

Smart Notes



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 SID

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 Wintin 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.

MAS Omni•Core

Ortho Shortname	Gen Applicability	Ortho Analyte Name	Vitros Technology	Body Fluid	Levels to be assigned	LabLink Analyte Name	WLSD Level 1	WLSD Level 2	WLSD Level 3
AAT	All Gens	Alpha-1-Antitrypsin	Tip	Serum	1-3	Alpha-1-Antitrypsin (AAT)	1.53	3.45	5.31
ACET	All Gens	Acetaminophen	Slide	Serum	1-3	Acetaminophen	1.27	2.37	3.68
ALB	All Gens	Albumin	Slide	Serum	1,2	Albumin	0.09	0.11	
ALC	All Gens	Ethanol (Alcohol)	Slide	Serum	1-3	Ethanol (EtOH)	7.5	10.7	14.6
ALKP	Gens 1-79	Alkaline Phosphatase	Slide	Serum	1-3	Alkaline Phosphatase (ALP)	1.09	7.37	13.11
ALT	All Gens	ALT (ALAT/GPT)	Slide	Serum	1-3	Alanine Aminotransferase (ALT)	2.9	4.3	4.9
ALTV	All Gens	ALT (ALAT/GPT)	Slide	Serum	1-3	Alanine Aminotransferase visible	1.6	3.1	4.6
AMYL	Gens 1-79	Amylase	Slide	Serum	1-3	Amylase Total	5.6	11.2	15.4
APOA1	All Gens	Apolipoprotein A-I	Tip	Serum	1-3	Apolipoprotein A1 (ApoA1)	1.16	2.54	4.26
APOB	All Gens	Apolipoprotein B	Tip	Serum	1-3	Apolipoprotein B (ApoB)	1.28	2.06	2.97
ASO	All Gens	Antistreptolysin-O (ASO)	Tip	Serum	1-3	Antistreptolysin O (ASO)	4.84	6.66	8.61
AST	All Gens	AST (ASAT/GOT)	Slide	Serum	1-3	Aspartate Aminotransferase (AST)	1.7	5.2	9.5
Bc	All Gens	Bilirubin, Direct/BC (DBIL)	Slide	Serum	1-3	Bilirubin, Direct	0.117	0.152	0.223
Bu	All Gens	Bilirubin, Indirect/BU	Slide	Serum	1-3	Bilirubin, Unconjugated	0.052	0.077	0.099
BUN	All Gens	Urea Nitrogen	Slide	Serum	1-3	Blood Urea Nitrogen (BUN)	0.5	1.1	1.4
C3	All Gens	C3	Tip	Serum	1-3	Complement Component 3 (C3)	1.85	4.65	7.20
C4	All Gens	C4	Tip	Serum	1-3	Complement Component 4 (C4)	0.28	0.45	0.60

Ortho Shortname	Gen Applicability	Ortho Analyte Name	Vitros Technology	Body Fluid	Levels to be assigned	LabLink Analyte Name	WLSL Level 1	WLSL Level 2	WLSL Level 3
Ca	All Gens	Calcium	Slide	Serum	1-3	Calcium	0.19	0.23	0.26
CAFFN	All Gens	Caffeine	Tip	Serum	1-3	Caffeine	0.41	1.03	1.58
CHE	Gens 1-79	Cholinesterase, Serum (PCHE)	Slide	Serum	1-3	Cholinesterase	0.09	0.11	0.12
CHOL	All Gens	Cholesterol, Total	Slide	Serum	1-3	Total Cholesterol	3.04	4.39	5.19
CK	Gens 1-79	CK (Creatine Kinase)	Slide	Serum	1-3	Creatine Kinase (CK)	11.5	18.7	21.6
Cl-	All Gens	Chloride	Slide	Serum	1-3	Chloride (Cl)	1.2	1.3	1.4
CRBM	All Gens	Carbamazepine (Tegretol)	Slide	Serum	1-3	Carbamazepine	0.3	0.6	1.1
CREA	All Gens	Creatinine	Slide	Serum	1-3	Creatinine	0.08	0.12	0.16
CRP	All Gens	CRP (C-Reactive Protein)	Slide	Serum	1-3	C-Reactive Protein (CRP)	1.44	2.74	3.96
DGXN	All Gens	Digoxin	Slide	Serum	1-3	Digoxin	0.11	0.17	0.17
dHDL	All Gens	Direct HDL Cholesterol	Slide	Serum	1-3	HDL Cholesterol (HDL)	0.42	1.39	2.37
dLDL	All Gens	Direct LDL Cholesterol	Tip	Serum	2,3	LDL Cholesterol (LDL)		3.60	5.83
dTIBC	All Gens	TIBC (Total Iron Binding Capacity)	Tip	Serum	1-3	Iron Binding Capacity, Total (TIBC) (dTIBC)	9.31	13.40	15.99
ECO2	All Gens	CO2 (Carbon Dioxide)	Slide	Serum	1-3	Carbon Dioxide (CO2)	0.94	1.11	1.40
Fe	All Gens	Iron	Slide	Serum	1-3	Iron	3.85	7.45	11.24
GENT	All Gens	Gentamicin	Tip	Serum	1-3	Gentamicin	0.06	0.16	0.26
GGT	Gens 1-79	GGT (Gamma Glutamyltransferase)	Slide	Serum	1-3	Gamma-Glutamyltransferase (GGT)	1.4	2.7	3.6
GLU	All Gens	Glucose	Slide	Serum	1-3	Glucose	1.68	3.55	5.65
HPT	All Gens	Haptoglobin	Tip	Serum	1-3	Haptoglobin	1.69	3.01	4.25
IgA	All Gens	IgA	Tip	Serum	1-3	Immunoglobulin A (IgA)	4.70	7.52	10.12
IgG	All Gens	IgG	Tip	Serum	1-3	Immunoglobulin G (IgG)	25.50	50.35	77.07
IgM	All Gens	IgM	Tip	Serum	1-3	Immunoglobulin M (IgM)	2.16	2.87	3.48
K+	All Gens	Potassium	Slide	Serum, Plasma	1-3	Potassium	0.10	0.15	0.21
LAC	All Gens	Lactate	Slide	Serum	1-3	Lactic Acid	0.07	0.20	0.27
LDH	Gens 1-49	LD (Lactate Dehydrogenase)	Slide	Serum	1-3	Lactate Dehydrogenase (LDH)	13.2	18.2	21.7
LADH	Gens 50-99	LD (Lactate Dehydrogenase)	Slide	Serum	1-3	Lactate Dehydrogenase (LDH)	5.3	7.3	9.4
Li	All Gens	Lithium	Slide	Serum	1-3	Lithium	0.06	0.06	0.08
LIPA	Gens 1-79	Lipase	Slide	Serum	1-3	Lipase	11.21	12.87	17.07
Mg	All Gens	Magnesium	Slide	Serum	1-3	Magnesium	0.06	0.08	0.09
Na+	All Gens	Sodium	Slide	Serum	1-3	Sodium	1.4	1.4	1.4
PALB	All Gens	Prealbumin	Tip	Serum	1,2	Prealbumin	0.60	1.39	N/A
PHOS	All Gens	Phosphorus	Slide	Serum	1-3	Phosphorus	0.13	0.19	0.26
PHYT	All Gens	Phenytoin (Dilantin)	Slide	Serum	1-3	Phenytoin	0.3	0.7	1.0
RF	All Gens	Rheumatoid Factor	Tip	Serum	1-3	Rheumatoid Factor (RF)	1.50	1.64	1.78
SALI	All Gens	Salicylate	Slide	Serum	1-3	Salicylate	0.46	0.53	0.63
TBIL	All Gens	Bilirubin, Total/TBIL	Slide	Serum	1-3	Bilirubin, Total	0.06	0.15	0.27
THEO	All Gens	Theophylline	Slide	Serum	1-3	Theophylline	0.52	0.74	0.95
TIBC	All Gens	TIBC (Total Iron Binding Capacity)	Slide	Serum	1-3	Total Iron Binding Capacity (TIBC)	20.1	25.2	31.1
Tobra	All Gens	Tobramycin	Tip	Serum	1-3	Tobramycin	0.07	0.14	0.21
TP	All Gens	Protein, Total, Serum	Slide	Serum	1,2	Total Protein	0.153	0.179	

MAS Omni•Core

Ortho Shortname	Gen Applicability	Ortho Analyte Name	Vitros Technology	Body Fluid	Levels to be assigned	LabLink Analyte Name	WLS Level 1	WLS Level 2	WLS Level 3
TRFRN	All Gens	Transferrin	Tip	Serum	1-3	Transferrin	5.7	11.9	18.4
TRIG	All Gens	Triglycerides	Slide	Serum	1-3	Triglycerides	2.4	4.4	6.7
Uric	All Gens	Uric Acid	Slide	Serum	1-3	Uric Acid	0.07	0.16	0.23
VALP	All Gens	Valproic Acid (Depakene)	Tip	Serum	1-3	Valproic Acid	2.13	3.96	5.65
VANC	All Gens	Vancomycin	Tip	Serum	1-3	Vancomycin	0.32	1.06	1.21

MAS Omni•Core Products for Japan

Ortho Shortname	Gen Applicability	Ortho Analyte Name	Vitros Technology	Body Fluid	Levels to be assigned	LabLink Analyte Name	WLS Level 1	WLS Level 2	WLS Level 3
AMYL	Gens 80-99	Amylase (Japan)	Slide	Serum	1-3	Amylase	5.7	11.4	15.7
ALKP	All Gens	Alkaline Phosphatase (Japan)	Slide	Serum	1-3	Alkaline Phosphatase (ALP)	3.1	19	33
ALT2	All Gens	ALT (ALAT/GPT) (Japan)	Slide	Serum	1-3	Alanine Aminotransferase (ALT)	1.9	3.6	4.8
ASTJ	All Gens	AST (ASAT/GOT) (Japan)	Slide	Serum	1-3	Aspartate Aminotransferase (AST)	1.6	5	8
CHE	Gens 80-99	Cholinesterase, Serum (PCHE) (Japan)	Slide	Serum	1-3	Cholinesterase	0.0038	0.0046	0.0053
CK	Gens 80-99	same as ROW				Creatine Kinase (CK)			
GGT	Gens 80-99	same as ROW				Gamma-Glutamyltransferase (GGT)			
LDH	Gens 80-99	LD (Lactate Dehydrogenase) (Japan)	Slide	Serum	1-3	Lactate Dehydrogenase (LDH)	5.3	7.3	9.4
LIPA	Gens 80-99	Lipase (Japan)	Slide	Serum	1-3	Lipase	3.29	3.67	4.63

MAS AAC - CSF - DBCL

Ortho Shortname	Gen Applicability	Ortho Analyte Name	Vitros Technology	Body Fluid	Levels to be assigned	LabLink Analyte Name	WLSL Level 1	WLSL Level 2
AMON	All Gens	Ammonia	Slide	Serum	1,2	Ammonia	2.92	3.52
GLU	All Gens	Glucose, CSF	Slide	CSF	1,2	Glucose	2.04	1.28
Prot	All Gens	Protein, Total, Spinal Fluid	Slide	CSF	1,2	Total Protein	5.5	9.8
HBA1C	All Gens	Hemoglobin A1c (NGSP), %	Tip	Whole blood	1,2	Hemoglobin A1c	0.151	0.243
%A1c	All Gens	Hemoglobin A1c (NGSP),mmol/mol	Tip	Whole blood	1,2	Hemoglobin A1c	1.65	2.66

MAS OIM CXL

Ortho Shortname	Gen Applicability	Ortho Analyte Name	Vitros Technology	Body Fluid	Levels to be assigned	LabLink Analyte Name	WLSL Level 1	WLSL Level 2	WLSL Level 3
HCY2	All Gens	Homocysteine	Tip	Serum	1-3	Homocysteine	0.25	0.33	0.40
hsCRP	All Gens	CRP, High Sensitivity	Tip	Serum	LL: no '1-3: yes	C-Reactive Protein, High Sensitivity (hsCRP)	0.08	0.15	0.30

MAS UrichemTRAK

Ortho Shortname	Gen Applicability	Ortho Analyte Name	Vitros Technology	Body Fluid	Levels to be assigned	LabLink Analyte Name	WLSL Level 1	WLSL Level 2
AMYL	Gens 1-79	Amylase, Urine	Slide	Urine	1,2	Amylase Total	5.2	10.6
Ca	All Gens	Calcium, Urine	Slide	Urine	1,2	Calcium	Data not available for derivation	Data not available for derivation
Cl-	All Gens	Chloride, Urine	Slide	Urine	1,2	Chloride (Cl)	Data not available for derivation	Data not available for derivation
CREA	All Gens	Creatinine, Urine	Slide	Urine	1,2	Creatinine	Data not available for derivation	Data not available for derivation
GLU	All Gens	Glucose, Urine	Slide	Urine	1,2	Glucose	Data not available for derivation	Data not available for derivation
K+	All Gens	Potassium	Slide	Urine	1,2	Potassium	1.04	3.08
mALB	All Gens	Microalbumin	Tip	Urine	1,2	Microalbumin	0.28	0.33
Mg	All Gens	Magnesium, Urine	Slide	Urine	1,2	Magnesium	Data not available for derivation	Data not available for derivation
Na+	All Gens	Sodium	Slide	Urine	1,2	Sodium	3.23	6.79
PHOS	All Gens	Phosphorus, Urine	Slide	Urine	1,2	Phosphorus	Data not available for derivation	Data not available for derivation
UPRO	All Gens	Protein, Total, Urine Fluid	Slide	Urine	1,2	Total Protein	1.1	7.3
Urea	All Gens	Urea	Slide	Urine	1,2	Urea Nitrogen	Data not available for derivation	Data not available for derivation
URIC	All Gens	Uric, Urine	Slide	Urine	1,2	Uric Acid	Data not available for derivation	Data not available for derivation

• Data not available for derivation

Thermo Scientific™ MAS™ Controls
distributed by Ortho Clinical Diagnostics

Product Name	Part Number
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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
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Ortho Clinical Diagnostics

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Clinical Diagnostics

USA
46500 Kato Road
Fremont, CA 94538 USA
Tel 800-232-3342 / + 1 510-979-5000
sales.diagnostics.fmt@thermofisher.com

Thermo Fisher Scientific B·R·A·H·M·S GmbH
Neuendorfstr. 25
16761 Hennigsdorf, Germany
Tel. +49 (0)3302 883 0
info.pct@thermofisher.com
thermofisherscientific.com/brahms

Thermo Fisher Scientific Oy
Ratastie 2, 01620 Vantaa, Finland
Tel. +358 10 329 200
thermofisher.com/indiko
thermofisher.com/indikoplus

Asia Pacific
Tel. +65 6499 9999
cdd.asia.info2@thermofisher.com

Australia
Tel. + 61 1800 333 110
auinfo@thermofisher.com

Canada
Tel. 905-286-4290
CDD.Canada@thermofisher.com

China
Tel. +86 400 650 5118
sales.china@thermofisher.com

France, Belgium (Brussels / Wallonia) & Luxembourg
Tel. + 33 (0) 1 40 86 65 00
cdx.fr.info@thermofisher.com

Germany
Tel. +49 (0) 3302 883 608
cdx.de.info@thermofisher.com

Hong Kong
Tel. Tel. + 852 3107 7600
SDG.HK@thermofisher.com

Italy
distributor.cdd@thermofisher.com

Japan
Tel. + 81 (0)120-489-211
JPYOK-CDD.QC@thermofisher.com

Netherlands & Belgium (Flemish)
Tel. +49 3302 883 660
Info.benelux.cdd@thermofisher.com

New Zealand
Tel. + 61 0800933 966
nzinfo@thermofisher.co.nz

Nordic
Tel. + 46 8 594 691 30
info.nordic.cdd@thermofisher.com

Russia
Tel. + 7 495 739 76 41
info.btd.moscow@thermofisher.com

South Africa
Tel. +27 11 792 6790
support-za.idd@thermofisher.com

Spain & Portugal (Iberia)
Tel. + 34 93589 8338
CDD.Info.ES@thermofisher.com

Switzerland & Austria
Tel. + 41 26 663 86 70
cdx.ch.info@thermofisher.com

United Kingdom & Ireland
Tel. + 44 1442 868 940
cdx.UK.info@thermofisher.com

For Countries Not Listed
distributor.cdd@thermofisher.com

Learn more at: thermofisher.com/diagnostics

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