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Diagnosis / monitoring of glioblastoma and acute myeloid leukemia by (D)-2-hydroxyglutarate test (P-977)

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Research for a Life without Cancer

Detection of D-2-Hydroxyglutarate (D2HG)



- can currently be performed with LC- or GC-MS
 - which is cost, time and labor intensive
 - and needs expensive machinery, not available in all labs
- **an affordable high throughput method is needed**

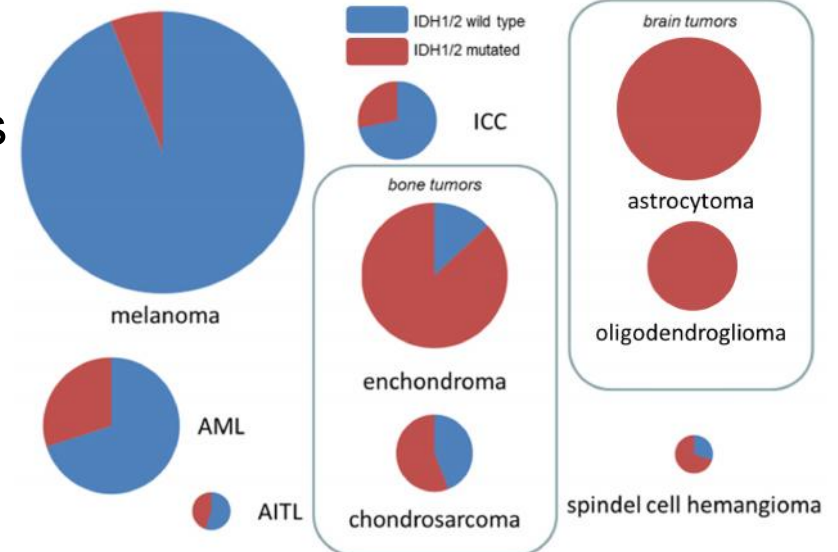
D2HG Assay



- an enzyme based assay
 - **fast, cheap and compatible with high throughput**
 - can be performed in nearly every lab

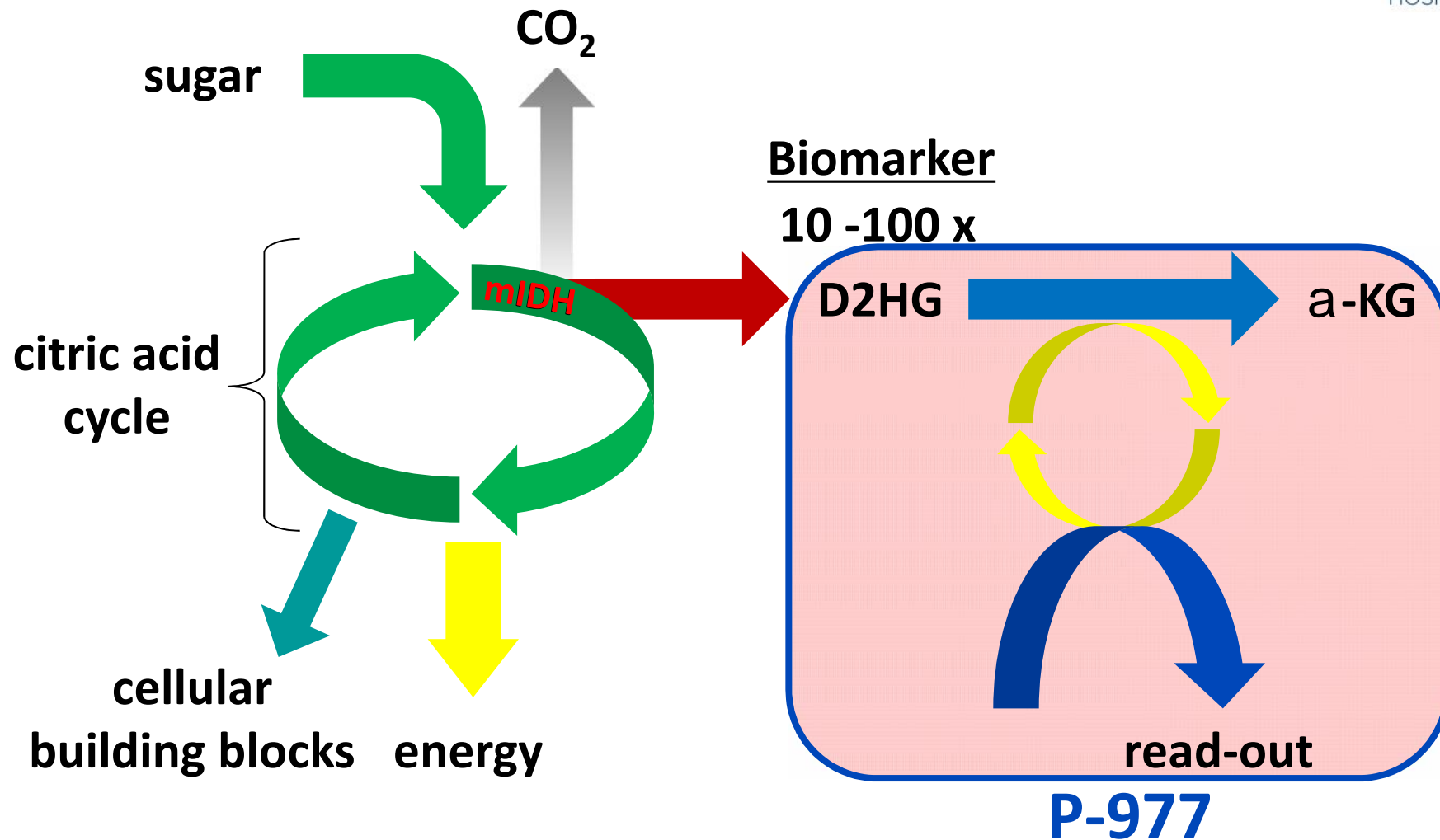
Isocitrate Dehydrogenase (IDH) Mutations

- can be found in different tumor entities
- are important for diagnostics
- valuable for prognostics
- will be important for therapy



- **can be found in different genes and types of mutations**
 - **but all have in common to produce D2HG**

Assay principle

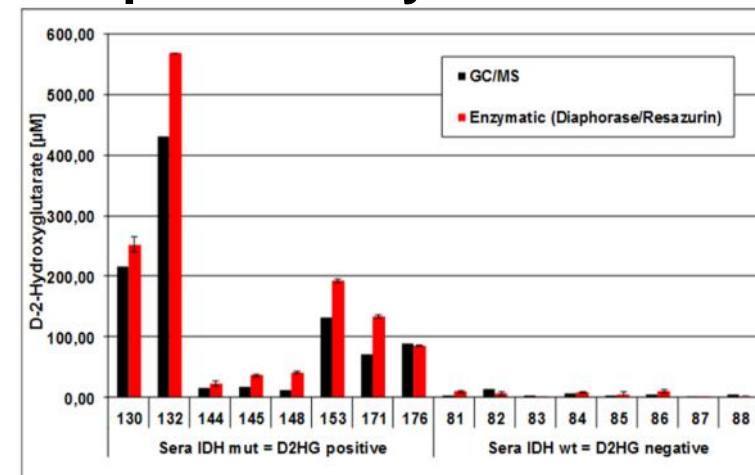




Comparison with the gold standard

- Gold standard for metabolite detection is:
 - **gas chromatography / mass spectrometry**

- equal sensitivity
- faster: 2-3 h vs. 1 day
- less material: 0,1 mL vs. 1 mL



“Oncometabolite” concentration in the serum of AML patients

- cheaper: < 0,5 € vs. ~ 80 €/ probe
- can distinguish D- and L- enantiomers (L not measurable)



Commercial potential

- **technical comparable assays are in clinical use**
- calculation keys are in place for these assays (in Germany)
 - **liquid sample** (GOÄ 4069): 51,77 €/ sample
 - **solid sample** (GOÄ 3781 + 4069): 66,96 €/ sample



Commercial potential

- diagnostic tool
- clinical parameter
 - correlation with tumor burden / progression
- monitor success of mIDH inhibitors (e.g. Enasidenib)
- rare disease screening (e.g. 2HG aciduria)
- 2HG is in the focus of current cancer research
 - **There is more to come!** (e.g. D2HG in breast cancer)

Development status

- the assay is established on:
 - cell culture supernatant and cell lysates
 - **human and mouse serum and blood**
 - **human and mouse tissue samples**
- established and validated on **96 - 1536 well format**
- high inter and intra batch reproducibility (> 95 %)
- enzyme is highly stable (> 2 years storage, > 95% activity)
- works reliable in more than 15 other labs around the world
- additional applications are feasible (on slice, on a surface, ...)

IP Status

- **Patent**

- granted in Europe - EP2820145 (CH, DE, FR, GB)

- granted in USA - US9487815

- ÷ pending in Japan and China



Resources needed

- **production:**
 - only HGDH enzyme, all other components are available
- **measurement:**
 - enzymatic assay components
 - 96-well plate
 - pipet tips
 - samples
 - plate reader (or photometer)

} material cost 1 sample + standard (each in triplicate) : ~ 9,50 €
- 1-2h working time for 24 samples plus internal standard + 1h incubation time
- reader time 5 min



Risk and bottlenecks

- automatization compatibility
- regulatory approval
- existing license limitations
- competitor response to market entry
- market penetration
 - i.e. moving away from “gold standard”

WE ARE SEEKING

- **a company for diagnostic kit development**

Thank you
for your attention!



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