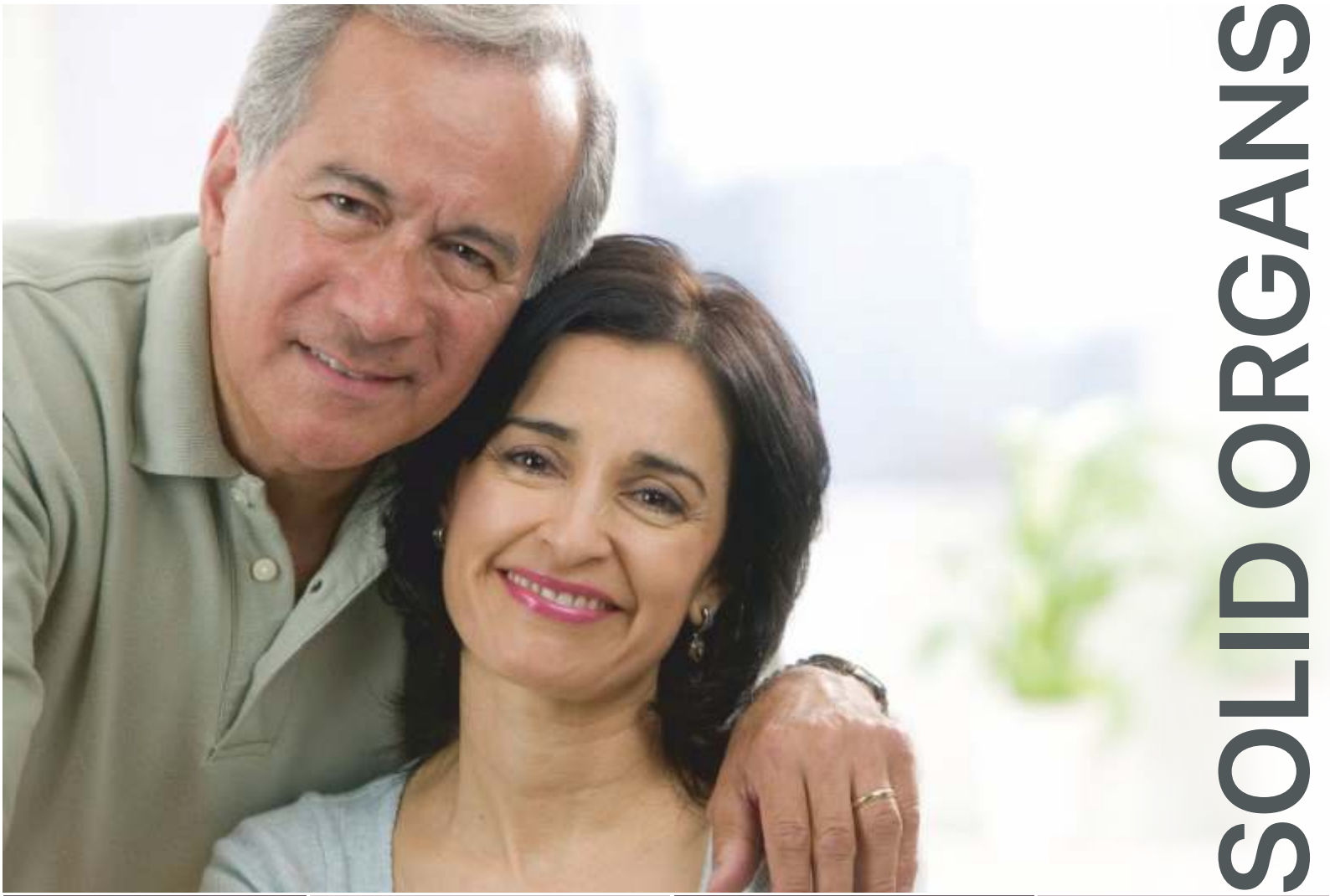
trublood®

the no risk biopsy



SOLID ORGANS

Guideline Compliant	Can Substitute Invasive Biopsy in Most Cases	Complete Diagnostic + Theranostic Work-up	Report in 5 Days

CLINICALLY VALIDATED ON 40,000+ SAMPLES

DATAR CANCER GENETICS

UNITED KINGDOM | GERMANY | INDIA

trublood®

CAN SUBSTITUTE INVASIVE BIOPSIES IN MOST CASES

A NON-INVASIVE, BLOOD-BASED INVESTIGATION

- ✓ Symptomatic individuals who have been advised an invasive tissue biopsy to check for malignancy.
- ✓ Patients where an invasive biopsy has been inconclusive or inconsistent with clinical observations.
- ✓ Suspected metastatic relapse to rule out new primary.

The anxiety, pain, risks and costs associated with invasive biopsies for cancer diagnosis are substantial. Yet, till date a reliable, safe and non-invasive test to establish diagnosis in suspected cases of cancer has not been available.

Trublood® is a revolutionary non-invasive, cost effective, safe and accurate blood test that can substitute invasive biopsies in most suspected cases of solid tumors and brain tumors. Starting with a simple 20-25 ml of blood draw, the process involves extremely sensitive, sophisticated and careful isolation and analysis of live tumor cells and circulating cell free nucleic acid fragments (DNA / RNA).

A comprehensive report is provided with unprecedented level of information which was hitherto thought impossible. Trublood® can be repeated as often as necessary, even during treatment or thereafter for real time characterization of tumor and personalization of treatment.

Trublood® is a result of several years of research involving our team of more than 150 scientists and clinicians using the world's latest equipment and software. Trublood® has been clinically validated on more than 40,000 samples from patients and healthy individuals to whom we are ever grateful.

Trublood® is a new paradigm in cancer diagnosis and management.

EXECUTIVE SUMMARY

WHAT

Non-Invasive Diagnostic biopsy to substitute invasive tissue extraction

FOR WHOM

Every Individual who desires a risk free biopsy.

WHY

Invasive biopsies are risky, inconvenient, painful and must be performed in a clinical setting. Trublood sample can be collected from patient's house or office.

HOW

Circulating Tumor Cells and Nucleic Acid are isolated from patient's blood sample and extensively analysed for diagnosis, prognosis and theranostics.

ANALYTES

Circulating Tumor Cells (CTCs), cell free DNA + RNA, Germline DNA

TESTS

Immunocytochemistry, NGS, FISH

SAMPLE TYPE

17 / 25 ml peripheral blood (5-6 hours fasting) as per protocol depending upon extent of test

TURN AROUND TIME

5 Days

Note

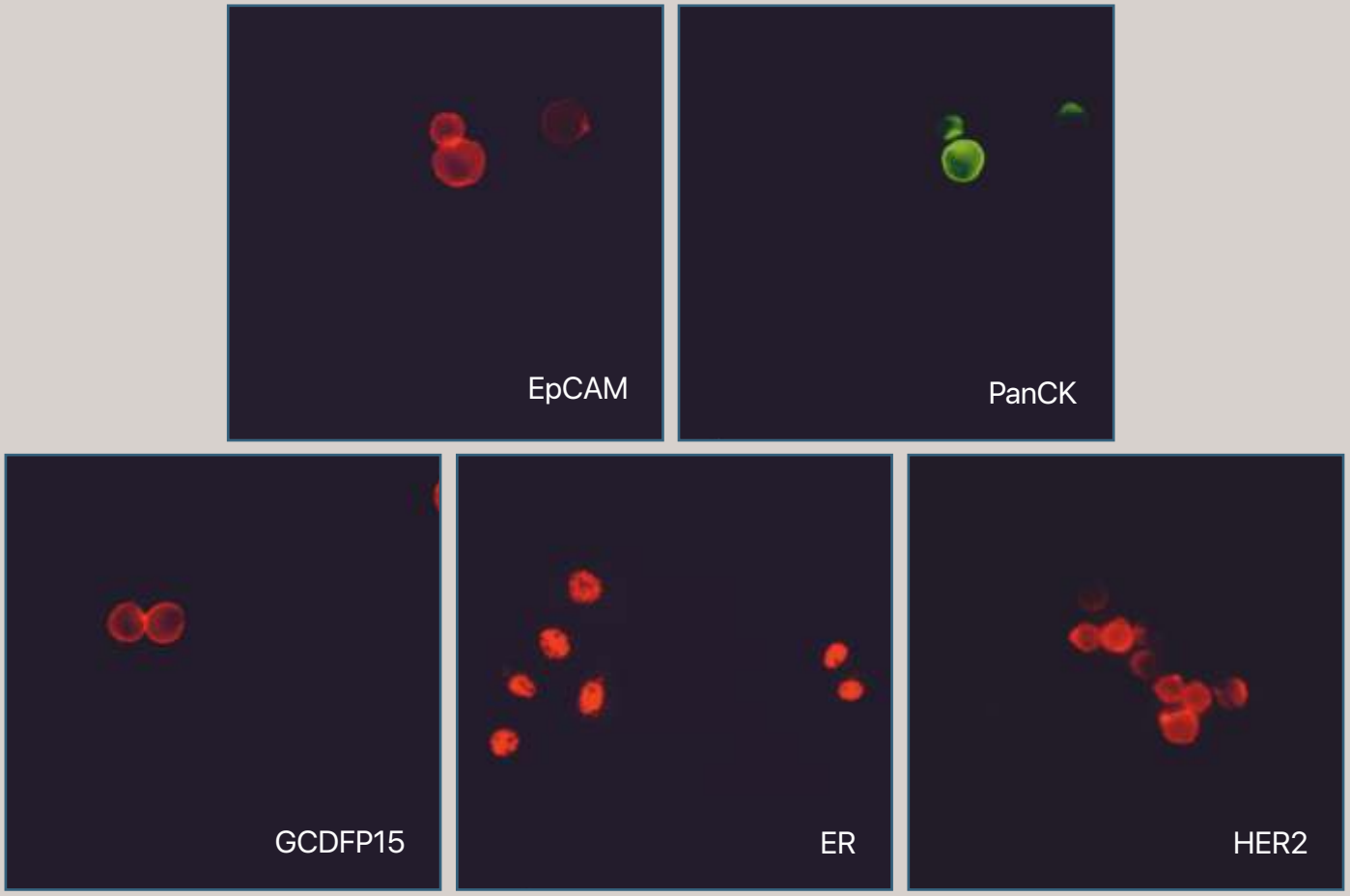
Trublood® - Basic test includes CTC detection and ICC for diagnosis only.

PD-L1, Theranostic ICC, cfDNA, Pharmacogenetics, FISH are available as add on tests at extra cost.

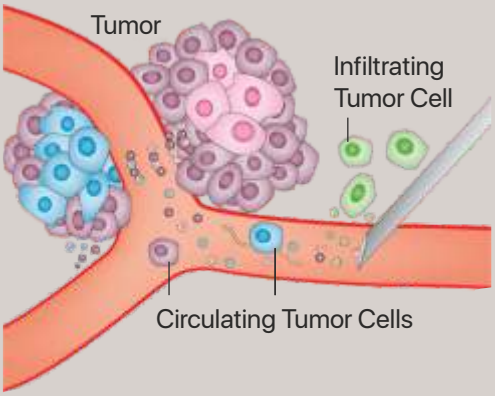
Usual Tissue Biopsy / FNAC	Trublood®
Invasive, needs tissue and is ultimately expensive	Totally non invasive and is ultimately less expensive
Can be performed only in Hospital / with Anesthesia	No need for Hospitalization / Anesthesia
Usually painful, may need stitches and leave scars	No Pain, No Stitches, No Scars
Serious risk of tumor cell 'Seeding'	No Risk
Can be very risky for organs like Lung, Liver, Pancreas	No risk of injury to any organ / bleeding
May be misleading as it is site / time dependent	Provides 'Real time' data and covers all active sites
Serial / sequential biopsies are impossible	Can be performed as often as necessary
Not viable if primary tumor is not easily visualized	Viable even if primary / metastasis are undetectable

Illustrative Immunocytochemistry Images

BREAST CANCER



Illustrative Image of Analytes



- Soluble molecules - proteins, cell-free nucleic acids and metabolites

Nature Reviews | Neurology

VALIDATION

Trublood®

Trublood® non-invasive diagnostic biopsy for solid organ cancers has been developed by Datar Cancer Genetics based on the findings of two clinical trials registered with the CTRI (Registration No. CTRI/2019/01/017219 and CTRI/2019/03/017918).

Trublood has been extensively validated with data from more than 22,000 samples from asymptomatic individual donors who underwent currently used screening tests such as LDCT, Mammography, PAP Smear, Serum CA Markers and clinical examinations, as well as more than 18,000 samples from cancer patients / patients with benign conditions totalling more than 40,000 evaluable samples till December, 2019.

Evaluated Samples (Patients)

Cancer Type	Patients
Breast	3967
Head and Neck	3552
Lung	1378
Colorectal	1341
Prostate	1196
Cervix	930
Ovary	855
Oesophagus	507
Sarcoma	440
Stomach	392
Uterus + Endometrium	365
Pancreas	385
Liver	381
CNS	349
Kidney	342
Bladder	249
Bone	220
Gallbladder	196
Thyroid	175
Testes	135
Skin	115
Melanoma	86
Penis	72
Neuroendocrine	51
Others	154
Total	17,833

Summary

Particulars	Samples
All Cancers	17,833
Benign Conditions	488
Asymptomatic Individuals	22,030
Total	40,351

OVERALL SENSITIVITY

89.8%

OVERALL SPECIFICITY

97.0%

Basis

- Tumors release thousands of cells into the circulation, where Circulating Tumor Cells (CTCs) survive for about 1–2.5 hours.
- In order to detach from the primary tumor and disseminate into the blood, cells must undergo a cellular process known as Epithelial-Mesenchymal Transition (EMT).
- EMT enhances migratory capabilities of tumor cells, which allows cells to penetrate into the vasculature and circulate as single or clusters of circulating tumor cells (CTCs).
- CTCs extravasate having undergone the reverse process known as Mesenchymal to Epithelial Transition (MET) and colonize at distant organs.
- Circulating Tumor Cells (CTCs) are defined as EpCAM (+), PanCK (+), CD45 (-) cells.
- Non-tumorigenic cells in peripheral blood have functional apoptotic mechanism, but CTCs are resistant to apoptosis.
- An epigenetically active stabilizing process can eliminate normal cells and confer survival privilege on apoptosis - resistant CTCs.
- Sufficient CTCs can be enriched and harvested for Immunocytochemistry (ICC) profiling with markers used in immunohisto-chemistry (IHC) which aid in determination of histopathological subtypes of tumor tissue.
- Antibody clones used in the trublood® assay for analysis of tumor antigens/markers are internationally approved for IVD use.

Cancer Type	Analysis			
	ICC	cfDNA* / RNA	FISH*	PGx*
Head and Neck	✓	✓	X	✓
Thyroid	✓	✓	X	✓
Breast	✓	✓	✓	✓
Lung	✓	✓	✓	✓
Liver	✓	✓	X	✓
Gallbladder	✓	✓	X	✓
Pancreas	✓	✓	X	✓
Uterine	✓	✓	✓	✓
Ovary	✓	✓	X	✓

Cancer Type	Analysis			
	ICC	cfDNA* / RNA	FISH*	PGx*
Cervix	✓	✓	X	✓
Esophagus	✓	✓	✓	✓
Gastric	✓	✓	✓	✓
Colorectal	✓	✓	✓	✓
Prostate	✓	✓	✓	✓
Kidney	✓	✓	X	✓
Bladder	✓	✓	X	✓
Sarcoma	✓	✓	X	✓
Melanoma	✓	✓	✓	✓

* Optional at extra cost

SPECIMEN REQUIREMENTS

BASIC DIAGNOSTICS

1st Draw
2ml SST Tube
(Yellow Colour Cap)

2nd Draw
3 x EDTA Tubes (Purple Colour Cap)
of 5 ml each - total 15 ml.

Thus, total 4 tubes containing 17 ml whole blood.

BASIC DIAGNOSTICS + cfDNA + RNA + FISH + PHARMACOGENETICS

1st Draw
2ml SST Tube
(Yellow Colour Cap)

2nd Draw
8ml DCG Tube
(Brown Colour Cap)

3rd Draw
3 x EDTA Tubes (Purple Colour Cap)
of 5 ml each - total 15 ml.

Thus, total 5 tubes containing 25 ml whole blood.

Note:

- Sequence of draw should not be altered.
- Blood should be drawn only and only as per above method.
- Blood drawn should be performed only by qualified phlebotomist under medical supervision.
- Ship at 4 °C in the container provided by DCG.

OTHER PRECAUTIONS PRIOR TO COLLECTION OF BLOOD SAMPLE

- The patient must not have received any form of cancer therapy (radiation / chemotherapy / surgery / endocrine etc.) at least 15 days prior to collection of sample.
- The patient must not have received oral or IV corticosteroids at least 15 days prior to collection of sample.
- Patient has no current febrile or any other acute inflammatory illness.
- Patient does not have acute exacerbation or flare-up of an inflammatory condition requiring escalation in medical therapy at least 5 days prior to collection of sample.
- Patient has not received blood transfusion / PET-CT / CT scan at least 5 days prior to collection of sample.
- Patient is not positive for HIV / HBV / HCV.

PD-L1, Cell Free DNA + RNA, FISH AND PHARMACOGENETICS ANALYSIS

- PD-L1, Cell Free DNA + RNA, FISH and Pharmacogenetics analysis will be performed on a special request at extra cost.
- Turn Around Time (TAT) for above report is 10 working days.

INTELLECTUAL PROPERTY

- Trublood comprises processes, technologies and trade-marks / copyrights which are proprietary to Datar Cancer Genetics and could be the subject matter of Intellectual Property rights under various jurisdictions.

PUBLICATIONS

IJC International Journal of Cancer

- ✓ Circulating Ensembles of Tumor Associated Cells: A Redoubtable New Systemic Hallmark of Cancer.

Journal of Thoracic Oncology

- ✓ Diagnostic Non-invasive Biopsy Can Substitute Conventional Tissue Dependent Procedures in Suspected Cases of Lung Cancer.
- ✓ Artificial Intelligence Can Detect Lung Cancer From High Resolution Microscopic Images of Conditioned Peripheral Blood.

AACR Cancer Research

- ✓ Viable Circulating Ensembles of Tumor Associated Cells Persist in Pre-treated Patients with Solid Organ Cancers showing No Radiologically Detectable Disease.
- ✓ Non-Invasive Liquid Biopsies for Guideline-Compliant Diagnostic Assessment in Ovarian Cancers.
- ✓ Encyclopedic Non-invasive Liquid Biopsies for Differential Diagnosis in Prostate Cancer.
- ✓ Wholesome Non-invasive Liquid Biopsies for Pharmacodiagnostic Work-up in Breast Cancer.
- ✓ Circulating Tumor Cells Express Tissue Specific Antigens In Multiple Cancers.
- ✓ Circulating Ensembles of Tumor Associated Cells are a Hallmark of Breast Cancer and Rare in Healthy Individuals.
- ✓ Circulating Ensembles of Tumor Associated Cells are a Hallmark of Lung Cancer and Rare in Healthy Individuals.
- ✓ Circulating Ensembles of Tumor Associated Cells are Ubiquitous in Lung Cancers.
- ✓ A mRNA Signature that Accurately Discerns Gliomas from Healthy Individuals.
- ✓ Circulating Ensembles of Tumor Associated Cells for Detection of Breast Cancer.
- ✓ Viable Circulating Ensembles of Tumor Associated Cells Persist in Patients with No Radiologically Detectable Disease After Treatment in Breast Cancer.

Journal of Clinical Oncology®

- ✓ Encyclopedic Liquid Biopsies for Guideline-compliant Diagnostic Work-up in Gastrointestinal Cancers.
- ✓ Circulating Ensembles of Tumor Associated Cells are Ubiquitous in Gastrointestinal Cancers.
- ✓ PD-L1 Profiling of Circulating Tumor Cells for Immune Checkpoint Inhibitor Therapy in Gastroesophageal Cancers.
- ✓ PD-L1 Profiling of Circulating Tumor Cells for Immune Checkpoint Inhibitor Therapy in Head and Neck Cancers.
- ✓ Circulating Ensembles of Tumor Associated Cells are Ubiquitous in Genitourinary Cancers.

OXFORD ACADEMIC Neuro-Oncology

- ✓ Diagnosis of Gliomas Using Circulating Glial Cells.
- ✓ Prospective, Blinded Plasma Based Analysis for Diagnosis of Newly Diagnosed Glioma.
- ✓ Algorithm Based Liquid Biopsy for the Diagnosis of Glioblastoma.
- ✓ Liquid Biopsy for Identification of Newly Diagnosed Glioma.

ANNALS OF ONCOLOGY

- ✓ PD-L1 Profiling of Circulating Tumor Cells is a Viable Companion Diagnostic for Checkpoint Inhibitor Therapy in Lung Cancer.

- ✓ Circulating Ensembles of Tumor Associated Cells are a Reliable Biomarker of Pancreatic Cancer.

NCRI National Cancer Research Institute

- ✓ Circulating Ensembles of Tumor Associated Cells are Ubiquitous in Breast, Ovarian and Cervical Cancers and Atypical in Asymptomatic Individuals.

EUROPEAN UROLOGY SUPPLEMENTS Forward faster. Together.

- ✓ Diagnostic Non-invasive Biopsy Can Substitute Conventional Tissue Dependent Procedures in Suspected Cases of Renal Cell Carcinoma.

International Journal of Radiation Oncology

- ✓ Viable Circulating Ensembles of Tumor Associated Cells Persist in Patients With no Radiologically Detectable Disease After Treatment in Head and Neck Cancer.

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ISO 9001:2015

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