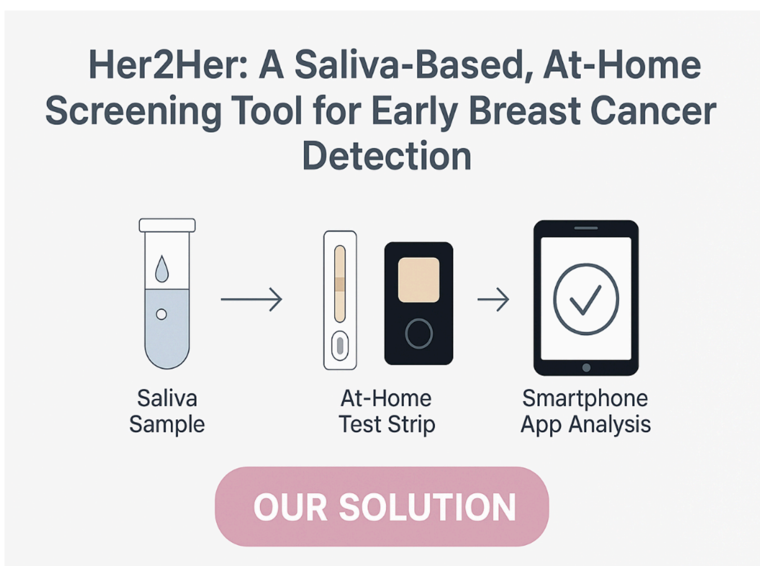
HER2HER Overview

Co-founders: Marie-Jeanne Baroudi, Tala Mehdi, Maxwell Weinstein, Kirti Saxena
External Authors: Justin Yuan, Mantej Cheema, Thariq Pasha, Ridham Goyal, Loago Zambe
Peer Reviewers:



Abstract

HER2HER is developing a non-invasive, at-home diagnostic test to address the gap in early breast cancer detection. Traditional screening methods, such as mammography, are often inaccessible to younger women, uncomfortable, and limited by cost and availability, leading to delays in diagnosis. These limitations undermine the need for a private, affordable, and scalable solution that empowers individuals with proactive health monitoring.

Our device uses saliva-based biosensing technology to detect biomarkers associated with HER2-positive breast cancer. Our product works by applying a saliva sample to a test strip, where a chemical reaction occurs. This reaction generates a very small electrical signal. An amplifier strengthens this weak signal, and a mini computer processes it into clean, usable data. The result can then be displayed on a screen, sent to a phone or computer, or used for further analysis. By doing this, the approach will make testing for breast cancer less invasive and more convenient.

Early tests and prototypes indicate that HER2HER's technology could provide people with quick insights into their health outside of clinics. While it starts with breast cancer, the platform can be expanded to other cancers and diseases. By combining advanced diagnostics with easy access, HER2HER aims to make cancer screening more inclusive, preventative, and patient-focused.

Business Overview

HER2HER originated with the University of Toronto's Entrepreneurship Hatchery in May 2025 and transitioned to H2i in September 2025, which is a focused accelerator in the biomedical space. Working with start-up accelerators associated with the University of Toronto has allowed HER2HER to develop their business model in conjunction with working on the prototype.

Problem Statement

Breast cancer is rising amongst younger women, yet current screening methods like mammograms are inaccessible. HER2HER offers a non-invasive, saliva-based biosensor for early breast cancer detection.

A solution that is not as invasive as a mammogram and that is more accessible in general, as it doesn't require long-term lab testing. Mammograms remain accessible to just anyone; they are invasive. With the HER2HER device, anyone would be able to take the test with comfort and accessibility. HER2HER's saliva-based testing kit offers an innovative pathway toward earlier, easier, and more effective breast cancer detection.

Scientific Background

In the development of the testing kit, various biomarkers were researched, including miRNAs, mRNAs, circRNAs, and lncRNAs. Extensive research was conducted on these biomarkers to determine which would best fit the testing kit. While mRNAs, lncRNAs, and circRNAs show emerging potential, miRNAs, particularly miR-21, stand out as the most stable, clinically supported, and technically suited for electrochemical biosensing.

Therefore, HER2HER's kit will focus on miRNA detection. miR-21 was found to be highly effective for this purpose. It is overexpressed in HER2+ tumours and is strongly associated with tumour progression and poor prognosis. miR-21 has been clinically validated as a diagnostic biomarker with high sensitivity and specificity and has been confirmed to be detected in saliva with strong diagnostic value. Detection methods for miR-21 include qRT-PCR, RT-LAMP, and electrochemical sensors.

Validation and Feasibility

Through documented research and results, it was concluded that using an electrochemical signal enhancement method is optimal due to its non-invasive, reproducible, and cost-effective nature. This approach can detect very small changes in current, making it highly sensitive. By integrating this approach using a screen-printed electrode, the biomarker signal can be amplified and measured using a compact amplifier-microcontroller setup with a digital readout, which will eventually be Bluetooth-enabled.

Our research also shows that miRNA-21's detectability under controlled experimental conditions is very high, with a correlation coefficient of 0.99 and similarity of 96.2% with artificial saliva. [1] The similarity between real and artificial samples verifies the high specificity and sensitivity of using this detection method. The screen-printed electrode used in the experiment also makes the detection of low miRNA-21 possible with concentrations on the order of 10^{-12}M. These findings support the feasibility of a low-cost, scalable diagnostic technology that delivers accurate results and is accessible to those who do not have access to other care methods.

Cashflow Analysis

For projected sales, our aim is to capture 3% of the market (26 million CAD) by Year 3. Our 24-month cash flow projections are included within our google drive in excel sheet format.

Target Market

The global breast cancer diagnostics market is projected to grow from USD 4.7 billion to USD 11.3 billion by 2035. The market growth is driven by initiatives for earlier screening and more accessible and effective testing solutions. [2] With the market growing at this rate, developing a technology that addresses consumers' need for quality screening services is paramount. Current approaches remain costly, inaccessible, and slow. For example, the standard for breast cancer screening, mammography, is widely used but can be uncomfortable, expensive, and inaccessible due to the legal guidelines in Canada, leaving younger individuals at risk, where breast cancer rates have increased by 45.5% over recent years.

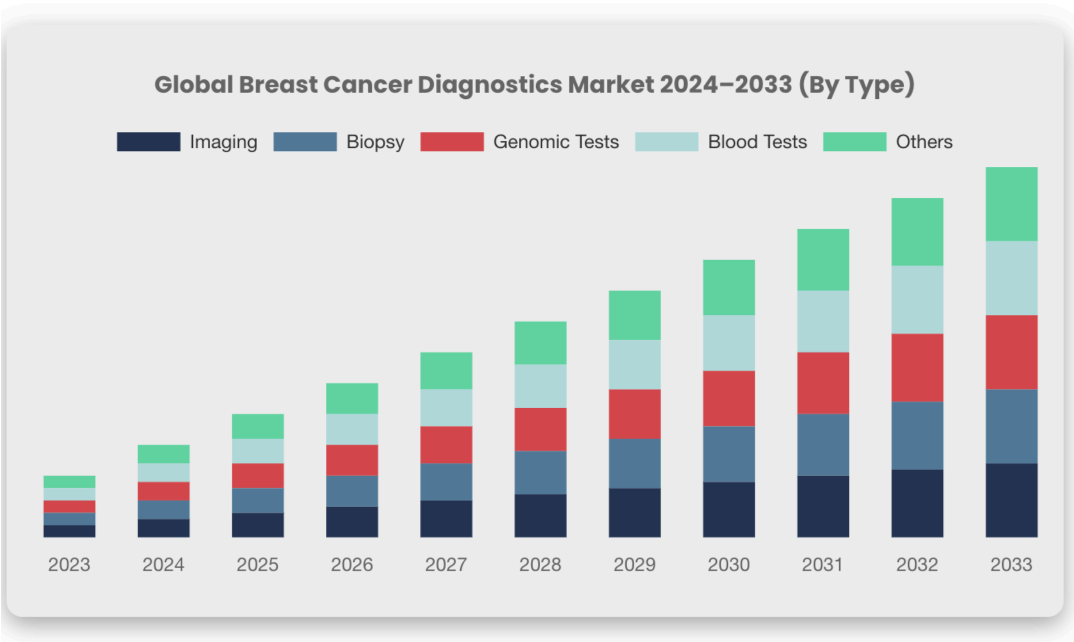


Figure 1. Global Breast Cancer Diagnostics Market Projection by 2033 [2]

Competitors in the market largely use mailed-in laboratory tests, which have delays. A point-of-care diagnostic tool provides immediate results, enabling patients to make informed decisions immediately so they can act early before the cancer becomes severe. Seeing as the market segment for point-of-care screening is proportionally small compared to other methods, bringing a device that can accurately and quickly diagnose gives younger individuals an option for getting early breast cancer screening.

The target audience identified for our technology is women between 25 and 50, as this is a group that is excluded from screening guidelines but is also at risk. [3] Broader access at an earlier age has the potential to significantly improve survival rates by detecting cancer when treatment is most effective. Since this is the target audience for the proposed product, focusing on the gap of not having an easily usable, accessible, non-invasive detection tool will influence the screening of this market substantially.

Current Team

Our current team is made up of a mixture of both graduate and undergraduate students all from the University of Toronto. Tala Mehdi (UofT Global Health & Pharmacology 2026), Marie-Jeanne Baroudi (UofT Health & Disease 2025), Maximilliano Weinstein (UofT Mechanical Engineering 2028) and Kirti Saxena (UofT Mechanical Engineering 2025) are the original founders of HER2HER. Both MJ and Kirti continuously pitched for HER2HER during the Hatchery Entrepreneurship program in the summer of 2025 and Tala pitched in the fall semester of 2025 during the H2i program. Currently the team is associated with the University of Toronto's H2i accelerator until April 2026. Down below is a quick summary of all founders. Ridham Goyal (Waterloo Mechatronics Engineering 2025) was brought on as an external contractor to help build the prototype and Justin Yuan (UofT Mechanical Engineering 2028), Mantej Cheema (TMU Biomedical Engineering 2028), Thariq Pasha (UofT Electrical Engineering 2028) and Loago Zambe (UofT Computer Science 2028) were brought on as interns for a term position.

Kirti Saxena - Founder

Kirti is a mechanical engineer specializing in Mechatronics, AI, and Materials Science, with industry experience at Tesla, Bombardier Aerospace, Seaspan, and PepsiCo. She led the University of Toronto Autonomous Rover team, specialized in machine learning, AI and Material Science. As a founder, she has built startups in AI-powered recruitment and sustainable materials (Ajna), and has maintained a parallel career as a signed fashion model and a Team Canada wrestler. She is ranked 5th in the world and was an Olympic alternate. She brings discipline, leadership, and resilience to every project.

Tala Mehdi - Founder

Tala holds a BSc in Pharmacology and Global Health from the University of Toronto and brings experience across global health programs, clinical management, and public health infrastructure. She has contributed to WHO-aligned TB management, safer supply toolkits, and health equity initiatives. As VP Student Life at UTSU, she helped shape university-wide policies and student engagement. Tala co-founded Darcenna Solutions, a health-tech venture improving antidepressant prescribing through pharmacogenomic insights. Her strengths include research, policy writing, stakeholder mapping, and strategic analysis.

Marie-Jeanne Baroudi - Founder

Marie-Jeanne holds a B.Sc. in Health & Disease with minors in Physiology and Philosophy and is a published co-author in rare disease genomics. She brings hands-on clinical experience supporting 20+ surgeries, conducting genomic analyses (Exome/NGS, PCR, Sanger), and applying clinical variant interpretation tools. She has contributed to AI startup Scopium through FDA pathway research and regulatory compliance strategy. As Founder & President of the Biotechnology Innovation and Development Club (500+ members), she has established industry and research partnerships. Her background spans global health research, mentorship, and art exhibitions.

Maximilliano Weinstein - Founder

Max is a mechanical engineering student specializing in Solid Mechanics and Energy Systems, with experience in aerospace propulsion and rocketry design. He has served as Safety and Testing Officer for U of T's Aerospace Team and as a F!ROSH Week leader. Through the Engineering Outreach Office, he develops and teaches courses in robotics and aviation for high school students. He brings strong technical skills, leadership abilities, and a passion for engineering education.

Team Advisors

- Norma Beauchamp
  - Independent director of various pharmaceutical companies
  - BBA in Marketing
- David Mousavi
  - FinTech & Regulatory Lawyer
  - JD/MBA
- Tarang Khare
  - Biomedical Scientist, Consultant
  - PhD in Molecular Genetics, MBA
- Celine Williams
  - Founder and Chief Strategist at reVisionary
  - Honors BA in Communication
- Paul Santerre
  - H2i connection at University of Toronto
  - Paul.Santerre@dentistry.utoronto.ca
- Joseph Ferenbok
  - Department of Laboratory Medicine & Pathobiology, University of Toronto, H2i connection
  - joseph.ferenbok@utoronto.ca
- Sal Amarasinghe
  - Waterloo Engineering Undergraduate, MIT Masters of Engineering
  - Created and sold a Saliva based prototype with biomarkers for cortisol levels and stress

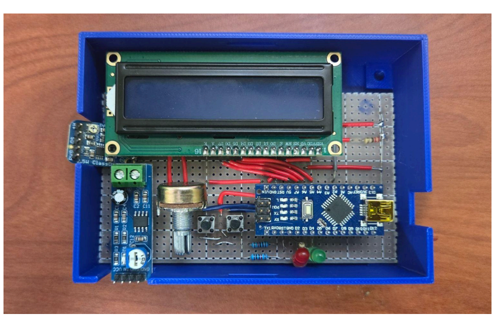
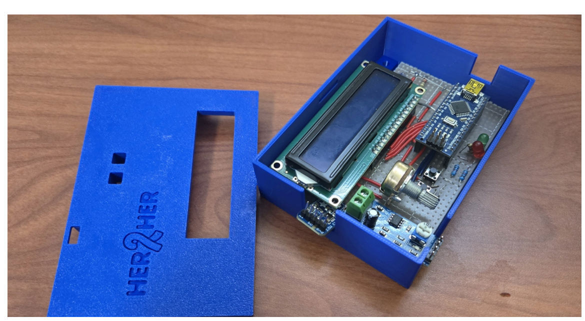
    - Saluka@gmail.com
- Dr. Raymond Khan
    - Raymond.khan1@astrazeneca.com
    - AstraZeneca connection
- Dr. Liu
    - liujw@uwaterloo.ca
    - Engineering Professor, University of Waterloo
- Dr. Mousumi Majumder
    - Professor, Brandon University
    - majumderm@brandonu.ca

Solution

Users will spit onto single-use electrode chips with a well for the saliva, which is then inserted into the device for analysis after the saliva interacts with the reagents. An electrochemical reaction occurs, generating a small current measurable on the rGO/Au nanocomposite-coated electrode strip. The amplified signal is processed digitally and transmitted to the mobile app for readout by the microcontroller. Once the analysis of the sample is complete, the biowaste is deposited into a waste chamber for easy disposal after use. For the sample analysis, an AI model will be used to improve prediction accuracy. The model will be trained on large clinical datasets to refine its sensitivity and specificity, reducing the number of false positives and negatives. To accomplish this workflow, choosing the correct components and understanding how they will interact will make this technology feasible and usable.

Technical Overview

The successful completion of our initial prototype, made possible by thorough research and development, was achieved through the meticulous selection and integration of multiple technological components into our design. This section highlights the tools/equipment, including the technical process, that were essential in enabling our design to perform its intended functions. These components play a key role in transforming our concept into a working prototype, and the overview is complemented by a diagram of our PCB design.

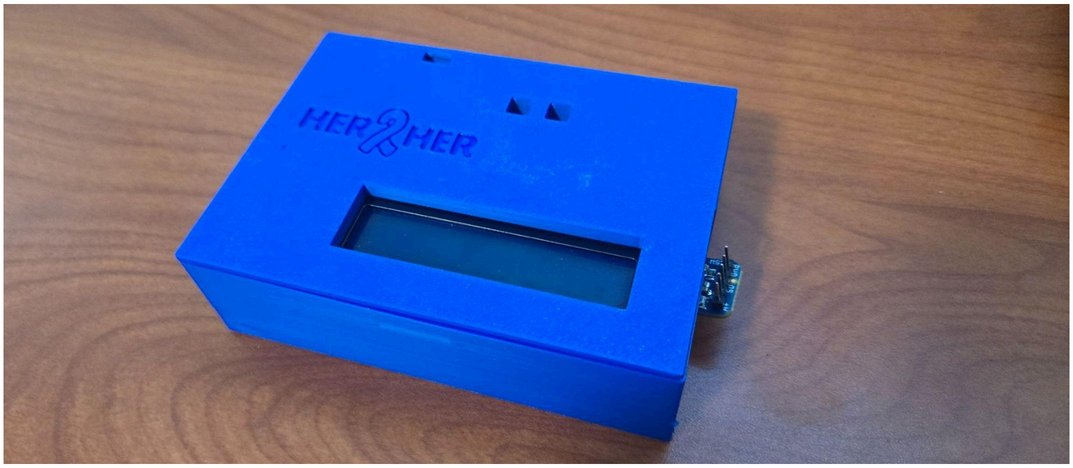


Figure 2: Prototype Design

Electrical Component Breakdown

This section goes over the electrical section of our prototype, identifying the parts used and their purpose, followed by a diagram of our PCB design.

Table 1: Overview of Electrical Components

Component Name	Component Purpose	Part Number	Datasheet
Arduino Nano	Microcontroller (brain)	Nano Board CH 340/ATmega+328P	https://docs.arduino.cc/hardware/nano/
16x2 LCD Display	Output to display information	1602A-1 LCD Display	https://www.openhacks.com/uploadsproductos/eone-1602a1.pdf
Push Buttons	Input for options	6mm Push Buttons	https://www.hdk.co.jp/pdf/eng/e291702.pdf
Potentiometer	Control screen brightness	Model P232/P233 24mm Rotary Potentiometer	https://components101.com/sites/default/files/component_datasheet/potentiometer%20datasheet.pdf
5mm LED	Output to display information	5mm LED, red, green	N/A
220, 10k Ohm Resistor	Prevent current overload to some	Type resistor	N/A

	components		
Audio Amplifier 1.0	To amplify the signal from the strip and compare	PAM8302	https://cdn-learn.adafruit.com/downloads/pdf/adafruit-pam8302-mono-2-5w-class-d-audio-amplifier.pdf
Audio Amplifier 2.0	To amplify the signal from the strip and compare	LM386	https://www.ti.com/lit/ds/symlink/lm386.pdf

There are 2 audio amplifiers shown, only 1 will be used in the final model. Both seem to be functional for the application, but testing to show accuracy needs to be done.

Schematic & PCB Layout

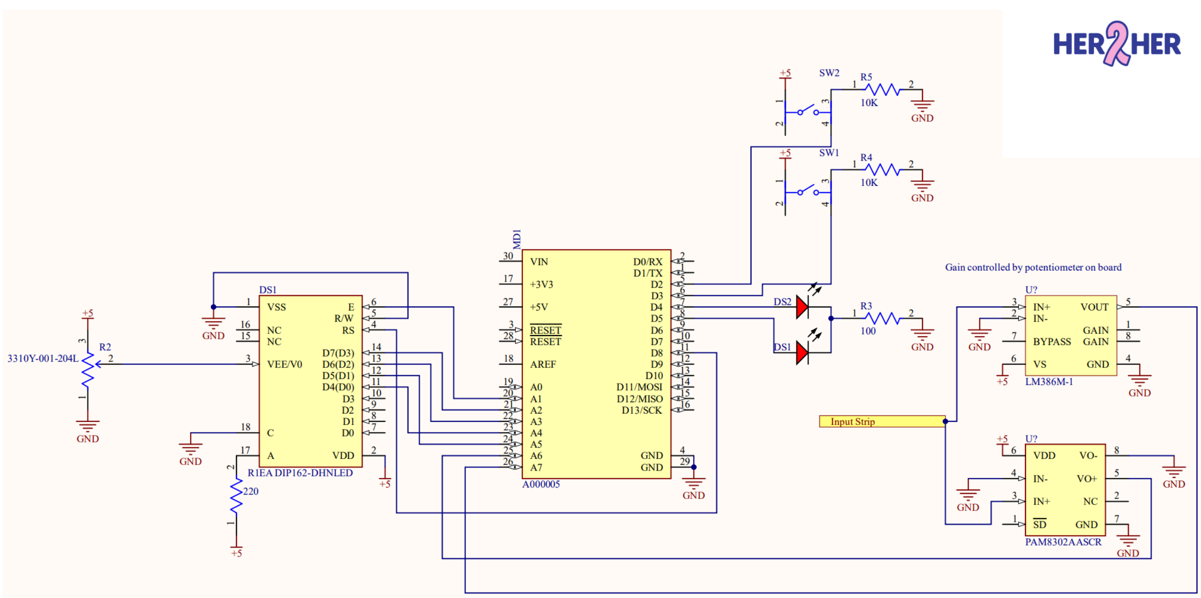


Figure 3: Prototype Layout

Methodology:

Since we want to detect miRNA-21, which is the biomarker we are using. But the concentration is very low or is scarce in samples, and hence is difficult to measure directly, so we need to amplify it. Amplification is used to try to make it easy to detect the samples. This can be achieved by creating more copies of the target, or by producing a big measurable change (electrical, optical, etc) whenever a target binds.

Some strategies which we decided to look into were:

1. Hybridization Chain Reaction (HCR)
2. Enzyme-Assisted Cascades (eg, DSN, EXO III, RCA)
3. DNA Nanostructure Cascades
4. Electrochemical Cascade Amplification [4]

Each option has different features and operating mechanisms, which have their pros and cons, but we use the following factors when making a decision:

- Sensitivity
- Speed
- Cost
- Compatibility with electrochemical sensors

We have decided to proceed with method 4, which is Electrochemical Cascade Amplification (ECA), because this is the least challenging and gives us the option to use/leverage electrochemistry (redox). This method also needs the use of a Catalytic Hairpin (CHA) [5][6], which is enzyme-free and hence has no conditions. The CHA can thereby be engineered to be used on electrode surfaces, which can, at later stages, also be used with transistors to monitor miRNA-21 and provide results.

Current Risk and Challenges

Some of the challenges that were encountered in the research and development of this non-invasive technology are as follows:

1. The low or scarce samples of miRNA-21, but this can be solved with amplification methods, since we chose ECA for amplification; Interference is a challenge. If there are other electrons present or any other transfer of electrons takes place due to other external factors, this may mislead the results used during ECA.
2. Electrically, there can be obstacles of possible sensitivity and signal issues. A few of these challenges are related to the saliva strip but can be overcome by using the right amplifiers and signal filters to reduce the noise and clean up the signal. The number of papers and resources available for this obstacle is advantageous in mitigating the imminent errors.

Moving forward, the risks and challenges to be addressed are the accuracy of the device when distinguishing between positive and negative cases, and having the discretion to separate between false positives (specificity) and false negatives (sensitivity). To resolve this problem, extensive testing will be completed to verify and validate the device's accuracy, and building AI tools with sufficient training and fine-tuning to aid with screening classification will give the product more credibility.

Furthermore, another risk that needs to be addressed is the collection of saliva samples and the process of preserving the samples to prevent degradation, so that tests and experiments are not skewed. Resolving this problem requires potential partnerships with clinics, biobanks, and other companies that can supply samples and prepare them in controlled environments. These partnerships will enable consistent and substantial testing of the prototype so that validation can be completed, leading to early optimization of saliva collection directly on the device using the single-use chips.

Once these risks and challenges have been addressed, the prototype will move onto the iterative design and optimization stage, where the overall design will be considered and modified to satisfy constraints, and the internal electrical components may be changed to make the generated signal and amplified signal stronger.

Future Scope

The use of transistors is a prospective modification to improve the generated signal during detection and enhance the functionality and versatility as well. The integration of transistors will enable more complex operations, such as acting as digital switches, forming the fundamentals for logic gate functions, and automating control processes. Additionally, they can aid the electronic signal amplification and improve the regulation of redox reaction, therefore expanding the systems' analytical and operational capabilities.

Another modification that can be made is implementing transistors in PCBs as a way to scale and create better circuit layouts, increasing the computational capacity. Overall, this can make the data processing more advanced and can enable real-time feedback, which can expand the range of biological interactions that can be monitored with precision.

Some general improvements that can be made to the overall design of the product are the fabrication of a single-board device for the electronics, and improving the design of the single-use saliva cartridge to allow better flow of the sample and mixture with reagents to increase the generated signal.

References:

[1] S. Shin Low, Y. Pan, D. Ji, Y. Li, Y. Lu, Y. He, Q. Chen, Q. Liu, “Smartphone-based portable electrochemical biosensing system for detection of circulating microRNA-21 in saliva as a proof-of-concept,” *Sensors and Actuators B: Chemical*, vol. 308, p. 127718, Apr. 2020. Available: https://doi.org/10.1016/j.snb.2020.127718

[2] “Web Series Reviews,” *Custom Market Insights*, Jan. 15, 2025. Available: https://www.custommarketinsights.com/report/breast-cancer-diagnostics-market/

[3] T. Deb, “Breast Cancer Statistics 2024 By Types, Risks, Ratio,” *Market.us Media*, Apr. 03, 2024. Available: https://media.market.us/breast-cancer-statistics/

[4] J. Liu, Y. Zhang, H. Xie, L. Zhao, L. Zheng, and H. Ye, “Applications of Catalytic Hairpin Assembly Reaction in Biosensing,” Small, vol. 15, no. 42, p. e1902989, Oct. 2019 [Online]. Available: https://pubmed.ncbi.nlm.nih.gov/31523917/

[5] J. Liu, Y. Zhang, H. Xie, L. Zhao, L. Zheng, and H. Ye, “Applications of Catalytic Hairpin Assembly Reaction in Biosensing,” Small, vol. 15, no. 42, p. e1902989, Oct. 2019. [Online]. Available: https://pubmed.ncbi.nlm.nih.gov/31523917/#:~:text=A%20typical%20CHA%20reaction%20is,circuits;%20toehold%20mediated%20strand%20displacement

[6] J. Li, R. Cai, and W. Tan, “A Novel ECL Sensing System for Ultrahigh Sensitivity miRNA-21 Detection Based on Catalytic Hairpin Assembly Cascade Nonmetallic SPR Effect,” Anal. Chem., vol. 94, no. 36, pp. 12280–12285, Sep. 13, 2022 [Online]. Available: https://pubs.acs.org/doi/10.1021/acs.analchem.2c03238

[7] "Transistor," Wikipedia. [Online]. Available: https://en.wikipedia.org/wiki/Transistor