Le consortium microétalage tissulaire de la Fondation cancer du sein du Québec pour l'évaluation de biomarqueurs

Quebec Breast Cancer Foundation Tissue Microarray Consortium for Biomarker Evaluation

QBCF-TMAC

We would like to thank you for your interest in participating in the project by proposing one or more biomarkers of interest in breast cancer. The QBCF-TMAC is a program that regroups several samples from breast cancer patients from three institutions (CHUM, MUHC and CHUQ).

The main objective of the QBCF-TMAC is to address important issues dealing with breast cancer diagnosis and management. The QBCF-TMAC is assembling a cohort of 2000 breast cancer specimens arrayed on tissue microarrays (TMAs). All patient specimens are associated with diagnosis, treatment and clinical outcome data.

The project goals:

- Provide the community with a Discovery-TMA composed of 225 breast cancer patient tissues and a validation cohort of 1775 patients associated with rich and harmonized clinical data annotation.
- Provide TMA series to evaluate the microenvironment (stroma / immune component) of breast cancer.
- Provide data on hormone receptors (ER and PR) and HER2 of each TMA cores.
- Allow combination of biomarkers within nomograms that can include clinical and pathological characteristics, to more accurately risk stratify the host-adjusted, individual risk-characteristics of each breast cancer patient.

This application is to access the Discovery-TMA series of 225 breast cancer patients. Specimens from this series were collected between 2006 and 2012 and represent the spectrum of receptor status. Indeed, 60 tumors are triple negative, 60 are HER2+ and 105 are ER+. This TMA-series is composed of 3 TMA blocks, each one of them containing specimens from 75 patients. Each tumor is arrayed in triplicate on the same block. In addition, control tissues were also included.

In order to preserve this precious and unique resource the QBCF-TMAC-Study Committee will review your proposal, and according to specific criteria, will decide if your proposal is to be accepted or not. Thus, it will be important for you to provide the study committee with enough details to assure proper evaluation of your proposal.

Flow chart of your proposal

1) Submission of the proposal along with required documents and images by email to: biobanquerrcancer.chum@ssss.gouv.qc.ca
2) Evaluation by the study committee.
3) For approved project, accession to the optimisation-TMA to verify if the assay is working properly.
4) Evaluation of the staining by a professional having received the approval of the study committee.
5) Accession to the Discovery-TMA of 225 patients.
6) Evaluation of the results (statistical analyses) by the study committee. If you do not have access to a slide scanner, you will be asked to provide us with the glass slides so we can scan them and return them back to you.

If your biomarker does not meet criteria to further access the validation TMA, the data may be nonetheless used, in the future, in multivariate analyses of the test-array. If your biomarker demonstrates usefulness, accession to the remaining samples will be possible

7) Accession (or not) to other specific TMA series.
8) **You will be asked to submit the scoring datasheet and associated TMA images (whole TMA scan) to the QBCF-TMAC**
9) Evaluation of the results (statistical analyses) by the study committee.

Should you have any questions/comments please contact

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Biomarker(s) ID (short name) If you are performing a multiplex assay, please state the name of all biomarkers evaluated on the same section)**:**	

Study Title	

1- CONTACT INFORMATION

a) Principal Investigator's contact information including complete name, address and email

b) Resource/contact person's information including complete name, address and email

☐ **Same as PI**

c) Shipping address as it should appear on the Fedex package and Fedex Number

Address:

Fedex number:

d) Co-Investigators(s) Please indicate complete name and affiliation

2- PROJECT DESCRIPTION

Provide the rational of your project to help the committee members to evaluate the importance of testing your biomarker(s) on the resource.

3- PROOF OF CONCEPTS AND FEASIBILITY OF THE STUDY

a) Experimental approach

b) Specification of the antibody(ies) to be used

Name of the biomarker	Antibody				
	Commercially available	Monoclonal	Host Species	Specificity tested*	Digital image analysis
	☐Yes ☐No	☐Yes ☐No		☐Yes ☐No	☐Yes ☐No
	☐Yes ☐No	☐Yes ☐No		☐Yes ☐No	☐Yes ☐No
	☐Yes ☐No	☐Yes ☐No		☐Yes ☐No	☐Yes ☐No
	☐Yes ☐No	☐Yes ☐No		☐Yes ☐No	☐Yes ☐No
	☐Yes ☐No	☐Yes ☐No		☐Yes ☐No	☐Yes ☐No

*Control images are requested for evaluation by the Study Committee

b) Biomarker tested in multiplex (ex. multiple proteins/genes tested at the same time)

☐ Yes Please specify which biomarkers were performed together

☐ No

d) A pathologist or a fellow in pathology is available to perform/assist scoring of the TMAs?

☐ Yes ☐ No

e) A statistician is available to perform/assist the statistical analyses?

☐ Yes ☐ No

4-ADDITIONNAL INFORMATION

a) Funding from another institution to support the study

☐ Funds not available for this study at the present time
☐ Study has been submitted for funding. Organization:
☐ Study is funded or funds are available for this study from another source.
Organization:

c) Timeline

d) Ethical committee approval

☐ Approval received
☐ Project is under review
☐ Project is not yet submitted

e) Intellectual Property protection process

☐ Not patentable
☐ Not yet done
☐ In preparation
☐ Pending / provisional
☐ Accepted Patent number :

f) Industry partnership

This proposal is performed in association with an industrial partner

☐ Yes ☐ No

5.0 Security and confidentiality

Proposed electronic measures for clinical data safety: (ex: Are computers protected by passwords? Who accesses them)	
Will tissue and/or data treatment and analysis be carried out by outsourced personnel? If yes, please explain	

I understand that I will receive samples, only after an MTA has been approved and signed by all concerned parties. I also understand that the MTA defines the requirement for me to deposit the results and data generated from my experiments with the QBCF-TMAC resources into the repository, and I agree to these conditions.

Signature: _____ Date: _____

Application checklist

- ☐ Completed application form.
- ☐ IHC/IF images.

- ☐ Images of the staining/hybridization along with their associated scoring.
- ☐ Positive and negative controls supporting the specificity of detection of your biomarkers (western blot and/or staining).
- ☐ Antibody datasheet or information regarding the non-commercial antibody.
- ☐ Manuscript or paper demonstrating the results.
- ☐ REB approval if available, the QBCF-TMAC will request your approval prior to send the Discovery-TMA
- ☐ Principal investigator cv (short version is sufficient).
- ☐ Award letter (if applicable).

Appendix A

SCORING TECHNIQUE DESCRIPTION

1. **BINARY**. A two-point scale. This is defined as either absent staining or staining in a sufficient number of cells so that you are convinced that at least some of the tumor cells express the antigen.

2. **4 POINT SCALE**. Assigning a value on a four-point scale to each immunostain. Descriptively, 0 represents no staining by any tumor cells, 1 represents a faint or focal, questionably present stain, 2 represents a stain of convincing intensity in a minority of cells and 3 a stain of convincing intensity in a majority of cells.

3. **COMPOSITIONAL** Estimation of the percentage of cells (expressed as increments of 5 to 25%) of cells expressing the antigen at each of three levels of reaction product - no expression, faint/equivocal expression, and intense. Methods for obtaining a single number for analysis

4. **CATEGORICAL COMPOSITIONAL** (CC) Expression on a four-point scale of 0 to 3, where 0 equals no expression, 1 equals $\leq$ 5% of the cells express the antigen, 2 equals 5 to 20% of the cells, 3 represents 20 to 100% of cells.

Kindly provided by the Vancouver Prostate Centre