



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} (mean) = (Σx_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:

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

= 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 Withinlab 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.

MAS Omni•CORE

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

| | 0 | WITDOO | 1 | | (| CONV unit | S | | SI units | |
|---------------------------------------|----------------------|----------------------|-------------------------------------|---------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| Ortho Analyte Name | Gen Applicability | VITROS Technology | Levels to be assigned | LabLink Analyte Name | WLSD Level 1 | WLSD Level 2 | WLSD Level 3 | WLSD Level 1 | WLSD Level 2 | WLSD 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-0 (ASO) | All Gens | Tip | 1-3 | Antistreptolysin 0 AS0 | 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 | СК | 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 | CI | 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 | C02 | 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 |
| lgG | 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

| | Con | VITROS | Levels to be | LabLink | (| CONV unit | S | | SI units | |
|---------------------------------------|----------------------|------------|--------------|-------------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| Ortho Analyte Name | Gen Applicability | TECHNOLOGY | assigned | Analyte Name | WLSD Level 1 | WLSD Level 2 | WLSD Level 3 | WLSD Level 1 | WLSD Level 2 | WLSD 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 |
| Standard CRP | All Gens | MicroTip | 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

| | Gen | VITROS | Levels to be | LabLink | (| CONV unit | S | SI units | | | |
|---------------------------------|---------------|------------|--------------|--------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|--|
| Ortho Analyte Name | Applicability | TECHNOLOGY | assigned | Analyte Name | WLSD Level 1 | WLSD Level 2 | WLSD Level 3 | WLSD Level 1 | WLSD Level 2 | WLSD 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

| | | Gen | VITROS | Levels to be | a ta ba lablink | | CONV units | | | SI units | | |
|---|--------------------|----------|------------|--------------|------------------|-----------------|-----------------|------|------|-----------------|------|--|
| | Ortho Analyte Name | | TECHNOLOGY | | ned Analyte Name | WLSD Level 1 | WLSD Level 2 | WLSD | | WLSD Level 2 | WLSD | |
| ł | | 411.0 | 0111 | 1.0 | • · | | | | | | | |
| l | 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

| | Gen | VITROS | Levels to be | Levels to be LabLink | | CONV units | | | SI units | | | |
|-----------------------------|---------------|------------|--------------|----------------------|---------|------------|---------|---------|-----------------|---------|--|--|
| Ortho Analyte Name | Applicability | TECHNOLOGY | assigned | Analyte Name | WLSD | WLSD | WLSD | WLSD | WLSD Level 2 | WLSD | | |
| | | | | | Level 1 | Level 2 | Level 3 | Level 1 | Level 2 | 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

| | Gen | VITROS | Levels to be | LabLink | CONV units | | | SI units | | |
|--------------------|---------------|------------|--------------|--------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| Ortho Analyte Name | Applicability | TECHNOLOGY | assigned | Analyte Name | WLSD Level 1 | WLSD Level 2 | WLSD Level 3 | WLSD Level 1 | WLSD Level 2 | WLSD 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

| | Gen | VITROS | Levels to be LabLink | | CONV units | | | SI units | | |
|-------------------------|---------------|------------|----------------------|--------------|------------|---------|---------|----------|---------|---------|
| Ortho Analyte Name | Applicability | TECHNOLOGY | assigned | Analyte Name | WLSD | WLSD | WLSD | WLSD | WLSD | WLSD |
| | | | | | Level 1 | Level 2 | Level 3 | Level 1 | Level 2 | 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

| | Gen | VITROS | assigned Name | | CONV units | | | SI units | | |
|-----------------------|---------------|------------|---------------|--------------|-----------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| Ortho Analyte Name | Applicability | TECHNOLOGY | | | WLSD Level 1 | WLSD Level 2 | WLSD Level 3 | WLSD Level 1 | WLSD Level 2 | WLSD 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 | 3-49 | hsCRP | 0.08 | 0.15 | 0.30 | 0.083 | 0.147 | 0.301 |

MAS UrichemTRAK

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

| | 0 o m | VITDOC | Levels | l oblight | | CONV units | | | SI units | |
|--------------------------------|----------------------|----------------------|-------------------|-------------------------|--|--|-----------------|--|--|-----------------|
| Ortho Analyte Name | Gen Applicability | VITROS TECHNOLOGY | to be assigned | LabLink Analyte Name | 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 | 5.2 | 10.6 | N/A | 5.19 | 10.61 | N/A |
| Calcium, Urine | All Gens | Slide | 1,2 | Calcium | Data not available for derivation | Data not available for derivation | N/A | Data not available for derivation | Data not available for derivation | N/A |
| Chloride, Urine | All Gens | Slide | 1,2 | CI | Data not available for derivation | Data not available for derivation | N/A | Data not available for derivation | Data not available for derivation | N/A |
| Creatinine, Urine | All Gens | Slide | 1,2 | Creatinine, Urine | Data not available for derivation | Data not available for derivation | N/A | Data not available for derivation | Data not available for derivation | N/A |
| Glucose, Urine | All Gens | Slide | 1,2 | Glucose | Data not available for derivation | Data not available for derivation | N/A | Data not available for derivation | Data not available for derivation | N/A |
| Potassium | All Gens | Slide | 1,2 | Potassium | 1.04 | 3.08 | N/A | 1.04 | 3.08 | N/A |
| Microalbumin | All Gens | Tip | 1,2 | Microalbumin | 0.28 | 0.33 | N/A | 2.81 | 3.28 | N/A |
| Magnesium, Urine | All Gens | Slide | 1,2 | Magnesium | Data not available for derivation | Data not available for derivation | N/A | Data not available for derivation | Data not available for derivation | N/A |
| Sodium | All Gens | Slide | 1,2 | Sodium | 3.23 | 6.79 | N/A | 3.23 | 6.79 | N/A |
| Phosphorus, Urine | All Gens | Slide | 1,2 | Phosphorus | Data not available for derivation | Data not available for derivation | N/A | Data not available for derivation | Data not available for derivation | N/A |
| Protein, Total, Urine Fluid | All Gens | Slide | 1,2 | Protein, Urine | 1.1 | 7.3 | N/A | 0.011 | 0.073 | N/A |
| Urea | All Gens | Slide | 1,2 | Urea, Urine | Data not available for derivation | Data not available for derivation | N/A | Data not available for derivation | Data not available for derivation | N/A |
| Uric, Urine | All Gens | Slide | 1,2 | Uric Acid | Data not available for derivation | Data not available for derivation | N/A | Data not available for derivation | Data not available for derivation | 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 CardioImmune·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 | 0IM-101 0IM-202 0IM-303 |
| Thermo Scientific MAS UrichemTRAK | UR11001 UR22002 |
| Thermo Scientific MAS Omni-CARDIO UltraLow | OCRD-UL |

For ordering information contact your local Ortho Clinical Diagnostics Sales Representative or visit: orthoclinical.com

Ortho Clinical Diagnostics

Because Every Test is a Life™

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 Ov 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

Hona Kona 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 cdx.UK.info@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

For Countries Not Listed distributor.cdd@thermofisher.com

Learn more at: thermofisher.com/diagnostics

Not all products are CE marked or have 510(k) clearance for sale in the U.S. Availability of products in each country depends on local regulatory marketing authorization status.

© 2017-2022 Thermo Fisher Scientific Inc. All rights reserved. All trademarks are the property of Thermo Fisher Scientific and its subsidiaries unless otherwise specified. VITROS is a trademark of Ortho Clinical Diagnostics. CDD-FR-MTL-0270 Rev 03

Thermo Físher SCIENTIFIC