SDS OPTIC®

inPROBE®
Smart Cancer Diagnostics

DIAGNOSTIC SYSTEM

CORPORATE PRESENTATION

Marcin Staniszewski
Chief Executive Officer

FORWARD LOOKING STATEMENTS

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LUBLIN, POLAND

HEADQUARTERS AND R&D CENTER

- inPROBE® sensors production
- Optoelectronics and molecular R&D
- Monoclonal antibodies lab production
- Virus diagnostic device platform development

PHILADELPHIA, USA

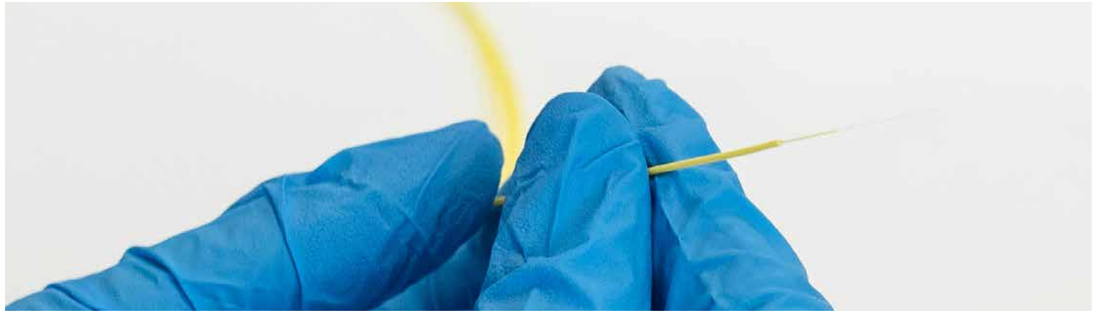
PHILADELPHIA LABORATORY

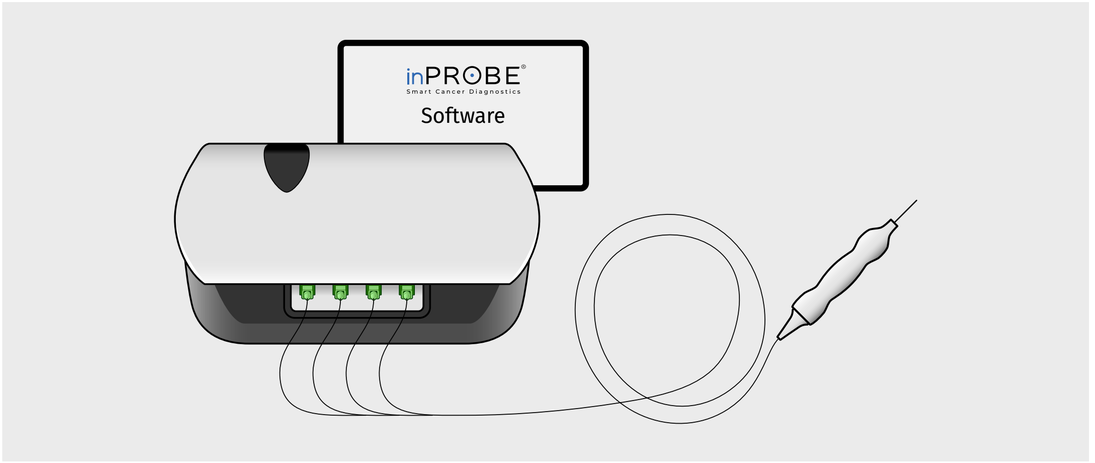
- Novel proteins and biomarkers development for cancer and eye research programs
- Protein cloning, expression and purification
- Protein characterization – properties and specificity

inPROBE® DIAGNOSTIC TECHNOLOGY

For both in-vivo and in-vitro applications

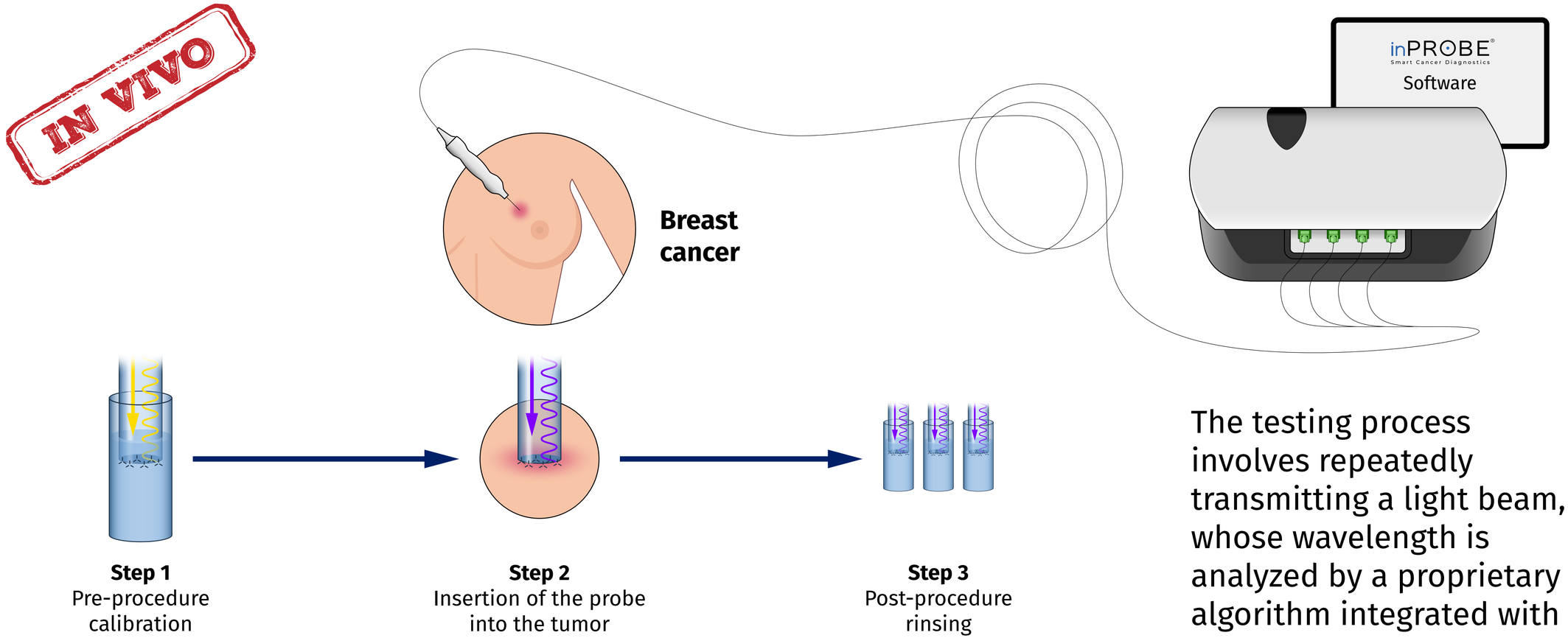
- **First photonic real-time immunoassay system,** utilizing molecular biology, chemistry, and biomedical engineering
- **Real-time detection of HER2 biomarker** and potentionally also other proteins, antibodies and peptides, including other cancer biomarkers
- **Potential point-of-care diagnostic aid** to support and reduce the time to diagnosis





- **Novel analyzer with photonic sensor probe** consisting of 4 microprobes for biomarker detection in tissue and liquid samples
- **Each microprobe tip covered with monoclonal antibodies (mAbs)** for HER2 or other chosen target detection

inPROBE® Dx OVERVIEW – BREAST CANCER



The testing process involves repeatedly transmitting a light beam, whose wavelength is analyzed by a proprietary algorithm integrated with a ML component

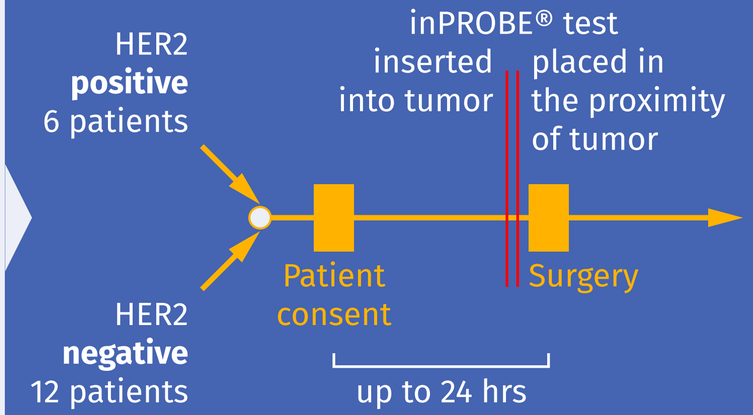
inPROBE® CLINICAL STUDY (PoC)

Open label, multicenter, single arm, Clinical Investigation of inPROBE® for the assessment of HER2 receptor expression in breast cancer completed March 2023

Study population

- 18 women with high risk breast cancer
- Age between 18 and 75 years old
- ECOG: 0 to 1
- Presence of breast cancer confirmed by core needle biopsy with a specified HER2 receptor status at the time of exam

Overall Study Design



Primary endpoint

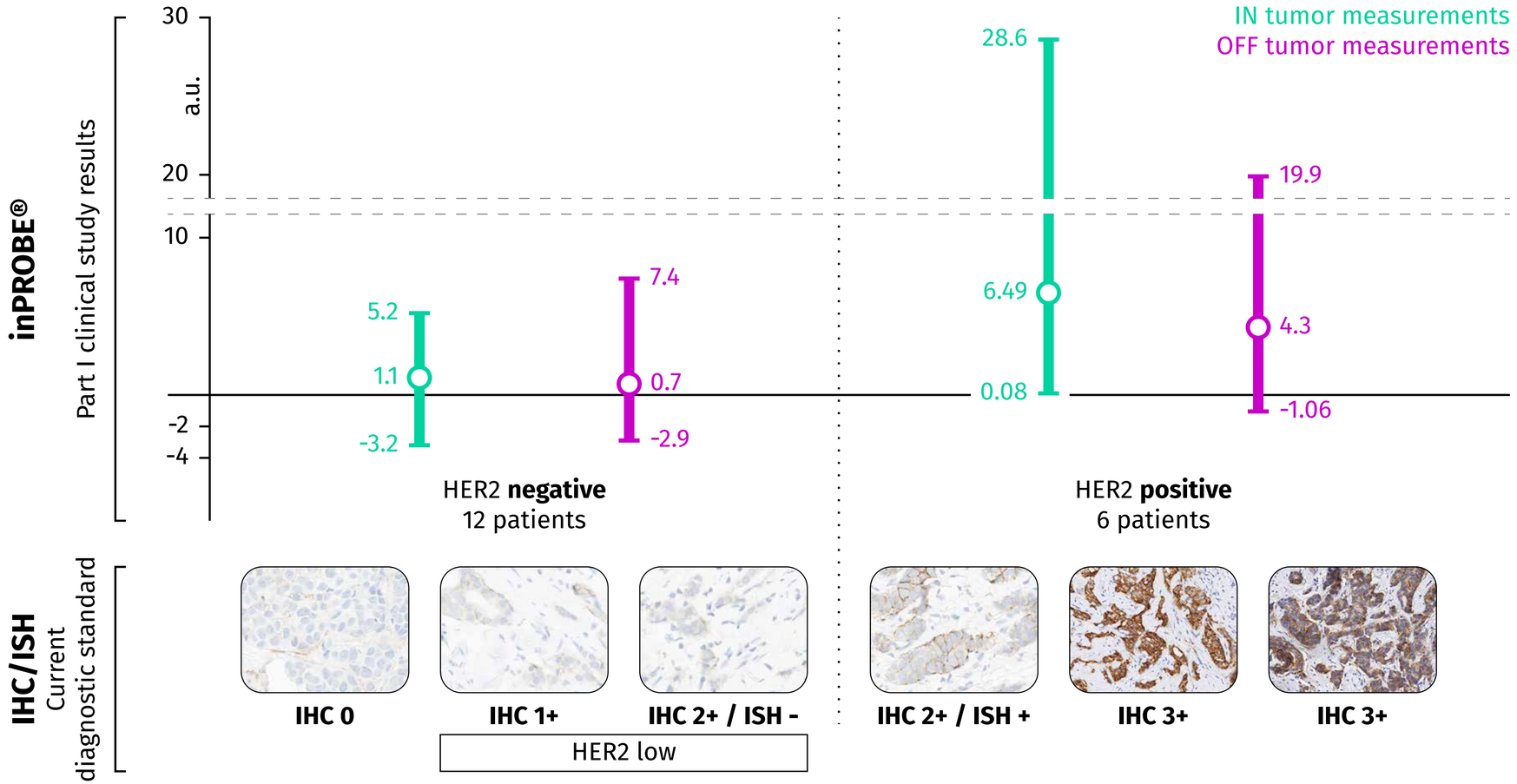
Determination of the range of HER2 receptor concentrations using inPROBE that correspond to the HER2 receptor status (positive/negative) determined by IHC/FISH (diagnostic standard).

Key secondary endpoints

Comparison of HER2 receptor concentrations detected using the inPROBE probe located in the tumor and its immediate surroundings (second probe) in HER2-positive patients.

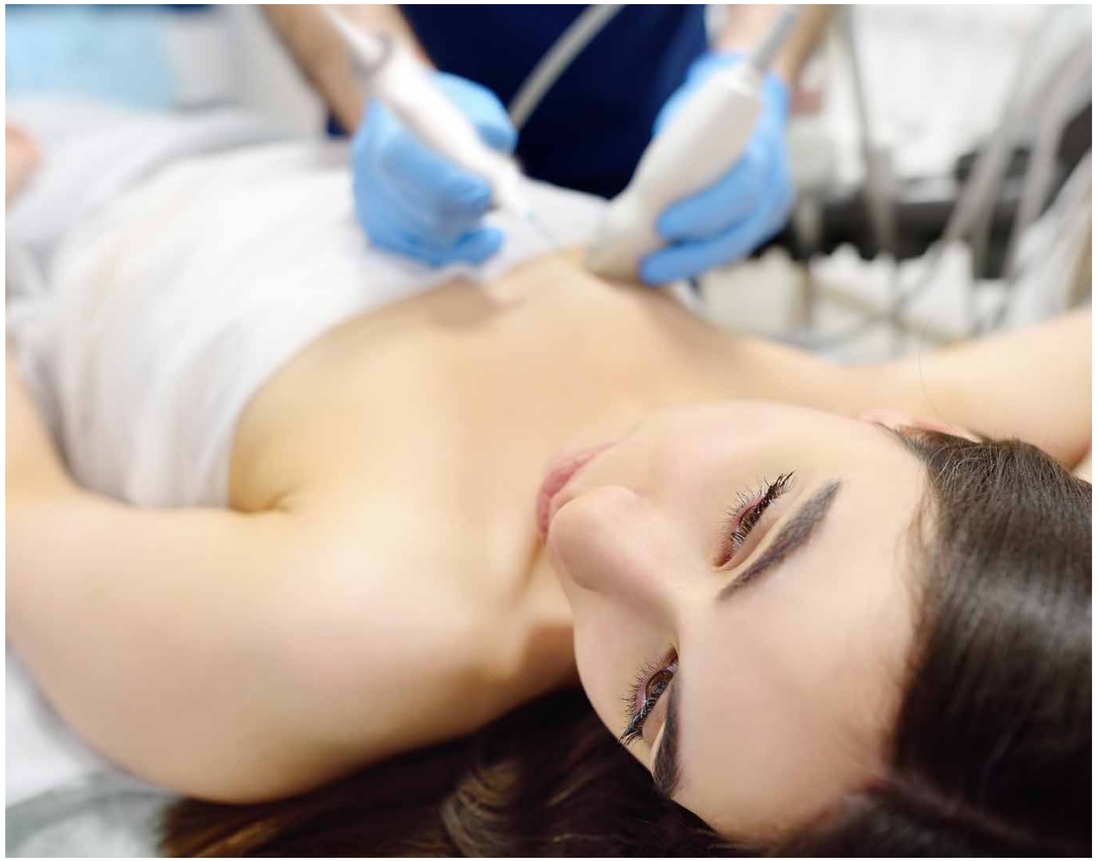
The occurrence of incidents involving damage, failure, or breakage of inPROBE during the diagnostic procedure, leading to AE/SAE.

inPROBE® CLINICAL STUDY (PoC)



inPROBE® CLINICAL STUDY (PoC) – PART II

- **Part II diagnostic efficacy study** previously planned to include 192 patients
- **We intend to adapt the Clinical Trial Protocol** to focus also on HER2–low patients
- **The final study design** to be consulted with US FDA
- **We are responding to the needs** of the current global trend in HER2-low and HER2-ultralow detection
- **Further inPROBE® calibration** vs. HER2 levels is planned to be performed



inPROBE® CASE REPORT GASTRIC CANCER

EORTC-NCI-AACR (2024)

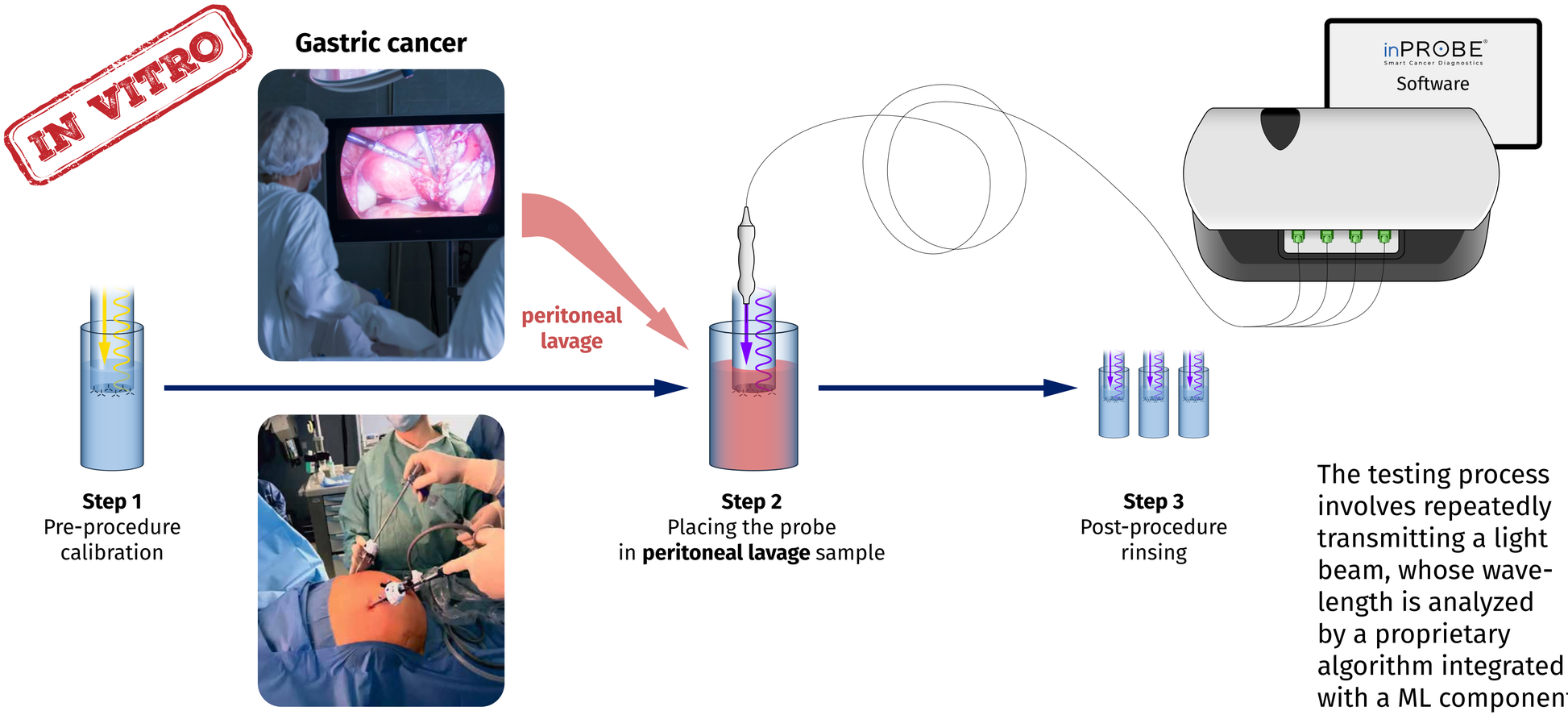
- **inPROBE® recorded a positive signal for HER2 in tested peritoneal lavage samples**

- Assessment of HER2 expression in peritoneal lavage (PL) in gastric cancer (GC) patients is feasible and may be an effective method of increasing the identification rate for potential target therapy among selected patients

- inPROBE® technology presents an opportunity for HER2 determination in vitro during diagnostic laparoscopy in GC patients

- HER2 is an established predictive and prognostic biomarker in GC patients, assessed by immunohistochemistry (IHC) in tumor cells

inPROBE® Dx OVERVIEW – GASTRIC CANCER



The testing process involves repeatedly transmitting a light beam, whose wave-length is analyzed by a proprietary algorithm integrated with a ML component

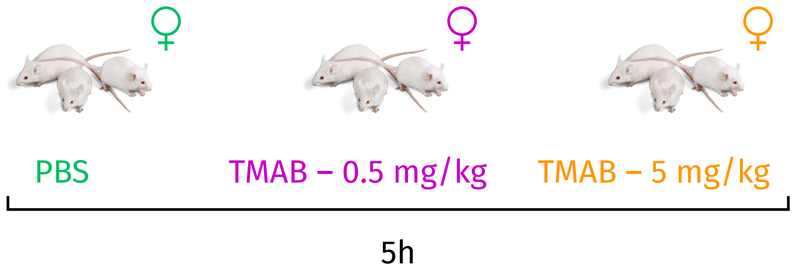
HER2 OVEREXPRESSING CANCERS

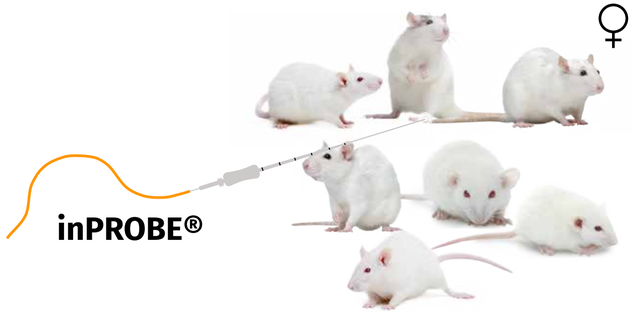
HER2-expressing cancers are a group of aggressive tumors often associated with faster progression and a poorer prognosis.

While HER2 positivity can accelerate tumor growth, targeted therapies have significantly improved patient outcomes. Accurate assessment of HER2 status is essential for selecting optimal treatments and advancing precision medicine research.

inPROBE® PRE-CLINICAL STUDY (PoC)

inPROBE® AS A PLATFORM FOR CANCER BIOMARKERS DETECTION IN SITU

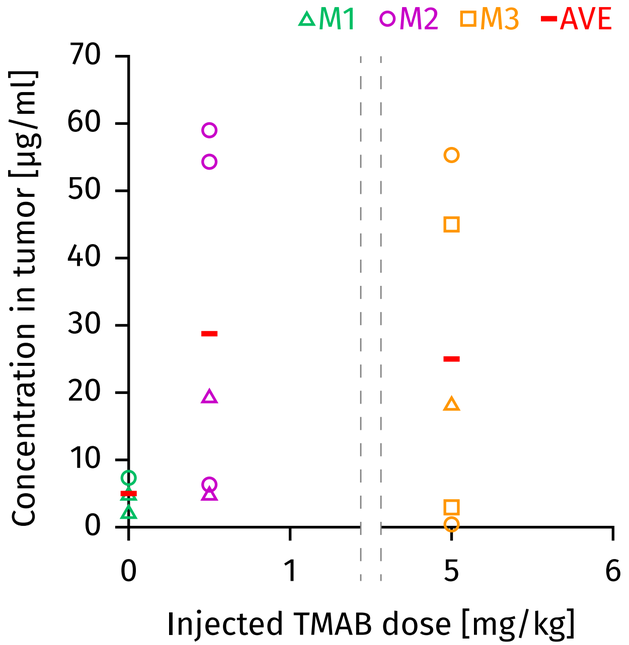




Tissue accumulation of TMAB was assessed in vivo using sensor dedicated for TMAB and the mouse xenograft model (SCID mice) of a human HER2+ cancer (SK-OV-3).

The device safety was confirmed on rats by probe insertion into the mammary glands.

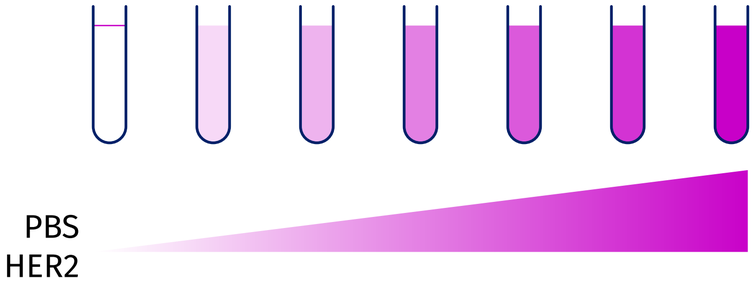
ESMO (2023), EORTC-NCI-AACR (2022)



After TMAB injection at 0.0, 0.5 or 5 mg/kg, measurements were performed inside tumor using inProbe sensor.

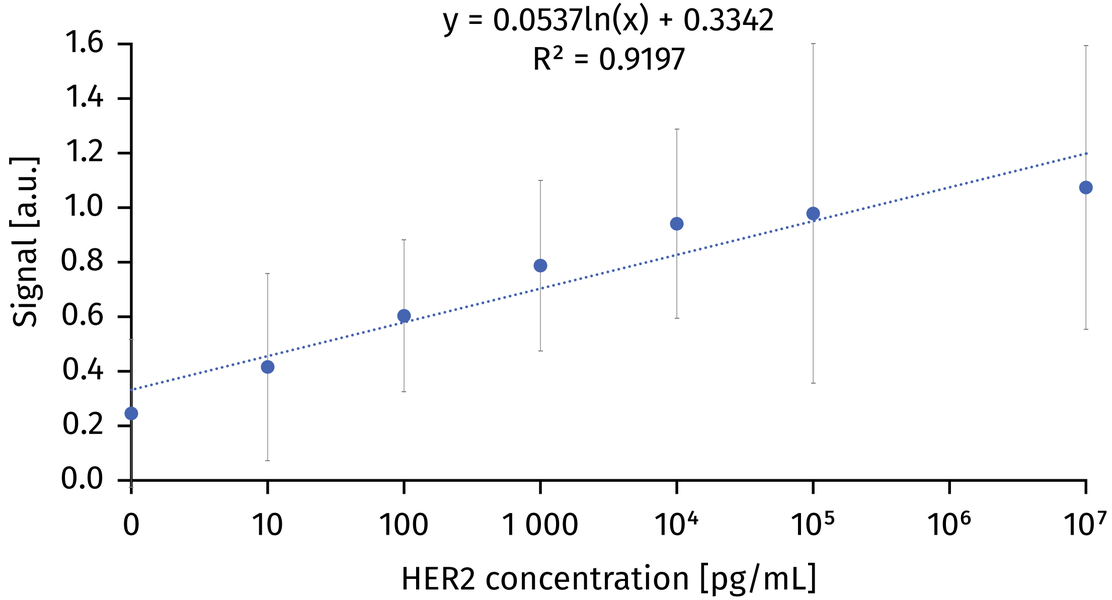
inPROBE® PRE-CLINICAL STUDY (PoC)

inPROBE® AS A PLATFORM FOR CANCER BIOMARKERS DETECTION IN LIQUID SAMPLES



inPROBE signal measurements (a.u.) was recorded for the PBS solution of recombinant human ECD HER2-Fc chimeric protein within a concentration range of 1 pg-10 mg/ml.

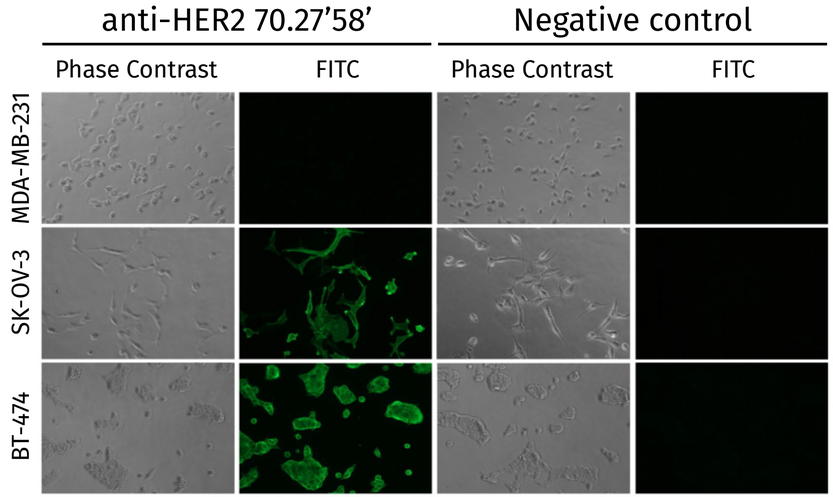
ESMO (2023), EORTC-NCI-AACR (2022)



Calibration curve for HER2 detection

inPROBE® PRE-CLINICAL STUDY (PoC)

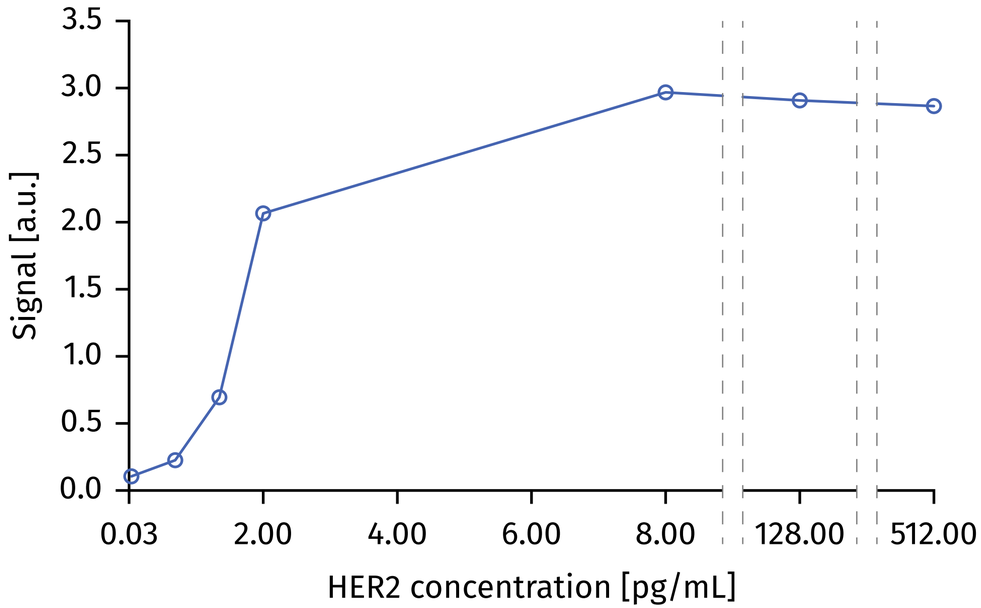
inPROBE® ANTIBODY SPECIFICITY AND SENSITIVITY FOR HER2 BIOMARKER DETECTION



Antibody specificity

HER2- (MDA-MB-231) and HER2+ (SK-OV-3, BT-474) human cancer cells were observed under light microscope (Phase contrast) and stained with SDS proparietary anti-HER2 antibody followed by FITC secondary antibody (green) or FITC secondary antibody alone (Negative control).

ESMO (2023), EORTC-NCI-AACR (2022)



Antibody sensitivity

ELISA on a plate with the immobilized recombinant ECD HER2-Fc chimeric protein was performed using the anti- HER2 antibody further applied for inPROBE sensor.

PUBLICATIONS 2024-2025

HER2-low and HER2-ultra-low 2024-2025 updates

ENHERTU® (fam-trastuzumab deruxtecan-nxki) approved in the US as first HER2-directed therapy for patients with HER2-low or HER2-ultralow metastatic breast cancer following disease progression after one or more endocrine therapies

PUBLISHED
27 January 2025

Based on DESTINY-Breast06 Phase III trial results which showed ENHERTU demonstrated superiority vs. chemotherapy with a median progression-free survival of more than one year

Approval brings AstraZeneca and Daiichi Sankyo's ENHERTU to an earlier HR-positive treatment setting and broadens the patient population eligible for treatment with a HER2-directed therapy to those with HER2-ultralow disease

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Journal of Clinical Oncology
An American Society of Clinical Oncology Journal

Meeting Abstract: 2024 ASCO Annual Meeting I

FREE ACCESS | Breast Cancer—Metastatic | May 29, 2024

DESTINY-Breast07: Dose-expansion interim analysis of T-DXd monotherapy and T-DXd + pertuzumab in patients with previously untreated HER2+ mBC.

Authors Fabrice Andre, Erika P. Hamilton, Sherene Loi, Carey K. Anders, Peter Schmid, Daniil Stroyakovskiy, Rafael Villanueva, ... SHOW ALL ..., and Komal L. Jhaveri | AUTHORS INFO & AFFILIATIONS

Publication: Journal of Clinical Oncology • Volume 42, Number 16_suppl • https://doi.org/10.1200/JCO.2024.42.16_suppl.1009

ASCO Guidelines | COLLEGE of AMERICAN PATHOLOGISTS | HER2 TESTING IN BREAST CANCER

GUIDELINE UPDATE

The 2018 ASCO-CAP recommendations for HER2 testing in breast cancer are affirmed.

The Panel recommends against creating new HER2 testing reporting categories such as "HER2 Low," because of a current lack of data on prediction of differential treatment response relative to patients with HER2 IHC 0 results. Standard semi-quantitative HER2 IHC results (0, 1+, 2+, 3+) should continue to be reported and best practices should be employed to distinguish these categories to identify patients eligible for approved HER2-related treatments, including those that meet DESTINY-Breast04 criteria (IHC 1+ or 2+/ISH negative). A new HER2 testing report comment is recommended to clarify the current clinical relevance of these semi-quantitative IHC results.

Wolff et al *J Clin Oncol* 2023
asco.org/breast-cancer-guidelines

Abbreviations. ASCO, American Society of Clinical Oncology; CAP, College of American Pathologists; HER2, human epidermal growth factor receptor 2; IHC, immunohistochemistry; ISH, in situ hybridization.

Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer: ASCO–College of American Pathologists Guideline Update

Antonio C. Wolff, MD[1]; Mark R. Somerfield, PhD[2]; Mitchell Dowsett, PhD[3]; M. Elizabeth H. Hammond, MD[4]; Daniel F. Hayes, MD[5]; Lisa M. McShane, PhD[6]; Thomas J. Saphner, MD[7]; Patricia A. Spears, BS[8]; and Kimberly H. Allison, MD[9]

DOI https://doi.org/10.1200/JCO.22.02864

ABSTRACT

PURPOSE To update ASCO–College of American Pathologists (CAP) recommendations for human epidermal growth factor receptor 2 (HER2) testing in breast cancer. The Panel is aware that a new generation of antibody–drug conjugates (ADCs) targeting the HER2 protein is active against breast cancers that lack protein overexpression or gene amplification.

ACCOMPANYING CONTENT
Appendix
Data Supplement

Accepted March 29, 2023
Published June 7, 2023

COLLEGE of AMERICAN PATHOLOGISTS

FAQs

Topic: HER2 Testing in Breast Cancer: Guideline Update
Date: June 7, 2023

What was the impetus of this guideline update?
In 2022, based on results of the DESTINY-Breast04 trial, the United Stated Food and Drug Administration (FDA) expanded the approval of the HER2 antibody-drug conjugate, trastuzumab deruxtecan, from metastatic breast cancer patients with HER2 protein over-expression/amplification to also include metastatic patients with HER2 IHC 1+ or 2+/ISH negative results. This clinical trial adopted new terminology, "HER2 Low," as short-hand for the HER2 IHC 1+ or 2+/ISH negative breast cancer cases that were in the trial (patients with IHC 0 results were excluded). Since the CAP/ASCO Guideline does not include "HER2 Low" as an interpretive category, a systematic review of the literature was performed to determine if changes to the guideline were needed.

ESMO GOOD SCIENCE BETTER MEDICINE BEST PRACTICE | ANNALS OF ONCOLOGY driving innovation in oncology

SPECIAL ARTICLE

ESMO expert consensus statements (ECS) on the definition, diagnosis, and management of HER2-low breast cancer

P. Tarantino[1,2,3], G. Viale[4], M. F. Press[5], X. Hu[6], F. Penault-Llorca[7], A. Bardia[2,8], A. Batistatou[9], H. J. Burstein[1,2], L. A. Carey[10], J. Cortes[11,12], C. Denkert[13], V. Diéras[14], W. Jacot[15], A. K. Koutras[16], A. Lebeau[17], S. Loibl[18,19], S. Modi[20], M. F. Mosele[21], E. Provenzano[22], G. Pruneri[1,23], J. S. Reis-Filho[24], F. Rojo[25], R. Salgado[26,27], P. Schmid[28], S. J. Schnitt[2,29], S. M. Tolaney[1,2], D. Trapani[1,30], A. Vincent-Salomon[31], A. C. Wolff[32], G. Pentheroudakis[33], F. André[34] & G. Curigliano[1,30]

SDS OPTIC®

inPROBE®
Smart Cancer Diagnostics

SDS OPTIC POSTERS

Full texts available upon request

2024 ASCO ANNUAL MEETING

May 31–June 4, 2024

McCormick Place | Chicago, IL & Online

#ASCO24

Innovative fiber-optic-based approach of HER2 expression quantitative assessment using inPROBE technology.

Dariusz M. Stencel, Marcin Staniszewski, Wojciech Polkowski, Andrzej Kurylcio, Przemysław Kopyto, Magdalena Staniszewska; SDS Optic Inc., Lublin, Poland; Medical University of Lublin, Lublin, Poland; Medical University, Lublin, Poland

Is HER2-negative breast cancer really negative? Clinical implication of novel assessment method using inPROBE technology.

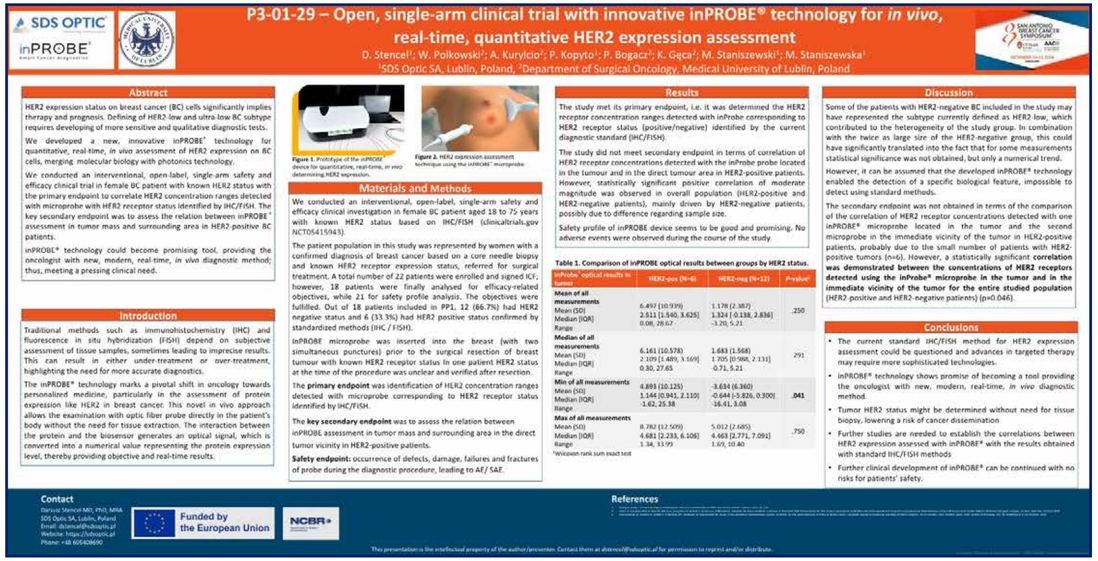
Dariusz M. Stencel, Wojciech Polkowski, Andrzej Kurylcio, Przemysław Kopyto, Marcin Staniszewski, Magdalena Staniszewska; SDS Optic Inc., Lublin, Poland; Medical University of Lublin, Lublin, Poland; Medical University, Lublin, Poland; Institute of Health Sciences Faculty of Medicine The John Paul II Catholic University of Lublin, Lublin, Poland

SAN ANTONIO BREAST CANCER SYMPOSIUM®

UT Health San Antonio Mays Cancer Center | AACR American Association for Cancer Research

DECEMBER 10–13, 2024

HENRY B. GONZALEZ CONVENTION CENTER • SAN ANTONIO, TX

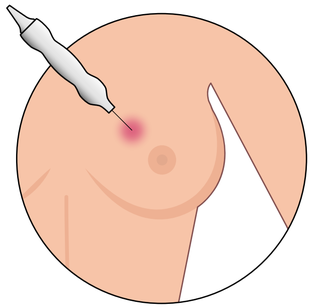


inPROBE® POTENTIAL FUTURE APPLICATIONS

Clinical needs
- disease risk for prognosis evaluation
- clinical diagnosis support
- therapeutic intervention monitoring

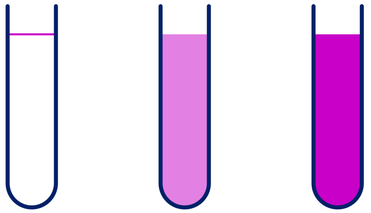
Possible detection
- targeted proteins and ADCs
- cell membrane fragments
- vesicles and viruses

SOLUBLE BIOMARKERS DETECTION AND QUANTIFICATION (AFTER A SENSOR CALIBRATION)



In vivo (in situ)
Solid tumours biomarkers
eg. breast cancer (HER2)

In vitro (liquid samples)
- cerebrolspinal fluid
- blood
- urine
- saliva



COMPETITIVE LANDSCAPE

inPROBE® is less-invasive, point-of-care and less expensive

Current diagnostic standard

Feature	inPROBE®	IHC	ISH	ELISA	ForteBIO Octet®
Tissue Biopsy	**NO**	YES	YES	YES	YES
Real time result	**YES**	NO	NO	NO	NO
Location of test	**In vivo in vitro point of care**	In vitro – external laboratory	In vitro – external laboratory	In vitro – external laboratory	In vitro – external laboratory
Quantitative results	**YES**	NO	NO/YES	NO	YES
Estimated investment needed (€k)	**30**	260	110	80	120
Core technology	**Photonics Biosensing**	Immunohistochemistry	Fluorescence/ Molecular Cytogenetic	Enzyme-linked Immunosorbent Assay	Photonics Biosensing

COMPETITIVE LANDSCAPE (CONT.)

inPROBE® is less-invasive, point-of-care and less expensive

Feature	inPROBE®	Northern Blot	SAGE (Serial Analysis of Gene Expression)	MicroArray	RT-PCR (qPCR)
Tissue Biopsy	**NO**	YES	YES	YES	YES
Real time result	**YES**	NO	NO	NO	NO
Location of test	**In vivo in vitro point of care**	In vitro – external laboratory	In vitro – external laboratory	In vitro – external laboratory	In vitro – external laboratory
Quantitative results	**YES**	NO	NO	NO	YES
Estimated investment needed (€k)	**30**	X	X	X	X
Core technology	**Photonics Biosensing**	Hybridization of immobilized RNA	Transcriptomic	Chip binding / RNA isolated bath	Transcription

SENIOR MANAGEMENT TEAM

Marcin Staniszewski

Co-Founder

CEO

Chief Technology Officer

Magdalena Staniszewska

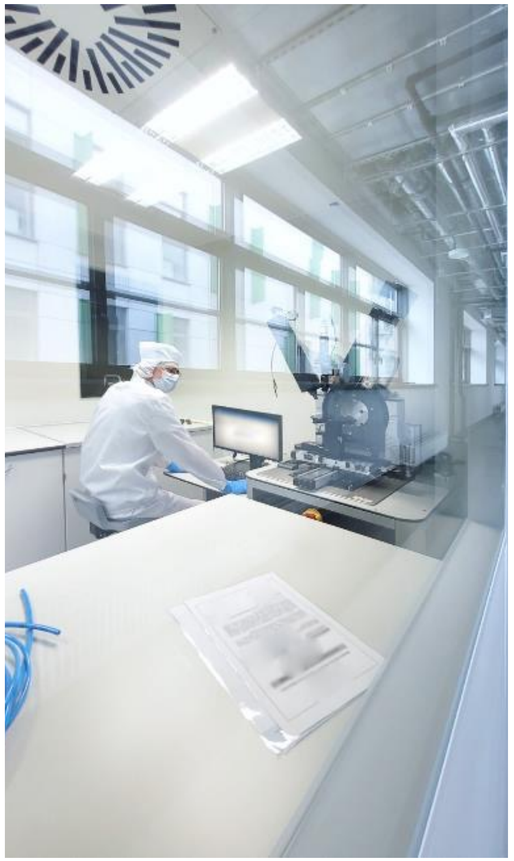
Co-Founder

CSO

Head of Scientific Advisory Board

SDS OPTIC FACILITY

- Own machine park valued at approximately $1M for the production of photonic components for inPROBE® biosensors
- Ability to scale up production from laboratory-scale to semi-industrial
- Full control of the quality of all production processes
- Planned production capacity of over 50,000 biosensors per year
- Confirmed compliance of process, technological, and manufacturing documentation audit by Orange (photonic division)
- **Dedicated Clean Room production and quality control facility compliant with EN ISO 14644**
- **Monoclonal antibody production facility**



QMS CERTIFICATION

inPROBE® REGULATORY STATUS

- External audit by TÜV Nord in 2023, 2024 and 2025
- EN ISO 13485 Quality Management System (QMS) Certification Granted in 2023
- Plans for initiation of EU-MDR certification for HER2+ Breast Cancer
- EU-MDR certification planned for 2027
- CE mark planned for 2027
- FDA consultation planned for 2025

TÜVNORD

CERTIFICATE

Management system as per
PN-EN ISO 13485:2016-04
Medical devices - Quality management systems - Requirements for regulatory purposes

In accordance with TÜV NORD Polska Sp. z o.o. procedures, it is hereby certified that

SDS OPTIC S.A.
ul. Głęboka 39, PL / 20-612 Lublin

SDS OPTIC Lifesaving Innovations

applies a management system in line with the above standard for the following scope

Design and production of a sterile probe for breast cancer diagnosis with accessories, an analyser and software.

Certificate Registration No. AC090 MD/2273/5431/2023
Audit Report No. PL5431/2023
Valid from 19-05-2023
Valid until 18-05-2026

Manager of Certification Body
TÜV NORD Polska Sp. z o.o.

Katowice, 19-05-2023

This certification was conducted in accordance with the TÜV NORD Polska Sp. z o.o. auditing and certification procedures and is subject to regular surveillance audits.

TÜV NORD Polska Sp. z o.o. ul. Mickiewicza 29 40-085 Katowice www.tuv-nord.pl

IAF MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT
PCA
AC 090

PHILIPS & CSEM / MEDPHAB

The Analyzer (detection device) industrialization and certification

- Scaling up from the clinical to the commercial prototype of the inPROBE® detection device (analyzer) and initiating medium-scale contract production
- Scaling up the project of optoelectronic and electronic elements of the analyzer
- Production (Philips) of a commercial prototype of the analyzer with comprehensive testing of its functional and systemic features
- Compliance with EU-MDR and EN ISO 13485 regulations
- Two optoelectronic system prototypes (System 1 & System 2) designed and tested, with quality set up and documentation preparations at PHILIPS – System SW 1 and System 2 Sprint
- 3D printed Housing design for System 1 (outer & inner) done with with elements and materials bill
- Risk analyses complianed with EU-MDR and EN ISO 14791 regulations
- Software designed according to EN 62304 and delivered

PHILIPS
Engineering Solutions

csem
FACING THE CHALLENGES OF OUR TIME

MedPhab
Photonic Medical Devices

Funded by: PHOTONICS21 PHOTONICS PUBLIC PRIVATE PARTNERSHIP

ANTIBODY MANUFACTURING SERVICES

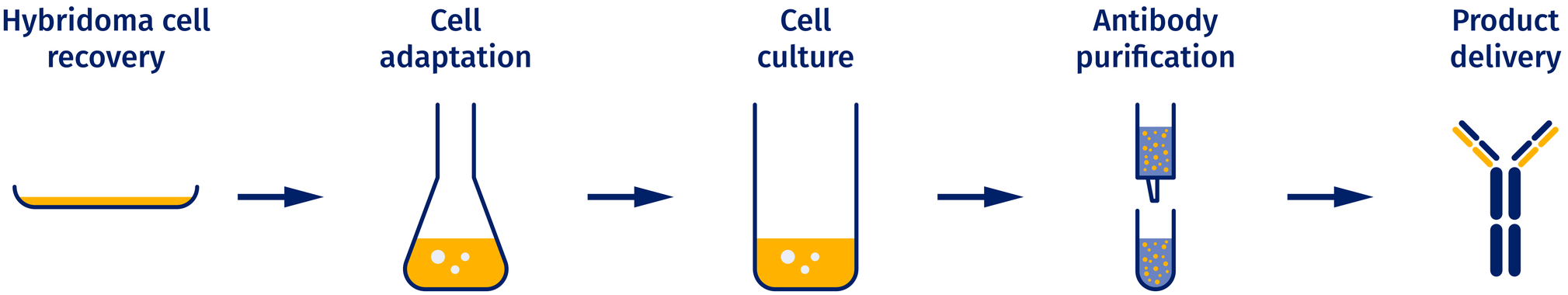
SDS OPTIC®

MONOCLONAL ANTIBODIES CAPABILITIES

for academic, biopharmaceutical and diagnostic entities

CUSTOM MONOCLONAL ANTIBODY SERVICES

Monoclonal antibodies discovery platform: hybridoma antibody production – up to 30 mg per month.



MONOCLONAL ANTIBODIES CAPABILITIES

for academic, biopharmaceutical and diagnostic entities

HYBRIDOMA CELL CULTURE AND ANTIBODY PRODUCTION TIMELINE

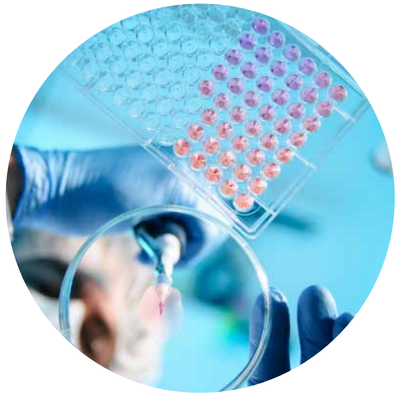
1-2 days	2-4 weeks	5-8 weeks	3 days	
Cell recovery Cell recovery and counting	**Cell adaptation** Cells adapted to serum-free or low-serum media Fed-batch cell culture process development	**Production and purification** Hybridoma cell culture at an appropriate scale Antibody purification by protein A/G	**QC analysis** SDS-PAGE, ELISA and UV analysis	**Deliverables** Purified antibodies CoA

- High purity
- Batch-to-batch reproducibility
- Low-serum or serum-free media
- Mycoplasma tested by PCR

INVESTMENT & PARTNERING OPPORTUNITIES

+€22 mln

raised for inPROBE®
research & development



€10 mln

EIB financing (venture
debt for 2024-2028)

€4 mln

Highest ever
Horizon2020 SME grant

€4 mln

Publicly listed

THANK YOU

CONTACT

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SDS OPTIC®