Recovery:

Known amounts of AMH/MIS were added to three serum samples containing different levels of endogenous AMH/MIS. The concentration of AMH/MIS was determined before and after the addition of exogenous AMH/MIS and the percent recovery was calculated.

Sample	Endogenous Conc. (ng/mL)	Expected Conc. (ng/mL)	Observed Conc. (ng/mL)	% Recovery
1	1.8408	2.329 2.817 3.305	2.257 2.598 3.039	97% 92% 92%
2	0.3218	0.886 1.450 2.014	0.821 1.250 1.749	93% 86% 87%
3	1.2683	1.785 2.301 2.818	1.676 2.027 2.493	94% 88% 88%

ANALYTICAL SPECIFICITY

This monoclonal antibody pair used in the assay detects human AMH/MIS. Specificity to other species has not been determined.

Cross-Reactant	Concentration	% Cross-reactivity
Inhibin A	I00 ng/mL	ND
Inhibin B	100 ng/mL	ND
Activin A	50 ng/mL	ND
Activin B	50 ng/mL	ND
Activin AB	50 ng/mL	ND
rAMH	130 ng/mL	ND
Mature AMH	120 ng/mL	2.35
hAMH(Pro)	300 ng/mL	0.24
ProMature hAMH	110 ng/mL	100

Interference:

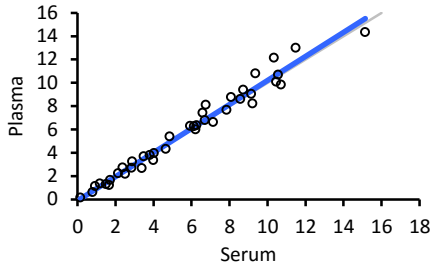
When potential interferents (hemoglobin, triglycerides and bilirubin) were added at least at two times their physiological concentration to control sample, AMH/MIS concentration were within ± 10% of the control as represented in the following table. This study was based on NCCLS EP7-P to serum matrix added.

Interferents	Analyte Conc. (mg/mL)	Unspiked Sample Value (ng/mL)	Spiked Sample Value (ng/mL)	% Difference
Hemoglobin	1.35	5.9979 9.0887	5.8795 9.081	-1.974 -0.085
Triglygerides	5.0	5.9979 9.0887	6.0296 8.8229	0.529 -2.925
Bilirubin	0.6	0.7818 9.3466	0.8009 9.0302	2.443 -3.385

Sample Type:

Forty matched serum and Lithium heparin plasma specimens in the range of 0.14-15.14 ng/mL were compared in AnshLite™ US AMH/MIS CLIA assay. Passing Bablok analysis of the results yielded the following Regression:

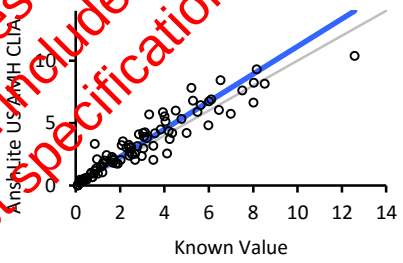
Plasma = 1.03 (serum) - 0.12, (r=0.995; P<0.0001)



Method Comparison:

The UltraSensitive AMH/MIS CLIA has been compared to Commercial AMH assay (Method A) using 90 serum samples. Passing Bablok analysis of the results yielded the following Regression:

US AMH/MIS CLIA (AL-205) = 1.10 (Method A) + 0.10
(r=0.975; P<0.0001)



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