

# Comparative Study of Monobind AccuBind<sup>®</sup> ELISA Vit D Direct versus Diasorin

Monobind Inc.

## Background

Different assay systems produce different values and labs generally desire to report values consistent with leading immunoassay manufacturers so doctors can more easily interpret patient results. While preference of manufacturer may vary market-to-market, Monobind's development process involves correlation with leading systems.

Value differences are generally related to the antibodies used in the respective systems which can have unique epitope recognition and response in patient samples<sup>1</sup>. In some cases antibodies may be owned by the manufacturer and not commercially available yet efforts are made to identify similar antibodies.

## Study Materials & Methods

System agreement of **Monobind AccuBind Vit D Direct ELISA** (Item # 9425-300) was assessed by running 83 patient samples manually and the same samples on the **Diasorin Vitamin D Liaison CLIA System**. The study was performed by Monobind QA and presented using the Bland-Altman plot in analytical chemistry to analyze the two assays correlation. The Passing-Bablok regression method was used to assess the distribution of samples and the measurement errors.

## Patient Samples

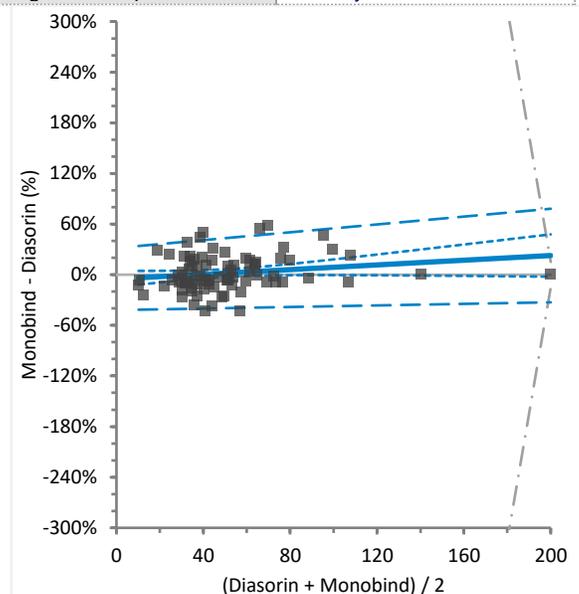
The 83 patients used were representative of the full range in the assay's measurement (low, middle and high values), which is imperative in any method comparison study<sup>2</sup>.

## Bland-Altman (BA) Plot Construction

Both assay sample results (2n data points) are represented on the graph by assigning the mean of the two measurements as the x-axis value, and the difference between the two values as the ordinate y-axis value.

## BA Data Analysis & Results

Sample size	83	
	Diasorin	Monobind
Lowest value	10.8	9.5
Highest value	200	200
Arithmetic mean	49.98	52.08
Median	44.4	43.5
Standard deviation	27.26	30.15
Regression equation	$y = -5.11\% + 0.14\% x$	



## Summary

The graph shows the samples distribution near the mean (solid blue line) for the two methods with a minimal standard deviation (95% LoA or large blue dotted line) indicating a good agreement.

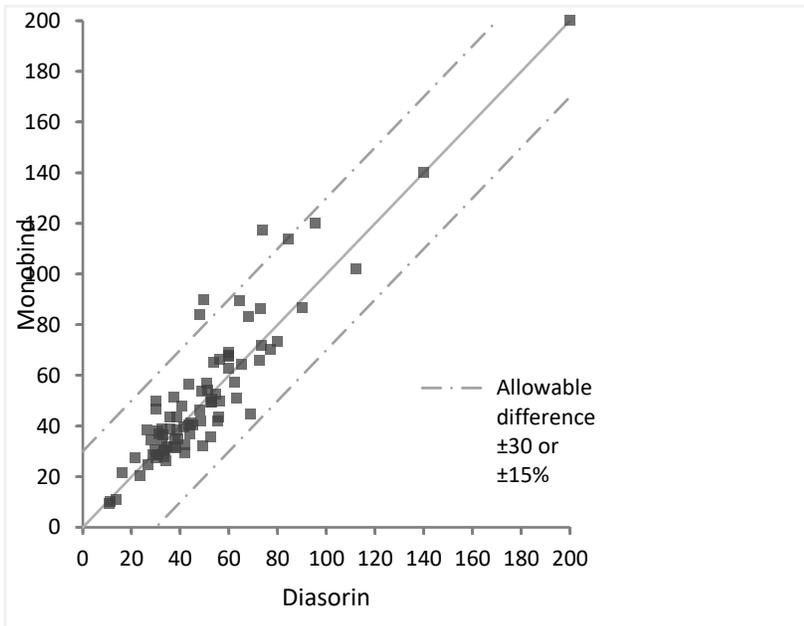


## The Passing Bablok (PB) Regression

Variable X was used for VIT D Diasorin and Variable Y for VIT D Monobind AccuBind ELISA.

### PB Regression Equation

Y = -3.972 + 1.068x	
Intercept A	-3.972
95% CI	-9.828 to -0.500
Slope B	1.068
95% CI	0.9872 to 1.262
R <sup>2</sup> Correlation	0.9812



### Summary

The Slope of 1.068 demonstrates great linearity between the methods and Correlation of 0.9812 measures a strong agreement.

### Acknowledgment

This work was performed in Monobind by QA Specialist in 2017 using Monobind VIT D ELISA Kit Lot # EIA-94K1C7.

## References

1. Mongia Shella K Dr., Rawlins Mindy, Owen William MT, Roberts William MD, PhD, "Performance Characteristics of Seven Automated CA 125 Assays," Clinical Chemistry, 6 (2006)
2. Klick Robert., "Decision Making in the Clinical Laboratory: A Quantitative and Statistical Approach for Methods Evaluation," Med TechNet, 17 (1997)



# Comparative Study of Monobind AccuBind® ELISA Vit D Direct versus Euroimmun

Monobind Inc.

## Background

Different assay systems produce different values and labs generally desire to report values consistent with leading immunoassay manufacturers so doctors can more easily interpret patient results. While preference of manufacturer may vary market-to-market, Monobind's development process involves correlation with leading systems.

Value differences are generally related to the antibodies used in the respective systems which can have unique epitope recognition and response in patient samples<sup>1</sup>. In some cases antibodies may be owned by the manufacturer and not commercially available yet efforts are made to identify similar antibodies.

## Test Design

This table compares the assays' design:

	Euroimmun	Monobind
<b>Method</b>	ELISA	ELISA
<b>Procedure</b>		
Sample Size	50 µl	50 µl
1 <sup>st</sup> Incubation	180 min	75 min
2 <sup>nd</sup> Incubation	30 min	0 (none)
Substrate Develop	15 min	20 min
# of Wash Steps	2 washes	1 wash
Total Assay Time	3 hour 45 min	95 min
<b>Components</b>		
Calibrators	6 at 0.5ml fill	6 at 1.0ml fill
Controls	2 at 0.5ml fill	2 at 1.0ml fill
Cal/Control Stability, Storage	Immediate -20°C after use	24-48 hours at 2- 8°C
Microplate	Anti-PTH Coat	Anti-PTH Coat
<b>Performance</b>		
Range	≥ 600 pg/ml	≥ 1,000 pg/ml
Sensitivity	1.5 pg/ml	< 2 pg/ml
Cross Reactivity	2 <sup>nd</sup> Gen (7-84 reactive)	3 <sup>rd</sup> Gen (7-84 nonreactive)

## Study Materials & Methods

System agreement of **Monobind AccuBind Vit D Direct ELISA** (Item # 9425-300) was assessed by running 83 patient samples manually and the

same samples on the **Euroimmun Vitamin D System**. The study was performed by Monobind QA and presented using the Bland-Altman plot in analytical chemistry to analyze the two assays correlation. The Passing-Bablok regression method was used to assess the distribution of samples and the measurement errors.

## Patient Samples

The 83 patients used were representative of the full range in the assay's measurement (low, middle and high values), which is imperative in any method comparison study<sup>2</sup>.

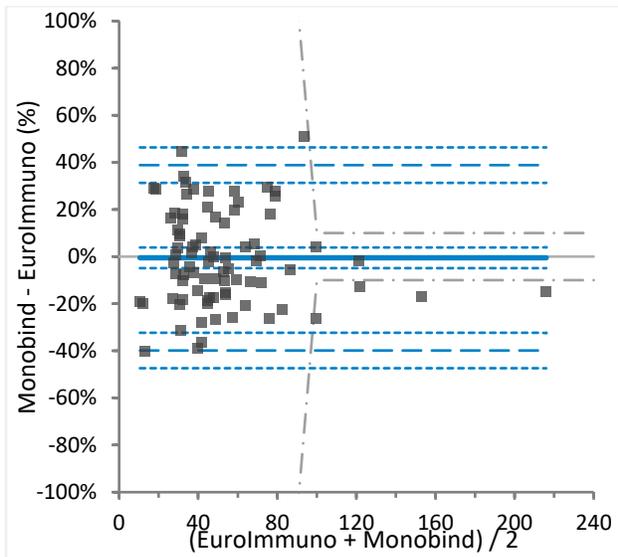
## Bland-Altman (BA) Plot Construction

Both assay sample results (2n data points) are represented on the graph by assigning the mean of the two measurements as the x-axis value, and the difference between the two values as the ordinate y-axis value.



## BA Data Analysis & Results

Sample size	83	
	Euroimmun	Monobind
Lowest value	11.5	9.5
Highest value	232	200
Arithmetic mean	52.76	52.08
Median	47.5	43.5
Standard deviation	33.15	30.15
Regression equation	$y = 1.68\% - 0.04\% x$	



## Summary

The graph shows the samples distribution near the mean (solid blue line) for the two methods with a minimal standard deviation (95% LoA or large blue dotted line) indicating a good agreement.



## The Passing Bablok (PB) Regression

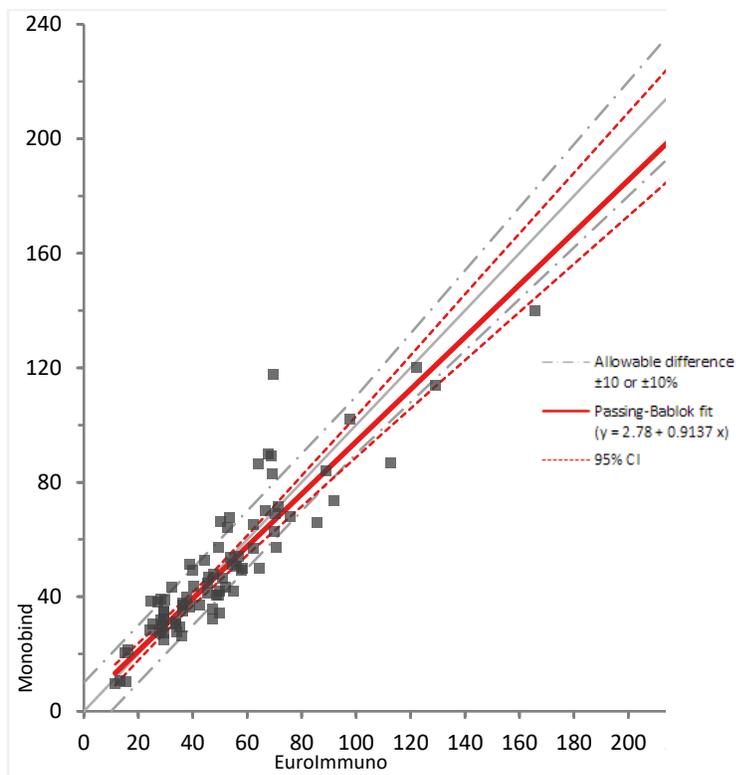
Variable X was used for VIT D Euroimmun and Variable Y for VIT D Monobind AccuBind ELISA.

## Acknowledgment

This work was performed in Monobind by QA Specialist in 2017 using Monobind VIT D ELISA Kit Lot # EIA-94K1C7.

## PB Regression Equation

Y = 2.78 + 0.9137x	
Intercept A	2.78
95% CI	-2.994 to 6.570
Slope B	0.9137
95% CI	0.8380 to 1.060
R <sup>2</sup> Correlation	0.937



## Summary

The Slope of 0.9137 demonstrates great linearity between the methods and Correlation of 0.937 measures a strong agreement.



## References

1. Mongia Shella K Dr., Rawlins Mindy, Owen William MT, Roberts William MD, PhD, "Performance Characteristics of Seven Automated CA 125 Assays," *Clinical Chemistry*, 6 (2006)
2. Klick Robert., "Decision Making in the Clinical Laboratory: A Quantitative and Statistical Approach for Methods Evaluation," *Med TechNet*, 17 (1997)

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# Comparative Study: Monobind AccuBind<sup>®</sup> ELISA & AccuLite<sup>®</sup> CLIA Vit D Direct versus Tosoh AIA-900

Monobind Inc.

## Background

Different assay systems produce different values and labs generally desire to report values consistent with leading immunoassay manufacturers so doctors can more easily interpret patient results. While preference of manufacturer may vary market-to-market, Monobind's development process involves correlation with leading systems.

Value differences are generally related to the antibodies used in the respective systems which can have unique epitope recognition and response in patient samples<sup>1</sup>. In some cases antibodies may be owned by the manufacturer and not commercially available yet efforts are made to identify similar antibodies.

## Study Materials & Methods

System agreement of **Monobind AccuBind Vit D Direct ELISA** (Item # 9425-300) and CLIA (Item 9475-300) were assessed by running 15 patient samples manually and the same samples on the **Tosoh Vit D AIA-900 System**. The study was performed by a third party and presented using the least-square method in analytical chemistry to analyze the two assays correlation.

## Patient Samples

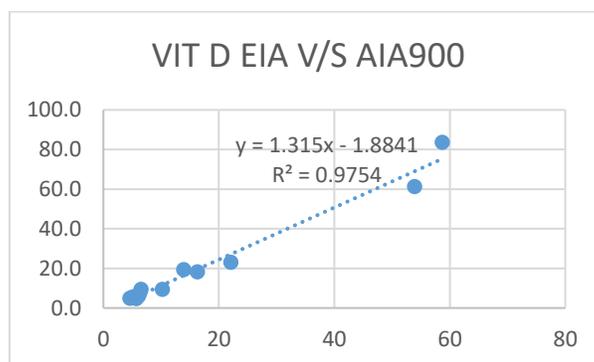
The 15 patients used were representative of the full range in the assay's measurement (low, middle and high values), which is imperative in any method comparison study<sup>2</sup>.

## Least Squares Method

Both assay sample results (2n data points) are represented on the graph to determine the best fit of the regression analysis. Method A is Monobind AccuBind and Method B is Tosoh.

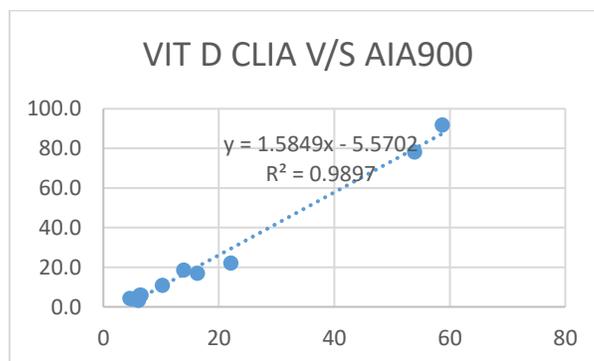
## ELISA Data Analysis & Results

N = 15  
R<sup>2</sup> (Correlation) = 0.9757



## CLIA Data Analysis & Results

N = 15  
R<sup>2</sup> (Correlation) = 0.9897



## Summary

The graphs show a very linear fit of samples between the two methods indicating a good agreement with a nearly perfect correlation of 0.9757 and 0.9897 for ELISA and CLIA, respectively.



## Regression Equation

ELISA	$y = 1.3150x - 1.8841$
CLIA	$y = 1.5849x - 5.5702$

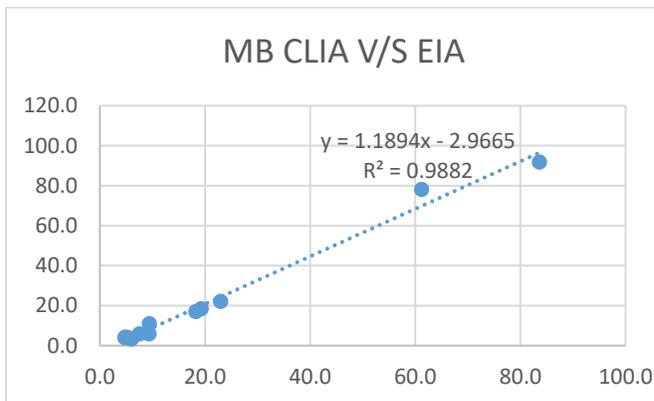
## Summary

The Slope of 1.315 and 1.5849 demonstrate great linearity between the methods Monobind ELISA and Tosoh AIA-900 as well as Monobind CLIA and Tosoh AIA-900, respectively.

## CLIA vs ELISA Data Analysis & Results

Additionally, Monobind CLIA was compared to its ELISA to determine the correlation between systems, which resulted in strong agreement.

N = 15  
R<sup>2</sup> (Correlation) = 0.9882



## Acknowledgment

This work was performed in India by a third party a QA Specialist in 2017 using Monobind VIT D ELISA Kit Lot # EIA-94K1A7 and Monobind Vit D CLIA Kit Lot # CIA94K1A7.

## References

1. Mongia Shella K Dr., Rawlins Mindy, Owen William MT, Roberts William MD, PhD, "Performance Characteristics of Seven Automated CA 125 Assays," Clinical Chemistry, 6 (2006)
2. Klick Robert., "Decision Making in the Clinical Laboratory: A Quantitative and Statistical Approach for Methods Evaluation," Med TechNet, 17 (1997)

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