Impact to Results on VITROS® 3600/5600 Systems

Testing was conducted for assays that are sensitive to well wash fluid temperature utilizing the MicroWell Wash module. Samples were tested at nominal temperature (37°C) and at ambient room temperature (~25°C). The data provided below summarizes our assessment.

NOTE: Seventeen assays were tested across multiple concentrations; the values deemed to affect a clinical decision are shown below. Data for other assays will be available upon request.

For assays that have cutoff values, only those samples with results close to the cutoff values may potentially lead to a misclassification.

Potential Bias if Assays Calibrated at Nominal Temperature (37°C), Samples Processed at Ambient Temperature (~25°C)		
Assay Name	**Concentration Range**	**Bias Observed**
NT proBNP	Cutoff value: 300 pg/mL	19.5%
TSH	Lower Reference Range: 0.465 mIU/L	6%
Intact PTH	Lower Reference Range: 7.5pg/mL	18%
Rubella IgG	Cutoff value for Negative: 9.99 IU/mL	-2.8%
Anti-HBs	Cutoff value for Positive: 10 mIU/mL	26%
Potential Bias if Assays Calibrated at Ambient Temperature (~25°C), Samples Processed at Nominal Temperature (37°C)		
Assay Name	**Concentration Range**	**Bias Observed**
NT proBNP	Cutoff value: 450 pg/mL	-16%
TSH	Upper Reference Range: 4.68 mIU/L	-1.6%
Intact PTH	Upper Reference Range: 53.5 pg/mL	-13%
Troponin	0.034 ng/mL	-8.8%
Anti-HBc	Cutoff value for Negative: 0.9	-10%
HBsAg	Cutoff value for Negative: 0.9	-2.9%
Rubella IgM	Cutoff value for Negative: 0.8	-2.8%
Syphilis	Cutoff value for Negative: 0.8	-6.6%
Toxoplasma IgG	Cutoff value for Negative: 3.99	-4.8%
Toxoplasma IgM	Cutoff value for Negative: 0.8	-5.5%
HAV Total	Cutoff for Positive: 0.8	-6.3%

NOTE: Testing is ongoing for other MicroWell assays and will be available upon request by contacting our Technical Solutions Center representatives.