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Title: Aptamer based fluorescent probe for serum HER2-ECD detection: The clinical utility in breast cancer

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# ACCEPTED MANUSCRIPT

#### Communication

Aptamer based fluorescent probe for serum HER2-ECD detection: the clinical utility in breast cancer

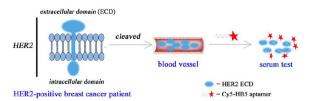
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#### Graphical abstract



HB5 aptamer-based probe have been developed for serum HER2-ECD test in auxiliary clinical diagnosis and treatment for HER2-positive breast cancer patients.

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### ABSTRACT

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The transmembrane protein HER2 is overexpressed in approximately 30% of breast cancer patients. HER2-positive breast cancers tend to spread more aggressively, which result in increased mortality in women. Nowadays, the real-time monitoring of HER2 status is important in clinical diagnosis and treatment for HER2-positive patients. Although IHC and FISH assay are standard methods to evaluate the tissue HER2 status, both approaches which required high quality tissue samples and are not suitable for monitoring the status of HER2 in real time. Since extracellular domain (ECD) of the HER2 receptor can be shed into the circulation, the serum test of HER2 ECD has been developed as an additional approach to probe HER2 overexpression. The serum test will be able to monitor the dynamic changes of HER2 status. In this paper, we detected serum HER2 ECD using Cy5-labeled HB5 aptamer as a result of its specific binding ability to HER2 ECD. This aptamer-based fluorescent probe is easily synthesized and modified and as sensitive as anti-HER2 antibodies. We believe that Cy5-HB5 may have application potentials in serum HER2 test for clinical utility of breast cancer, such as recurrence and metastases.

Breast cancer, as the second most common malignant tumor and the fifth main reason of death from cancer, plays a great health problem all over the world. There is approximately 25% of all cancer patients suffer from breast cancer, which result in 15% cancer-related mortality in women [1]. Recently, Human epidermal growth factor receptor 2 (HER2) has been suggested as an important biomarker for breast cancer patients. HER2 is overexpressed in approximately 30% of breast cancer patients. Since HER2 is a protein that stimulates the growth of breast cancer cells, these HER2-positive breast cancers tend to grow and spread more aggressively [2, 3]. Therefore, the early detection of HER2 protein is very important in the development and progression of certain aggressive types of breast cancer.

HER2, also known as Erb-B2, is a 185 kDa transmembrane protein belonging to the epidermal growth factor receptor family [4]. HER2 has been regarded as a tumor-specific target in molecular therapies for part of breast cancer patients. Nowadays, immunohistochemistry (IHC) assay and fluorescent *in situ* hybridization (FISH) assay are standard methods to evaluate the tissue

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