Weqas Unit 6, Parc Tŷ Glas Llanishen, Cardiff, CF14 5DU

Tel: 02920 314750 Email: contact@weqas.com



EXTERNAL QUALITY ASSESSMENT



INTERNAL QUALITY CONTROL



REFERENCE MEASUREMENT SERVICES



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## Weqas Connect EQA Report Interpretation

Gareth Davies

Deputy Director, Weqas

# **Programme Design**



## **Common Report format (quantitative)**

| Ammonia                  |
|--------------------------|
| b123 Co-oximetry         |
| Bile Acids               |
| Bilirubin                |
| Blood Gas                |
| BNP                      |
| Cardiac Markers          |
| Co-oximetry              |
| CRP                      |
| ED Toxicology            |
| Endocrine                |
| fFN                      |
| Haematinics              |
| HbA1c                    |
| Homocysteine             |
| Immunosuppressants       |
| Lipids                   |
| NT Pro BNP               |
| pH Meter                 |
| Plasma Cardiac Markers   |
| pO <sub>2</sub> Accuracy |

| pO2 Accuracy                |
|-----------------------------|
| POCT Creatinine             |
| POCT CRP                    |
| POCT D-dimer                |
| POCT Haemoglobin            |
| POCT INR                    |
| POCT Urine ACR              |
| Porphyrin                   |
| Pre-Eclampsia               |
| Procalcitonin               |
| Quantitative Faecal Hb      |
| SARS-CoV-2 Ab               |
| SARS-CoV-2 Ag               |
| Serum ACE                   |
| Serum Chemistry             |
| Serum hCG                   |
| Serum Indices               |
| Therapeutic Drug Monitoring |
| Urine Chemistry             |
| Urine Oxalate & Citrate     |



# Why multiple samples are important

Identifies components of both Imprecision and Inaccuracy

Identifies systematic errors

Assesses method linearity – required for ISO 15189

Powerful error detection tool

# **Gaussian Distribution**



The Weqas Report Statistical Indices

• Imprecision: Sy.x, r, IS

• Inaccuracy: Bias plot, y=mx+c

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# Interpretation of Imprecision

**Sy.x** is the deviation around the best fit line and is an indication of scatter. It is used as an index of within run imprecision. This is given in the units of the analyte in question.

Correlation coefficient (**r value**) is also an index of within run imprecision. The closer to 1.0 the value is, the better the precision (less scatter about the best fit line).

| 'r' value |           | In | nprecision score             |
|-----------|-----------|----|------------------------------|
| 0.9990    | 0 to 10   | -  | Good                         |
| to        |           |    |                              |
| 1.0000    |           |    |                              |
| 0.9850    | 11 to 150 | -  | Acceptable to Warning level  |
| to        |           |    |                              |
| 0.9989    |           |    |                              |
| <         | > 150     | -  | Unacceptable                 |
| 0.9850    |           |    | (including Curvilinear Data) |

# Imprecision indices





Standard dev of residuals  
Sy.x = 
$$\sqrt{\frac{\sum (\tilde{y}-y)^2}{d.f.}}$$

where  $\tilde{y}$  = the value on the line of best fit



# **Imprecision** – Scatter around the "best fit line", Sy.x

Sodium (mmol/l)

Measurement of scatter





# Imprecision – how to calculate *Sy.x*

| Target value | Lab result           | Line of best<br>fit      | Deviation                   |               |
|--------------|----------------------|--------------------------|-----------------------------|---------------|
| <i>x</i>     | у                    | ỹ                        | <i>y</i> - $\tilde{y}=dy.x$ | $dy.x^2$      |
|              |                      |                          |                             |               |
| 111          | 108                  | 109.9                    | -1.9                        | 3.62          |
| 123.5        | 128                  | 123.3                    | 4.7                         | 21.97         |
| 135.7        | 136                  | 136.4                    | -0.4                        | 0.16          |
| 148          | 144                  | 149.6                    | -5.6                        | 31.30         |
| 160.3        | 166                  | 162.8                    | 3.2                         | 10.31         |
|              |                      |                          |                             |               |
| slope        | 1.07                 |                          | $\sum dy.x$                 | $\sum dy.x^2$ |
| int          | -9.17                |                          | 0.0                         | 67.36         |
|              |                      |                          | <i>d.f</i> = n-1 = 4        |               |
|              |                      |                          |                             |               |
|              | $\mathbf{S}_{y.x} =$ | $\sqrt{\sum dy.x^2/d.f}$ | √67.4/4                     | 4.10          |
|              |                      |                          |                             |               |

# Interpretation of Inaccuracy











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|           | Impre  | ecision     |      | Inaccurac | y        |
|-----------|--------|-------------|------|-----------|----------|
|           | Random | Curvilinear | Prop | Mixed     | Constant |
| Slope     | No     | Yes/No      | Yes  | Yes       | No       |
| Intercept | No     | Yes/No      | No   | Yes       | Yes      |
| Sy,x      | Yes    | Yes         | No   | No        | No       |
| r         | Yes    | Yes         | No   | No        | No       |

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## How do we set Analytical Performance Specifications (APS) and Target Values?



# The Weqas Report Target values used in Statistical Analysis

Hierarchy

Reference values – used for bias plot & SDI / PI calculation Method mean – used for SDI / PI calc if no ref value and n≥8 Overall mean – used for SDI / PI calc and bias plot if no ref value and n <8

Instrument mean – on report for information only



# **Generation of Reference Target Values**

- Specialist Laboratories Required
- Accredited to ISO17025 (in accordance with ISO15195)
- Limited number of laboratories worldwide

# Value of Reference Targets

- Traceable to higher order (traceable to SI unit)
- Establishes method traceability for the lab requirement of ISO 15189
- Highlights the pitfalls of using the trimmed overall mean as an accuracy target in EQA programmes
- Useful in the post market vigilance of the IVD Directive

# **Reference Methods**



#### **Spectrometry**

- Sodium, Potassium, Calcium
- Magnesium, Lithium

#### **IFCC Enzymes**

• AST, ALT, LDH, GGT, CK, Amylase

### <u>HPLC</u>

• Homocysteine

<u>LC-MS/MS</u>

- Testosterone
- •Cortisol

IDGC-MS

- •17ß-Oestradiol
- Progesterone
- •Bile Acids
- •Creatinine
- Cholesterol
- •Glucose
- •Urate
- •Triglyceride

•HDL \*

• HbA1c \*\*

\*\* Provided by IFCC Ref lab, Netherlands





# Hierarchy for setting APS



# Interlaboratory variation (state of the art) FT4



Relationship of analyte conc. to SD follows a polynomial equation for most analytes and is non linear therefore using fixed % TE is not appropriate Wegas



# "State of the art" v Biology



Biological goals not achievable. Although Performance has improved over time.

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## Weqas Connect Reports

# Standard Quantitative Report

Participant Code: WQ00000

\*\*\*\*\*

Wegas

Unit 6, Parc Ty Glas

Email: office@wegas.com

Programme Organiser: Mrs Annette Thomas

United Kingdom CF14 5DU Tel: 02920 314750

Llanishen

Cardiff

Weqas



|                      | PI So      | ores     |         |
|----------------------|------------|----------|---------|
| Location             | Hospital 1 | Hosp     | oital 2 |
| Instrument Name      | *******    | ******** | ******* |
| Instrument Serial #  | SN0001     | SN0002   | SN0003  |
| Salicylate           | Good       | Warning  | Poor    |
| Paracetamol          | Good       | Good     | Warning |
| Ethanol              | Good       | N/A      | Good    |
| Overall % poor PI    | 0%         | 13%      | 17%     |
| Overall % Non-return | 0%         | 0%       | 0%      |

 
 PI Code
 Meaning

 N/A
 Not enrolled for this analyte

 NRR
 Analyte enrolled but no results returned

 N/S
 This quantitative analyte not scored for this distribution

#### \*\*\*\*\* Please note\*\*\*\*\*\*\*\*

The NQAAP expects 100% compliance on EQA returns. If you are enrolled for an analyte and have not returned a result (denoted by NRR in your PI table), this will be treated as a poor performance score. Please let us know as soon as possible if you are no longer providing this analyte as part of your diagnostic service.

#### Distribution Specific Comment There is no specific comment for this distribution

No participant comments have been submitted for any instruments for this distribution.



Weqas

Unit 6, Parc Ty Glas Llanishen Cardiff United Kingdom CF14 5DU Tel: 02920 314750 Email: office@weqas.com Programme Organiser: Mrs Annette Thomas





Participant Code: WQ00000

########

########

|                      | PI Se                | cores                                   |                       |
|----------------------|----------------------|---|-----------------------|
| Location             | Hospital 1           | Hosp                                    | ital 2                |
| Instrument Name      | <del>#########</del> | ####################################### | <del>##########</del> |
| Instrument Serial #  | SN0001               | SN0002                                  | SN0003                |
| Salicylate           | Good                 | Warning                                 | Poor                  |
| Paracetamol          | Good                 | Good                                    | Warning               |
| Ethanol              | Good                 | N/A                                     | Good                  |
| Overall % poor PI    | 0%                   | 13%                                     | 17%                   |
| Overall % Non-return | 0%                   | 0%                                      | 0%                    |

| PI<br>Code | Meaning   |
|------------|---|
| N/A        | Not enrolled for this analyte                                 |
| NRR        | Analyte enrolled but no<br>results returned                   |
| N/S        | This quantitative analyte not<br>scored for this distribution |

#### \*\*\*\*\* Please note\*\*\*\*\*\*\*

The NQAAP expects 100% compliance on EQA returns. If you are enrolled for an analyte and have not returned a result (denoted by NRR in your PI table), this will be treated as a poor performance score. Please let us know as soon as possible if you are no longer providing this analyte as part of your diagnostic service.

#### **Distribution Specific Comment**

There is no specific comment for this distribution.

No participant comments have been submitted for any instruments for this distribution.

Programme: ED Toxicology - Distribution Code: SP1223 Distribution Start: 04-Dec-2023 - Distribution End: 18-Dec-2023 - Report Issued: 27-Dec-2023 - Report Status: Final

#### Participant Code: WQ00000 • Location: Hospital 1 • Analyser Name: ####### • Serial #: SN0001 Date Samples received: 05-Dec-2023 • Date of Analysis: 08-Dec-2023 • Operator Details: r/a • Storage Conditions: 2 - 8 °C

Analyte: Salicylate • Method: Roche Enzymatic • Kit: SALI

|          |                             |             | Salicylate mg/L            |                                  |         |
|----------|-----------------------------|-------------|----------------------------|----------------------------------|---------|
|          | Your reported result (mg/L) |             | Method:<br>Roche Enzymatic | Instrument Model:<br>cobas c 501 | Overall |
|          |                             | Mean        | 160.1                      | 161.1                            | 159.9   |
| Sample 1 | 160                         | SD          | 4.5                        | 4.0                              | 6.1     |
|          |                             | Uncertainty | 0.93                       | 1.67                             | 1.03    |
|          |                             | n           | 37                         | 9                                | 54      |
|          |                             | Mean        | 252.5                      | 253.3                            | 252.9   |
| Sample 2 | 250                         | SD          | 6.2                        | 4.0                              | 7.3     |
|          |                             | Uncertainty | 1.28                       | 1.66                             | 1.24    |
|          |                             | n           | 37                         | 9                                | 54      |
|          |                             | Mean        | 704.6                      | 703.9                            | 713.8   |
| Sample 3 | 705                         | SD          | 23.1                       | 18.9                             | 32.1    |
|          |                             | Uncertainty | 5.18                       | 8.33                             | 5.78    |
|          |                             | n           | 31                         | 8                                | 48      |
|          |                             | Mean        | 537.1                      | 534.6                            | 536.4   |
| Sample 4 | 531                         | SD          | 12.8                       | 13.4                             | 18.4    |
|          |                             | Uncertainty | 2.63                       | 5.58                             | 3.12    |
|          |                             | n           | 37                         | 9                                | 54      |





| Precision |        |        |        |        |        |                       | Sy.  | x is the av | erage deviation from the best fit lin |
|-----------|--------|--------|--------|--------|--------|-----------------------|------|-------------|---------------------------------------|
|           |        |        |        |        |        | This<br>distribution: | ING. | S Score     | Interpretation                        |
|           | SP0723 | SP0823 | SP0923 | SP1023 | SP1123 | SP1223                | 0    | to 10       | Good                                  |
| Sy.x      | 8.28   | 6.26   | 2.05   | 1.72   | 22.32  | 3.62                  | 11   | 1 to 150    | Acceptable to Warning level           |
| IS        | 4      | 2      | 0      | D      | 27     | 1                     | 3    | 150         | Unacceptable (Incl. Curvilinea        |







| All Results | My Method | My Instrument | • My Result |
|-------------|-----------|---------------|-------------|

| SP1223                        | Sam   | Sample 1 Sample 2 |       | ple 2 | Sample 3 |     | Sample 4 |     |
|-------------------------------|-------|-------------------|-------|-------|----------|-----|----------|-----|
| Method Name                   | Mean  | CV%               | Mean  | CV%   | Mean     | CV% | Mean     | CV% |
| Abbott Enzymatic (n=2)        | 159.8 | 1.4               | 258.0 | 0.7   | 760.7    | 1.0 | 557.4    | 1.2 |
| CLS Enzymatic (n=1)           | 162.6 | 0.0               | 262.6 | 0.0   | 747.3    | 0.0 | 549.7    | 0.0 |
| Emit tox Salicylic Acid (n=9) | 162.8 | 6.0               | 256.3 | 4.3   | 744.2    | 5.1 | 539.4    | 6.0 |
| Roche Enzymatic (n=37)        | 160.1 | 2.8               | 252.5 | 2.5   | 704.6    | 3.3 | 537.1    | 2.4 |
| Siemens Enzymatic (n=5)       | 150.6 | 4.3               | 244.3 | 4.1   | 699.7    | 1.6 | 513.1    | 1.9 |

There are no Weqas or Participant supplied comments for Salicylate for this distribution.

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Programme: ED Toxicology • Distribution Code: SP1223 Distribution Start: 04-Dec-2023 • Distribution End: 18-Dec-2023 • Report Issued: 27-Dec-2023 • Report Status: Final

#### Participant Code: WQ00000 • Location: Hospital 1 • Analyser Name: ######## • Serial #: SN0001

Date Samples received: 05-Dec-2023 • Date of Analysis: 06-Dec-2023 • Operator Details: n/a • Storage Conditions: 2 - 8 °C

Analyte: Salicylate • Method: Roche Enzymatic • Kit: SALI

|          |                             |             | Salicylate mg/L            |                                  |         |
|----------|-----------------------------|-------------|----------------------------|----------------------------------|---------|
|          | Your reported result (mg/L) |             | Method:<br>Roche Enzymatic | Instrument Model:<br>cobas c 501 | Overall |
|          |                             | Mean        | 160.1                      | 161.1                            | 159.9   |
| Sample 1 | 160                         | SD          | 4.5                        | 4.0                              | 6.1     |
| campio i |                             | Uncertainty | 0.93                       | 1.67                             | 1.03    |
|          |                             | n           | 37                         | 9                                | 54      |
|          |                             | Mean        | 252.5                      | 253.3                            | 252.9   |
| Sample 2 | 250                         | SD          | 6.2                        | 4.0                              | 7.3     |
| Campie 2 | 250                         | Uncertainty | 1.28                       | 1.66                             | 1.24    |
|          |                             | n           | 37                         | 9                                | 54      |
|          |                             | Mean        | 704.6                      | 703.9                            | 713.8   |
| Sample 3 | 705                         | SD          | 23.1                       | 18.9                             | 32.1    |
| ounpie o |                             | Uncertainty | 5.18                       | 8.33                             | 5.78    |
|          |                             | n           | 31                         | 8                                | 48      |
|          |                             | Mean        | 537.1                      | 534.6                            | 536.4   |
| Sample 4 | 531                         | SD          | 12.8                       | 13.4                             | 18.4    |
| oumpio 4 |                             | Uncertainty | 2.63                       | 5.58                             | 3.12    |
|          |                             | n           | 37                         | 9                                | 54      |

| Scoring               |       |       |       |       |                        | Ru  | nnii   | ng Pl  |        |         |         |        |        |   |  |
|-----------------------|-------|-------|-------|-------|------------------------|-----|--------|--------|--------|---------|---------|--------|--------|---|--|
| Sample                | 1     | 2     | 3     | 4     | Overall<br>Performance |     | 3<br>2 |        |        |         |         |        |        | • |  |
| Target: (Method Mean) | 160.1 | 252.5 | 704.6 | 537.1 |                        | e   | 1      |        |        |         |         |        |        |   |  |
| Weqas TAE             | 13    | 18.2  | 68.6  | 45.1  |                        | Sco | 0      |        |        | -       |         |        |        |   |  |
| PI                    | -0.02 | -0.28 | 0.01  | -0.27 | Good                   | P   | -1     |        |        |         |         | Ť      |        |   |  |
|                       |       |       |       |       |                        |     | -2     |        |        |         |         |        |        |   |  |
|                       |       |       |       |       |                        |     | -3     | SP0723 | SP0823 | SP0923  | SP1023  | SP1123 | SP1223 |   |  |
|                       |       |       |       |       |                        |     |        |        |        | Distrik | outions |        |        |   |  |





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|      | SP0723 | SP0823 | SP0923 | SP1023 | SP1123 | This<br>distribution:<br>SP1223 |
|------|--------|--------|--------|--------|--------|---------------------------------|
| Sy.x | 8.28   | 6.26   | 2.05   | 1.72   | 22.32  | 3.62                            |
| IS   | 4      | 2      | 0      | 0      | 27     | 1                               |

Sy.x is the average deviation from the best fit line and is an index of scatter.

| IS Score  | Interpretation                        |
|-----------|---------------------------------------|
| 0 to 10   | Good                                  |
| 11 to 150 | Acceptable to Warning level           |
| > 150     | Unacceptable (incl. Curvilinear Data) |

## Weqas





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| Method Summary                |       |          |       |          |       |          |       |       |
|-------------------------------|-------|----------|-------|----------|-------|----------|-------|-------|
| SP1223                        | Sam   | Sample 1 |       | Sample 2 |       | Sample 3 |       | ole 4 |
| Method Name                   | Mean  | CV%      | Mean  | CV%      | Mean  | CV%      | Mean  | CV%   |
| Abbott Enzymatic (n=2)        | 159.8 | 1.4      | 258.0 | 0.7      | 760.7 | 1.0      | 557.4 | 1.2   |
| CLS Enzymatic (n=1)           | 162.6 | 0.0      | 262.6 | 0.0      | 747.3 | 0.0      | 549.7 | 0.0   |
| Emit tox Salicylic Acid (n=9) | 162.8 | 6.0      | 256.3 | 4.3      | 744.2 | 5.1      | 539.4 | 6.0   |
| Roche Enzymatic (n=37)        | 160.1 | 2.8      | 252.5 | 2.5      | 704.6 | 3.3      | 537.1 | 2.4   |
| Siemens Enzymatic (n=5)       | 150.6 | 4.3      | 244.3 | 4.1      | 699.7 | 1.6      | 513.1 | 1.9   |

There are no Weqas or Participant supplied comments for Salicylate for this distribution.

# **Overall Performance**

| Weqas |
|-------|
|-------|

| Traffic light | Performance | Description  |
|---------------|-------------|--|
| colour        | category    |  |
|               | Non-Return  | (Any number of samples in distribution) and (No results submitted for any samples)   |
|               |             | (Any number of sample in distribution) and (one or more  PI  > 3)  |
|               |             | (number of samples in distribution = 1) and $(2 <  PI  \le 3)$   |
| Red           |             | (number of samples in distribution > 1) and (2 or more $ PI  > 2$ ) (Westgard $2_{2s}$ )   |
|               | Poor        | (number of samples in distribution > 1) AND (sign $x_i \neq sign x_j$ )] AND $ x_i >2$ AND $ x_j  > 2 *$ for at least one pair of scores $x_i$ and $x_i$ |
|               |             | where x <sub>n</sub> with i≠j are the individual sample-analyte scores for the instrument in   |
|               |             | question   |
|               |             | (Westgard $R_{4s}$ )   |
| 0             |             | (number of samples in distribution > 1) and (single sample with $2 <  PI  \le 3$ ) and   |
| Orange        | vvarning    | (no sample with [PI] > 3)  |
| Yellow        | Acceptable  | (any number of samples in distribution) AND (1 < Max $ PI  \le 2$ )  |
| Green         | Good        | PI  < 1 for all samples  |
|               |             | Green is only assigned if all the individual samples are good.   |

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## **Problem Solving and Cases**

# **Problem Solving Flow Chart**





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Pages 18-19 of SP-QL1-IntLabEQA

# **Problem Solving Flow Chart**



Pages 18-19 of SP-QL1-IntLabEQA



Wegas

mixed

(m, c)

YES

constant

**(c)** 

Check zero

(reagent blank,

serum blank,

instrument zero).

NO

Check method

specificity

Are you satisfied

with intercept?

Recalibrate, run linearity check.



# Bias plot (1)

#### Sodium (mmol/l)





# Bias plot (1)

#### Sodium (mmol/l)





# Bias plot (2)

Chloride (mmol/l)



y = 1.01x -4.01 r = 0.9995 IS = 5 Sy.x = 0.49



# Bias plot (2)

Chloride (mmol/l)





# Bias plot (3)

#### Bicarbonate (mmol/l)



IS = 1516

Sy.x = 2.41



# Bias plot (3)

#### Bicarbonate (mmol/l)



## Weqas

# Bias plot (4)

#### Calcium (mmol/l)



y = slope not calculated r = 0.9810 IS = 190

Sy.x = 0.09

## Weqas

# Bias plot (4)

#### Calcium (mmol/l)



y = slope not calculated r = 0.9810IS = 190Sy.x = 0.09

Imprecision – unsatisfactory, r = 0.9810, Sy.x = 0.09 mmol/L Error – curvilinear data **Cause – time expired reagents** 



# Bias plot (5)

ALP (IU/L) 60 100 140 180 220 260 300 150 100 50 Ч 0 0 n  $\mathbf{C}$ -50 Х -100 -150 ⊥

y = 0.50x +1.16 r = 0.9999 IS = 1 Sy.x = 1.30



# Bias plot (5)



| y = 0.50x +1.16 | Imprecision – satisfactory  |
|-----------------|---|
| ,<br>r = 0.9999 | Inaccuracy – identify error   |
| IS = 1          | m = 0.57  |
| Sy.x = 1.30     | Error – systematic proportional error. Results low by 41% over the whole range      |
| 1               | Cause – incorrect method group classification. The lab was using AMP not DEA buffer |

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## Case Study - example



Summary Report Analyte: Overall Performance Category: Running PI analyte –sample scores:

Standard Report Analyte results table: Scoring Table: Running PI scores: Bias Chart (Absolute): Bias Chart (Relative): Precision Scores: Sample Histograms: Method Summary Data: Programme: Lipids • Distribution Code: LP0124 Distribution Start: 22-Jan-2024 • Distribution End: 05-Feb-2024 • Report Issued: n/a • Report Status: n/a Requested By: gareth@weqas.com





| PI Scores            |              |  |  |  |
|----------------------|--------------|--|--|--|
| Location             | The Path Lab |  |  |  |
| Instrument Name      | Cobas C 311  |  |  |  |
| Instrument Serial #  | 2039-05      |  |  |  |
| Cholesterol          | Acceptable   |  |  |  |
| Triglyceride         | Acceptable   |  |  |  |
| HDL Cholesterol      | Poor         |  |  |  |
| LDL Cholesterol      | Good         |  |  |  |
| Overall % poor PI    | 19%          |  |  |  |
| Overall % Non-return | 0%           |  |  |  |



#### \*\*\*\*\* Please note\*\*\*\*\*\*\*

The NQAAP expects 100% compliance on EQA returns. If you are enrolled for an analyte and have not returned a result (denoted by NRR in your PI table), this will be treated as a poor performance score. Please let us know as soon as possible if you are no longer providing this analyte as part of your diagnostic service.

#### **Distribution Specific Comment**

There is no specific comment for this distribution.

No participant comments have been submitted for any instruments for this distribution.



Summary Report

Analyte: HDL

**Overall Performance Category:** Poor

Running PI analyte --sample scores: >50% good, some acceptable some poor. More poor and less good than median



Programme: Lipids • Distribution Code: LP0124

Distribution Start: 22-Jan-2024 • Distribution End: 05-Feb-2024 • Report Issued: • Report Status: n/a

Participant Code: WQ00942 • Location: The Path Lab • Analyser Name: Cobas C 311 • Serial #: 2039-05 Date Samples received: 23-Jan-2024 • Date of Analysis: 23-Jan-2024 • Operator Details: YW • Storage Conditions: Ambient Temperature (18 - 30 °C)

Analyte: HDL Cholesterol • Method: Roche HDLC4 • Kit: HDLC4 (07528566 190)

|          |                                  |             | HDL Cholester          | ol mmol/L                        |         |                                |
|----------|----------------------------------|-------------|------------------------|----------------------------------|---------|--------------------------------|
|          | Your reported result<br>(mmol/L) |             | Method:<br>Roche HDLC4 | Instrument Model:<br>cobas c 311 | Overall | Non-Scoring Reference<br>Value |
|          |                                  | Mean        | 0.911                  | 0.990                            | 0.950   | 1                              |
| Sample 1 | 1.1                              | SD          | 0.024                  | 0.109                            | 0.070   |                                |
|          |                                  | Uncertainty | 0.0039                 | 0.0789                           | 0.0094  | n/a                            |
|          |                                  | n           | 60                     | 3                                | 86      |                                |
|          |                                  | Mean        | 1.000                  | 1.087                            | 1.065   | 1.12                           |
| Sample 2 | 1.2                              | SD          | 0.008                  | 0.116                            | 0.106   |                                |
|          |                                  | Uncertainty | 0.0013                 | 0.0840                           | 0.0143  | n/a                            |
|          |                                  | n           | 60                     | 3                                | 86      |                                |
|          |                                  | Mean        | 1.553                  | 1.630                            | 1.565   | 1.61                           |
| Sample 3 | 1.8                              | SD          | 0.059                  | 0.172                            | 0.069   |                                |
|          |                                  | Uncertainty | 0.0096                 | 0.1238                           | 0.0093  | n/a                            |
|          |                                  | n           | 60                     | 3                                | 86      |                                |
|          |                                  | Mean        | 2.197                  | 2.333                            | 2.217   | 2.29                           |
| Sample 4 | 2.6                              | SD          | 0.068                  | 0.268                            | 0.083   |                                |
|          |                                  | Uncertainty | 0.0110                 | 0.1934                           | 0.0112  | n/a                            |
|          |                                  | n           | 60                     | 3                                | 86      |                                |



# <u>Summary Report</u> Analyte: HDL Overall Performance Category: Poor Running PI analyte –sample scores: >50% good, some acceptable some poor. More poor and less good than median

<u>Standard Report</u> Analyte results table: your results higher than method mean, higher than instrument mean but n only 3. Non scoring ref value









|      |        |        |        |        |        | This   |
|------|--------|--------|--------|--------|--------|--------|
|      |        |        |        |        |        |        |
|      | LP0823 | LP0923 | LP1023 | LP1123 | LP1223 | LP0124 |
| Sy.x | 0.02   | 0.05   | 0.04   | 0.05   | 0.06   | 0.03   |
| 10   | -      | 44     | 40     | 00     | 20     | 0      |

| IS Score  | Interpretation                        |  |  |  |
|-----------|---------------------------------------|--|--|--|
| 0 to 10   | Good                                  |  |  |  |
| 11 to 150 | Acceptable to Warning level           |  |  |  |
| > 150     | Unacceptable (incl. Curvilinear Data) |  |  |  |



#### Summary Report Analyte: HDL Overall Performance Category: Poor Running PI analyte –sample scores: >50% good, some acceptable some poor. More poor and less good than median

#### **Standard Report**

**Analyte results table:** your results higher than method mean, higher than instrument mean but n only 3. Non scoring ref value

**Scoring Table:** 3 samples poor PI, 1 sample acceptable but PI 1.99.

**Running PI scores:** LP0823 acceptable, since them got worse, mostly poor for LP0124

Bias Chart (Absolute): longstanding positive bias, this dist worse than previous, instrument mean close to method

mean, y = 1.16\*x + 0.03, 16% positive proportional bias. Instrument SDs wide but n = 3

**Bias Chart (Relative):** longstanding positive bias

Precision Scores: precision good, previously good or acceptable



| All Results | My | Method | M | / Instrument | • M) | Result |
|-------------|----|--------|---|--------------|------|--------|
|             | _  |        |   |              |      |        |

| LP0124                            | Sample 1 |      | Sample 2 |      | Sample 3 |     | Sample 4 |     |
|-----------------------------------|----------|------|----------|------|----------|-----|----------|-----|
| Method Name                       | Mean     | CV%  | Mean     | CV%  | Mean     | CV% | Mean     | CV% |
| Elimination (n=8)                 | 1.225    | 13.0 | 1.381    | 10.9 | 1.754    | 1.5 | 2.475    | 7.8 |
| Enzymatic Immunoinhibition (n=14) | 1.046    | 4.8  | 1.193    | 4.3  | 1.564    | 3.7 | 2.217    | 3.4 |
| NMR Spectroscopy (n=1)            | 1.280    | 0.0  | 1.290    | 0.0  | 1.590    | 0.0 | 2.280    | 0.0 |
| Roche HDLC4 (n=60)                | 0.911    | 2.6  | 1.000    | 0.8  | 1.553    | 3.8 | 2.197    | 3.1 |
| Vitros (n=3)                      | 1.033    | 6.3  | 1.200    | 0.0  | 1.633    | 4.0 | 2.333    | 2.8 |

There are no Weqas or Participant supplied comments for HDL Cholesterol for this distribution.

Weqas



#### Summary Report Analyte: HDL Overall Performance Category: Poor Running PI analyte –sample scores: >50% good, some acceptable some poor. More poor and less good than median

**Standard Report** 

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Bias Chart (Relative): longstanding positive bias

Precision Scores: precision good, previously good or acceptable

**Sample Histograms:** samples 3 and 4 off the scale, samples 1 and 2 not gaussian distributions but our result to the right of majority

Method Summary Data: Roche method negative bias to other methods









