay control)
- Optional - analysis of midasin expression by BioIVT's Histopathologist
- Reporting

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STAGE 2 RESEARCH FEES	**Without analysis** **With analysis**	**$ 2,065** **or** **$ 3,570**
Project specific disbursements Tissues = $1,095 Antibody and IHC reagents = $900		
PROJECT DISBURSEMENTS		**$ 1,995**
	Price Total Without analysis With analysis	 **$ 9,100** **or** **$ 10,605**

Once this project outline and price estimate is agreed in principle, BioIVT will provide a full Project Proposal detailing the agreed experimental approach, methodologies, deliverables and payment terms.

The fees and timelines presented here may change once final experimental details and project deliverables have been discussed and agreed with Florida A&M University.

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INTEGRATED RESEARCH CAPABILITIES

Supporting human target & biomarker validation with expertise in genomics and molecular histopathology combined with characterization of novel therapeutics using a variety of human-cell and tissue- based models, BioIVT offers a comprehensive portfolio of services to help our clients develop their discovery research strategies.

Our experienced BioIVT scientific teams take a collaborative approach to each project and work with clients as partners to design, implement, and interpret study results, recommending appropriate scientific approaches based on your research objectives. Working from our GLP-accredited facility with dedicated scientific project management, we ensure timely delivery of high-quality data.

Visit the BioIVT web site to learn more about our integrated research capabilities:

Biologics safety IND - GLP TCR
Target validation - IHC
Target validation - multiplex IHC
Target validation - ISH
Target validation - XPRESSWAY gene expression profiles
Target safety - XPRESSWAY gene expression profiles
Human cell based assays

ABOUT BIOIVT

BioIVT, formerly BioreclamationIVT, is a leading global provider of research models and value-added research services for drug discovery and development. We specialize in control and disease-state biospecimens including human and animal tissues, cell products, blood and other biofluids. Our unmatched portfolio of clinical specimens directly supports precision medicine research and the effort to improve patient outcomes by coupling comprehensive clinical data with donor samples. Our PHASEZERO® Research Services team works collaboratively with clients to provide target and biomarker validation, phenotypic assays to characterize novel therapeutics, clinical assay development and in vitro hepatic modeling solutions. And as the premier supplier of ADME-toxicology model systems, including hepatocytes and subcellular fractions, BioIVT enables scientists to better understand the pharmacokinetics and drug metabolism of newly discovered compounds and their effects on disease processes. By combining our technical expertise, exceptional customer service, and unparalleled access to biological specimens, BioIVT serves the research community as a trusted partner in ELEVATING SCIENCE™.