1. Introduction
INTRODUCTION

Breast Cancer (BC) is a malignant cell mass that initiates in to the cells of the mammary gland occurs mostly in females but males can also get BC, too. BC comprise many divisions, among these few are extremely rare. Sometimes a mammary gland tumor may be a combination of invasive and in situ cancer. BC is classified into Ductal carcinoma in situ (DCIS), Invasive (or infiltrating) ductal carcinoma (IDC), Invasive (infiltrating) lobular carcinoma. In DCIS abnormal cells initiates growing in the cells lining of the ducts without growing (invading) through the walls of the ducts towards tissue of mammary gland. At this stage these cells lacks metastasis property. In some cases DCIS is reported to finally develop into invasive cancer.

The IDC is the common BC. It initiates in the cells lining a duct, and breaks through the wall of the duct, and invades the tissue of the mammary gland. From there it may easily evade (metastasize) to surrounding lymph nodes and other organs. The frequency of IDC is 8 in 10 diagnosed patients.

ILC is the BC that in the cells lining the mammary glands (the lobules). It accounts for about 8 out of 10 invasive BCs. Cells grow through the lining of the lobules. Hence making cells to evade (metastasize) nearby lymph nodes and other organs of the individual. About 1 in 10 invasive BC are of this type.

IBC is the uncommon type of invasive BC and the frequency is 1 out 3 of every diagnosed females. The major signs of IBC are redness, and warming of breast skin alone with thick and pitted appearance similar that of orange peel. The mammary gland increases in size, gets hard, tender, or itchy. In its early stages, IBC is misjudged as infection because of absence of lump.

Therefore it shows higher chance of metastasis and worse condition than invasive ductal or lobular carcinoma.
The pathophysiology of BC is extremely complex and henceforth is yet not utterly identified. Several factors are said to be the cause for getting BC, Viz; Ages, personal family history, breast pathology, genetic predisposition the alteration to the genetic material may cause BC have been experimentally correlated to estrogen exposure. Few individuals may have defects in the genetic material by birth and genes such as BRCA1 BRCA2 and P53 are the most noted genetic alteration that lead to BC in a normal person the immune system checks out aberrant cells and destroys them.

BC also may be an outcome of failures in effective immune response and surveillance several signalling pathways of growth regulators and other intermediates that signals in between stromal cells and epithelial cells. Disrupting these may lead to BC as well. The cause and origin of BC vestiges a mystical view.

Experts are still looking for unclear and conflicting clues. Some of the best known "clues" are heredity, early menopause, late menarche, late childbirth, obesity, nulliparity, a high-fat diet, oral contraceptives and other exogenous estrogens, age, environmental toxins, alcohol, smoking, exposure to radiographs at an early age, and even high socioeconomic status.

Disease protein markers are proteins present in biological fluids such as plasma, serum, and other cellular components, or a genetic testing component. The gold standard recommended for diagnosis of BC is histology of the biopsy specimens collected along with other clinical evidence. Serological biomarkers are a promptly increasing list of non-invasive assays for early detection, rapid diagnosis, and calculation of the prognosis and clinical surveillance of BC.

The diagnostic industry relies on serological, and imaging biomarkers, as well as genetically inclined gene polymorphisms to aid the diagnosis of BC only with certain accuracy. However, as of today, none of the available serological biomarkers can be
marketed as gold standard for detection of BC. CA15-3 sets as a reasonable standard prognostic marker to monitor the performance of therapy during the treatment of BC.

CA15-3 test is considered to be the first line of test before proceeding towards other supporting tests to confirm BC. Commonly used markers for BC prognosis are CA15-3, Ki67 (Sahin et al.,1991) , Estrogen and Progesterone Receptors, HeR2 along with this genetic polymorphism in BRACA1 and BRACA2 gene is also considered as a strong supportive biomarker for predicting BC.

Based upon the current diagnostic scenario, this project aims to enhance the knowledge in the field of biomarkers and immunoassays for early detection of BC/ serum circulatory CA15-3. It describes the development and validation of process for generation of BC cell line based CA15-3, with consideration that the CA15-3 secreted by BC Cell lines will be much more similar to that of secreted during the development of BC. And may readily available for various clinical and research purposes.

This project also aims to develop novel, time efficient and cost effective sandwich based assays for the estimation of serum level of CA15-3 biomarker in the Indian population. This assay may prove to be very efficient in the diagnosis of BC relapse, through estimation of CA15-3 amongst the Indian population. Along with this the produced antigen and antibodies can be utilized for various scientific and therapeutic procedures.