

Estimation of within-lab SD for MAS[™] 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 Σ 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 (WLS D) 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™ Alcohol and Ammonia*

QO short name	LabLink analyte name	VITROS technology	Gen applicability	Levels assigned	CONV WLS D			SI WLS D			Units	
					Level 1	Level 2	Level 3	Level 1	Level 2	Level 3	CONV	SI
AMON	Ammonia	Slide	All Gens	1,2	2.92	3.52	N/A	2.92	3.52	N/A	µmol/L	µmol/L

MAS™ Bilirubin*

QO short name	LabLink analyte name	VITROS technology	Gen applicability	Levels assigned	CONV WLS D			SI WLS D			Units	
					Level 1	Level 2	Level 3	Level 1	Level 2	Level 3	CONV	SI
Bc	Bilirubin, Direct	Slide	All Gens	1-3	0.082	0.19	0.466	0.98	2.25	5.53	mg/dL	µmol/L
Bu	Bilirubin, Unconjugated	Slide	All Gens	1-3	0.06	0.15	0.32	1.03	2.57	5.47	mg/dL	µmol/L
TBIL	Bilirubin, Total	Slide	All Gens	1-3	0.1	0.29	0.51	1.7	4.9	8.7	mg/dL	µmol/L

MAS™ Cerebrospinal Fluid*

QO short name	LabLink analyte name	VITROS technology	Gen applicability	Levels assigned	CONV WLS D			SI WLS D			Units	
					Level 1	Level 2	Level 3	Level 1	Level 2	Level 3	CONV	SI
GLU	Glucose	Slide	All Gens	1,2	2.04	1.28	N/A	0.113	0.071	N/A	mg/dL	mmol/L
PROT	Total Protein, CSF	Slide	All Gens	1,2	5.5	9.8	N/A	54.5	97.8	N/A	mg/dL	mg/L

*Note that product availability will vary by country. Contact your local QuidelOrtho sales representative to inquire.

MAS™ Diabetes*

QO short name	LabLink analyte name	VITROS technology	Gen applicability	Levels assigned	CONV WLSD			SI WLSD			Units	
					Level 1	Level 2	Level 3	Level 1	Level 2	Level 3	CONV	SI
A1C1	A1C1	Slide	All Gens	1,2	0.106	0.131	N/A	1.16	1.43	N/A	%	mmol/mol
%A1c	%A1c	Tip	All Gens	1,2	0.151	0.243	N/A	N/A	N/A	N/A	%	%
HbA1c	Hemoglobin A1c	Tip	All Gens	1,2	1.65	2.66	N/A	1.65	2.66	N/A	mmol/mol	mmol/mol

MAS™ Omni•CORE*

QO short name	LabLink analyte name	VITROS technology	Gen applicability	Levels assigned	CONV WLSD			SI WLSD			Units	
					Level 1	Level 2	Level 3	Level 1	Level 2	Level 3	CONV	SI
AAT	Alpha-1-Antitrypsin	Tip	All Gens	1-3	1.53	3.45	5.31	0.015	0.035	0.053	mg/dL	g/L
ACET	Acetaminophen	Slide	All Gens	1-3	1.27	2.37	3.68	8.41	15.70	24.38	µg/mL	µmol/L
ALB	Albumin	Slide	All Gens	1,2	0.09	0.11	N/A	0.90	1.13	N/A	g/dL	g/L
ALC	Ethanol (EtOH)	Slide	All Gens	1-3	7.5	10.7	14.6	1.64	2.32	3.16	mg/dL	mmol/L
ALKP	Alkaline Phosphatase	Slide	Gens 1-79	1-3	1.09	7.37	13.11	1.09	7.37	13.11	U/L	U/L
ALTV	ALTV	Slide	All Gens	1-3	1.60	3.10	4.60	1.63	3.13	4.63	U/L	U/L
AMYL	Amylase	Slide	Gens 1-79	1-3	5.6	11.2	15.4	5.59	11.20	15.4	U/L	U/L
ApoA1	Apolipoprotein A1	Tip	All Gens	1-3	1.16	2.54	4.26	0.012	0.025	0.043	mg/dL	g/L
ApoB	Apolipoprotein B	Tip	All Gens	1-3	1.28	2.06	2.97	0.013	0.021	0.03	mg/dL	g/L
ASO	Antistreptolysin O	Tip	All Gens	1-3	4.84	6.66	8.61	4.84	6.66	8.61	IU/mL	IU/mL
AST	Aspartate Aminotransferase	Slide	All Gens	1-3	1.7	5.2	9.5	1.68	5.18	9.48	U/L	U/L
BUN	Urea Nitrogen	Slide	All Gens	1-3	0.5	1.1	1.4	0.18	0.39	0.51	mg/dL	mmol/L
C3	Complement Component C3	Tip	All Gens	1-3	1.85	4.65	7.20	18.50	46.51	72.01	mg/dL	mg/L
C4	Complement Component C4	Tip	All Gens	1-3	0.28	0.45	0.60	2.84	4.51	6.01	mg/dL	mg/L
Ca	Calcium	Slide	All Gens	1-3	0.19	0.23	0.26	0.048	0.057	0.064	mg/dL	mmol/L
CAFFN	Caffeine	Tip	All Gens	1-3	0.41	1.03	1.58	2.12	5.28	8.12	µg/mL	µmol/L
CRBM	Carbamazepine	Slide	All Gens	1-3	0.27	0.60	0.95	1.14	2.54	4.02	µg/mL	µmol/L
CHE	Cholinesterase	Slide	Gens 1-79	1-3	0.09	0.11	0.12	90.0	110.0	120.0	U/mL	U/L
CHOL	Total Cholesterol	Slide	All Gens	1-3	3.04	4.39	5.19	0.08	0.11	0.13	mg/dL	mmol/L

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MAS™ Omni•CORE*

QO short name	LabLink analyte name	VITROS technology	Gen applicability	Levels assigned	CONV WLSD			SI WLSD			Units	
					Level 1	Level 2	Level 3	Level 1	Level 2	Level 3	CONV	SI
CK	Creatine Kinase	Slide	Gens 1-79	1-3	11.5	18.7	21.6	11.55	18.67	21.59	U/L	U/L
Cl-	Chloride	Slide	All Gens	1-3	1.2	1.3	1.4	1.18	1.30	1.36	mmol/L	mmol/L
CREA	Creatinine	Slide	All Gens	1-3	0.08	0.12	0.16	6.86	10.30	14.33	mg/dL	μmol/L
CRP	C-Reactive Protein	Slide	All Gens	1-3	1.44	2.74	3.96	0.14	0.27	0.40	mg/L	mg/dL
DGXN	Digoxin	Slide	All Gens	1-3	0.11	0.17	0.17	0.14	0.22	0.22	ng/mL	nmol/L
dHDL	HDL Cholesterol	Slide	All Gens	1-3	0.42	1.39	2.37	0.01	0.04	0.06	mg/dL	mmol/L
dLDL	LDL Cholesterol	Tip	All Gens	2,3	N/A	3.60	5.83	N/A	0.093	0.151	mg/dL	mmol/L
dTIBC	Iron Binding Capacity, Total	Tip	All Gens	1-3	9.31	13.40	15.99	1.67	2.40	2.86	μg/dL	μmol/L
ECO2	Carbon Dioxide	Slide	All Gens	1-3	0.94	1.11	1.40	0.94	1.11	1.40	mmol/L	mmol/L
Fe	Iron	Slide	All Gens	1-3	3.85	7.45	11.24	0.69	1.33	2.01	μg/dL	μmol/L
GENT	Gentamicin	Tip	All Gens	1-3	0.06	0.16	0.26	0.14	0.34	0.56	μg/mL	μmol/L
GGT	Gamma-Glutamyltransferase	Slide	All Gens	1-3	1.4	2.7	3.6	1.37	2.66	3.58	U/L	U/L
GLU	Glucose	Slide	All Gens	1-3	1.68	3.55	5.65	0.093	0.197	0.314	mg/dL	mmol/L
HPT	Haptoglobin	Tip	All Gens	1-3	1.69	3.01	4.25	0.017	0.030	0.042	mg/dL	g/L
IgA	Immunoglobulin A	Tip	All Gens	1-3	4.70	7.52	10.12	0.047	0.075	0.101	mg/dL	g/L
IgG	Immunoglobulin G	Tip	All Gens	1-3	25.50	50.35	77.07	0.255	0.503	0.771	mg/dL	g/L
IgM	Immunoglobulin M	Tip	All Gens	1-3	2.16	2.87	3.48	0.022	0.029	0.035	mg/dL	g/L
K+	Potassium	Slide	All Gens	1-3	0.10	0.15	0.21	0.10	0.15	0.21	mmol/L	mmol/L
LAC	Lactic Acid	Slide	All Gens	1-3	0.07	0.20	0.27	0.07	0.20	0.27	mmol/L	mmol/L

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MAS™ Omni•CORE*

QO short name	LabLink analyte name	VITROS technology	Gen applicability	Levels assigned	CONV WLSD			SI WLSD			Units	
					Level 1	Level 2	Level 3	Level 1	Level 2	Level 3	CONV	SI
LDH	Lactate Dehydrogenase	Slide	Gens 50-99	1-3	5.3	7.3	9.4	5.3	7.3	9.4	U/L	U/L
Li	Lithium	Slide	All Gens	1-3	0.06	0.06	0.08	0.06	0.06	0.08	mmol/L	mmol/L
LIPA	Lipase	Slide	All Gens	1-3	11.21	12.87	17.07	11.21	12.87	17.07	U/L	U/L
Mg	Magnesium	Slide	All Gens	1-3	0.06	0.08	0.09	0.02	0.03	0.04	mg/dL	mmol/L
Na+	Sodium	Slide	All Gens	1-3	1.4	1.4	1.4	1.4	1.4	1.4	mmol/L	mmol/L
PALB	Prealbumin	Tip	All Gens	1,2	0.60	1.39	N/A	6.01	13.93	N/A	mg/dL	mg/L
PHBR	PHBR	Slide	All Gens	1-3	0.51	1.25	3.58	2.20	5.39	15.43	µg/mL	µmol/L
PHOS	Phosphorus	Slide	All Gens	1-3	0.13	0.19	0.26	0.04	0.06	0.09	mg/dL	mmol/L
PHYT	Phenytoin	Slide	All Gens	1-3	0.3	0.7	1.0	1.4	2.8	4.0	µg/mL	µmol/L
RF	Rheumatoid Factor	Tip	All Gens	1-3	1.50	1.64	1.78	1.50	1.64	1.78	IU/mL	kIU/L
SALI	Salicylate	Slide	All Gens	1-3	0.46	0.53	0.63	0.033	0.039	0.045	mg/dL	mmol/L
sCRP	CRP, Wide Range-Standard	Tip	All Gens	1-3	0.503	1.062	1.907	0.503	1.062	1.907	mg/L	mg/L
THEO	Theophylline	Slide	All Gens	1-3	0.52	0.74	0.95	2.90	4.10	5.29	µg/mL	µmol/L
TIBC	Total Iron Binding Capacity	Slide	All Gens	1-2	20.1	25.2	N/A	3.61	4.52	N/A	µg/dL	µmol/L
TOBRA	Tobramycin	Tip	All Gens	1-3	0.07	0.14	0.21	0.15	0.30	0.45	µg/mL	µmol/L
TP	Total Protein	Slide	All Gens	1,2	0.153	0.179	N/A	1.53	1.79	N/A	g/dL	g/L
TRFRN	Transferrin	Tip	All Gens	1-3	5.7	11.9	18.4	0.06	0.12	0.18	mg/dL	g/L
TRIG	Triglycerides	Slide	All Gens	1-3	2.4	4.4	6.7	0.03	0.05	0.08	mg/dL	mmol/L
URIC	Uric Acid	Slide	All Gens	1-3	0.07	0.16	0.23	4.4	9.3	N/A	mg/dL	µmol/L
VALP	Valproic Acid	Tip	All Gens	1-3	2.13	3.96	5.65	14.8	27.5	39.1	µg/mL	µmol/L
VANC	Vancomycin	Tip	All Gens	1-3	0.32	1.06	1.21	0.21	0.71	0.81	µg/mL	µmol/L

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MAS™ Omni•CORE for Japan*

QO short name	LabLink analyte name	VITROS technology	Gen applicability	Levels assigned	CONV WLSD			SI WLSD			Units	
					Level 1	Level 2	Level 3	Level 1	Level 2	Level 3	CONV	SI
AMYL	Amylase	Slide	Gens 80-99	1-3	5.7	11.4	15.7	5.7	11.4	15.7	U/L	U/L
ALKP	Alkaline Phosphatase	Slide	All Gens	1-3	3.1	19	33	3.1	18.9	33.2	U/L	U/L
ALT	Alanine Aminotransferase	Slide	All Gens	1-3	1.9	3.6	4.8	1.9	3.6	4.8	U/L	U/L
AST	Aspartate Aminotransferase	Slide	All Gens	1-3	1.6	5	8	1.6	4.7	7.5	U/L	U/L
CHE	Cholinesterase	Slide	Gens 80-99	1-3	0.0038	0.0046	0.0053	3.8	4.6	5.3	U/mL	U/L
LDH	Lactate Dehydrogenase	Slide	Gens 80-99	1-3	5.3	7.3	9.4	5.3	7.3	9.4	U/L	U/L
LIPA	Lipase	Slide	Gens 80-99	1-3	3.29	3.67	4.63	3.3	3.7	4.6	U/L	U/L

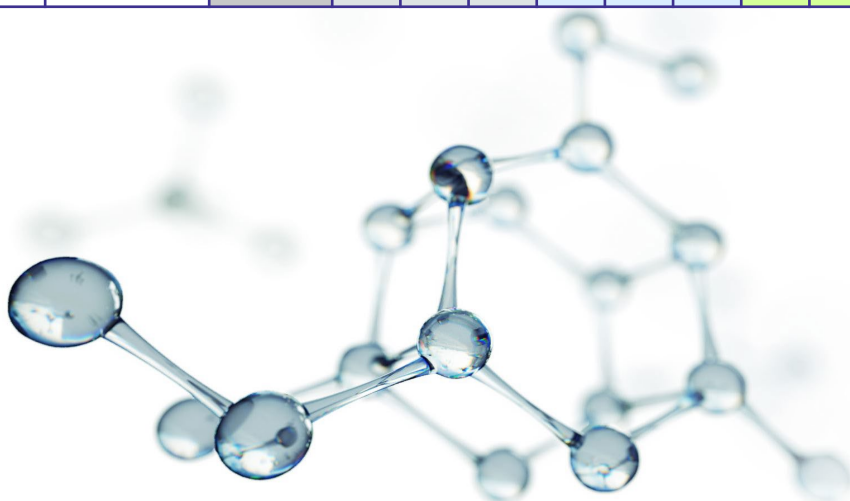
MAS™ Cardio•Immune XL Control*

QO short name	LabLink analyte name	VITROS technology	Gen applicability	Levels assigned	CONV WLSD			SI WLSD			Units	
					Level 1	Level 2	Level 3	Level 1	Level 2	Level 3	CONV	SI
HCY 2	Homocysteine	Tip	All Gens	1-3	0.25	0.33	0.40	0.254	0.335	0.398	µmol/L	µmol/L
hsCRP	C-Reactive Protein, High Sensitivity	Tip	All Gens	1-3	0.08	0.15	0.30	0.083	0.147	0.301	mg/L	mg/L
uCRP	C-Reactive Protein, Wide Range - Ultrasensitive	Tip	All Gens	1-3	0.052	0.086	0.205	0.052	0.086	0.205	mg/L	mg/L

*Note that product availability will vary by country. Contact your local QuidelOrtho sales representative to inquire.

MAS™ UrichemTRAK*

QO short name	LabLink analyte name	VITROS technology	Gen applicability	Levels assigned	CONV WLSD			SI WLSD			Units	
					Level 1	Level 2	Level 3	Level 1	Level 2	Level 3	CONV	SI
AMYL	Amylase	Slide	All Gens	1-2	3.88	6.82	N/A	3.88	6.82	N/A	U/L	U/L
Ca	Calcium	Slide	All Gens	1-2	0.16	0.22	N/A	0.04	0.055	N/A	mg/dL	mmol/L
Cl-	Chloride	Slide	All Gens	1-2	1.16	1.88	N/A	1.16	1.88	N/A	mmol/L	mmol/L
CREA	Creatinine	Slide	All Gens	1-2	4.41	10.9	N/A	389.84	963.56	N/A	mg/dL	μmol/L
GLU	Glucose	Slide	All Gens	1-2	1.39	6.09	N/A	0.077	0.338	N/A	mg/dL	mmol/L
K+	Potassium	Slide	All Gens	1-2	0.75	2.18	N/A	0.75	2.18	N/A	mmol/L	mmol/L
mALB	Microalbumin	Tip	All Gens	1-2	0.13	0.34	N/A	1.30	3.40	N/A	mg/dL	mg/L
Mg	Magnesium	Slide	All Gens	1-2	0.32	0.32	N/A	0.13	0.13	N/A	mg/dL	mmol/L
Na+	Sodium	Slide	All Gens	1-2	3.73	4.80	N/A	3.73	4.80	N/A	mmol/L	mmol/L
PHOS	Phosphorus	Slide	All Gens	1-2	1.37	1.49	N/A	0.44	0.48	N/A	mg/dL	mmol/L
UPRO	Total Protein, Urine	Slide	All Gens	1-2	1.40	5.40	N/A	0.014	0.054	N/A	mg/dL	g/L
UREA	Urea Nitrogen, Urine	Slide	All Gens	1-2	14.10	25.27	N/A	5.032	9.019	N/A	mg/dL	mmol/L
URIC	Uric Acid	Slide	All Gens	1-2	0.78	1.04	N/A	46.40	61.90	N/A	mg/dL	μmol/L



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