DIAGNOSTIC INFORMATION: AN UNPOLISHED JEWEL

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The MedTech Forum
DIAGNOSTIC INFORMATION:
AN UNPOLISHED JEWEL
In Vitro Diagnostics have a story to tell, the patient & clinician viewpoint.
The Value of Diagnostics
*IVD’s underestimated*

Hospital costs

Healthcare decision-making

In on average 75% of patients, IVDs are used**


**DOI: 10.1371/journal.pone.0149586
Uses of diagnostic tests in the patient pathway.

The economic, medical and societal benefits of IVD tests are often overlooked

IVDs improve patient care, contribute to protecting consumer health, help to limit healthcare spending.

* Between brackets (Proportion of IVD use)
Screening: Hepatitis C in Europe
50% of HCV infections remain undiagnosed

50% DIAGNOSED

CAN NOW BE CURED

50% UNDIAGNOSED

TRANSMISSION

DISEASE PROGRESSION
Risk stratification: “Angelina Jolie effect”

Oncogenic mutations in the BRCA1/2 genes are associated with a high risk of developing breast and ovarian cancers.
The role of guidelines in diagnostic approaches

Diagnostic uncertainty is common in heart failure patients with dyspnea.

Heart Failure (HF) symptoms are often non-specific.

This makes it hard to discriminate between HF and other conditions.

Symptoms are difficult to interpret in the obese, elderly and patients with chronic lung disease.

Major heart failure guidelines recommend Natriuretic Peptide (NP) testing (CLASS I, LOE A), BUT ....

ESC, European Society of Cardiology; HF, heart failure; NP, natriuretic peptide

Every person is unique.
So is every cancer.

- 250 types of cancer
- 350 genes that contribute to cancer development
- 100,000 mutations (approx.) found in some types of lung cancers
- 1 unique cancer profile
The value of understanding disease mechanisms

Diagnose of LUNG CANCER

In 2014, the expected number of tests for cancer in the UK population was 59,294, but the provision of testing was only 34,675, i.e. a difference of around 24,000 tests.

This included 16,000 patients with NSCLC who would have been eligible for testing.

Of these patients, 3,500 would have been eligible for targeted medicines that could have prolonged their progression-free survival, but missed out.
The value of understanding disease mechanisms

2005

NSCLC 2nd Line
No biomarkers
OS = 7 mo

RESPONSE TO THERAPY
9% 0%

RESPONSE TO THERAPY
~65%

OS: Overall Survival

2012

NSCLC 1st Line
EGFR mutated
OS > 22 mo

RESPONSE TO THERAPY
0% 40%

RESPONSE TO THERAPY
~80%

OS: Overall Survival

2017

Multiple markers
PFS >18.9 mo

RESPONSE TO THERAPY
0% 40%

RESPONSE TO THERAPY
~80%

PFS: Progression Free Survival

References:
3. Ramalingam S, et al. Presidential Symposium I of the ESMO 2017 Congress; September 8 –12; Madrid (3rd Generation)
BUT... clinicians would be lost w/o diagnostic testing
Non Small Cell Lung Cancer treatment becomes complex

Non-squamous Cell

1L treatment
- Crizotinib
- 1st or 2nd gen EGFR-TKI

Maintenance (responders only)

2L treatment
- T790M+
- T790M-

Squamous Cell

1L treatment
- Pembrolizumab
- Chemo ± bev

PD-L1 ≥ 50% TPS
- Pembrol
- Chemo ± bev

PD-L1 1-49% TPS
- Pembrol
- Chemo

PD-L1 < 1% TPS
- Pembrol or azeo
- Chemo ± Ram

PD-L1 ≥ 50% TPS
- Pembrol
- Chemo

PD-L1 1-49% TPS
- Pembrol
- Chemo

PD-L1 < 1% TPS
- Pembrol or azeo
- Chemo

Adapted from presentation by Sylvie Lantejoul at ELCC 2017
# Increased collaboration between Pharma & Diagnostics companies in Immunotherapy

## PD-L1 Assays: A complex & dynamic landscape

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<thead>
<tr>
<th>Product Name</th>
<th>Pharma Partner &amp; Associated Drug</th>
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<tr>
<td>Ventana (SP263)</td>
<td>AstraZeneca, Durvalumab</td>
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<tr>
<td>Ventana (SP142)</td>
<td>Roche, TECENTRIQ, Atezolizumab</td>
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<tr>
<td>Dako (28-8)</td>
<td>Merck, KEYTRUDA, Pembrolizumab</td>
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<td>Dako (22C3)</td>
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<tr>
<th>VENTANA PD-L1 (SP263) Assay</th>
<th>VENTANA PD-L1 (SP142) Assay</th>
<th>PD-L1 IHC 28-8 PharmDx</th>
<th>PD-L1 IHC 22C3 PharmDx</th>
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BUT what if no CE IVD tests are used?
False positive or false negative test results will generate more anxiety, distress, sometimes unneeded surgery or unnecessary treatments

~Around 1/6 patients receive a wrong treatment

EU In Vitro Diagnostic Medical Device Regulation 2017/746.
New technologies like Next Generation Sequencing will make it more complex but will also bring more medical information to the patient and clinician.

Find out what your DNA says about you and your family.
- See how your DNA breaks out across 31 populations worldwide
- Discover DNA relatives from around the world
- Share reports with family and friends

order now  $99


We hear from thousands of customers around the world who write in to tell us about their 23andMe experience—and the impact it has had on their life.

See stories that inspire us.
Patients and the complexity of laboratory testing

Patients are interested in receiving their laboratory medicine results, the majority with explanatory notes.
Summary

IVDs are an essential part of healthcare decision-making.

Laboratory testing plays an important role from screening to diagnosis to treatment, contributing to the available medical information regarding a patient.

IVDs can limit healthcare spending, which is a major economic issue in every country throughout the world.
Thank You

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