Vitros® QC Solutions and MAS™ Quality Controls SmartNote

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.

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

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:

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

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® Alcohol Ammonia

Within-lab SD in CONV and SI units for Ammonia in MAS Alcohol/Ammonia Control Level 1 and 2

QuidelOrtho analyte name	LabLink analyte name	Vitros technology	Gen applicability	Levels assigned	CONV units			SI units		
					WLSD Level 1	WLSD Level 2	WLSD Level 3	WLSD Level 1	WLSD Level 2	WLSD Level 3
Ammonia	Ammonia	Slide	All Gens	1,2	2.92	3.52	N/A	2.92	3.52	N/A

MAS® Bilirubin

Within-Lab SD in CONV and SI units for MAS Bilirubin Controls, Level 1, 2 and 3

QuidelOrtho analyte name	LabLink analyte name	Vitros technology	Gen applicability	Levels assigned	CONV units			SI units		
					WLSD Level 1	WLSD Level 2	WLSD Level 3	WLSD Level 1	WLSD Level 2	WLSD Level 3
Bilirubin, Direct/BC (DBIL)	Bilirubin, Direct	Slide	All Gens	1-3	0.082	0.190	0.466	0.98	2.25	5.53
Bilirubin, Indirect/BU	Bilirubin, Unconj	Slide	All Gens	1-3	0.06	0.150	0.32	1.03	2.57	5.47
Bilirubin, Total/TBIL	Bilirubin, Total	Slide	All Gens	1-3	0.1	0.29	0.51	1.7	4.9	8.7

MAS® CSF

Within-lab SD in CONV and SI units for CSF Control Level 1 and Level 2

QuidelOrtho analyte name	LabLink analyte name	Vitros technology	Gen applicability	Levels assigned	CONV units			SI units		
					WLSD Level 1	WLSD Level 2	WLSD Level 3	WLSD Level 1	WLSD Level 2	WLSD Level 3
Glucose, CSF	Glucose	Slide	All Gens	1,2	2.04	1.28	N/A	0.113	0.071	N/A
Total Protein, CSF	CSF	Slide	All Gens	1,2	5.5	9.8	N/A	54.5	97.8	N/A

MAS® Diabetes

Within-lab SD in CONV and SI units for DBCL- MP Control

QuidelOrtho analyte name	LabLink analyte name	Vitros technology	Gen applicability	Levels assigned	CONV units			SI units		
					WLSD Level 1	WLSD Level 2	WLSD Level 3	WLSD Level 1	WLSD Level 2	WLSD Level 3
Hemoglobin A1C1	A1C1	Slide	All Gens	1,2	0.106	0.131	N/A	1.16	1.43	N/A
Hemoglobin A1c % (NGSP)	%A1c	Tip	All Gens	1,2	0.151	0.243	N/A	N/A	N/A	N/A
Hemoglobin A1c mmol/mol	HbA1c	Tip	All Gens	1,2	1.65	2.66	N/A	1.65	2.66	N/A

MAS® Omni•CORE

Within-lab SD in CONV and SI units applicable to OCR-101, OCR-202 and OCR-303

QuidelOrtho analyte name	LabLink analyte name	Vitros technology	Gen applicability	Levels assigned	CONV units			SI units		
					WLSD Level 1	WLSD Level 2	WLSD Level 3	WLSD Level 1	WLSD Level 2	WLSD Level 3
Alpha-1-Antitrypsin	AAT	Tip	All Gens	1-3	1.53	3.45	5.31	0.015	0.035	0.053
Acetaminophen	Acetaminophen	Slide	All Gens	1-3	1.27	2.37	3.68	8.41	15.70	24.38
Albumin	Albumin	Slide	All Gens	1,2	0.09	0.11	N/A	0.90	1.13	N/A
Alcohol	ETOH	Slide	All Gens	1-3	7.5	10.7	14.6	1.64	2.32	3.16
Alkaline Phosphatase	ALP	Slide	Gens 1-79	1-3	1.09	7.37	13.11	1.09	7.37	13.11
ALT	ALT	Slide	All Gens	1-3	2.9	4.3	4.9	2.88	4.28	4.91
ALTV	ALT	Slide	All Gens	1-3	1.6	3.1	4.6	1.63	3.13	4.63
Amylase	Amylase	Slide	Gens 1-79	1-3	5.6	11.2	15.4	5.59	11.20	15.40
Apolipoprotein A-I	Apolipoprotein A-I	Tip	All Gens	1-3	1.16	2.54	4.26	0.012	0.025	0.043
Apolipoprotein B	Apolipoprotein B	Tip	All Gens	1-3	1.28	2.06	2.97	0.013	0.021	0.030
Antistreptolysin-O (ASO)	Antistreptolysin O ASO	Tip	All Gens	1-3	4.84	6.66	8.61	4.84	6.66	8.61
AST	AST	Slide	All Gens	1-3	1.7	5.2	9.5	1.68	5.18	9.48
Urea Nitrogen	BUN	Slide	All Gens	1-3	0.5	1.1	1.4	0.18	0.39	0.51
C3	Complement C3	Tip	All Gens	1-3	1.85	4.65	7.20	18.50	46.51	72.01
C4	Complement C4	Tip	All Gens	1-3	0.28	0.45	0.60	2.84	4.51	6.01
Calcium	Calcium	Slide	All Gens	1-3	0.19	0.23	0.26	0.048	0.057	0.064
Caffeine	Caffeine	Tip	All Gens	1-3	0.41	1.03	1.58	2.12	5.28	8.12
Carbamazepine (Tegretol)	CRBM	Slide	All Gens	1-3	0.27	0.60	0.95	1.14	2.54	4.02
Cholinesterase, Serum	Cholinesterase	Slide	Gens 1-79	1-3	0.09	0.11	0.12	90.00	110.00	120.00
Cholesterol, Total	Cholesterol	Slide	All Gens	1-3	3.04	4.39	5.19	0.08	0.11	0.13

MAS® Omni•CORE

Within-lab SD in CONV and SI units applicable to OCR-101, OCR-202 and OCR-303

QuidelOrtho analyte name	LabLink analyte name	Vitros technology	Gen applicability	Levels assigned	CONV units			SI units		
					WLSD Level 1	WLSD Level 2	WLSD Level 3	WLSD Level 1	WLSD Level 2	WLSD Level 3
CK (Creatine Kinase)	CK	Slide	Gens 1-79	1-3	11.5	18.7	21.6	11.55	18.67	21.59
Chloride	Cl	Slide	All Gens	1-3	1.2	1.3	1.4	1.18	1.30	1.36
Carbamazepine (Tegretol)	Carbamazepine	Slide	All Gens	1-3	0.3	0.6	1.1	1.27	2.54	4.65
Creatinine	Creatinine	Slide	All Gens	1-3	0.08	0.12	0.16	6.86	10.30	14.33
CRP (C-Reactive Protein)	CRP	Slide	All Gens	1-3	1.44	2.74	3.96	0.14	0.27	0.40
Digoxin	Digoxin	Slide	All Gens	1-3	0.11	0.17	0.17	0.14	0.22	0.22
Direct HDL Cholesterol	HDL Cholesterol	Slide	All Gens	1-3	0.42	1.39	2.37	0.01	0.04	0.06
Direct LDL Cholesterol	LDL Cholesterol	Tip	All Gens	2,3	N/A	3.60	5.83	N/A	0.093	0.151
TIBC (Total Iron Binding Capacity)	TIBC	Tip	All Gens	1-3	9.31	13.40	15.99	1.67	2.40	2.86
ECO2 (Carbon Dioxide)	CO2	Slide	All Gens	1-3	0.94	1.11	1.40	0.94	1.11	1.40
Iron	Iron	Slide	All Gens	1-3	3.85	7.45	11.24	0.69	1.33	2.01
Gentamicin	Gentamicin	Tip	All Gens	1-3	0.06	0.16	0.26	0.14	0.34	0.56
GGT (Gamma Glutamyltransferase)	GGT/GGTP	Slide	All Gens	1-3	1.4	2.7	3.6	1.37	2.66	3.58
Glucose	Glucose	Slide	All Gens	1-3	1.68	3.55	5.65	0.093	0.197	0.314
Haptoglobin	Haptoglobin	Tip	All Gens	1-3	1.69	3.01	4.25	0.017	0.030	0.042
IgA	Immunoglobulin A	Tip	All Gens	1-3	4.70	7.52	10.12	0.047	0.075	0.101
IgG	Immunoglobulin G	Tip	All Gens	1-3	25.50	50.35	77.07	0.255	0.503	0.771
IgM	Immunoglobulin M	Tip	All Gens	1-3	2.16	2.87	3.48	0.022	0.029	0.035
Potassium	Potassium	Slide	All Gens	1-3	0.10	0.15	0.21	0.10	0.15	0.21
Lactate	Lactate	Slide	All Gens	1-3	0.07	0.20	0.27	0.07	0.20	0.27
LDHI (Lactate Dehydrogenase)	LDH	Slide	Gens 50-99	1-3	5.3	7.3	9.4	5.3	7.3	9.4
Lithium	Lithium	Slide	All Gens	1-3	0.06	0.06	0.08	0.06	0.06	0.08
Lipase	Lipase	Slide	All Gens	1-3	11.21	12.87	17.07	11.21	12.87	17.07
Magnesium	Magnesium	Slide	All Gens	1-3	0.06	0.08	0.09	0.02	0.03	0.04
Sodium	Sodium	Slide	All Gens	1-3	1.4	1.4	1.4	1.4	1.4	1.4
Prealbumin	Prealbumin	Tip	All Gens	1,2	0.60	1.39	N/A	6.01	13.93	N/A
Phenobarbital	PHBR	Slide	All Gens	1-3	0.51	1.25	3.58	2.20	5.39	15.43

MAS® Omni•CORE

Within-lab SD in CONV and SI units applicable to OCR-101, OCR-202 and OCR-303

QuidelOrtho analyte name	LabLink analyte name	Vitros technology	Gen applicability	Levels assigned	CONV units			SI units		
					WLSD Level 1	WLSD Level 2	WLSD Level 3	WLSD Level 1	WLSD Level 2	WLSD Level 3
Phosphorus	Phosphorus	Slide	All Gens	1-3	0.13	0.19	0.26	0.04	0.06	0.09
Phenytoin	Phenytoin	Slide	All Gens	1-3	0.3	0.7	1.0	1.4	2.8	4.0
Rheumatoid Factor	Rheumatoid Factor	Tip	All Gens	1-3	1.50	1.64	1.78	1.50	1.64	1.78
Salicylate	Salicylate	Slide	All Gens	1-3	0.46	0.53	0.63	0.033	0.039	0.045
CRP, Wide Range - Standard (sCRP)	sCRP	Tip	All Gens	1-3	0.503	1.062	1.907	0.503	1.062	1.907
Theophylline	Theophylline	Slide	All Gens	1-3	0.52	0.74	0.95	2.90	4.10	5.29
TIBC (Total Iron Binding Capacity)	TIBC	Slide	All Gens	1-2	20.1	25.2	N/A	3.61	4.52	N/A
Tobramycin	Tobramycin	Tip	All Gens	1-3	0.07	0.14	0.21	0.15	0.30	0.45
Total Protein	Total Protein	Slide	All Gens	1,2	0.153	0.179	N/A	1.53	1.79	N/A
Transferrin	Transferrin	Tip	All Gens	1-3	5.7	11.9	18.4	0.06	0.12	0.18
Triglycerides	Triglycerides	Slide	All Gens	1-3	2.4	4.4	6.7	0.03	0.05	0.08
Uric Acid	Uric Acid	Slide	All Gens	1-3	0.07	0.16	0.23	4.4	9.3	N/A
Valproic Acid	Valproic Acid	Tip	All Gens	1-3	2.13	3.96	5.65	14.8	27.5	39.1
Vancomycin	Vancomycin	Tip	All Gens	1-3	0.32	1.06	1.21	0.21	0.71	0.81

MAS®Omni•CORE for Japan

Within-lab SD in CONV and SI units applicable to OCR-101, OCR-202 and OCR-303

QuidelOrtho analyte name	LabLink analyte name	Vitros technology	Gen applicability	Levels assigned	CONV units			SI units		
					WLSD Level 1	WLSD Level 2	WLSD Level 3	WLSD Level 1	WLSD Level 2	WLSD Level 3
Amylase	N/A	Slide	Gens 80-99	1-3	5.7	11.4	15.7	5.7	11.4	15.7
Alkaline Phosphatase	N/A	Slide	All Gens	1-3	3.1	19	33	3.1	18.9	33.2
ALT	N/A	Slide	All Gens	1-3	1.9	3.6	4.8	1.9	3.6	4.8
AST	N/A	Slide	All Gens	1-3	1.6	5	8	1.6	4.7	7.5
Cholinesterase, Serum	N/A	Slide	Gens 80-99	1-3	0.0038	0.0046	0.0053	3.8	4.6	5.3
LDHI (Lactate Dehydrogenase)	N/A	Slide	Gens 80-99	1-3	5.3	7.3	9.4	5.3	7.3	9.4
Lipase	N/A	Slide	Gens 80-99	1-3	3.29	3.67	4.63	3.3	3.7	4.6

MAS® Omni•Immune and Cardio•Immune XL Control

Within-lab SD in CONV and SI units for OmniIMMUNE and Cardioimmune XL Control

QuidelOrtho analyte name	LabLink analyte name	Vitros technology	Gen applicability	Levels assigned	CONV units			SI units		
					WLSD Level 1	WLSD Level 2	WLSD Level 3	WLSD Level 1	WLSD Level 2	WLSD Level 3
Homocysteine	Homocysteine	Tip	All Gens	1-3	0.25	0.33	0.40	0.254	0.335	0.398
CRP, High Sensitivity	hsCRP	Tip	All Gens	1-3	0.08	0.15	0.30	0.083	0.147	0.301
CRP, Wide Range – Ultrasensitive (uCRP)	uCRP	Tip	All Gens	1-3	0.052	0.086	0.205	0.052	0.086	0.205

MAS®UrichemTRAK

WLSD in CONV and SI units for UR 11001 and UR 22002 Control levels

QuidelOrtho analyte name	LabLink analyte name	Vitros technology	Gen applicability	Levels assigned	CONV units			SI units		
					WLSD Level 1	WLSD Level 2	WLSD Level 3	WLSD Level 1	WLSD Level 2	WLSD Level 3
Amylase, Urine	Amylase	Slide	All Gens	1-2	3.88	6.82	N/A	3.88	6.82	N/A
Calcium, Urine	Calcium	Slide	All Gens	1-2	0.16	0.22	N/A	0.04	0.055	N/A
Chloride, Urine	Cl	Slide	All Gens	1-2	1.16	1.88	N/A	1.16	1.88	N/A
Creatinine, Urine	Creatinine, Urine	Slide	All Gens	1-2	4.41	10.9	N/A	389.84	963.56	N/A
Glucose, Urine	Glucose	Slide	All Gens	1-2	1.39	6.09	N/A	0.077	0.338	N/A
Potassium	Potassium	Slide	All Gens	1-2	0.75	2.18	N/A	0.75	2.18	N/A
Microalbumin	Microalbumin	Tip	All Gens	1-2	0.13	0.34	N/A	1.30	3.40	N/A
Magnesium, Urine	Magnesium	Slide	All Gens	1-2	0.32	0.32	N/A	0.13	0.13	N/A
Sodium	Sodium	Slide	All Gens	1-2	3.73	4.80	N/A	3.73	4.80	N/A
Phosphorus, Urine	Phosphorus	Slide	All Gens	1-2	1.37	1.49	N/A	0.44	0.48	N/A
Protein, Total, Urine Fluid	Protein, Urine	Slide	All Gens	1-2	1.40	5.40	N/A	0.014	0.054	N/A
Urea	Urea, Urine	Slide	All Gens	1-2	14.10	25.27	N/A	5.032	9.019	N/A
Uric, Urine	Uric Acid	Slide	All Gens	1-2	0.78	1.04	N/A	46.40	61.90	N/A