

# Islet Autoantibody Assay

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## Multiplex (5-Plex) ECL Assay For the ASK Study

Liping Yu, MD



Barbara Davis Center for Childhood Diabetes  
UNIVERSITY OF COLORADO ANSCHUTZ MEDICAL CAMPUS

# Challenges of Current Assay (RBA) for General Population Screening

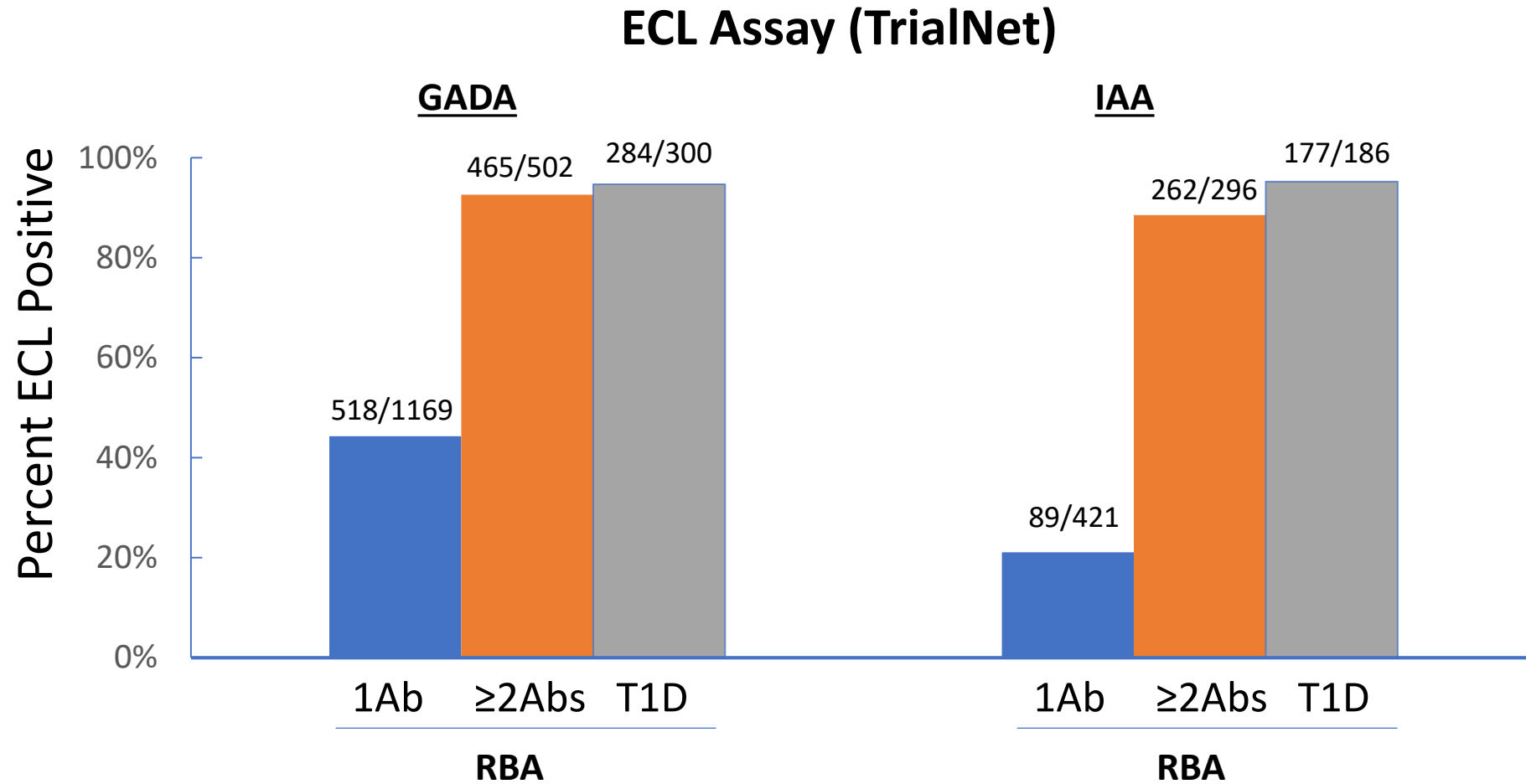
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- 1. Disease specificity (antibody-affinity)**
- 2. Cost – efficiency (high-throughput)**



# 1. Disease specificity (antibody-affinity)

## ECL assay discriminate high-risk from low-risk Abs

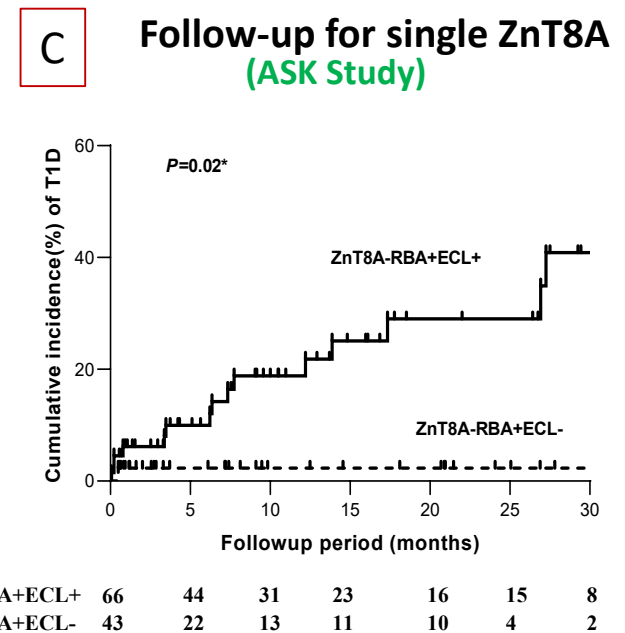
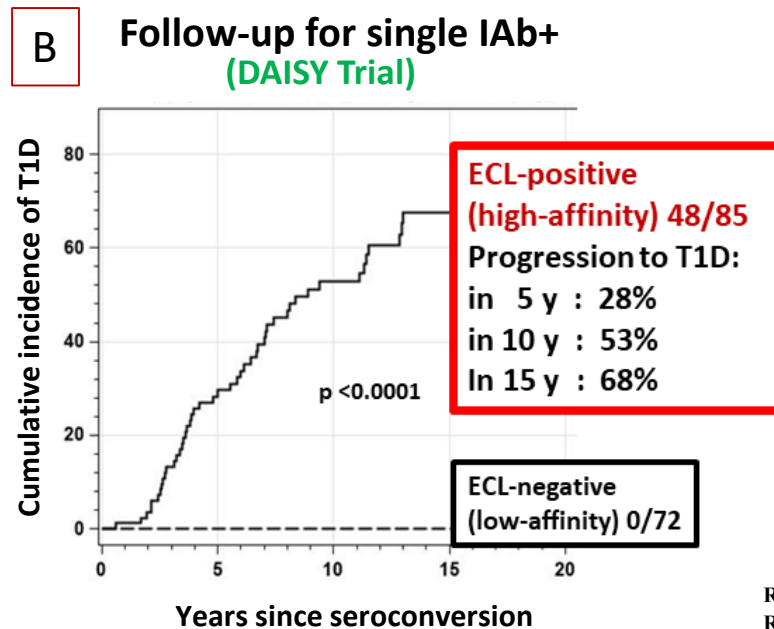
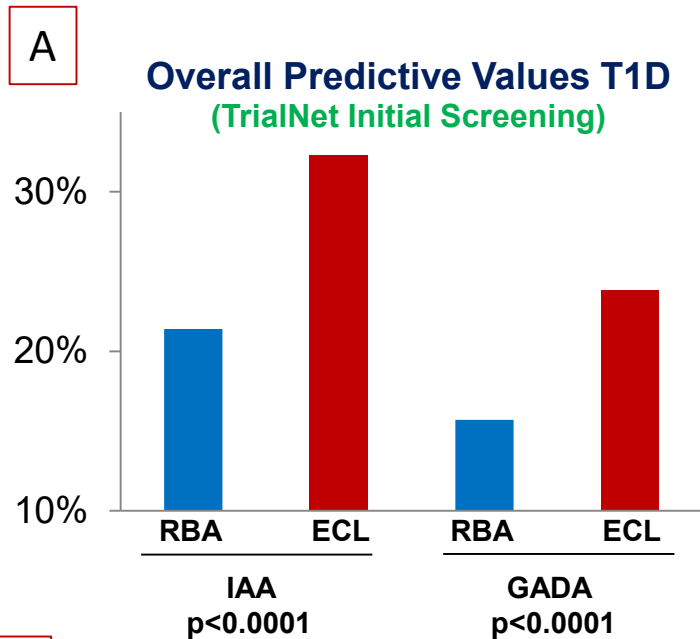


Miao D, et al. Diab Tech & Therapeutics 17:119-27, 2015



# 1. Disease specificity (antibody-affinity)

## ECL assay discriminate high-risk from low-risk Abs



**D**

TrialNet Study	RBA positive, <b>GADA only</b>			RBA positive, <b>IAA only</b>		
	ECL+ (n=107)	ECL- (n=78)	p-value	ECL+ (n=24)	ECL- (n=63)	p-value
PS6M* (mg/dl)	22 ± 90	-19 ± 71	0.001	36 ± 75	-9 ± 70	0.009
Progressed to T1D	14.0% (n=15)	1.3% (n=1)	0.002	16.7% (n=4)	0% (n=0)	0.005

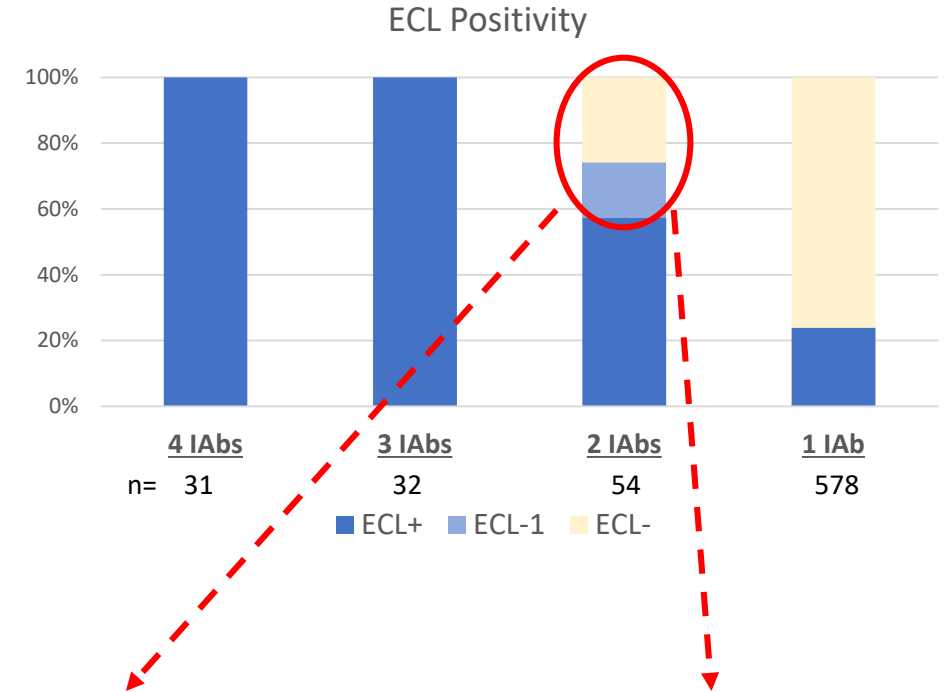
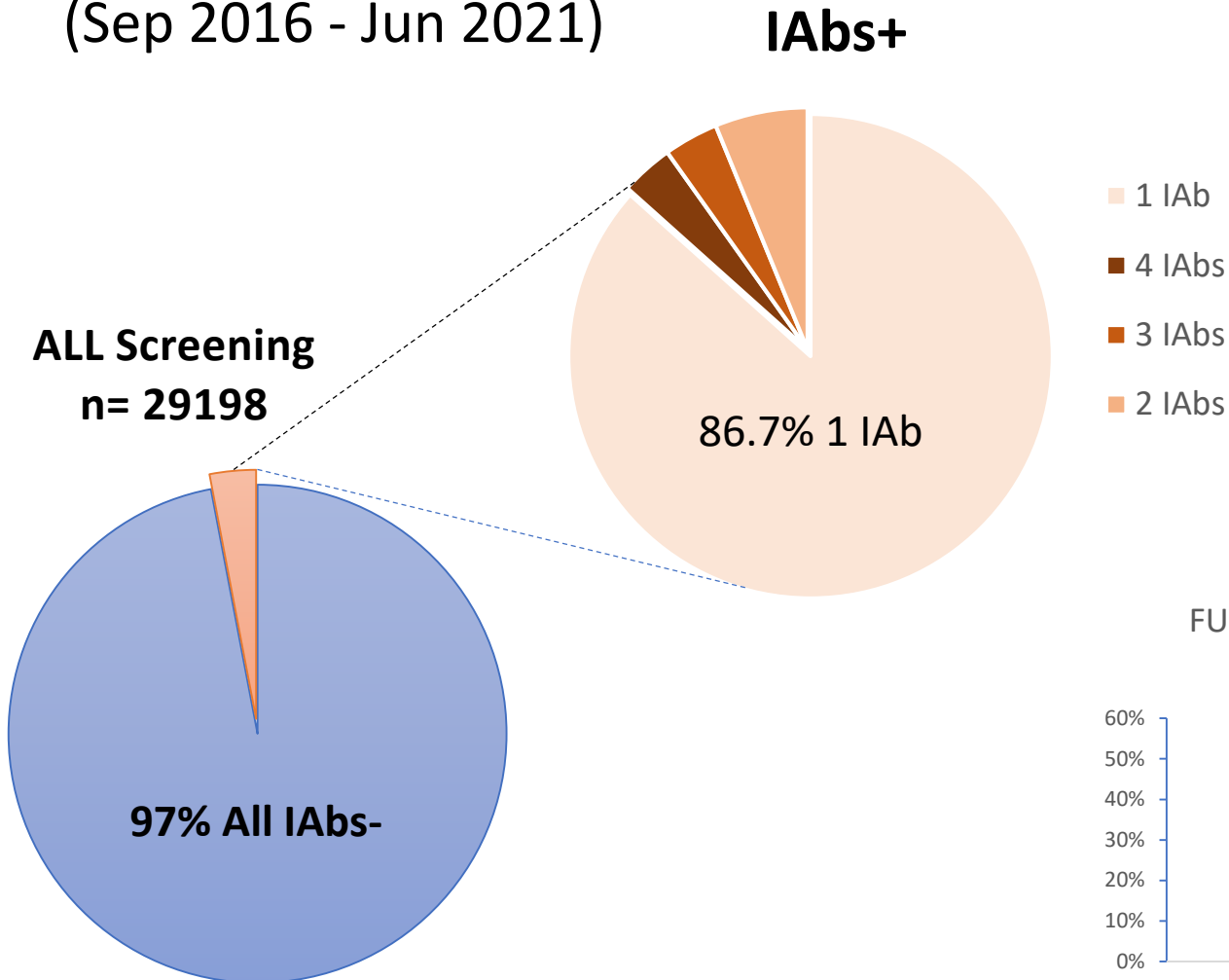


# 1. Disease specificity (antibody-affinity)

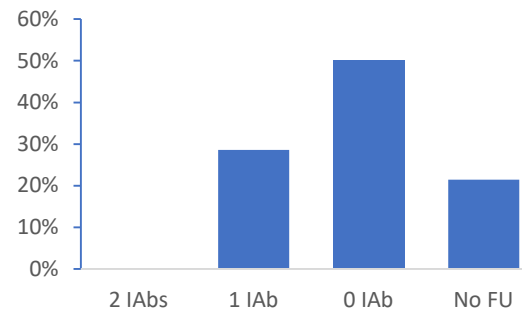
## ECL assay has higher predictive values

### ASK IAb Positivity

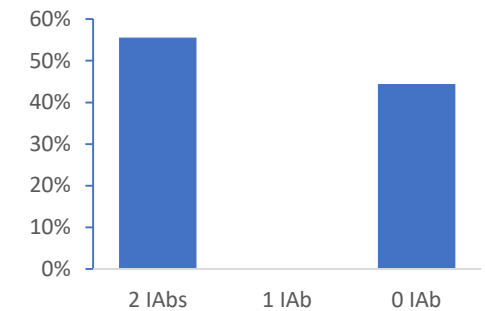
(Sep 2016 - Jun 2021)



FU for 2 IAbs RBA+/ECL- (n=14)



FU for 2 IAbs RBA+/ECL-1 (n=9)



## 2. Cost – efficiency (high-throughput)

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### Combining multi-ECL assays into single well (Multiplex ECL assay)

#### Cost (5 autoantibodies)

Multiplex ECL: \$30 (33%)

RBA: \$90

#### Throughput (5 Abs/week)

Multiplex ECL: 800 (4x)

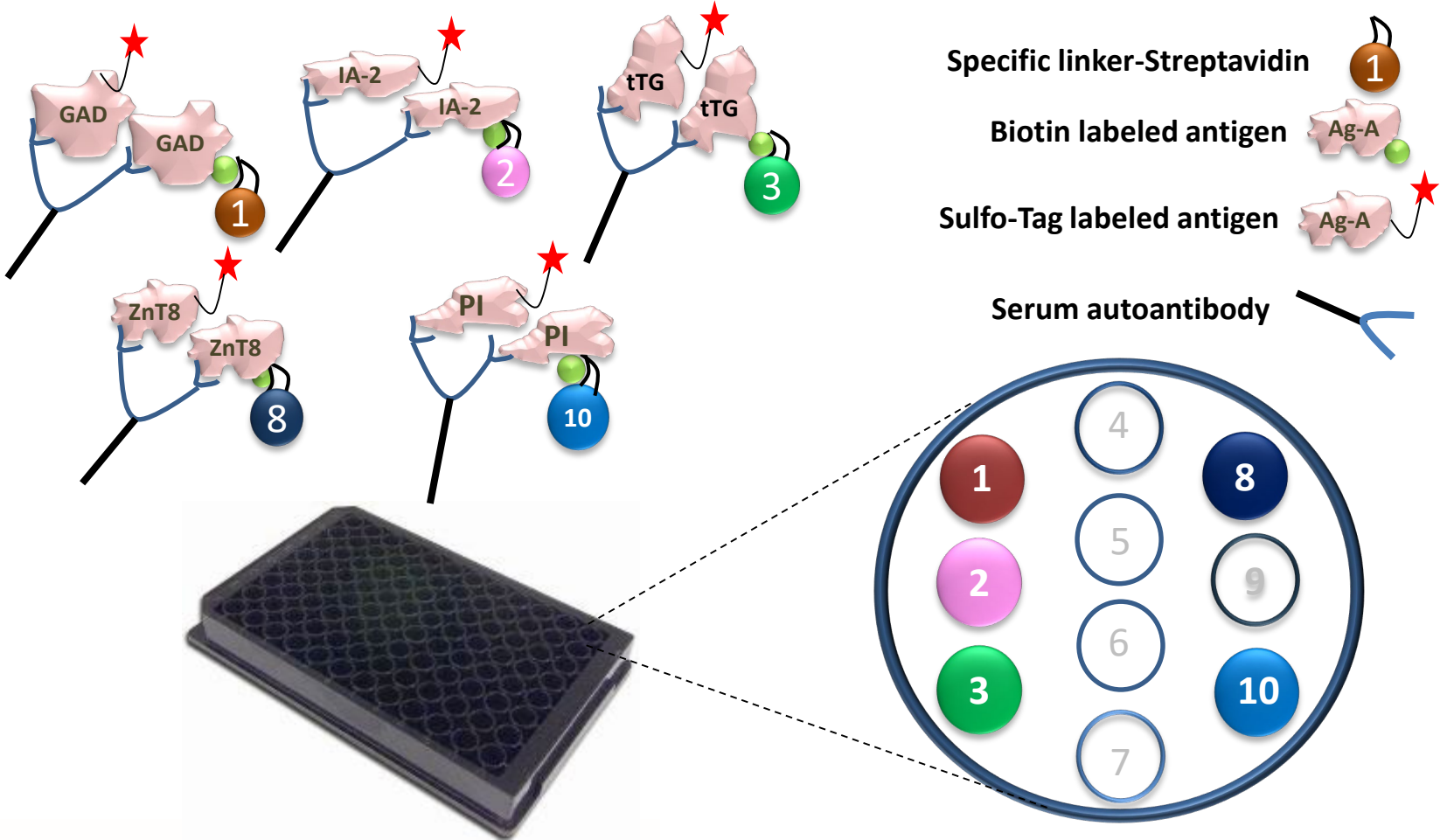
RBA: 200



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# Multiplex (5-Plex) ECL Assay For the ASK Study

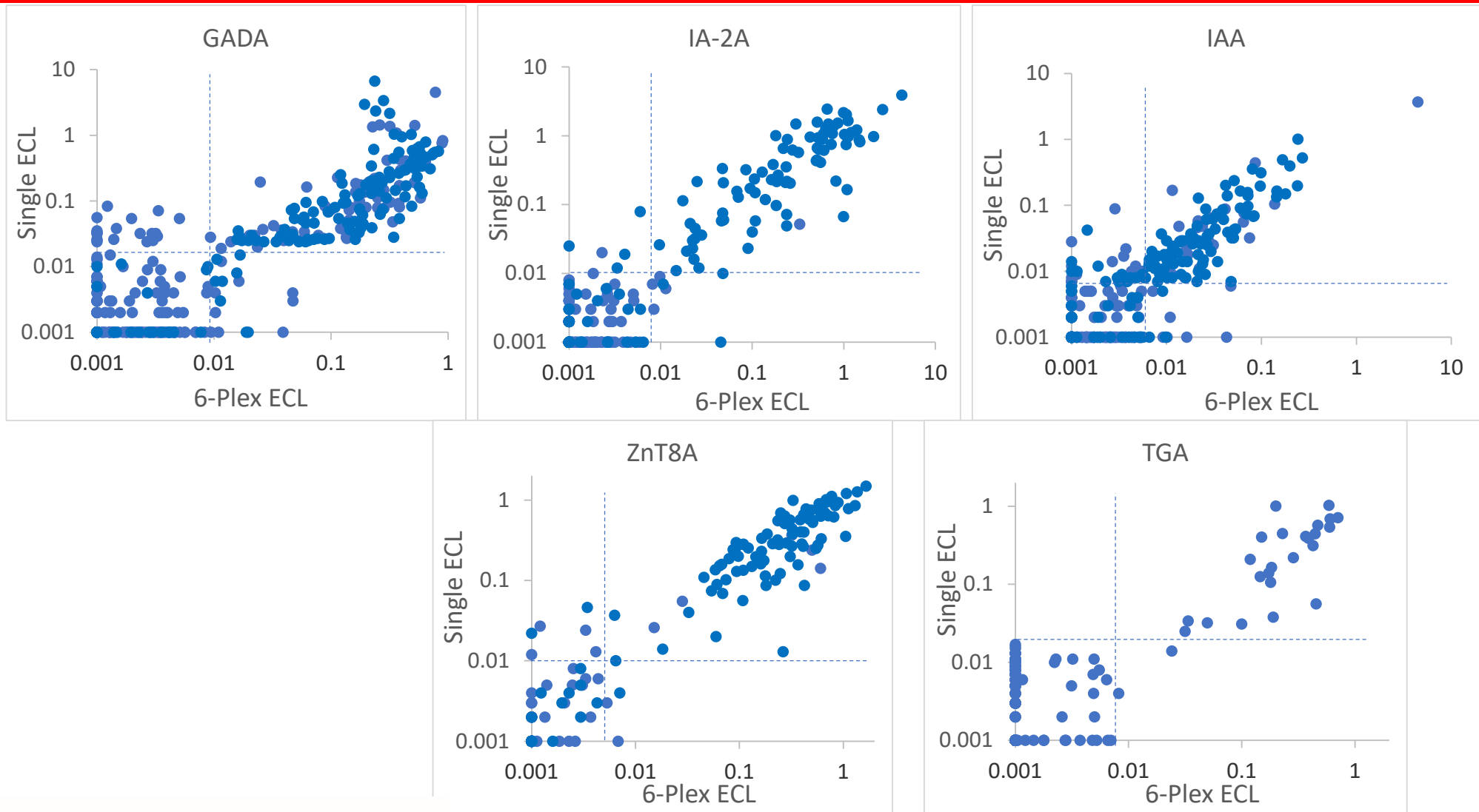


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# Multiplex (6-Plex) ECL assay

## Compare with each single ECL assay

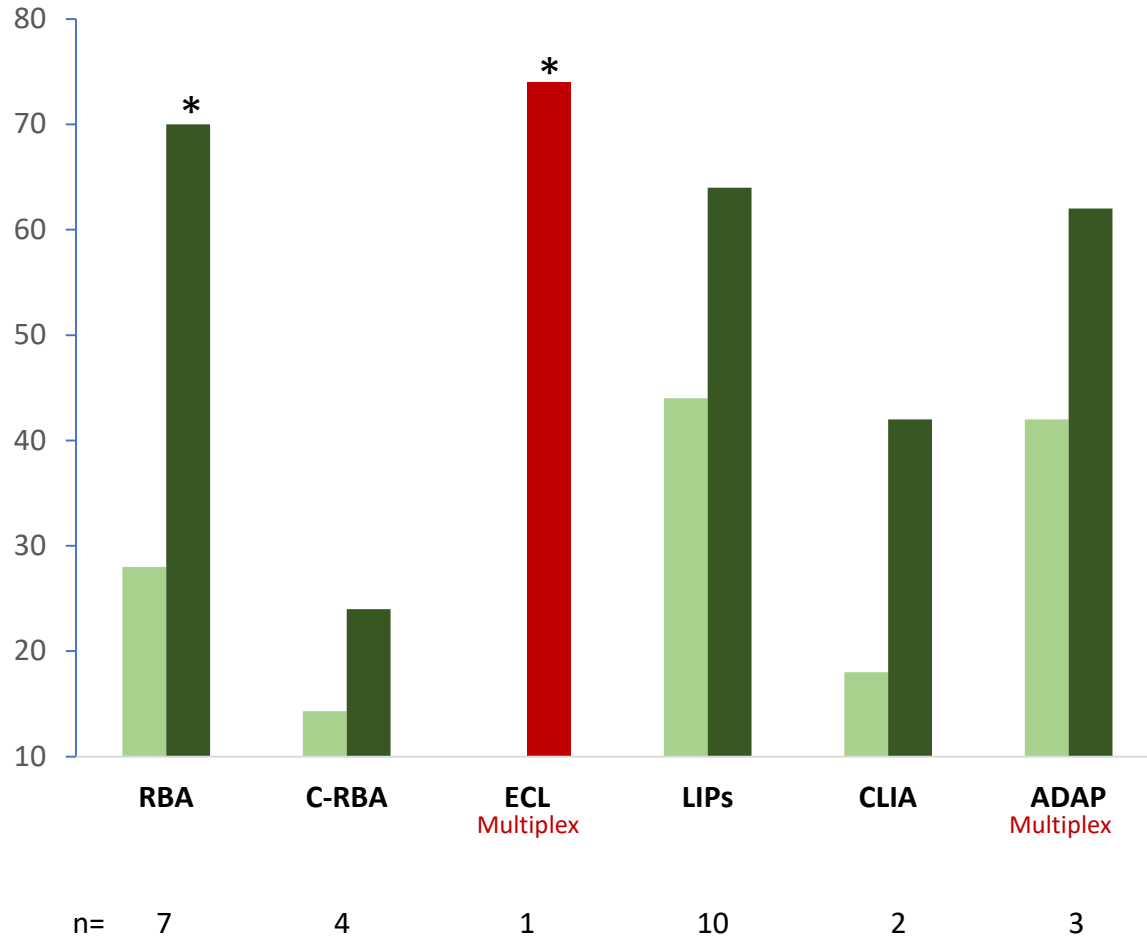




# 2023 IASP Workshop

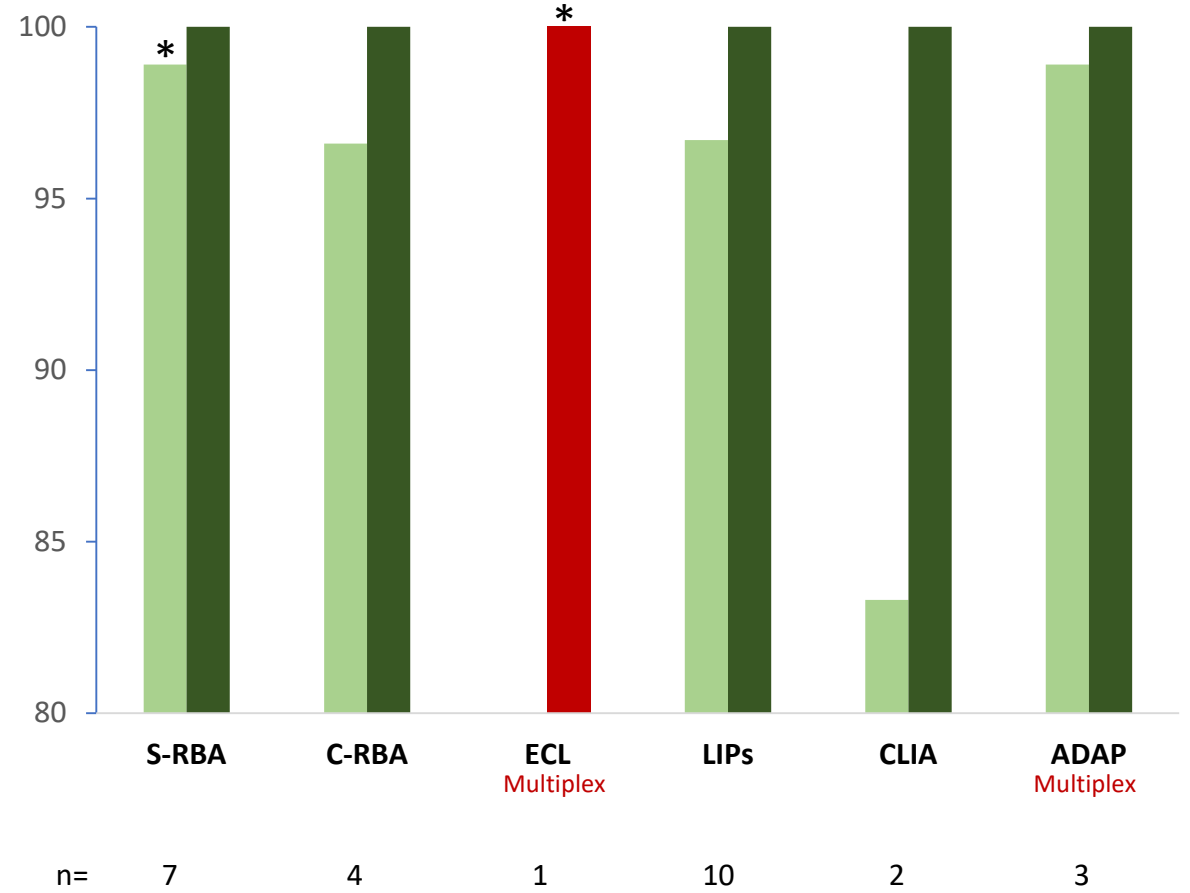
## IAA-Sensitivity

■ mini ■ maxi



## IAA-Specificity

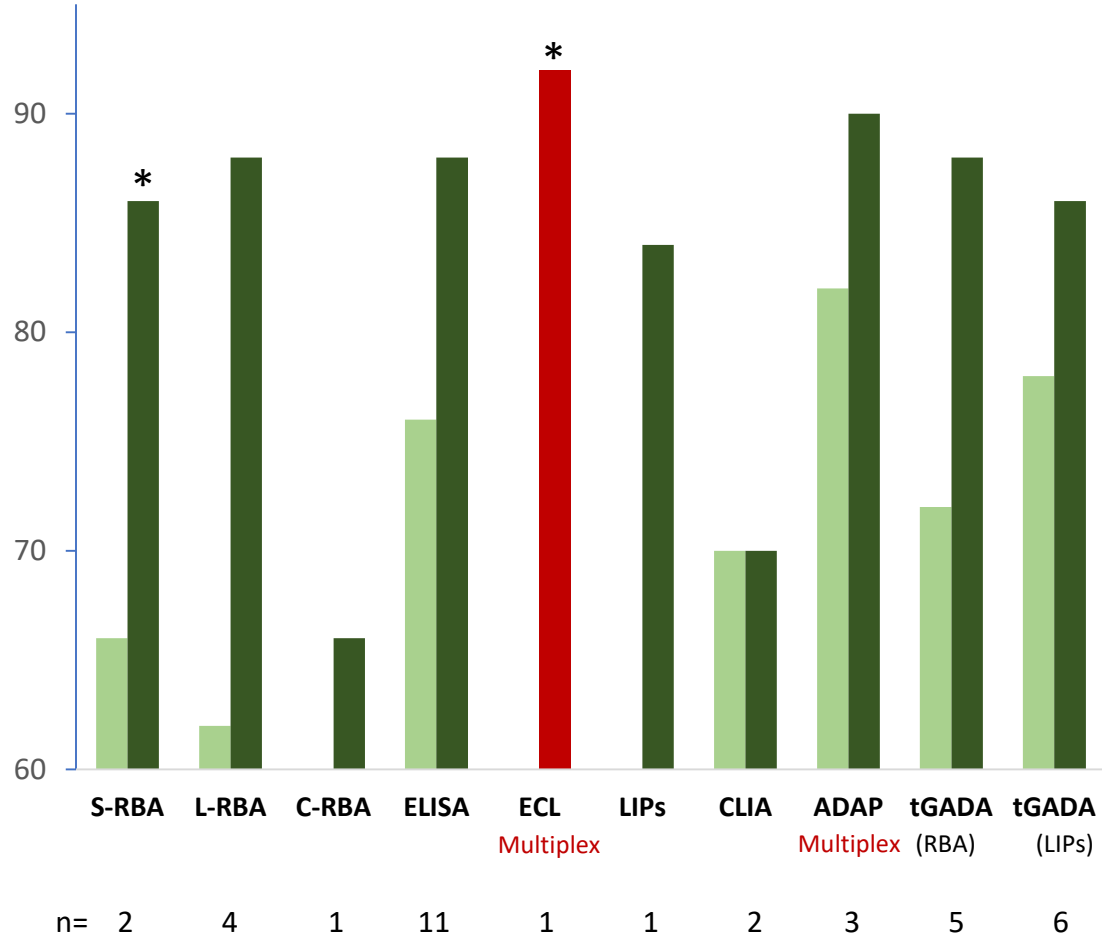
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# 2023 IASP Workshop

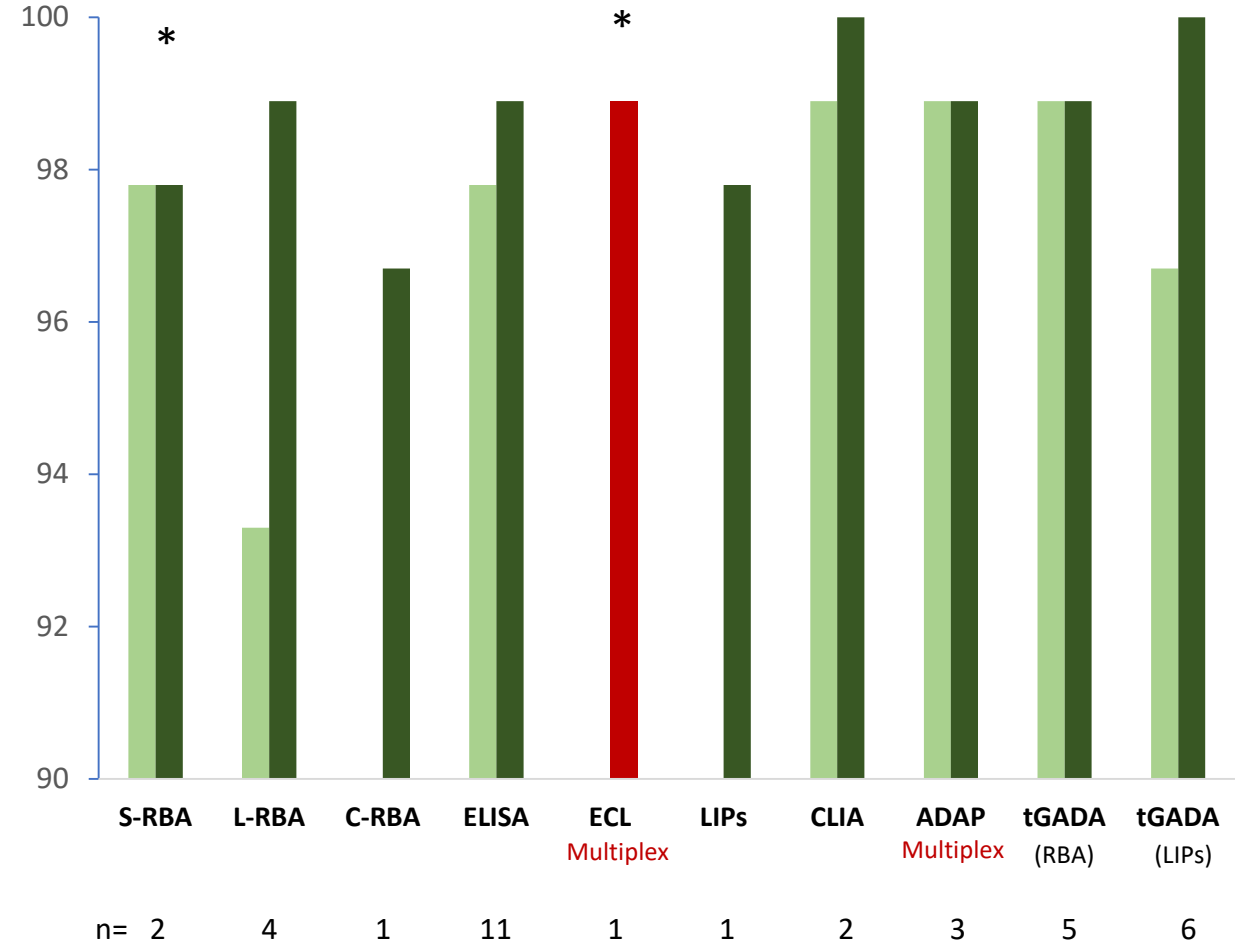
## GADA-Sensitivity

■ mini ■ Maxi



## GADA-Specificity

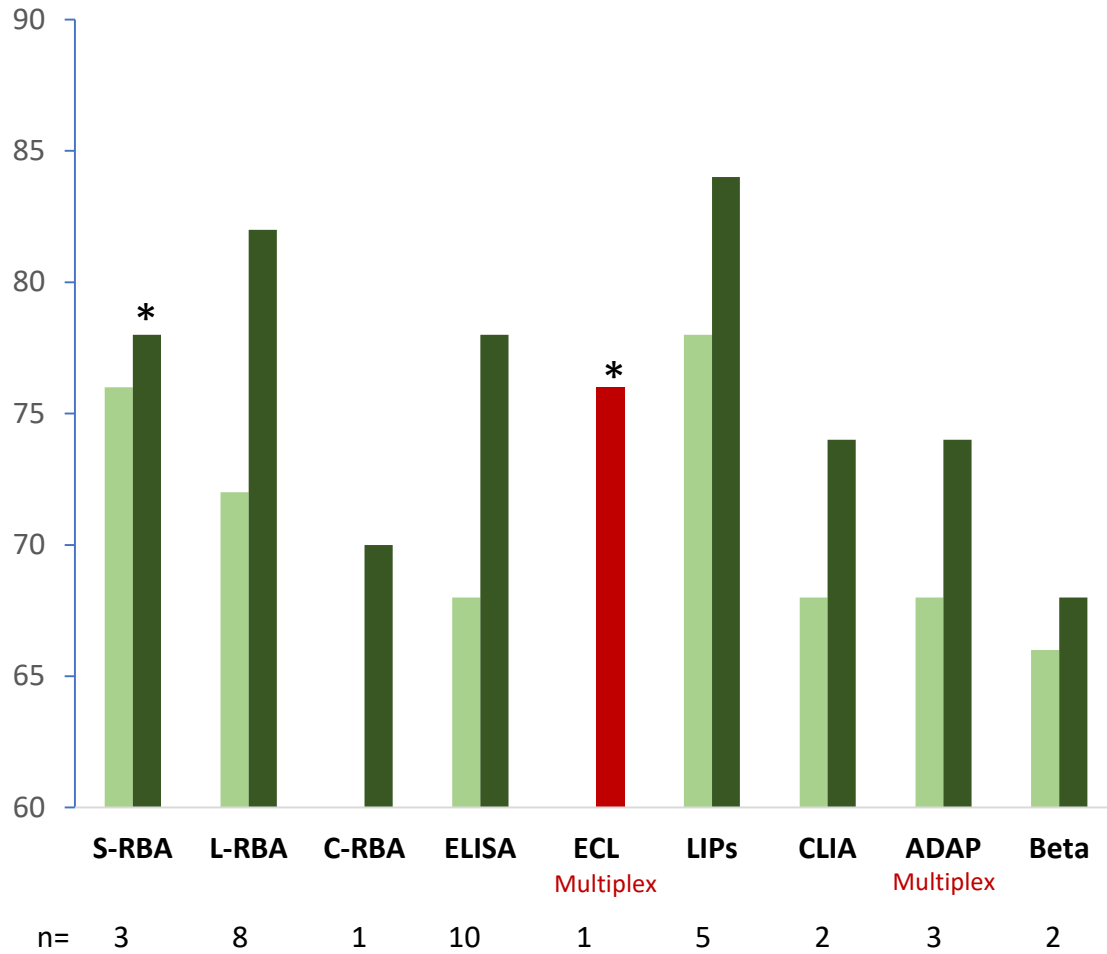
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# 2023 IASP Workshop

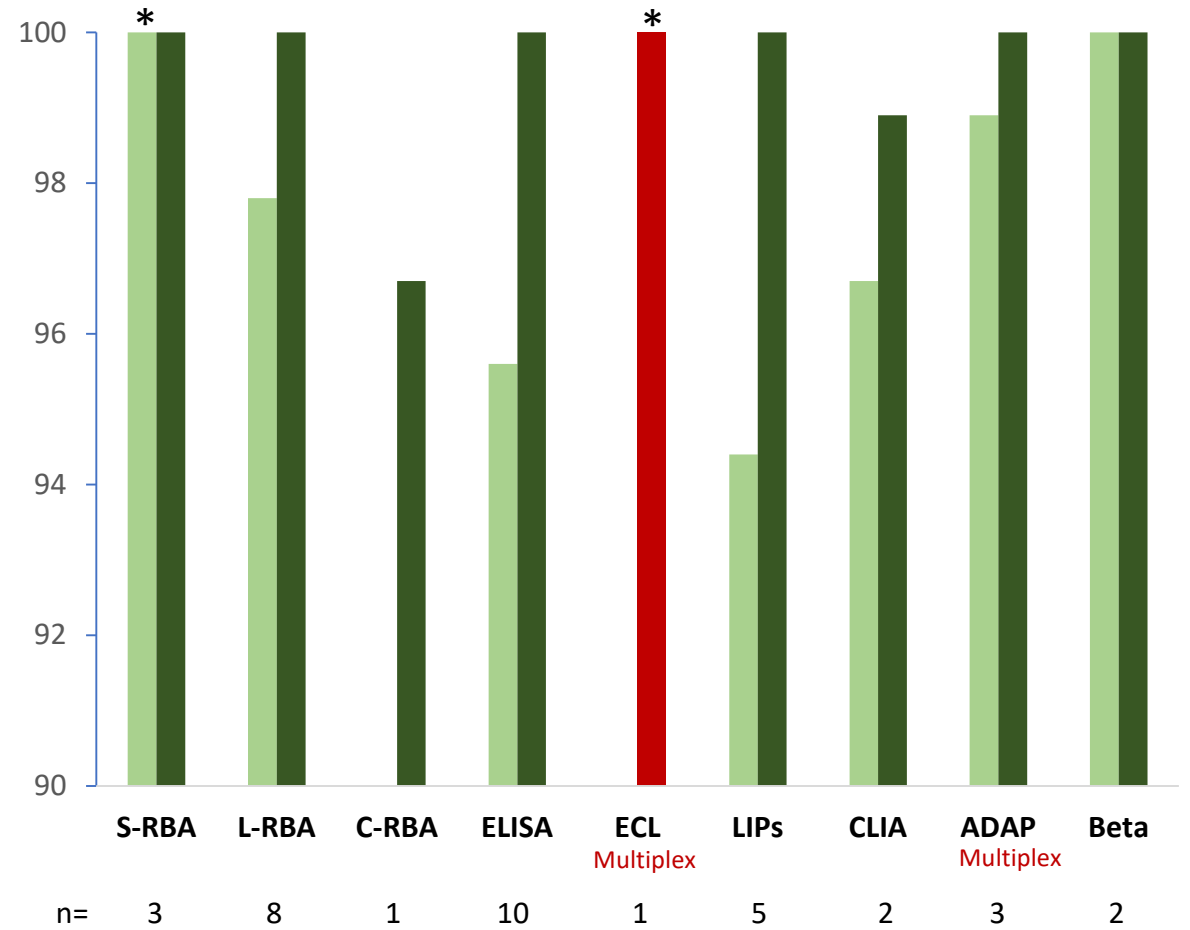
## IA2A-Sensitivity

■ mini ■ maxi



## IA2A-Specificity

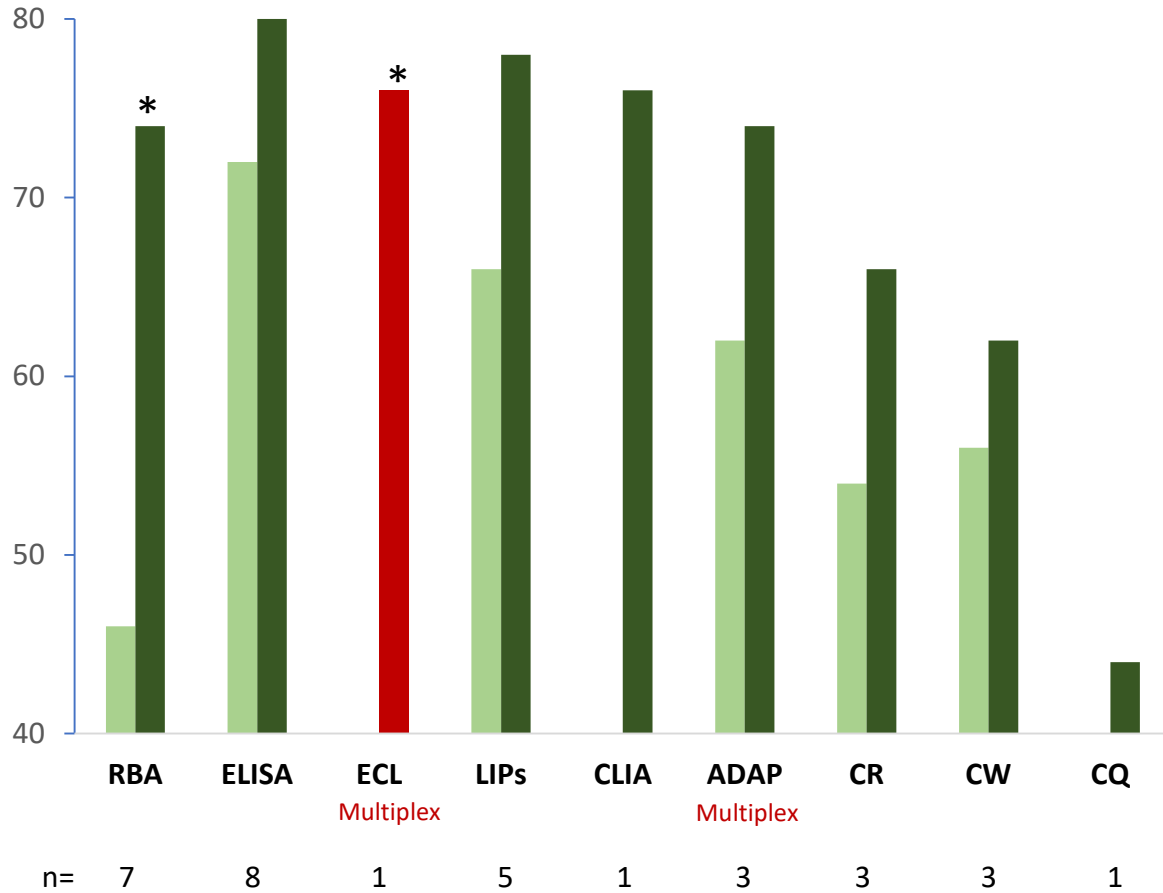
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# 2023 IASP Workshop

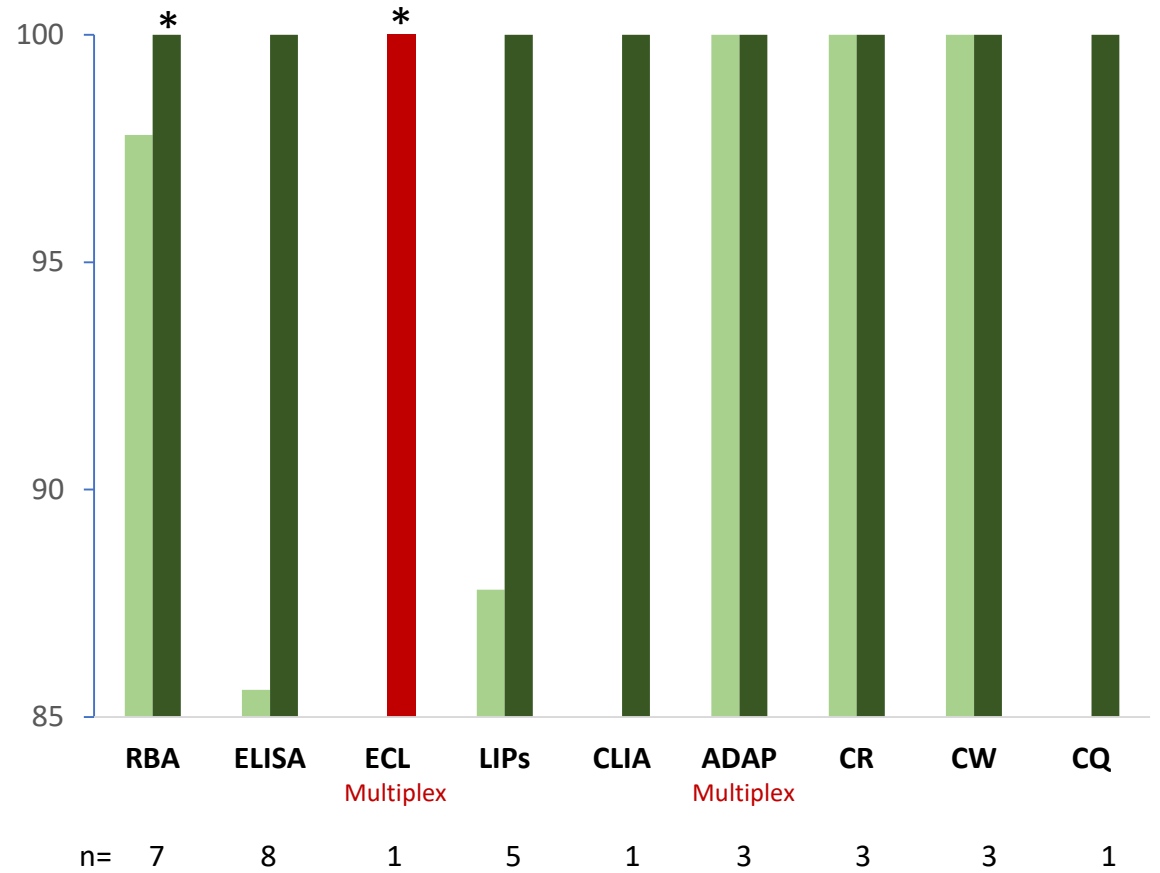
## ZnT8A-Sensitivity

■ mini ■ maxi



## ZnT8A-Specificity

■ mini ■ maxi



# Summary

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## Multiplex ECL assay

1. Higher throughput, lower cost, lower volume of sera;
2. More disease specific with higher predictive values

