



BIOMARKERS: THE FUTURE FOR IMPROVING PATIENT OUTCOMES

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- How to extract ISF via a non-invasive wearable device

Diagnostic blood tests are the entry point for 70% of NHS Patients

Blood Pathway



Travel to clinic



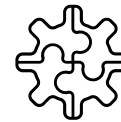
Blood draw



Sample sent to lab



Sample Received



Sample Processing



Plasma Sampled



Test Results

ISF Pathway



At-home Sample



Sample sent to lab



Sample Received



ISF Sampled



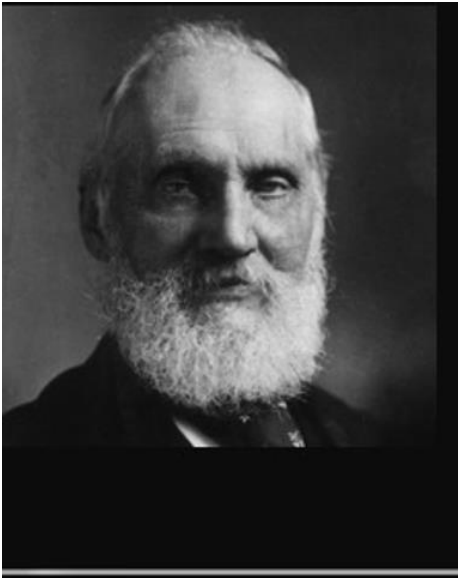
Test Results

What is a biomarker

- A measurable indicator of some biological state or condition.
- A distinctive biological or biologically derived indicator of a process, event or condition.
- Often measured or evaluated using blood, urine or soft tissues to examine normal biological processes, pathogenic processes, or pharmacologic response to a therapeutic intervention.



The importance of biomarkers



Lord Kelvin

British physicist and engineer (1824–1908)

"I often say that when you can measure what you are speaking about, and express it in numbers, you know something about it; but when you cannot measure it, when you cannot express it in numbers, your knowledge is of a meagre and unsatisfactory kind."

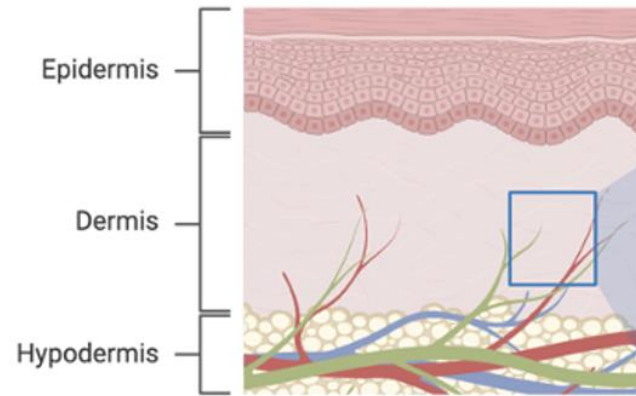
- Lord Kelvin

FDA Guidance Document
Guidance for Industry1
E16 Biomarkers Related
to Drug or Biotechnology
Product Development:
Context, Structure, and
Format of Qualification
Submissions

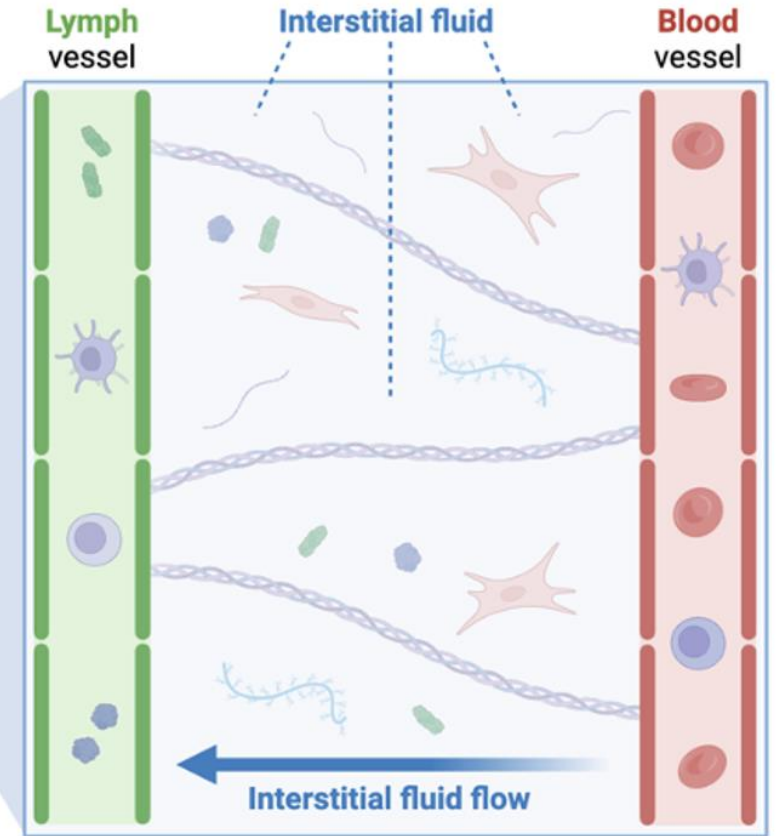
August 2011

•“Qualification is a conclusion that, within the stated context of use, the results of assessment with a biomarker can be relied upon to adequately reflect a biological process, response, or event, and support use of the biomarker during drug or biotechnology product development, ranging from discovery through post approval”

What is Interstitial Fluid?

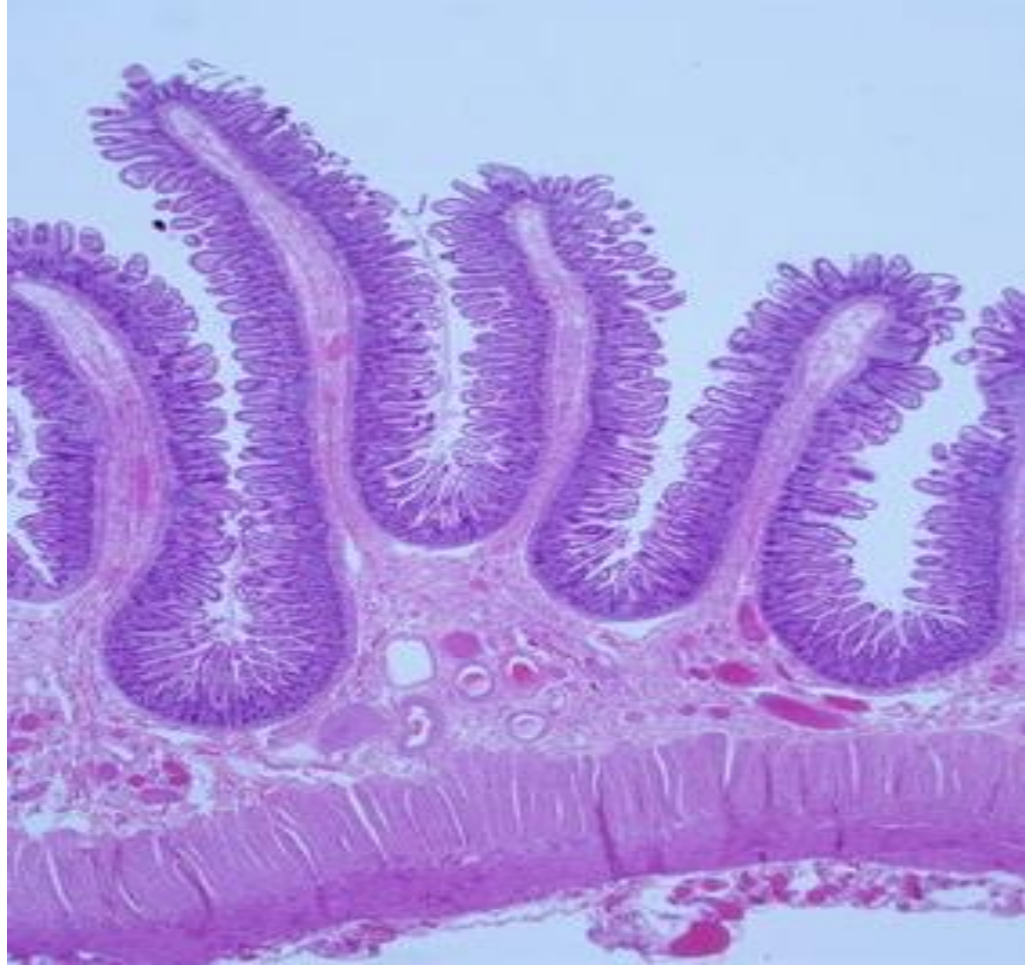


Legend



The Interstitium

- MARCH 27, 2018
- 4 MIN READ
- Meet Your Interstitium, a Newfound "Organ"
- These fluid-filled spaces were found in the body's connective tissue
- BY [RACHAEL RETTNER](#) & [LIVESCIENCE](#)
-



[Bing Videos](#) Dr Neil Thiese

Trends in Medicine

Tele-Medicine

- Improves access and efficiency
- Reduces care delays
- Eco-friendly

Precision Medicine

- Right dose for this patient
- Higher treatment efficacy
- Reduces trial and error prescribing

Personalized Medicine

- Right dose delivered in a manner suitable for this patient
- Tailors care to the individual
- Enables proactive interventions
- Drives better long-term outcomes

Virtual Ward/ Hospital at Home

- Reduces costs
- Frees up hospital resources
- Improves patient satisfaction

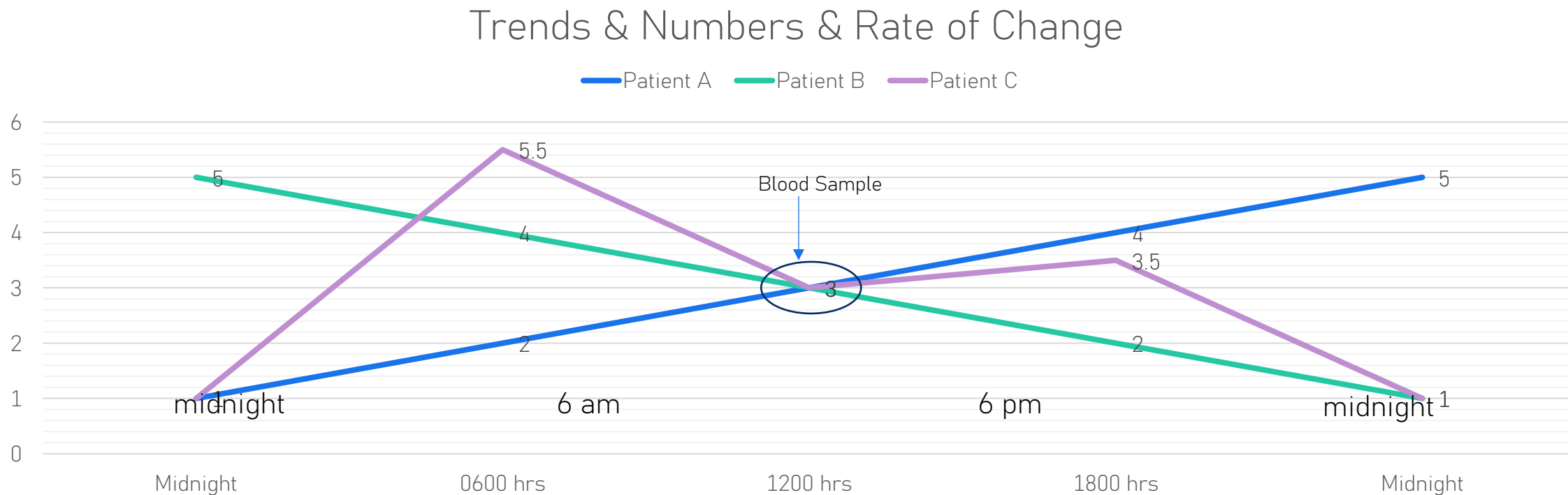
Why Use Blood Samples if You Don't Have To



- Blood levels are considered the Gold Standard
- Question: When were your “normal range” levels established?
- Blood levels are surrogates for what is happening at the target cells
- UK College of Pathology
 - 500 million blood samples per year¹
- US estimates 7-14 billion samples per year
- **Europe spends €18 billion per annum**

1: UK College of Pathologists

So, What Does That Mean?



Blood Reports Today

•General Biochemistry

- Urea 4.3 mM/L
- Creatinine 93 μ M/L
- Sodium 138 mM/L
- Potassium 3.8 mM/L
- Chlorides 102 mM/L
- Total CO₂ 26 mM/L
- Total calcium 2.52 mM/L



RESEARCH ARTICLE

Prevalence, causes, impacts, and management of needle phobia: An international survey of a general adult population

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Abstract

Needle phobia is an overlooked condition that affects virtually all medical procedures. Our study aimed to identify how commonly needle phobia is experienced, its underlying reasons, impacts, and potential mitigation strategies. A global survey was conducted in a general adult population using a questionnaire based on a targeted literature review that identified under-researched areas. The 21-item questionnaire was completed on a secure, web-based survey platform. Statistical analyses and models were utilized to identify relationships between participant characteristics and needle phobia. **Of the 2,098 participants enrolled in the study, 63.2% (n = 1,325) reported experiencing needle phobia**, and rated the intensity of their fear as 5.7 (± 2.6) on average on a scale from 0 (no fear) to 10 (very strong/unreasonable fear or avoidance). According to the logistic regression model, other medical fears (odds coefficient = 2.14) and family history (1.67) were the most important factors associ-

OPEN ACCESS

Citation: Alsbrooks K, Hoerauf K (2022) Prevalence, causes, impacts, and management of needle phobia: An international survey of a general adult population. PLoS ONE 17(11): e0276814. <https://doi.org/10.1371/journal.pone.0276814>

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Trypanophobia: Fear of medical procedures involving needles

Healthcare Equity: Aiding Medical Inclusion



- Low-income families
- Disabled people
- Single Parents
- Trypanophobics
- Self Employed / Busy Executives
- Religious & Cultural Barriers
- Remote sampling in large geographic area with limited healthcare resources

The Green Agenda

- In the UK:
 - 500 million blood samples = 1 Billion healthcare related travel events*
 - Patients travel to clinic for many complex interactions with Providers and medical technology
 - Assume 12.5% are for only blood tests
- **125 million events just for a blood sample!**

*Assume roundtrip patient journeys





WHAT IS THE FUTURE FOR DIAGNOSTIC BIOMARKERS?

- Binary: Yes, the biomarker is present = you need therapy
- Traffic Lights: Red go see the doctor, Amber more tests needed, Green you are OK
 - Near Patient Testing for chronic patients – home sample into black box results transmitted
 - Population monitoring for epidemics – wearable with results sent electronically to Public Health
 - Screening to monitor recurrence of disease e.g. post prostatectomy
- Complex Panels need lab analysis
 - Confidence in movements of a panel of biomarkers rather than a single biomarker
 - Differentiation of various disease types e.g. you have type 13 Diabetes
 - Screening in the community

— Introducing the KIFFIK Lab™
Rapid Cancer Test



**POWERED BY
DURACELL®**



The KIFFIK Lab is not yet FDA Cleared. For Investigational Use Only

Thank you

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