Analytical DSS module - how to support decisions in the analytical lab

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Analytical DSS model

Decision support for evaluation of the methods:

Methods developed within WP5&6

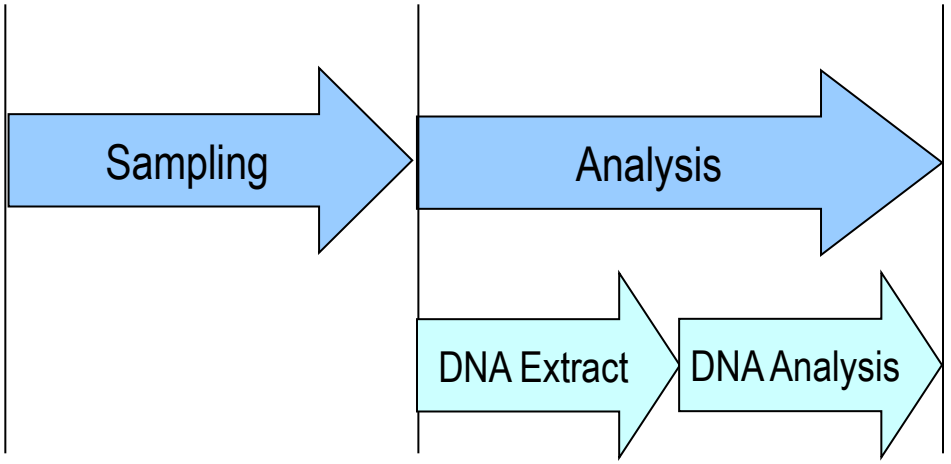
- How to evaluate which is the most promising for routine analysis?

Can be generalised – question asked in the routine detection lab

- Which methods are best applied in our lab?
- For certain sample type?

Analytical DSS model

"Product"



"Purpose":

- Screening:
  Does "product" contain GMO?
- Quantification:
  How much GMO is in the "product"?
- On site analysis
- DNA extraction

Decision Questions:

- Is a given method "fit for purpose"?
- Which method is "best for purpose"?
- Which new method is "best for development"?

Analytical DSS model

Objective to cope with diverse methods:

- DNA extraction/detection
- Simplex/multiplex
- PCR/nonPCR based

Analytical DSS model

Parameters behind decision:

- Applicability
- Performance
- Cost
- Practicability

Analytical DSS model

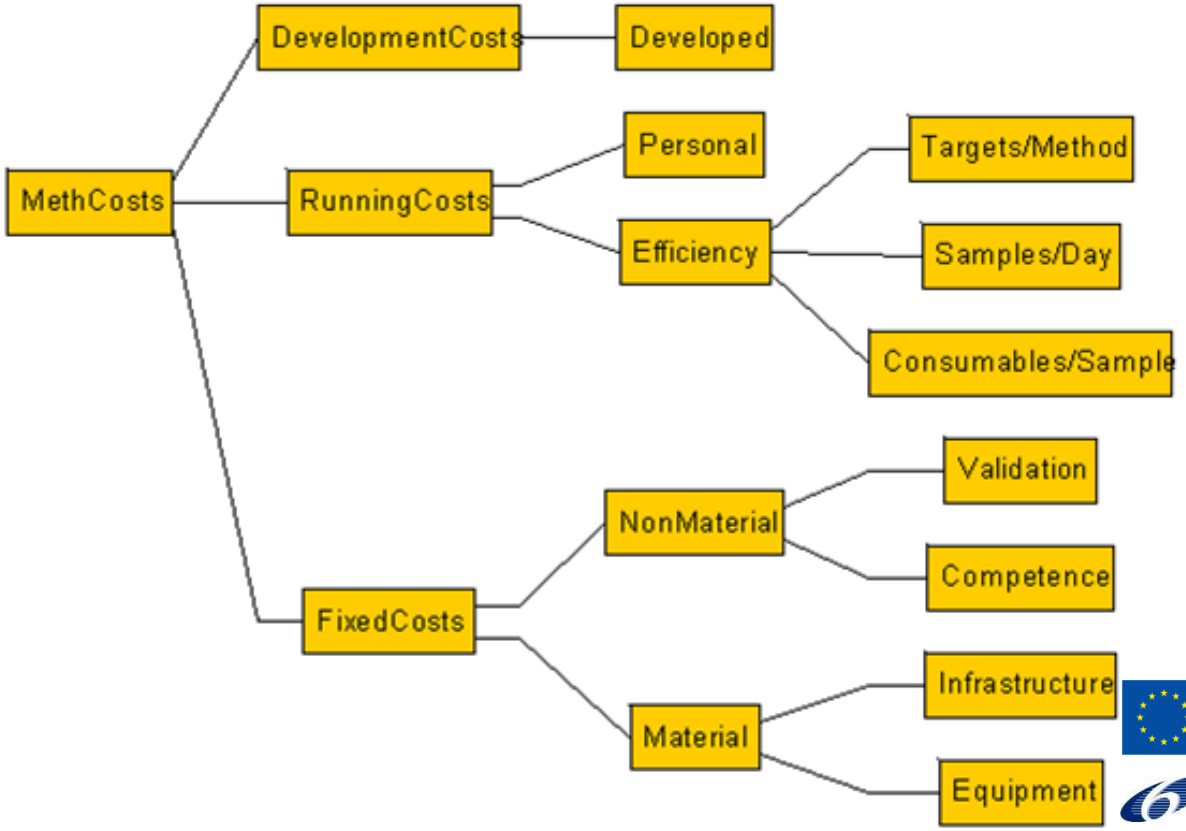
	characteristic	evaluation
Performance LOD	2 copies	+++
Performance LOQ	50 – 10000 copies	+++
Equipment required	Real-time PCR	+
Time per sample analysis	2h	++
Cost of chemicals		
Method implementation		
….		

Decision rules – method costs

	Material	NonMaterial	FixedCosts
	67%	33%	
1	high	*	high
2	<=med	high	high
3	med	>=med	med
4	>=med	med	med
5	low	<=med	med
6	low	low	low

	Equipment	Infrastructure	Material
	50%	50%	
1	high	*	high
2	*	high	high
3	med	>=med	med
4	>=med	med	med
5	low	low	low

	Competence	Validation	NonMaterial
	67%	33%	
1	high	<=med	high
2	<=med	low	med
3	med	*	med
4	>=med	high	med
5	low	>=med	low



Decision rules – Fit for screening

Context: *Analytical Method* Assessment Model
Purposes: DNA Extraction, *Screening*, Quantification

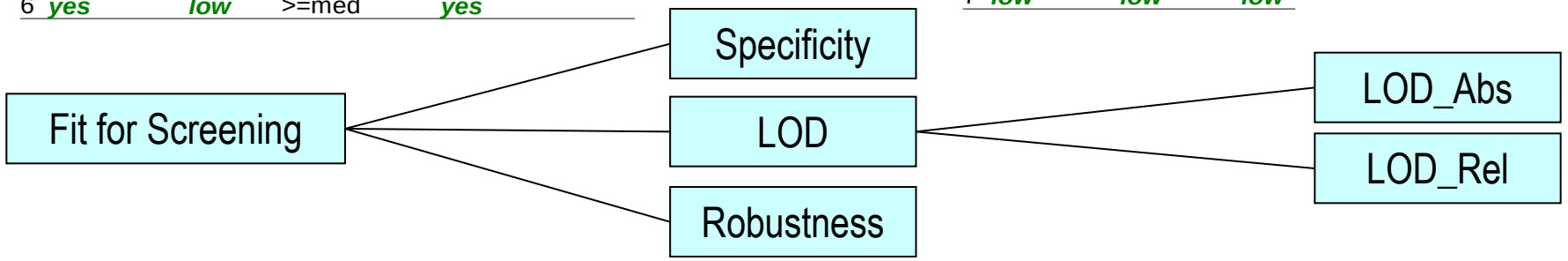
A *Screening method* is "fit for purpose", if it:

- is *specific*,
- has sufficiently low limit of detection (*LOD*), and
- is sufficiently *robust*.

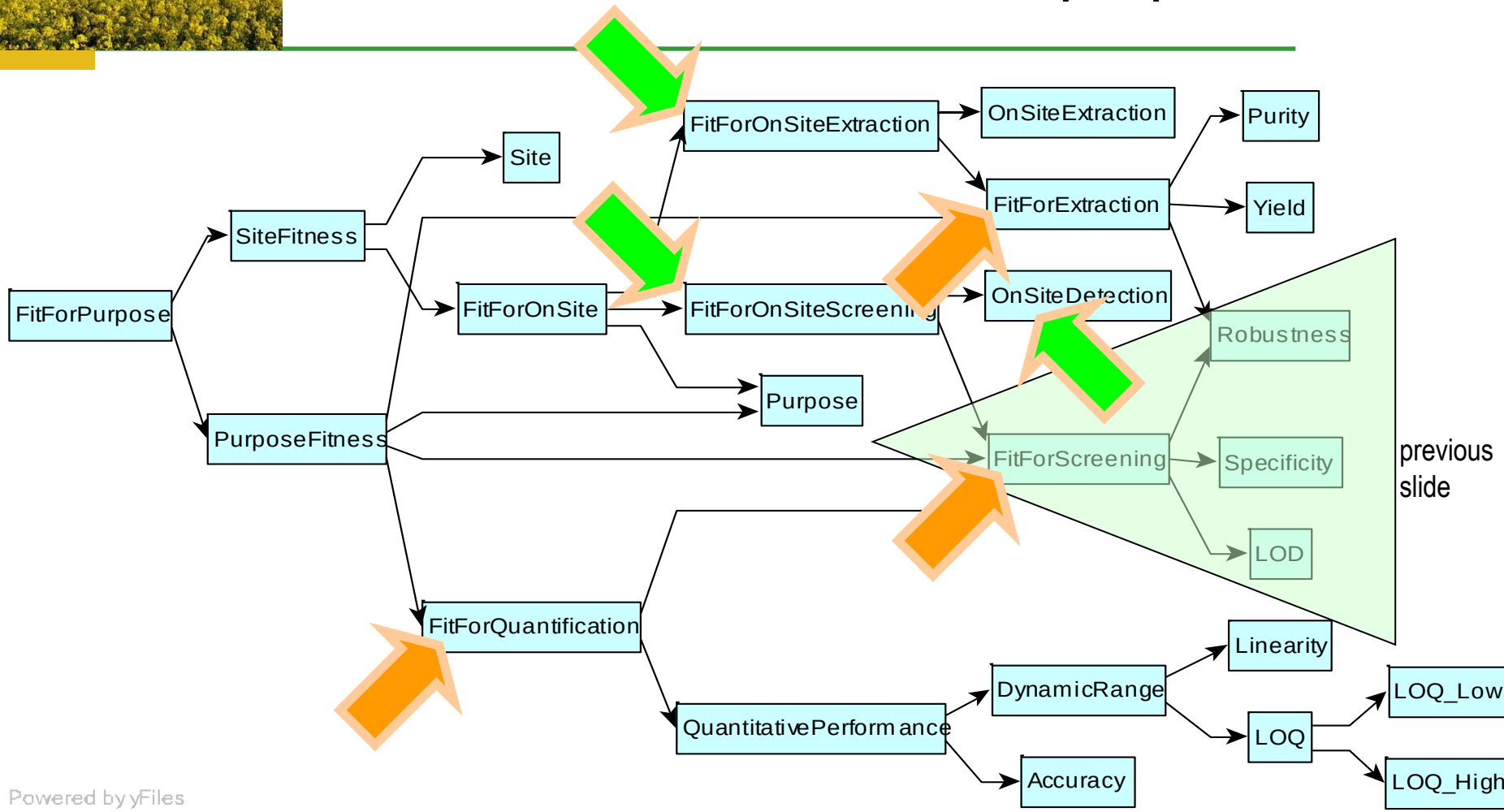
Decision rules

	Specificity	LOD	Robustness	FitForScreening
1	no	*	*	no
2	*	high	<=med	no
3	*	*	low	no
4	yes	<=med	high	partly
5	yes	med	>=med	partly
6	yes	low	>=med	yes

	LOD_Abs	LOD_Rel	LOD
1	high	<=med	high
2	<=med	high	high
3	<=med	low	med
4	med	>=med	med
5	>=med	med	med
6	low	<=med	med
7	low	low	low



Decision rules – Fit for purpose



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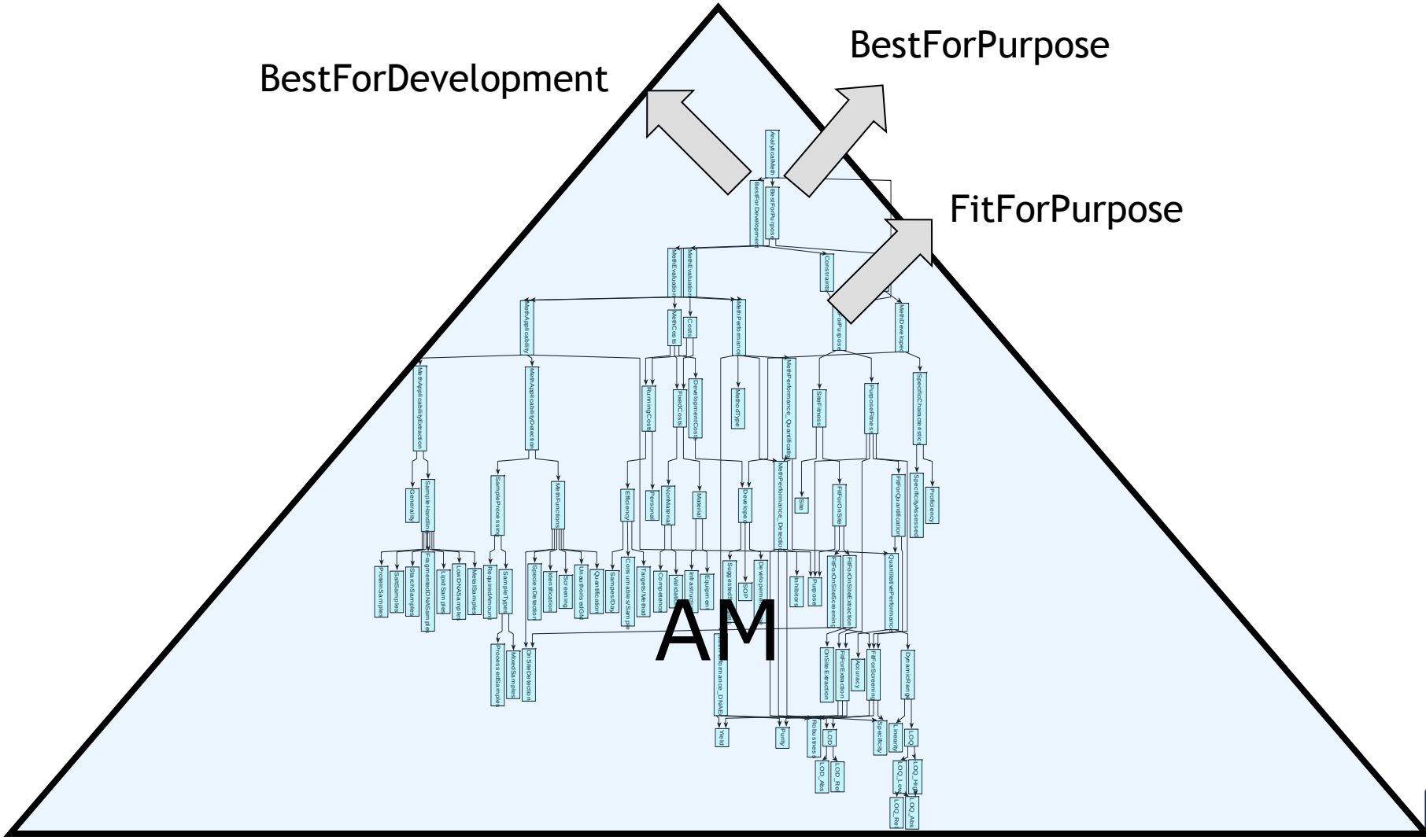
Assessment of Analytical Methods



Analytical DSS module - validation

- DNAEx methods:
  - NucleoSpin, CTAB, Biolytix lecithin method
  - In combination with different sample types: maize grains, compound feed, soya tofu, soya lecithin

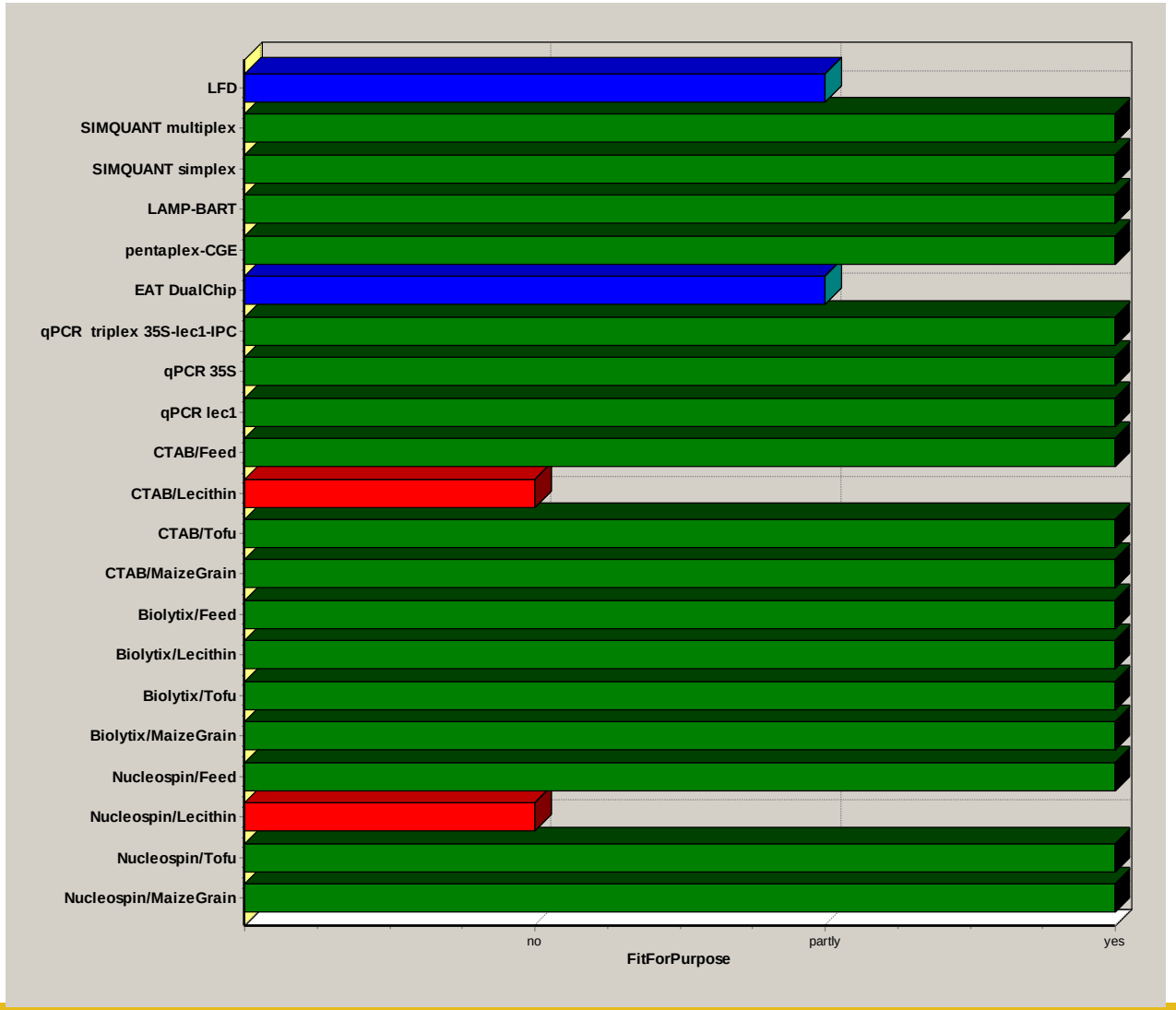
- DNA Detection:
  - real-time PCR lec1, real-time PCR 35S
  - real-time PCR triplex 35S-lec1-IPC
  - pentaplex-CGE, SIMQUANT, EAT DualChip
  - LAMP-BART

Analytical DSS module - validation

Basic Attribute	Scale	Precise description of scale	Description
Equipment	**high**,med,***low***	Range of qPCR, range of conv. PCR, basic lab or even on-site	Costs of required equipment, including maintenance
Infrastructure	**high**,med,***low***	Mol.lab with some sprcial equipm, basic mol. lab, no lab needed	Cost of infrastructure
Competence	**high**,med,***low***	Experienced tech., any techn. or student, not qualified personnel	Personal competence required for method
Validation	**high**,med,***low***	Range of multiplex methods, range of simplex qPCR, lower	Cost of in-house validation (implementation in the lab)
Consumables/Sample	**high**,med,***low***	Higher than PCR or column based extraction, as in PCR or column based extraction, lower than PCR or column based extraction	Costs of consumables per sample
Samples/Day	**low**,med,***high***	Under 10, 10-50, more than 50	Number of samples that can be analysed in one working day
Targets/Method	**low**,med,***high***	1, 2 to 5, more than 5	Number of targets that can be detected simultaneously
Personal	**high**,med,***low***	More than 3h, 30 min to 3h, less than 30 min	Costs of labour per sample = working hours needed per sample
DevelopementStage	**proof**,opt.assay,tested, prevalidation,***validation***		Current state of method development

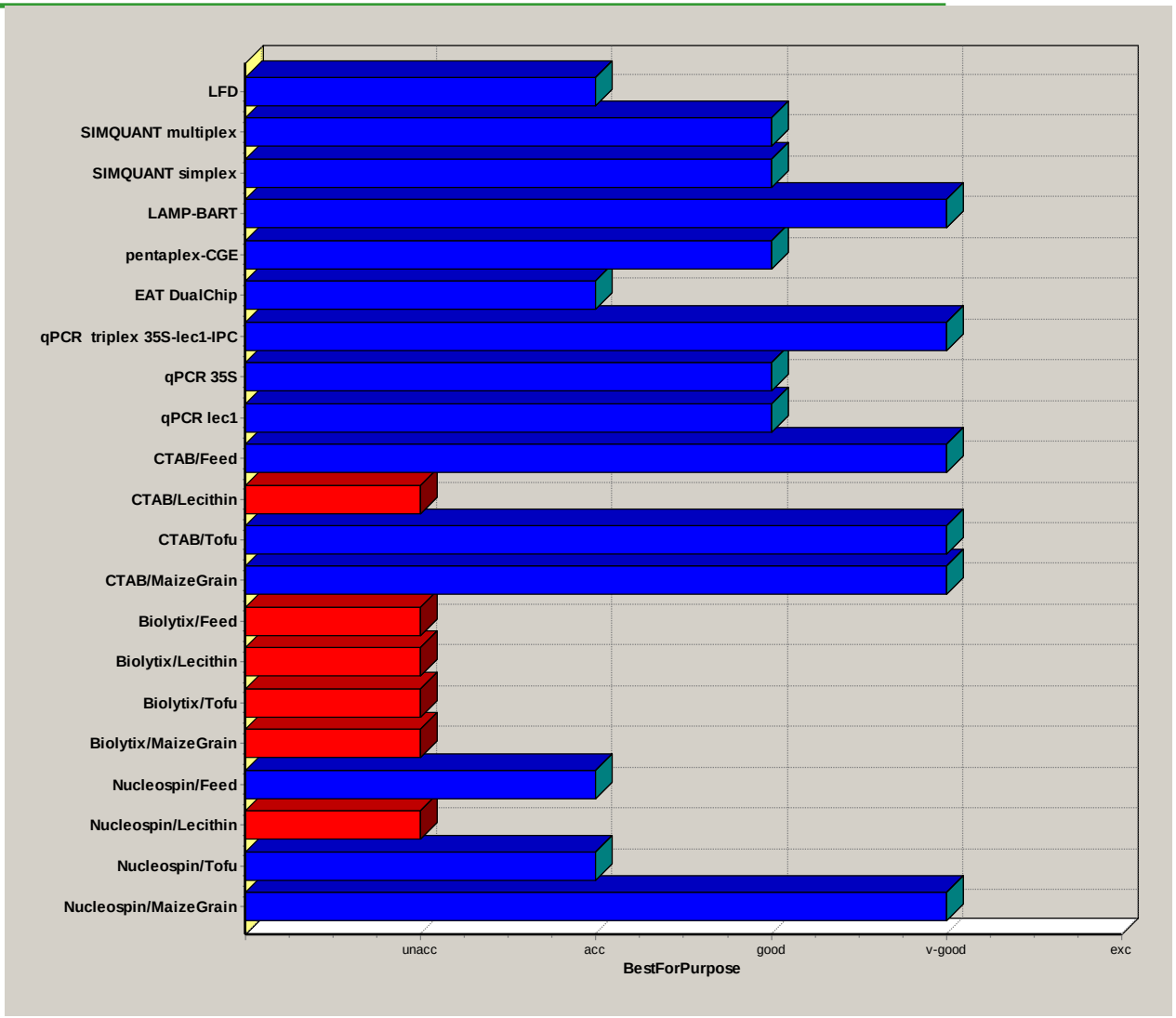
Evaluation of methods

Fit for purpose



Evaluation of methods

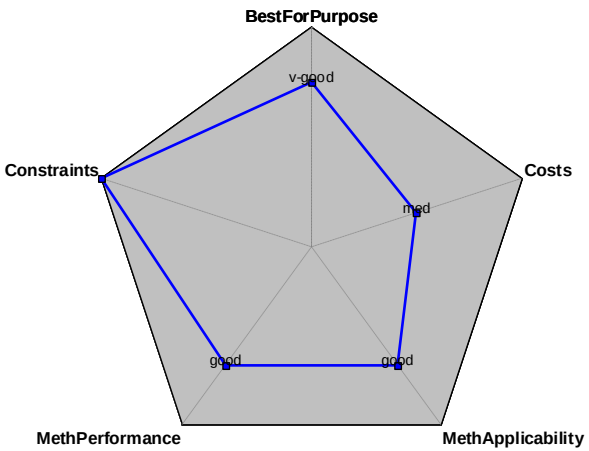
Best for purpose



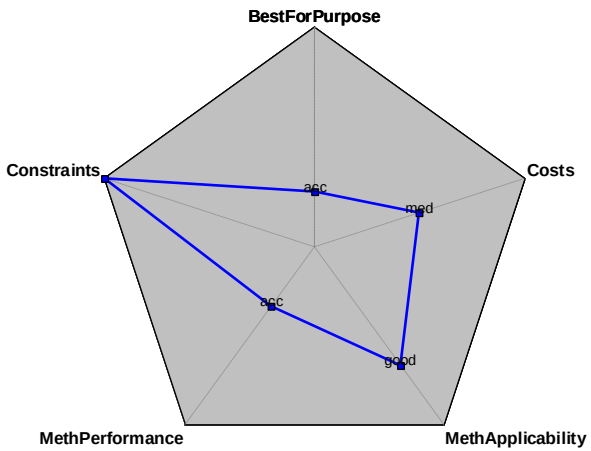
Evaluation of methods

Nucleospin

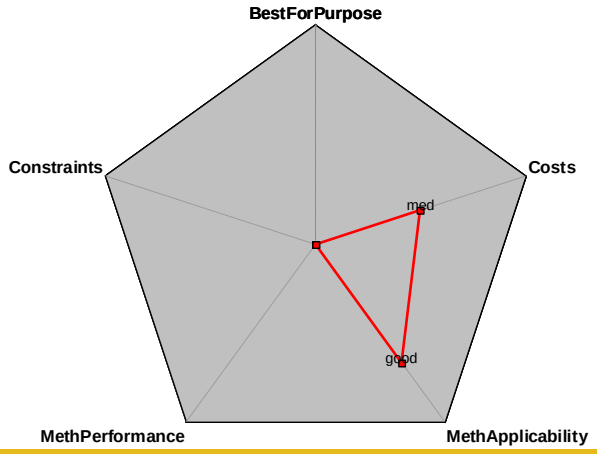
Nucleospin/MaizeGrain



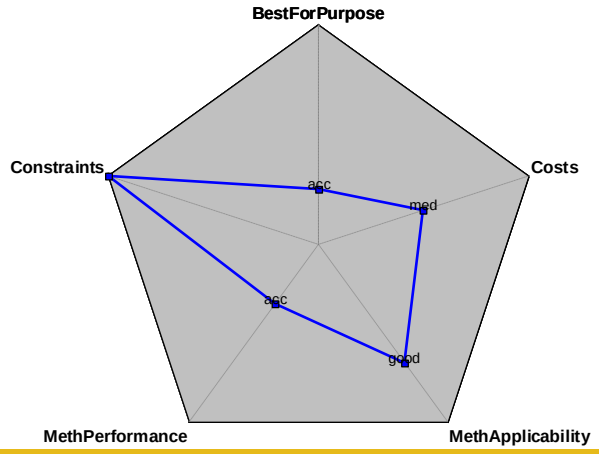
Nucleospin/Tofu



Nucleospin/Lecithin



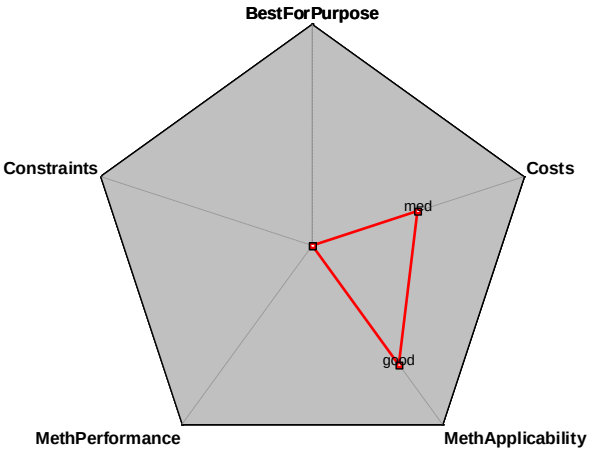
Nucleospin/Feed



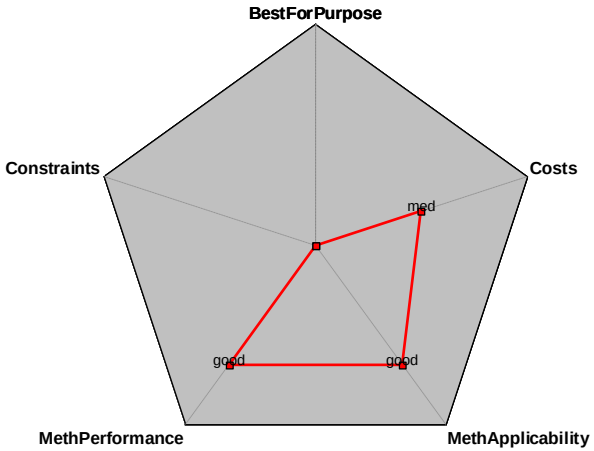
Evaluation of methods

Lecithin

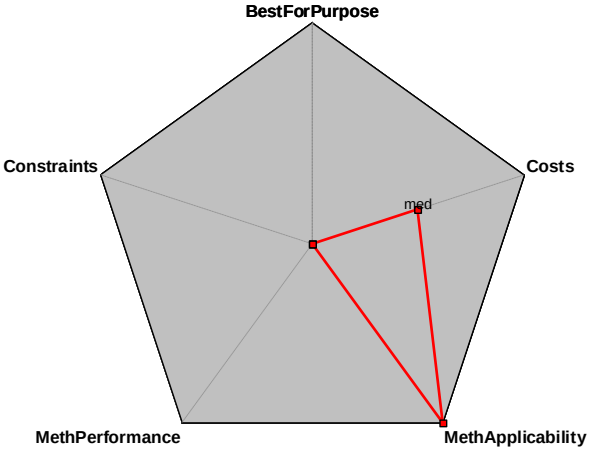
Nucleospin/Lecithin



Biolytix/Lecithin



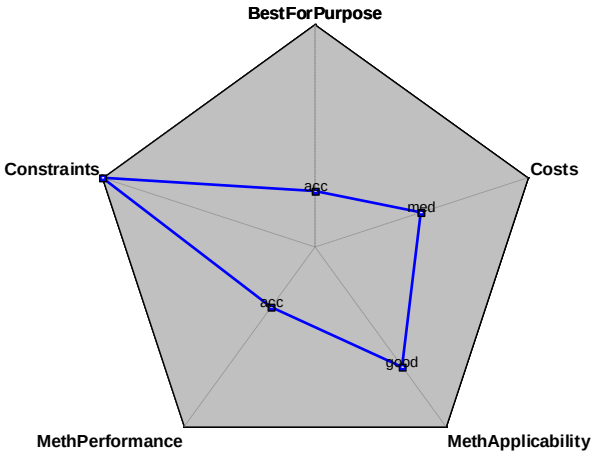
CTAB/Lecithin



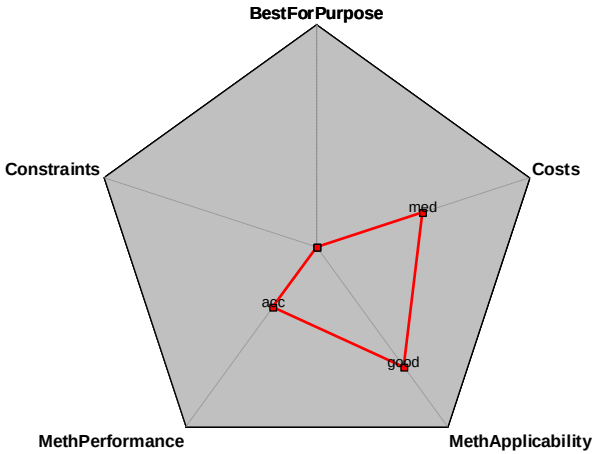
Evaluation of methods

Tofu

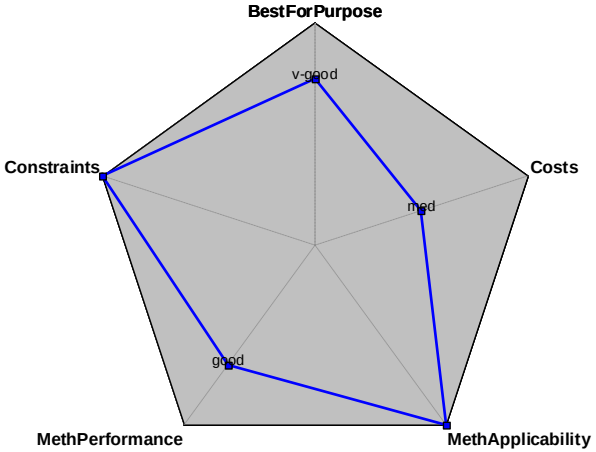
Nucleospin/Tofu



Biolytix/Tofu



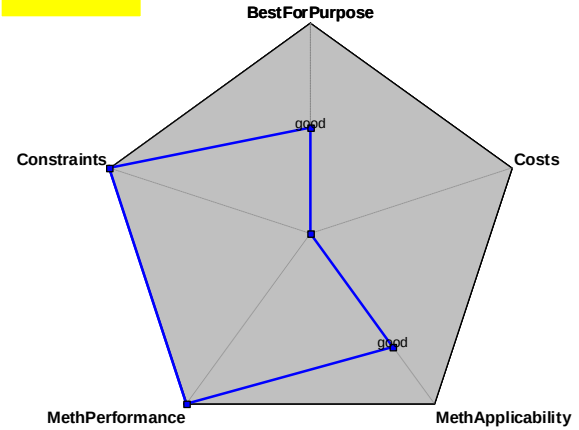
CTAB/Tofu



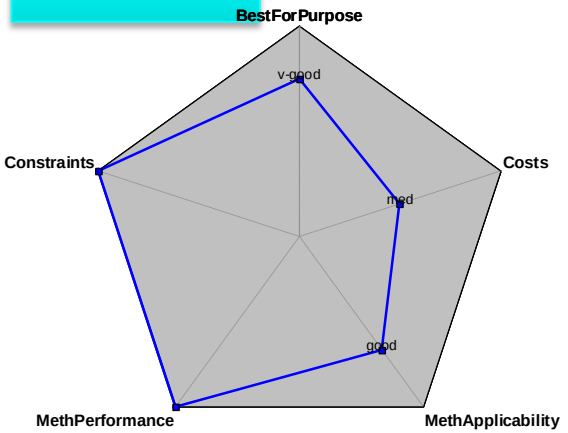
Evaluation of methods

Multiplexing methods

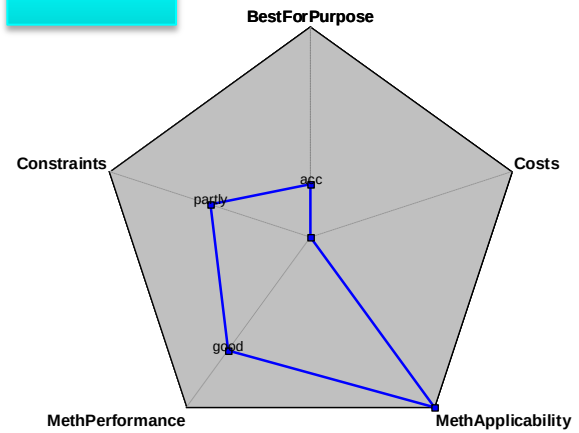
qPCR 35S



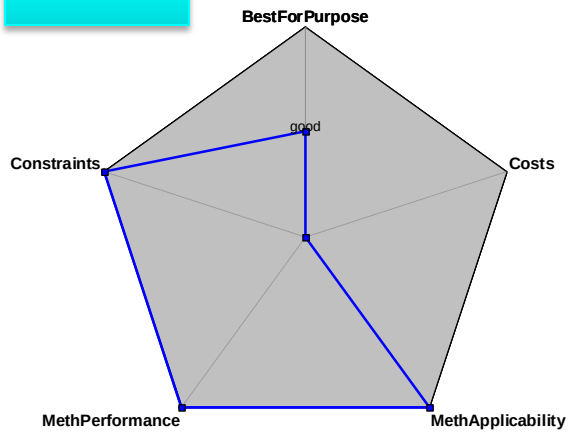
qPCR triplex 35S-lec1-IPC



EAT DualChip



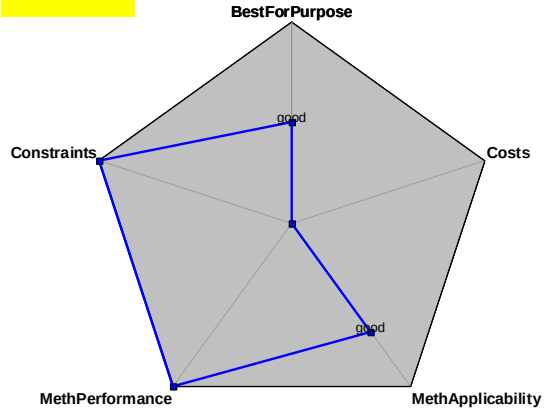
pentaplex-CGE



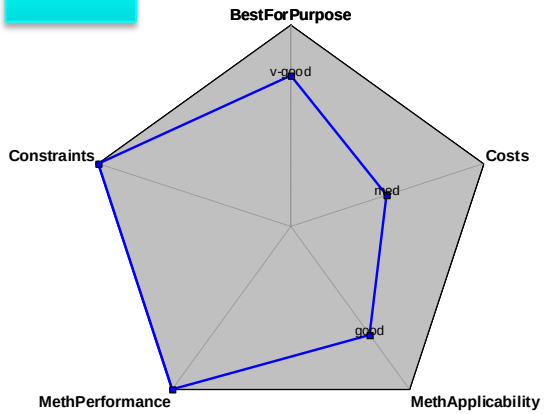
Evaluation of methods

Alternatives

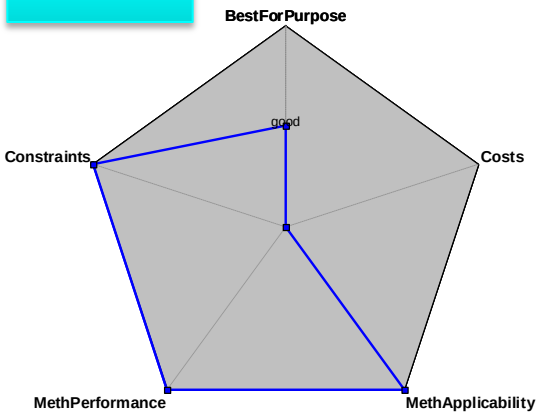
qPCR 35S



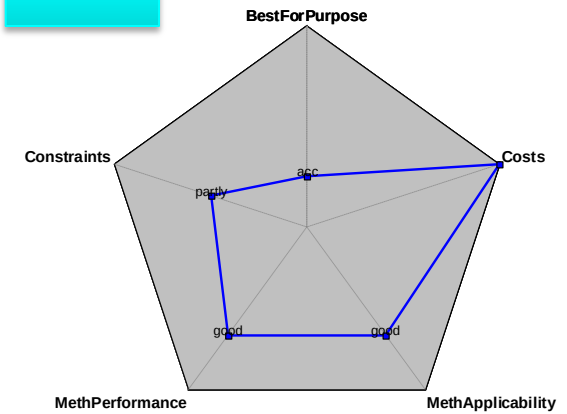
LAMP-BART



SIMQUANT simplex



LFD



Analytical DSS module - conclusions

- DSS is working nicely for evaluation of DNA extraction methods
- some „Fine-tuning“ of Detection method model

Further activities:

- User friendly interface
- Validation by differenct users

Acknowlegments

JSI:

Marko Bohanec

Martin Žnidaršič

NVI:

Arne Holst-Jensen

INRA:

Yves Bertheau