

Diagnostics

Estimation of Within-Lab SD for MAS™ Quality Controls on Ortho VITROS® Instrumentation

Quality Control 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 potential errors that may affect patient results that could arise from improper calibration, matrix differences and not including the appropriate controls for testing.

Quality Control in the clinical laboratory requires statistical calculations that include determining mean and establishing standard deviation. The CLIA recommendations require for 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 of measurements included. Mathematically the equation can be expressed as below.

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

As expressed above the \sum 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 Standard Deviation (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 can the measurement procedure 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 standard deviation of the results, then the obtained standard deviation 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 Smart Note were extrapolated for the Thermo Scientific™ MAS™ Quality Controls using data from Ortho VITROS® controls, which were originally established using monthly Within-lab SD for VITROS® Chemistry System 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 USA 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 SD's 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 Ortho Clinical Diagnostics Customers?

A Within-lab SD can be calculated from your daily quality control results and compared to the Smart Note within-lab SD. A calculated laboratory SD larger than the Smart Note within-lab SD indicates that system troubleshooting may be necessary. If the calculated SD is much smaller than the Smart Note 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 established

The width of the ROM (highest mean value minus the lowest mean value) is a fixed parameter. The ROM reflects the performance of properly operating VITROS® Chemistry Systems as monitored with MAS Quality Controls. The ROM width for each analyte was compared to USA and European proficiency testing goals and adjusted as appropriate. The numerical values that define the ROM for each slide generation are established by collecting data from internal testing performed on multiple analyzers and among different slide lot numbers within the slide generation.

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.
- For calibration verification, the mean of 2 or more replicate measurements of MAS Quality Controls (called a Preliminary Baseline Mean) should fall within the ROM listed on the assay sheet.
- 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 on 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.

How Ortho Clinical Diagnostics customers use Within-lab SD for the MAS Controls?

The Within-lab SD (WLSD) provided in the Smart Note 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.

See tables on following pages.

Ortho Analyte Name	Gen Applicability	VITROS TECHNOLOGY	Levels to be assigned	LabLink Analyte Name	CONV units			SI units		
					WLS D Level 1	WLS D Level 2	WLS D Level 3	WLS D Level 1	WLS D Level 2	WLS D Level 3
Alpha-1-Antitrypsin	All Gens	Tip	1-3	AAT	1.53	3.45	5.31	0.015	0.035	0.053
Acetaminophen	All Gens	Slide	1-3	Acetaminophen	1.27	2.37	3.68	8.41	15.70	24.38
Albumin	All Gens	Slide	1,2	Albumin	0.09	0.11	N/A	0.90	1.13	N/A
Alcohol	All Gens	Slide	1-3	ETOH	7.5	10.7	14.6	1.64	2.32	3.16
Alkaline Phosphatase	Gens 1-79	Slide	1-3	ALP	1.09	7.37	13.11	1.09	7.37	13.11
ALT	All Gens	Slide	1-3	ALT	2.9	4.3	4.9	2.88	4.28	4.91
ALTV	All Gens	Slide	1-3	ALT	1.6	3.1	4.6	1.63	3.13	4.63
Amylase	Gens 1-79	Slide	1-3	Amylase	5.6	11.2	15.4	5.59	11.20	15.40
Apolipoprotein A-I	All Gens	Tip	1-3	Apolipoprotein A-I	1.16	2.54	4.26	0.012	0.025	0.043
Apolipoprotein B	All Gens	Tip	1-3	Apolipoprotein B	1.28	2.06	2.97	0.013	0.021	0.030
Antistreptolysin-O (ASO)	All Gens	Tip	1-3	Antistreptolysin O ASO	4.84	6.66	8.61	4.84	6.66	8.61
AST	All Gens	Slide	1-3	AST	1.7	5.2	9.5	1.68	5.18	9.48
Urea Nitrogen	All Gens	Slide	1-3	BUN	0.5	1.1	1.4	0.18	0.39	0.51
C3	All Gens	Tip	1-3	Complement C3	1.85	4.65	7.20	18.50	46.51	72.01
C4	All Gens	Tip	1-3	Complement C4	0.28	0.45	0.60	2.84	4.51	6.01
Calcium	All Gens	Slide	1-3	Calcium	0.19	0.23	0.26	0.048	0.057	0.064
Caffeine	All Gens	Tip	1-3	Caffeine	0.41	1.03	1.58	2.12	5.28	8.12
Carbamazepine (Tegretol)	All Gens	Slide	1-3	CRBM	0.27	0.60	0.95	1.14	2.54	4.02
Cholinesterase, Serum	Gens 1-79	Slide	1-3	Cholinesterase	0.09	0.11	0.12	90.00	110.00	120.00
Cholesterol, Total	All Gens	Slide	1-3	Cholesterol	3.04	4.39	5.19	0.08	0.11	0.13
CK (Creatine Kinase)	Gens 1-79	Slide	1-3	CK	11.5	18.7	21.6	11.55	18.67	21.59
CK-MB Activity	N/A	Slide	N/A Not Being Supported (CXL)	CK-MB	N/A	N/A	N/A	N/A	N/A	N/A
Chloride	All Gens	Slide	1-3	Cl	1.2	1.3	1.4	1.18	1.30	1.36
Carbamazepine (Tegretol)	All Gens	Slide	1-3	Carbamazepine	0.3	0.6	1.1	1.27	2.54	4.65
Creatinine	All Gens	Slide	1-3	Creatinine	0.08	0.12	0.16	6.86	10.30	14.33
CRP (C-Reactive Protein)	All Gens	Slide	1-3	CRP	1.44	2.74	3.96	0.14	0.27	0.40
Digoxin	All Gens	Slide	1-3	Digoxin	0.11	0.17	0.17	0.14	0.22	0.22
Direct HDL Cholesterol	All Gens	Slide	1-3	HDL Cholesterol	0.42	1.39	2.37	0.01	0.04	0.06
Direct LDL Cholesterol	All Gens	Tip	2,3	LDL Cholesterol	N/A	3.60	5.83	N/A	0.093	0.151
TIBC (Total Iron Binding Capacity)	All Gens	Tip	1-3	TIBC	9.31	13.40	15.99	1.67	2.40	2.86
ECO2 (Carbon Dioxide)	All Gens	Slide	1-3	CO2	0.94	1.11	1.40	0.94	1.11	1.40
Iron	All Gens	Slide	1-3	Iron	3.85	7.45	11.24	0.69	1.33	2.01
Gentamicin	All Gens	Tip	1-3	Gentamicin	0.06	0.16	0.26	0.14	0.34	0.56
GGT (Gamma Glutamyltransferase)	All Gens	Slide	1-3	GGT/GGTP	1.4	2.7	3.6	1.37	2.66	3.58
Glucose	All Gens	Slide	1-3	Glucose	1.68	3.55	5.65	0.093	0.197	0.314
Haptoglobin	All Gens	Tip	1-3	Haptoglobin	1.69	3.01	4.25	0.017	0.030	0.042
IgA	All Gens	Tip	1-3	Immunoglobulin A	4.70	7.52	10.12	0.047	0.075	0.101
IgG	All Gens	Tip	1-3	Immunoglobulin G	25.50	50.35	77.07	0.255	0.503	0.771
IgM	All Gens	Tip	1-3	Immunoglobulin M	2.16	2.87	3.48	0.022	0.029	0.035

MAS Omni•CORE

Within-lab SD in CONV and SI units applicable to OCR-101, OCR-202 and OCR303

Ortho Analyte Name	Gen Applicability	VITROS TECHNOLOGY	Levels to be assigned	LabLink Analyte Name	CONV units			SI units		
					WLS D Level 1	WLS D Level 2	WLS D Level 3	WLS D Level 1	WLS D Level 2	WLS D Level 3
Potassium	All Gens	Slide	1-3	Potassium	0.10	0.15	0.21	0.10	0.15	0.21
Lactate	All Gens	Slide	1-3	Lactate	0.07	0.20	0.27	0.07	0.20	0.27
LD (Lactate Dehydrogenase)	Gens 1-49	Slide	1-3	LDH	13.2	18.2	21.7	13.2	18.2	21.7
LDHI (Lactate Dehydrogenase)	Gens 50-99	Slide	1-3	LDH	5.3	7.3	9.4	5.3	7.3	9.4
Lithium	All Gens	Slide	1-3	Lithium	0.06	0.06	0.08	0.06	0.06	0.08
Lipase	All Gens	Slide	1-3	Lipase	11.21	12.87	17.07	11.21	12.87	17.07
Magnesium	All Gens	Slide	1-3	Magnesium	0.06	0.08	0.09	0.02	0.03	0.04
Sodium	All Gens	Slide	1-3	Sodium	1.4	1.4	1.4	1.4	1.4	1.4
Prealbumin	All Gens	Tip	1,2	Prealbumin	0.60	1.39	N/A	6.01	13.93	N/A
Phenobarbital	All Gens	Slide	1-3	PHBR	0.51	1.25	3.58	2.20	5.39	15.43
Phosphorus	All Gens	Slide	1-3	Phosphorus	0.13	0.19	0.26	0.04	0.06	0.09
Phenytoin	All Gens	Slide	1-3	Phenytoin	0.3	0.7	1.0	1.4	2.8	4.0
Rheumatoid Factor	All Gens	Tip	1-3	Rheumatoid Factor	1.50	1.64	1.78	1.50	1.64	1.78
Salicylate	All Gens	Slide	1-3	Salicylate	0.46	0.53	0.63	0.033	0.039	0.045
CRP, Wide Range - Standard (sCRP)	All Gens	Tip	1-3	sCRP	0.503	1.062	1.907	0.503	1.062	1.907
Theophylline	All Gens	Slide	1-3	Theophylline	0.52	0.74	0.95	2.90	4.10	5.29
TIBC (Total Iron Binding Capacity)	All Gens	Slide	1-2	TIBC	20.1	25.2	N/A	3.61	4.52	N/A
Tobramycin	All Gens	Tip	1-3	Tobramycin	0.07	0.14	0.21	0.15	0.30	0.45
Total Protein	All Gens	Slide	1,2	Total Protein	0.153	0.179	N/A	1.53	1.79	N/A
Transferrin	All Gens	Tip	1-3	Transferrin	5.7	11.9	18.4	0.06	0.12	0.18
Triglycerides	All Gens	Slide	1-3	Triglycerides	2.4	4.4	6.7	0.03	0.05	0.08
Uric Acid	All Gens	Slide	1-3	Uric Acid	0.07	0.16	0.23	4.4	9.3	N/A
Valproic Acid	All Gens	Tip	1-3	Valproic Acid	2.13	3.96	5.65	14.8	27.5	39.1
Vancomycin	All Gens	Tip	1-3	Vancomycin	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 OCR303

Ortho Analyte Name	Gen Applicability	VITROS TECHNOLOGY	Levels to be assigned	LabLink Analyte Name	CONV units			SI units		
					WLS D Level 1	WLS D Level 2	WLS D Level 3	WLS D Level 1	WLS D Level 2	WLS D Level 3
Amylase	Gens 80-99	Slide	1-3	N/A	5.7	11.4	15.7	5.7	11.4	15.7
Alkaline Phosphatase	All Gens	Slide	1-3	N/A	3.1	19	33	3.1	18.9	33.2
ALT	All Gens	Slide	1-3	N/A	1.9	3.6	4.8	1.9	3.6	4.8
AST	All Gens	Slide	1-3	N/A	1.6	5	8	1.6	4.7	7.5
Cholinesterase, Serum	Gens 80-99	Slide	1-3	N/A	0.0038	0.0046	0.0053	3.8	4.6	5.3
LDHI (Lactate Dehydrogenase)	Gens 80-99	Slide	1-3	N/A	5.3	7.3	9.4	5.3	7.3	9.4
Lipase	Gens 80-99	Slide	1-3	N/A	3.29	3.67	4.63	3.3	3.7	4.6

MAS Alcohol Ammonia

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

Ortho Analyte Name	Gen Applicability	VITROS TECHNOLOGY	Levels to be assigned	LabLink Analyte Name	CONV units			SI units		
					WLS Level 1	WLS Level 2	WLS Level 3	WLS Level 1	WLS Level 2	WLS Level 3
Ammonia	All Gens	Slide	1,2	Ammonia	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

Ortho Analyte Name	Gen Applicability	VITROS TECHNOLOGY	Levels to be assigned	LabLink Analyte Name	CONV units			SI units		
					WLS Level 1	WLS Level 2	WLS Level 3	WLS Level 1	WLS Level 2	WLS Level 3
Bilirubin, Direct/BC (DBIL)	All Gens	Slide	1-3	Bilirubin, Direct	0.082	0.190	0.466	0.98	2.25	5.53
Bilirubin, Indirect/BU	All Gens	Slide	1-3	Bilirubin, Unconj	0.06	0.150	0.32	1.03	2.57	5.47
Bilirubin, Total/TBIL	All Gens	Slide	1-3	Bilirubin, Total	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

Ortho Analyte Name	Gen Applicability	VITROS TECHNOLOGY	Levels to be assigned	LabLink Analyte Name	CONV units			SI units		
					WLS Level 1	WLS Level 2	WLS Level 3	WLS Level 1	WLS Level 2	WLS Level 3
Glucose, CSF	All Gens	Slide	1,2	Glucose	2.04	1.28	N/A	0.113	0.071	N/A
Total Protein, CSF	All Gens	Slide	1,2	CSF	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

Ortho Analyte Name	Gen Applicability	VITROS TECHNOLOGY	Levels to be assigned	LabLink Analyte Name	CONV units			SI units		
					WLS Level 1	WLS Level 2	WLS Level 3	WLS Level 1	WLS Level 2	WLS Level 3
Hemoglobin A1C1	All Gens	Slide	1,2	A1C1	0.106	0.131	N/A	1.16	1.43	N/A
Hemoglobin A1c % (NGSP)	All Gens	Tip	1,2	%A1c	0.151	0.243	N/A	N/A	N/A	N/A
Hemoglobin A1c mmol/mol	All Gens	Tip	1,2	HbA1c	1.65	2.66	N/A	1.65	2.66	N/A

MAS Omni•IMMUNE and Cardioimmune XL Control

Within-lab SD in CONV and SI units for Omni•IMMUNE and Cardioimmune XL Control

Ortho Analyte Name	Gen Applicability	VITROS TECHNOLOGY	Levels to be assigned	LabLink Analyte Name	CONV units			SI units		
					WLS Level 1	WLS Level 2	WLS Level 3	WLS Level 1	WLS Level 2	WLS Level 3
Homocysteine	All Gens	Tip	1-3	Homocysteine	0.25	0.33	0.40	0.254	0.335	0.398
CRP, High Sensitivity	All Gens	Tip	1-3	hsCRP	0.08	0.15	0.30	0.083	0.147	0.301
CRP, Wide Range – Ultrasensitive (uCRP)	All Gens	Tip	1-3	uCRP	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**

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

Thermo Scientific™ MAS™ Controls distributed by Ortho Clinical Diagnostics

Product Name	Part Number
Thermo Scientific MAS Alcohol Ammonia	AAC-MP
Thermo Scientific MAS Bilirubin	BC-101 BC-102 BC-103
Thermo Scientific MAS Cardiolmmune-XL	CAI-XLL CAI-XL1 CAI-XL2 CAI-XL3
Thermo Scientific MAS CSF	CSF-MP
Thermo Scientific MAS Diabetes	DBCL-MP
Thermo Scientific MAS Omni-CORE	OCR-101 OCR-202 OCR-303
Thermo Scientific MAS Omni-IMMUNE	OIM-101 OIM-202 OIM-303
Thermo Scientific MAS UrichemTRAK	UR11001 UR22002
Thermo Scientific MAS Omni-CARDIO UltraLow	OCRD-UL

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Because Every Test is a Life™

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