Comparative Study of Monobind AMH AccuBind® ELISA versus Beckman Access

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[1]. 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 AMH AccuBind ELISA** (Item # 9725-300) was assessed by running 142 female patient samples with values obtained on the **Beckman Access ELISA System** via a local clinical lab. The study was performed by Monobind QA whom analyzed patient results from both systems using the Passing-Bablok regression to assess sample distribution and measurement error. Further the Bland-Altman plot was also utilized to analyze the two assays correlation by studying mean difference within the 95% confidence interval.

Patient Samples

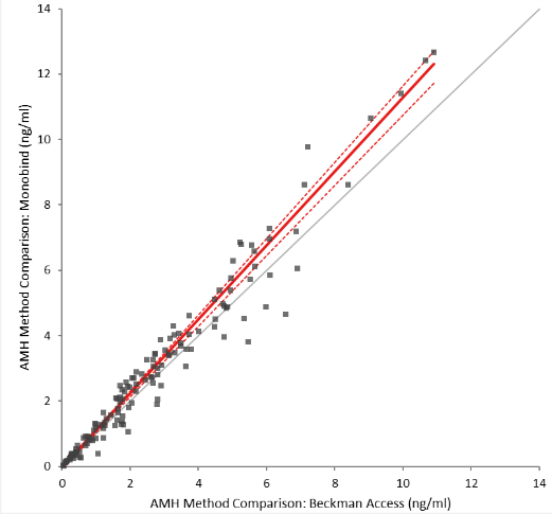
The 142 female patients were representative of the full range in the assay's measurement (low, middle and high values), which is imperative in any method comparison study[2] and segmented according to age as AMH is understood to peak in puberty ≤15 ng/ml and gradually decline over time near <1 ng/ml at menopause. The patient results for three key age demographics are shown.

Age Ranges Values

Females		Monobind				Beckman			
Age	Count	Mean	Median	High	Low	Mean	Median	High	Low
20-29	24	5.95	5.94	12.41	1.77	5.16	4.99	10.67	1.64
30-39	81	2.85	2.48	12.67	0.11	2.78	2.19	10.91	0.10
40-49	38	1.33	0.59	9.76	0.02	1.15	0.54	7.21	0.04

The Passing Bablok Regression

Analyse-it® statistical software compared the methods within each age range as well the entire sample set which is presented below. Variable X was used for AMH Beckman and Variable Y for AMH Monobind AccuBind ELISA.



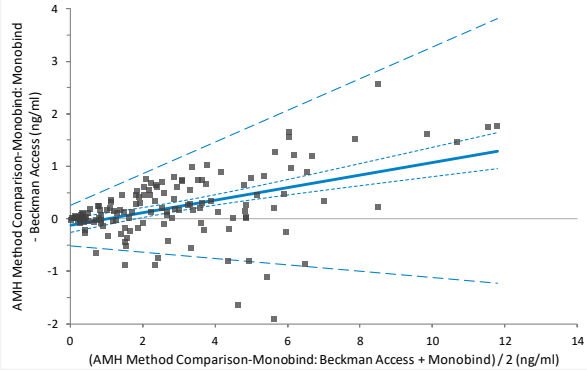
Regression Equation	**y = -0.03621 + 1.132x**
Intercept A	-0.03621
95% CI	-0.1148 to -0.002655
Slope B	1.132
95% CI	1.076 to 1.171
R Correlation	0.976
R^2 Correlation	0.953

Summary

The Slope of 1.132 demonstrates great linearity between the methods and Correlation of 0.953 measures a strong agreement.

Bland-Altman Plot

Both assays' patient results (2n data points) are represented on the graph by assigning the mean of the two measurements as the x-axis value (as a best estimate of true value), and the difference between the two values as the ordinate y-axis value for the purpose of showing relative differences between the methods within various intervals expressed below.



Sample size 142

	Beckman	Monobind
Lowest value	0.04	0.015
Highest value	10.91	12.67
Arithmetic mean	2.742	2.958
Median	2.09	2.457

Summary

The plot reveals the sample distribution near the mean (solid blue line) for the two methods with a minimal deviation at the 95% Limits of Agreement (large blue dotted lines) and at 95% Confidence Interval (smaller blue dotted lines) indicating a good agreement with minimum bias especially within the clinically significant lower-end values.

Acknowledgment

This work was performed in Monobind by QA Specialist in 2019 using Monobind AMH ELISA Kit Lot # EIA-97K1G9.

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)

Key Details Monobind AMH ELISA

Incubation time	1 hour no shaking
Assay time	1 hour, 20 minutes
Sample size	50 µl
Sensitivity	0.04 ng/ml
Calibrators	0, 0.2, 0.5, 1.0, 5, 15 ng/ml

Further Information

For more details on Monobind's AMH AccuBind ELISA (and AccuLite CLIA) products, including instructions for use, IFU, please visit www.monobind.com and/or contact Monobind at info@monobind.com

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