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BACKGROUND

- Quantification of anti-HBs antibodies (**HBsAb**) is a key parameter to assess vaccination efficacy or to monitor hepatitis B immunoglobulin protection level in liver transplanted patients.
- Reliability of HBsAb quantification depends on technique standardization accuracy
- Naturally acquired or vaccine induced antibodies are not identical and may not be similarly quantified

OBJECTIVE

- to assess the performance of **Liaison XL Murex Anti-HBs Plus (DiaSorin)**
- to compare anti-HBs quantification with **Roche Elecsys anti HBs II** and **Abbott Architect** assays
- to appraise anti-HBs quantification after natural or vaccine-induced immunization

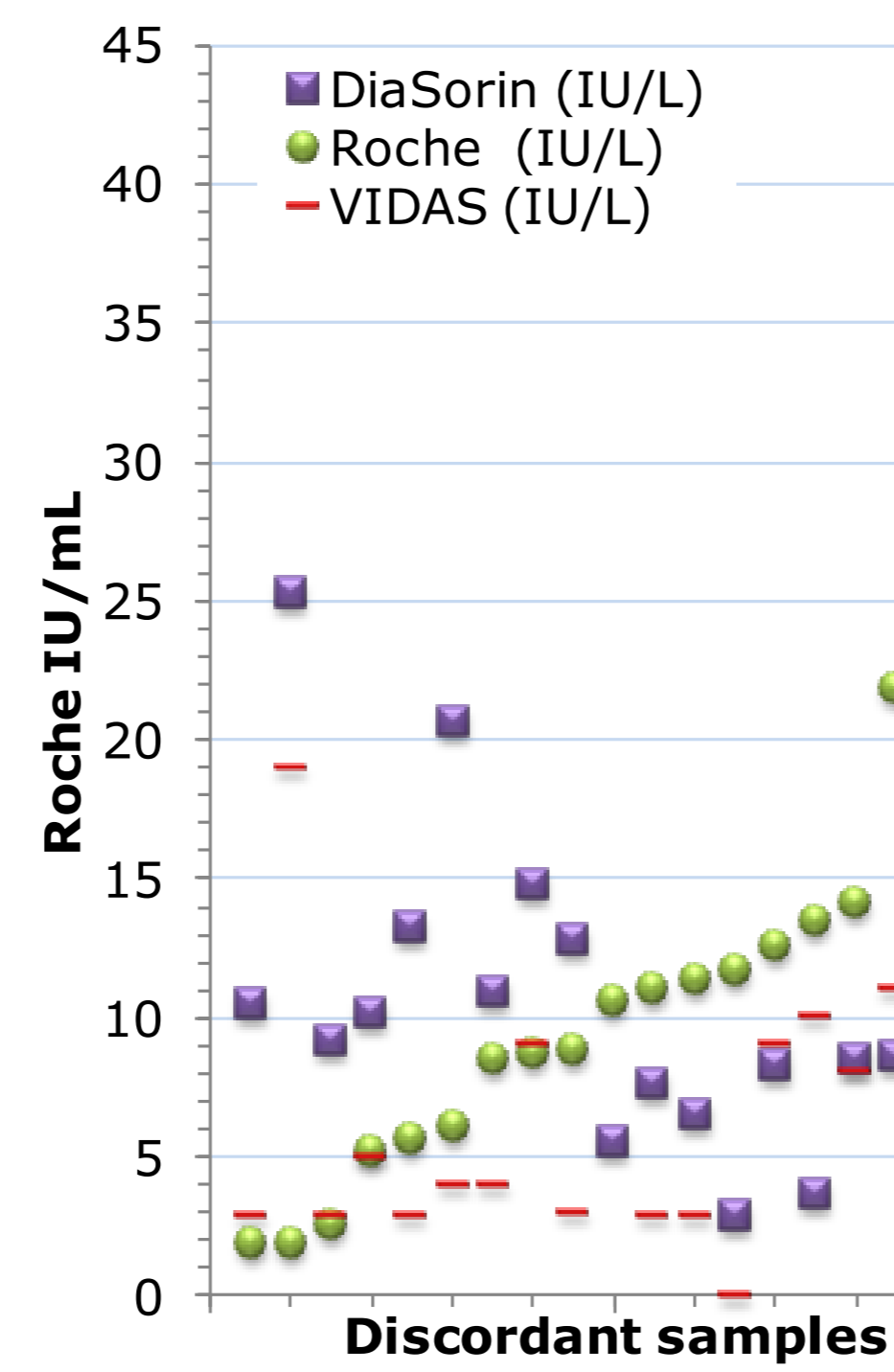
RESULTS

1 Overall agreement rate between DiaSorin and Roche qualitative results (n=563)

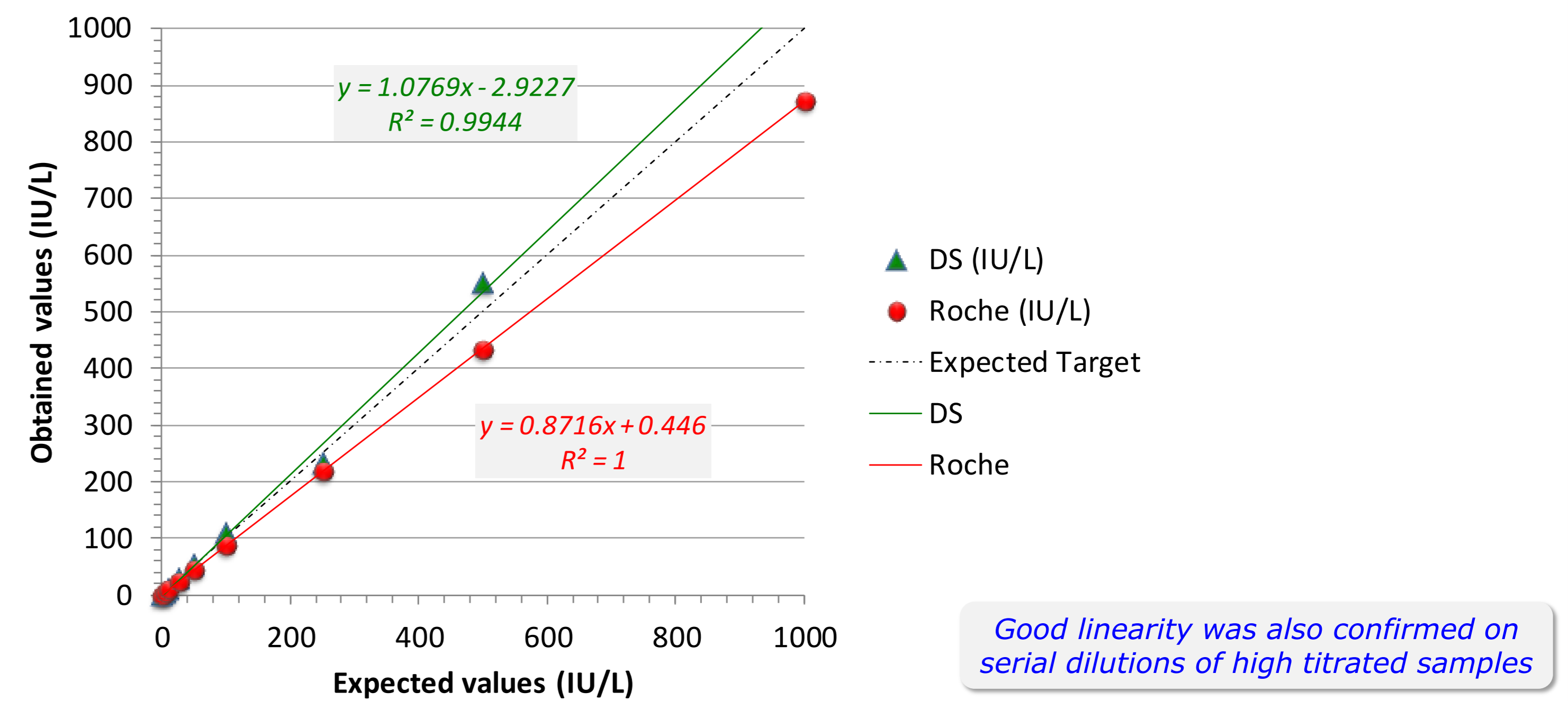
Roche	DiaSorin		Total
	NEGATIVE	POSITIVE	
NEGATIVE	223 39.6%	9 1.6%	232 41.2%
POSITIVE	10 1.8%	321 57.0%	331 58.8%
Total	233 41.4%	330 58.6%	563 100.0%

The overall agreement between both techniques was 96.6% [95-98%]

Distribution HBsAb values of discordant samples retested with BioMerieux Vidas

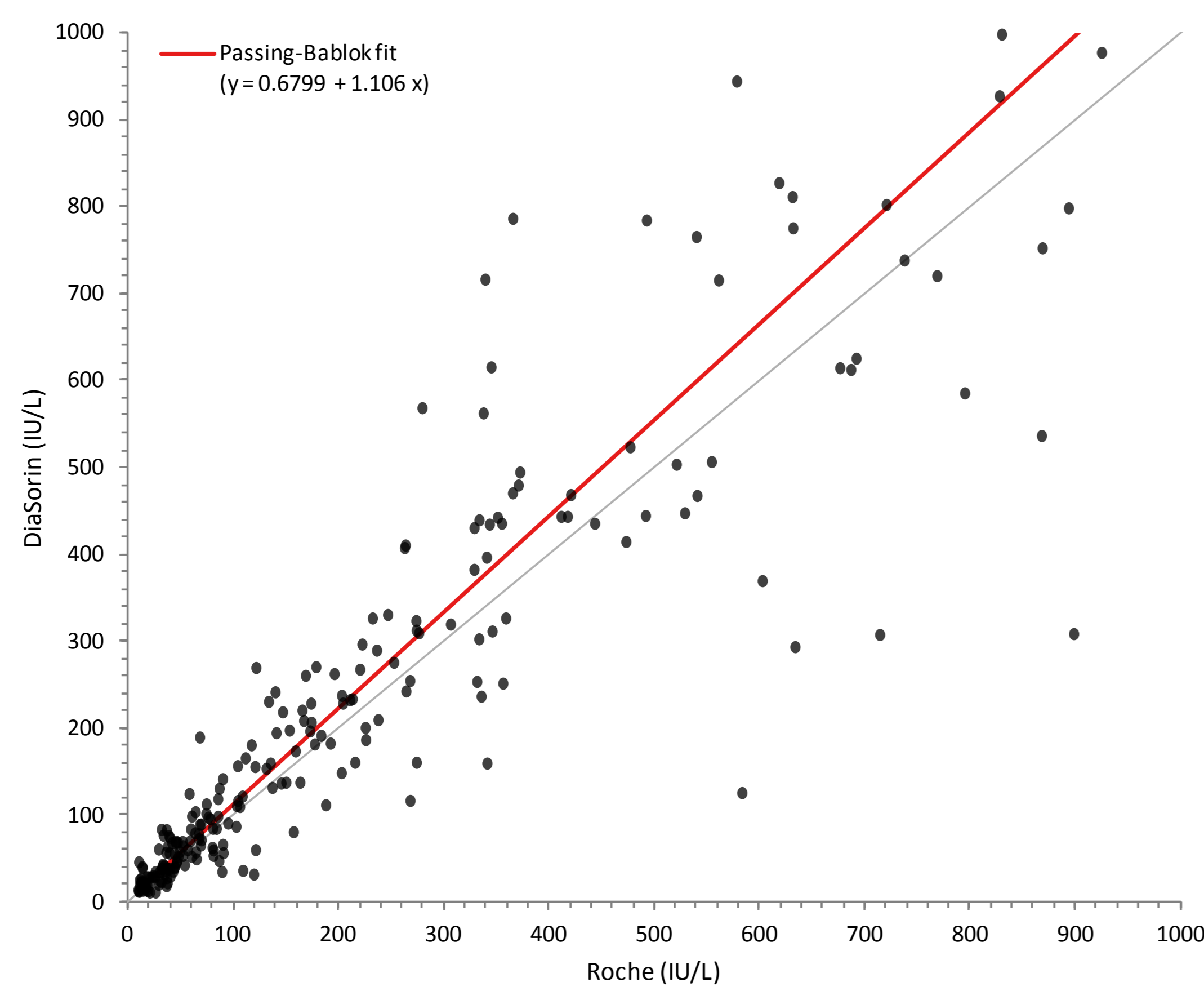


2 Standardisation of both Roche and DiaSorin techniques against the WHO standard

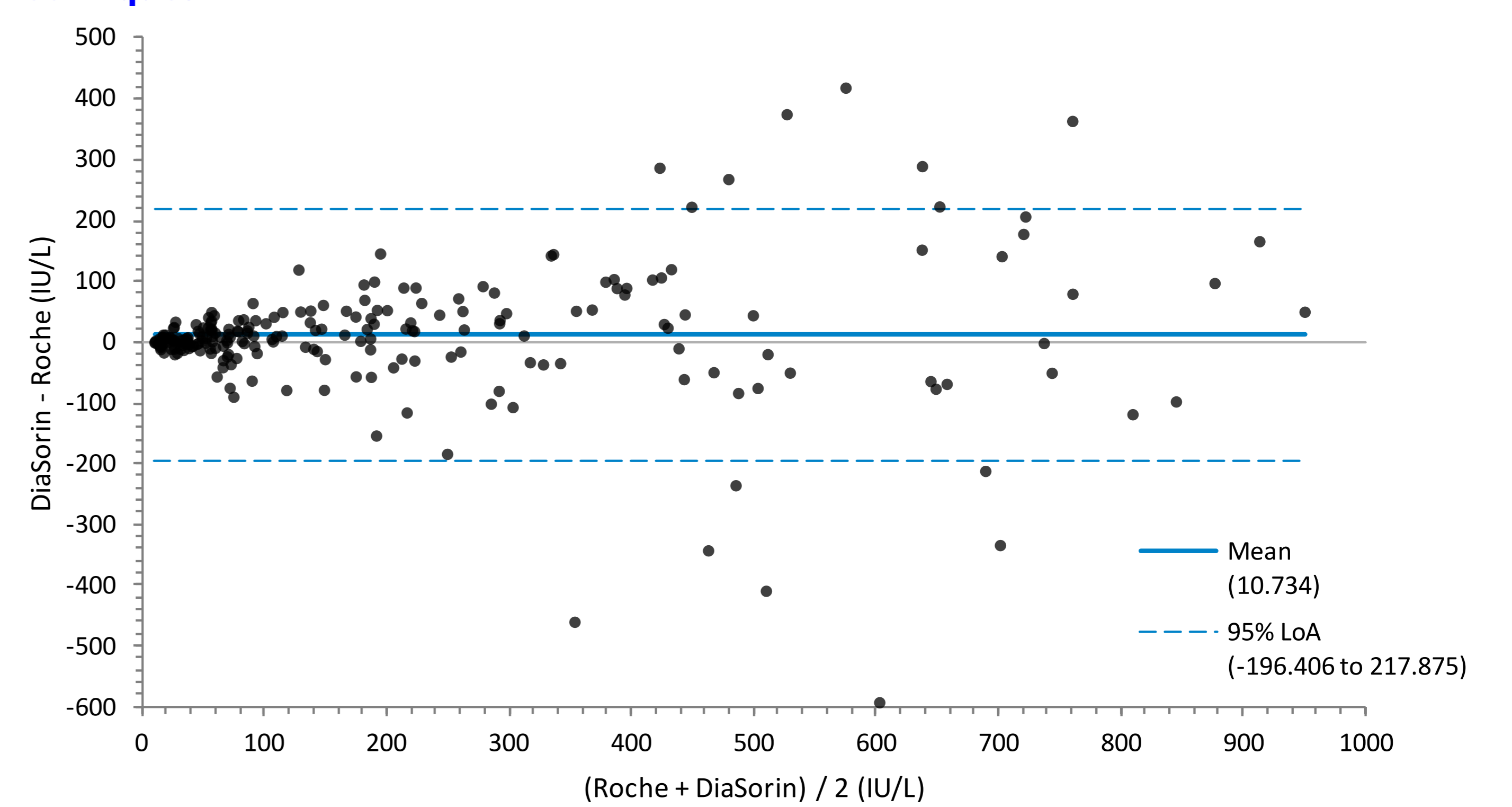


Good linearity was also confirmed on serial dilutions of high titrated samples

3 Passing-Bablok analysis on 225 values within the quantification range for both techniques

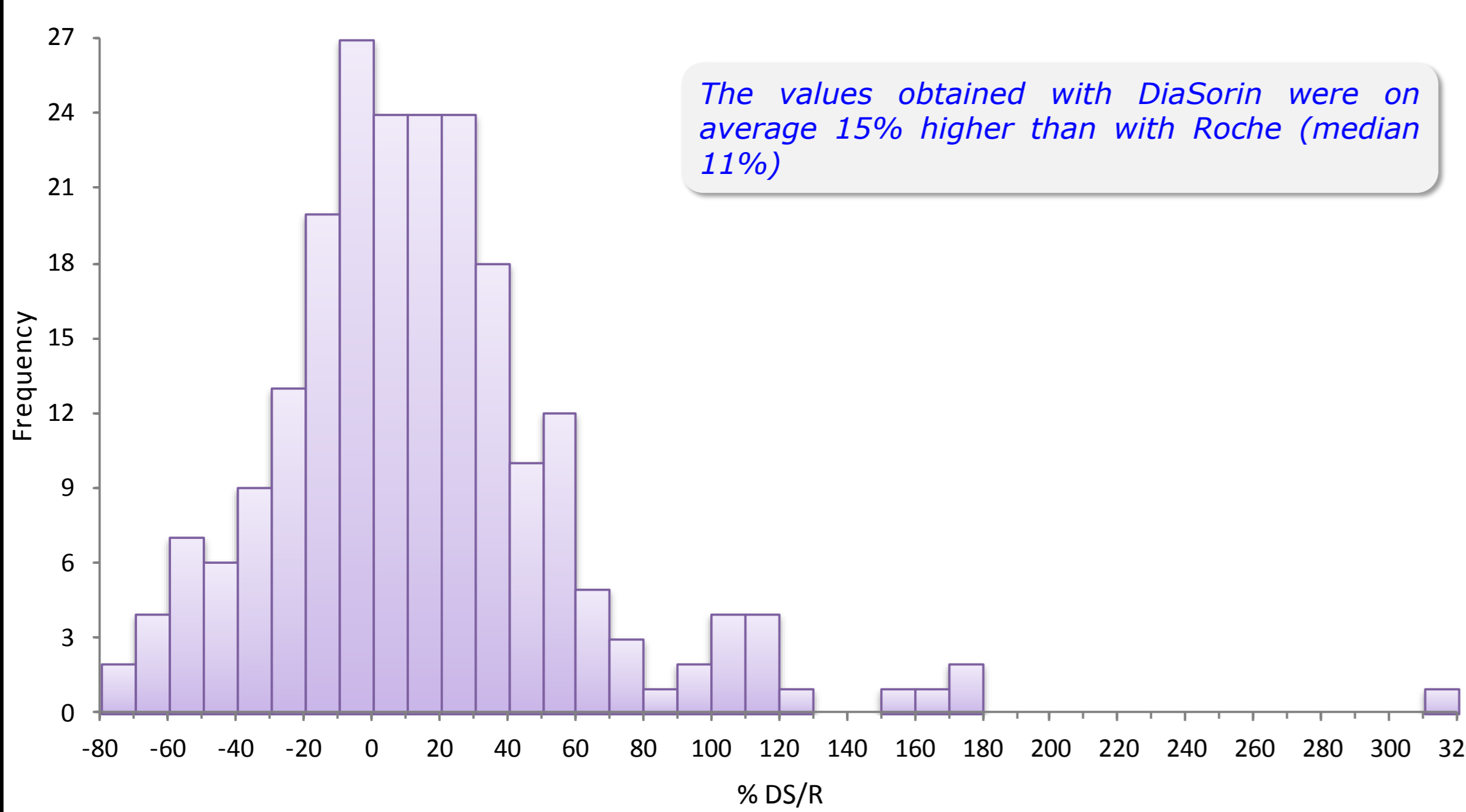


4 Bland-Altman analysis on 225 samples within the quantification range for both techniques



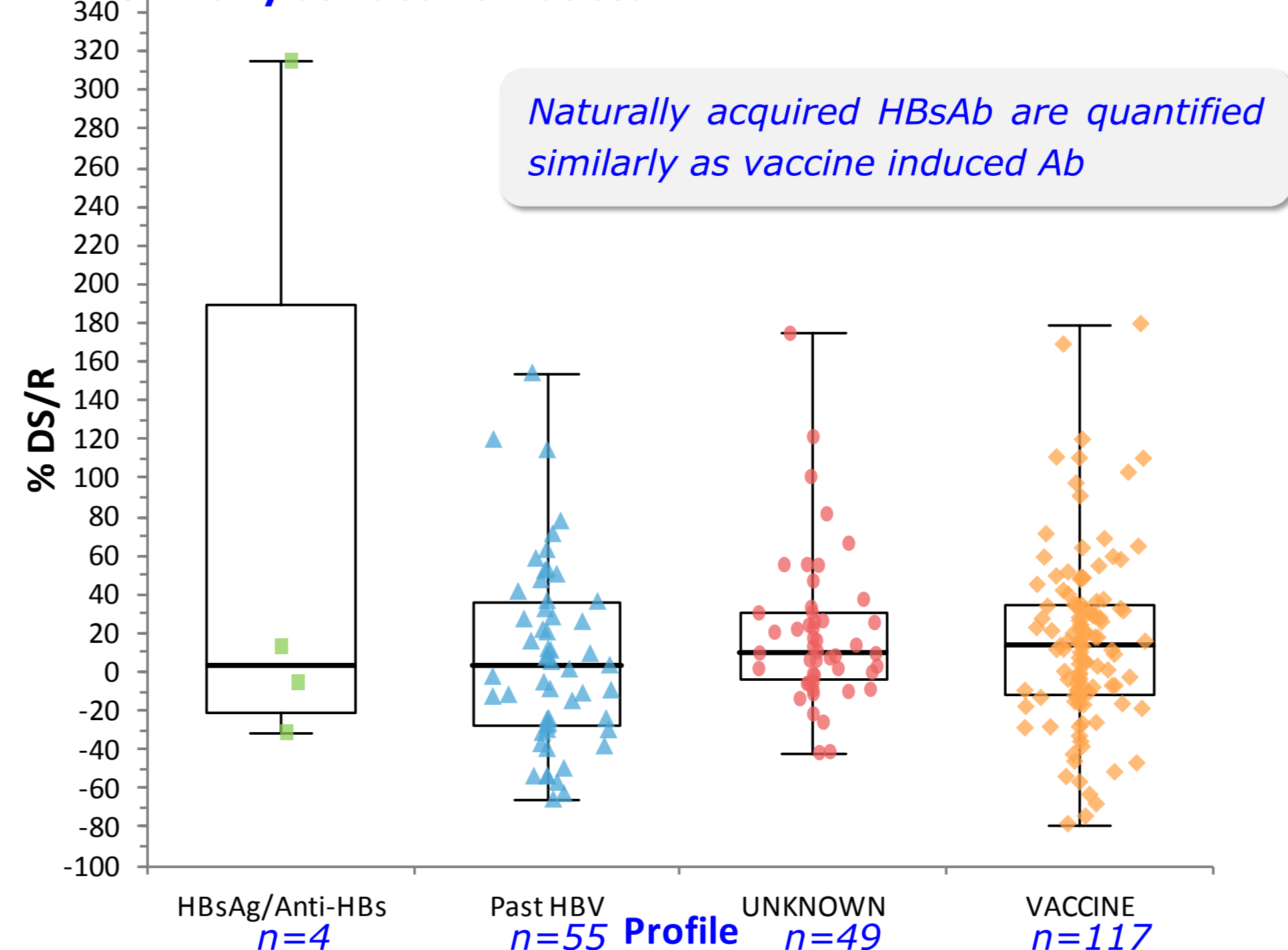
The mean bias between the two techniques is 10.7 IU/L [-3.15 - 24.6]

5 Distribution of HBsAb quantification differences expressed as a percentage of DiaSorin over Roche (n=225)



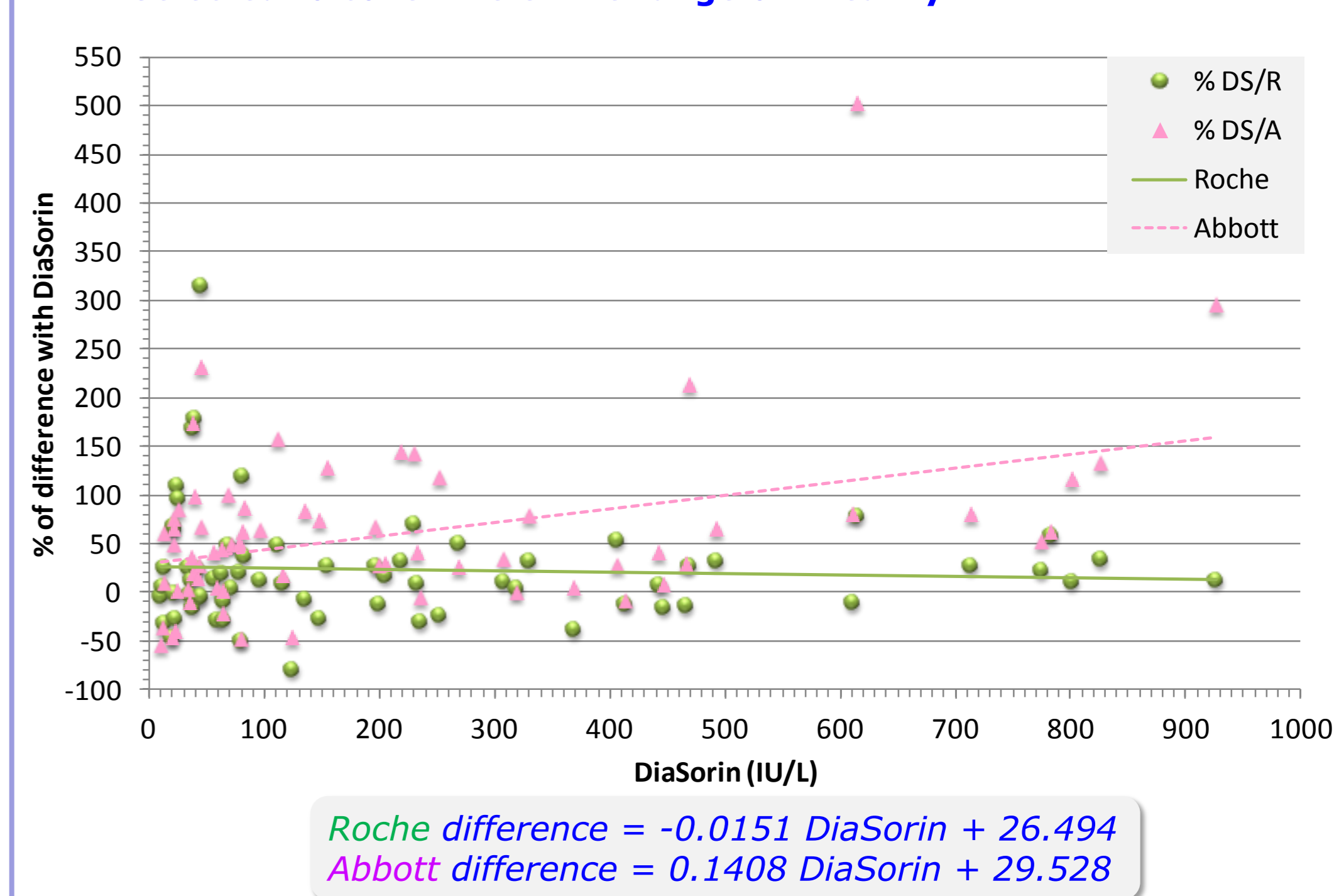
The values obtained with DiaSorin were on average 15% higher than with Roche (median 11%)

6 Difference of quantification according to HBV serological profiles (p=0.5; ns): naturally acquired HBsAb are quantified similarly as vaccine induced Ab.



Naturally acquired HBsAb are quantified similarly as vaccine induced Ab

7 Difference of DiaSorin quantification compared to Roche Cobas and Abbott Architect on 100 samples randomly selected to cover the entire range of linearity



Roche difference = -0.0151 DiaSorin + 26.494
Abbott difference = 0.1408 DiaSorin + 29.528

CONCLUSIONS

- the DiaSorin assay possesses at least **comparable performances** as the Roche test.
- The 96.6% **qualitative agreement** between both techniques is satisfactory. The **few qualitative discordant** results did not favor one assay over the other when tested on a third party assay.
- Standardization** to the WHO standard was excellent as well as **linearity**. The overall correlation between Roche and DiaSorin on clinical samples was good whatever the encountered serological profile.
- A **limited** comparison with the Abbott Architect confirms previous data and tends to indicate an **imperfect standardization** of Abbott assay to the international unit.

METHODS

The **methods** were:

- ROCHE Elecsys Anti-HBs II as our routine technique and used to determine the serological profiles, HBsAb BioMerieux Vidas was used to confirm most discordant samples.

The **material** consisted of several categories of samples:

- 100 HBV vaccines (fresh and frozen)
- 100 past HBV infection (fresh and frozen)
- Up to 200 hundred serum samples from patients and health care workers from daily submissions for routine anti-HBs testing without any selection (fresh).
- 100 positive specimens (selected and provided by DiaSorin, frozen)
- WHO International Standard - Second International Standard for anti-hepatitis B surface antigen (anti-HBs) - (provided by DiaSorin)
- 5-10 samples with high anti-HBs titers, serially diluted, to check the recovery test with both methods.