Standardization of immune markers for screening and confirmation

Challenges

Test requirements

- Reliable
- Reproducible
- Accurate
- Concordant
- Highly specific and sensitive
- Multiplex and single antigen tests
- Readily applicable
- Validated in large sample sets
- Affordable
- Certified for diagnostic use

Current tests / formats vary

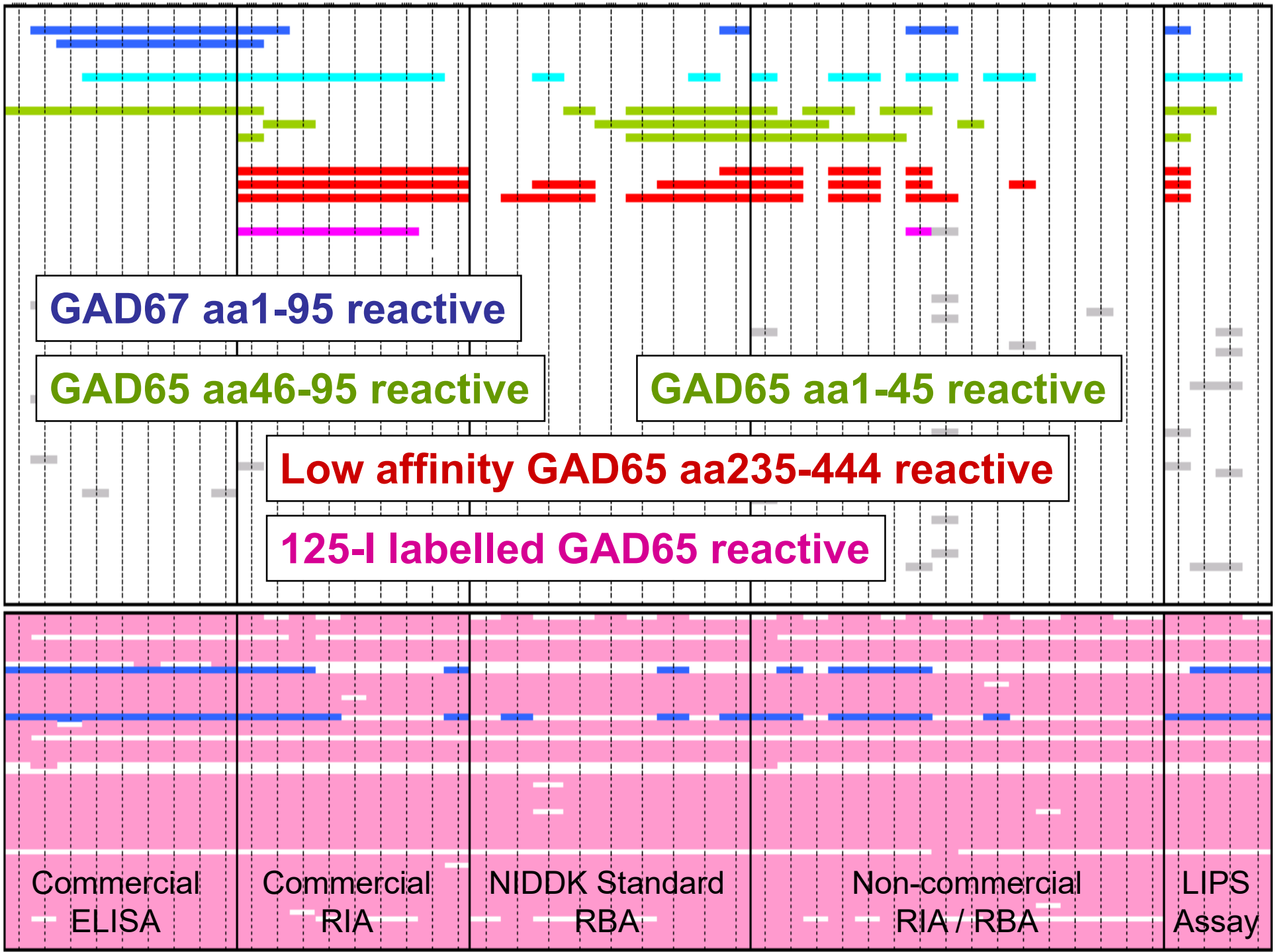
- Type of target antigen
- Number and combination of antigens
- Antigen constructs
- Specific properties / protocols
- Sample volume (and type)
- Quantitative results / units / thresholds

- Common standard samples
- Common callibrators / units
- Stable, inexhaustible source desirable
- Common antigen constructs

- Intrinsic characteristics of tests

Diabetes Autoantibody Standardization Program

DASP 2010
GADA



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Standardization of immune markers for screening and confirmation

Challenges

Autoantibodies

- Heterogeneous analyte type (e.g. polyclonal, different epitopes, affinities, IgG subclasses)
- Implications for large-scale screening

How to gain diagnostic certainty?

- More heterogeneity for single positive and/or low titer autoantibodies
- Adjustment of thresholds?
- Confirmation and persistence of results matters
- “2 (assays) x 2 (samples) concept”? and potentially “x 2 (labs)”

Proficiency testing

- Continuation of the IASP workshop format?
- Feasible on large scale / if many more participants?
- Infrastructure expansion required?
- Test materials?
- Sufficient sample volumes for automated platforms?
- Additional/less complex proficiency tests required?
- Intervals and scope?
- Mandatory participation for screening labs?
- Mandatory disclosure of proficiency testing results?