



## Estimation of within-lab SD for MAS<sup>™</sup> Quality Controls on Vitros Systems

Quality control (QC) in the core laboratory is a complex process. This involves looking at several processes to ensure both precision and accuracy of patient sample results.

The integrity of quality control samples is crucial for management of overall quality and patient management. Addressing quality issues is crucial in the identification of laboratory and requires statistical calculations that include determining mean and establishing standard deviation. The CLIA recommendations require the laboratory to establish their own mean and standard deviation for each lot of reagents that are used.

### Determining the mean

The mean is determined by adding a group of measurement values and dividing the total by the actual number or measurements included. Mathematically, the equation can be expressed as below.

$$\bar{x}(\text{mean}) = \left( \sum x_i \right) / n$$

As expressed above, the  $\Sigma$  translates to the summation of the number of measurements represented by the sign  $x_i$  and  $n$  is the number of measurements included.

## Calculating the standard deviation (SD)

The SD is calculated using the mathematical formula below:

$$SD = \sqrt{\frac{\sum (x_i - \bar{x})^2}{(n - 1)}}$$

$n$  = number of data points  
 $x_i$  = an individual data point  
 $\bar{x}$  = mean of the data points  
SD = standard deviation

- Calculate the mean of all measurements
- For each measurement, subtract the mean from the measurement and square the result
- Calculate the mean of the squared differences
- Square root of that will give you the SD

To calculate the within-lab reproducibility, it is necessary to estimate the within-lab SD.

The within-lab reproducibility standard deviation characterizes how well the measurement procedure can reproduce the same results on different days with the same sample. If the sample is not the same (as in this self-test) then if you just calculate the SD of the results, then the obtained SD includes both the reproducibility of the procedure and the difference between the samples. The difference between the samples is, in the case of this self-test, much larger than the within-lab reproducibility.

So, if you simply calculate the standard deviation over all the results then you will not obtain within-lab reproducibility but the variability of analyte concentrations in samples, with a (small) within-lab reproducibility component added.

The recommended within-lab SD on the SmartNote were extrapolated for the Thermo Scientific™ MAS™ Quality Controls using data from QuidelOrtho Vitros® controls, which were originally established using monthly within-lab SD for Vitros chemistry systems users participating in a commercial quality control service. These values are representative of the performance of properly operating Vitros chemistry systems in multiple laboratories using multiple quality control lots. Additionally, each SD was compared to U.S. and European proficiency testing goals and adjusted accordingly.

The published within-lab SD includes the variability associated with performing replicate measurements within a day and measurements from one day to the next. The day-to-day variability includes the small variation introduced by different slide cartridges, different vials of control material, multiple calibration events, environmental influences and preventive maintenance events. These values do not include the variability due to using different slide lot numbers.

Note: suggested within-lab SDs will be reevaluated in the future using actual Thermo Scientific™ MAS™ Quality Control data on Vitros systems, once enough data is available to generate the analysis. Any suggested changes will be communicated at that time.

## Why is within-lab SD important for QuidelOrtho customers?

A within-lab SD can be calculated from your daily quality control results and compared to the SmartNote within-lab SD. A calculated laboratory SD larger than the SmartNote within-lab SD indicates that system troubleshooting may be necessary.

If the calculated SD is much smaller than the SmartNote within-lab SD, you may not have included all the expected sources of variability or valid QC results may have been excluded from the calculation. If you use this calculated SD as your baseline SD, valid data points may be rejected, and troubleshooting may be performed more frequently than needed.

## Range of means: how the range of means (ROM) is used

When evaluating the performance of a Vitros chemistry system using gen-assigned MAS™ Quality Controls, the mean based on two or more replicate measurements of these fluids must be within the ROM to be acceptable.

Since MAS™ Quality Controls are manufactured fluids, they do not have the same physical and chemical characteristics or “matrix” as fresh patient specimens. These differences may cause the results on different slide lots to vary. The term “matrix effects” is commonly used to describe this phenomenon. Matrix effects result in wider ROM than would otherwise be observed.

- The mean of two or more measurements can fall anywhere in the ROM (not necessarily in the center) for that particular slide gen

- When using MAS™ Quality Controls for routinely monitoring a properly operating system, all calculated means should be within the ROM. Each estimate of the mean should be statistically the same as all other estimates of the mean. The assessment of any two means will be discussed later in this module.
- It is not expected that all individual daily QC values will fall within the ROM even if the system is showing acceptable performance. However, the mean of a distribution of daily QC values for properly operating systems should always fall within the ROM.
- For calibration verification, the mean of two or more replicate measurements of MAS™ Quality Controls (called a Preliminary Baseline Mean) should fall within the ROM listed on the assay sheet.

### How QuidelOrtho customers use within-lab SD for the MAS™ Controls?

The within-lab SD (WLSD) provided in the SmartNote are the recommendations for the baseline SD which each analyte should be evaluated against. This ensures that results exceeding medically acceptable guidelines are flagged and helps ensure that valid results are not unduly flagged.

### MAS® CardioImmune · XL

MAS QC lot	QO short name	QuidelOrtho analyte name	LabLink analyte name	Conventional SD				CV to SI	SI SD			
				Level L	Level 1	Level 2	Level 3		Level L	Level 1	Level 2	Level 3
CXL2504	CK-MB	CK-MB	CK-MB	N/A	0.49	1.75	4.34	N/A	N/A	0.49	1.75	4.34
	CKMB2	CKMB2	CKMB2	N/A	0.437	1.74	4.07	N/A	N/A	0.437	1.74	4.07
	Myog	Myoglobin	Myoglobin	2.71	4.9	24.22	56.2	2.71	2.71	4.9	24.22	56.2
	NTBNP	NT-pro BNP	NT-pro BNP	14.9	48.4	227	792	1.76	1.76	5.71	26.8	93.5
	NBNP2	NT-pro BNP II	NT-pro BNP II	6.24	24.7	115	537	0.74	0.74	2.91	13.6	63.4
	TrpES	Troponin I ES	Troponin I ES	0.0139	0.0693	0.174	1.86	0.0139	0.0139	0.0693	0.174	1.86
	hsTnI	Troponin I, High Sensitivity (hsTNI)	Troponin I, High Sensitivity (hsTNI)	11.1	50.96	155.9	2270	11.1	11.1	50.96	155.9	2270

### MAS®Omni•Cardio Ultra Low Control

MAS QC lot	QO short name	QuidelOrtho analyte name	LabLink analyte name	Conventional SD				CV to SI	SI SD			
				Level L	Level 1	Level 2	Level 3		Level L	Level 1	Level 2	Level 3
OCD2503U	hsTnI	Troponin I, High Sensitivity (hsTNI)	Troponin I, High Sensitivity (hsTNI)	0.895	N/A	N/A	N/A	1	0.895	N/A	N/A	N/A

**MAS® Omni•IMMUNE**

MAS QC lot	QO short name	QuidelOrtho analyte name	LabLink analyte name	Conventional SD			CV to SI	SI SD		
				Level 1	Level 2	Level 3		Level 1	Level 2	Level 3
OIM2612	AFP	Alpha-Fetoprotein (AFP)	Alpha-Fetoprotein (AFP)	0.888	5	10.1	1.04	0.924	5.20	10.50
	AFP2	AFP2	AFP2	0.888	5	10.1	1.21	1.074	6.05	12.22
	B12	Vitamin B12	Vitamin B12	27.5	53.7	88.1	0.738	20.3	39.6	65.0
	BhCG2	Beta Human Chorionic Gonadotropin	Beta Human Chorionic Gonadotropin	1.118	3.374	65.298	1	1.118	3.374	65.30
	CA125	Cancer Antigen 125 (CA125)	Cancer Antigen 125 (CA125)	0.95	5.08	11.7	1	0.95	5.08	11.7
	C125a	C125a	C125a	0.95	5.08	11.7	1	0.95	5.08	11.7
	CA153	Cancer Antigen 15-3 (CA153)	Cancer Antigen 15- 3 (CA153)	1.18	4.36	8.02	1	1.18	4.36	8.02
	CA19-9	Cancer Antigen 19-9 (CA 19-9)	Cancer Antigen 19-9 (CA 19-9)	1.27	3.54	14.9	1	1.27	3.54	14.9
	CEA	Carcinoembryonic Antigen (CEA)	Carcinoembryonic Antigen (CEA)	0.0775	0.94	1.64	1	0.078	0.94	1.64
	Cort	Cortisol	Cortisol	11	40.7	85.5	0.0363	0.40	1.48	3.10
	E2	Estradiol	Estradiol	52.427	158.08	278.93	0.2724	14.281	43.061	75.981
	Ferr	Ferritin	Ferritin	1.02	11.8	24.9	N/A	N/A	N/A	N/A
	Fol	Folate (Folic Acid)	Folate (Folic Acid)	0.368	0.563	0.902	2.265	0.83	1.28	2.04
	FSH	Follicle-Stimulating Hormone (FSH)	Follicle-Stimulating Hormone (FSH)	0.374	2.97	5.47	1	0.374	2.97	5.47
	FT3	Free Triiodothyronine (FT3)	Free Triiodothyronine (FT3)	0.69	2.37	0	0.651	0.45	1.54	N/A
	FT3II	Free Triiodothyronine (FT3II)	Free Triiodothyronine (FT3II)	0.649	1.24	0	0.651	0.42	0.81	N/A
	FT4	Thyroxine, Free (FT4)	Thyroxine, Free (FT4)	0.91	3.71	0	0.0777	0.07	0.29	N/A
	INS	Insulin	Insulin	1.32	5.98	12.7	6	7.92	35.9	76
	LH	Luteinizing Hormone (LH)	Luteinizing Hormone (LH)	0.638	4.91	7.26	1	0.638	4.91	7.26
	PCT	Procalcitonin (PCT)	Procalcitonin (PCT)	0.0564	0.16	1.55	1	0.0564	0.160	1.55
	Prog	Progesterone	Progesterone	0.479	2.61	4.7	0.3145	0.151	0.821	1.48
	Prol2	Prol2	Prol2	14.41	33.83	49.84	0.047	0.7	1.6	2.3
	PSA	Prostate Specific Antigen	Prostate Specific Antigen	0.0855	0.266	2.03	1	0.0855	0.266	2.03
fPSA	Prostate Specific Antigen, Free (fPSA)	Prostate Specific Antigen, Free (fPSA)	0.0154	0.104	0.282	1	0.0154	0.104	0.282	
tPSA	Prostate Specific Antigen, Total (tPSA)	Prostate Specific Antigen, Total (tPSA)	0.0705	0.289	2.31	1	0.0705	0.289	2.31	

**MAS® Omni•IMMUNE**

MAS QC lot	QO short name	QuidelOrtho analyte name	LabLink analyte name	Conventional SD			CV to SI	SI SD		
				Level 1	Level 2	Level 3		Level 1	Level 2	Level 3
<b>OIM2612</b>	T3U	T3 Uptake/T-Uptake	T3/T-Uptake %	1.75	2.54	0	1	1.75	2.54	N/A
	Testo	Testosterone	Testosterone	0.197	1.48	2.66	28.84	5.7	42.7	76.7
	TSH	Thyroid Stimulating Hormone (TSH)	Thyroid Stimulating Hormone (TSH)	0.0825	1.91	3.27	1	0.0825	1.91	3.27
	TSH3	Thyroid Stimulating Hormone (TSH3)	Thyroid Stimulating Hormone (TSH3)	0.05184	1.211	2.14	1	0.05	1.21	2.14
	TT3	Total Triiodothyronine (T3)	Total Triiodothyronine (T3)	0.103	0.193	0.288	0.651	0.067	0.126	0.187
	TT4	Total Thyroxine (T4)	Total Thyroxine (T4)	2.76	5.56	2.87	0.0777	0.214	0.432	0.223

**MAS® Omni•IMMUNE (Amnio)**

MAS QC lot	QO short name	QuidelOrtho analyte name	LabLink analyte name	Conventional SD			CV to SI	SI SD		
				Level 1	Level 2	Level 3		Level 1	Level 2	Level 3
<b>OIM2612</b>	AFP	Alpha-Fetoprotein (AFP)	Alpha-Fetoprotein (AFP)	0.888	5	10.1	1.04	0.92	5.20	10.50

**MAS® Omni•IMMUNE (Urine)**

MAS QC lot	QO short name	QuidelOrtho analyte name	LabLink analyte name	Conventional SD			CV to SI	SI SD		
				Level 1	Level 2	Level 3		Level 1	Level 2	Level 3
<b>OIM2612</b>	Cort	Cortisol	Cortisol	11	40.7	85.5	0.0363	0.40	1.48	3.10

