

**Requirements for a driver for data calculation and
transfer to an Empower Percentile e-mail address of
STT Consulting**

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Revision history

1. Stratification of laboratory data for outpatients
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8. Examples

| <i>Revision History</i> Revision | Revision date | Description | Author |
|---------------------------------------------------|----------------------|--------------------------------|----------------|
| 1.0 | November 30 2013 | First version of this document | Dietmar Stöckl |

Introduction

The Empower Percentile project of STT Consulting aims at documentation of stability and comparability of in-vitro-diagnostic tests in medical laboratories across laboratories and manufacturers.

For that purpose, instrument-specific, daily outpatient medians, number of results, and daily outpatient flagging frequencies (%-hypo, %-hyper) are calculated and transmitted by a laboratory from their middleware or laboratory Information system (LIS) to STT Consulting.

The data are transmitted by e-mail, which is automatically read by STT-software into a MySQL database.

The document describes:

1. Stratification of laboratory data for outpatients
2. Calculation of daily outpatient medians
3. Calculation of the number of results that constitute the daily outpatient median
4. Calculation of daily flagging rates (%-hypo/-hyper)
5. e-mail type
6. Receiver site
7. Structure of the data to be transmitted by e-mail
8. Examples

1. Stratification of laboratory data for outpatients

Medical laboratories, particularly hospital laboratories, receive samples from many different sites:

- Inpatients (often specified by ward)
- Special treatment units (diabetic centers; dialysis centers; wellness centers; nursing homes)
- Samples from chronically diseased patients from general practitioners/specialists
- Samples from “New” patients from General Practitioners
- Samples for general health checks from General Practitioners

The middleware/LIS should be able to code these different “sender-sites” by type (the actually coded types will depend on the situation in the laboratory).

“Outpatients” may then be defined by the laboratory in principally 2 different ways:

- “Total minus” (total minus inpatients, minus dialysis, for example)
- “Add-on”: samples from general practitioners + chronically diseased + wellness + others.

The driver should support the “Total-minus” solution; this allows the laboratory a step-wise stratification of their patient population.

The middleware/LIS should be able to code the results by measuring instrument; for example, when there are 2 Cobas c701 instruments on a “Cobas 8000 analyzer” those should be given 2 different identifiers (for example: Cobas c701 A, Cobas c701 B).

2. Calculation of daily outpatient medians

Daily data are data from a complete production day, for example, Time period: 27/05/2013 00:00 - 27/05/2013 23:59 (produced). Calculation (and sending), typically, will be done in times of little middleware/LIS action (for example: 1:00 am); quality control results must be excluded.

If possible, the middleware/LIS should be able to set values expressed as >1, <100 as 1 or 100, respectively or should exclude them; also, non-numeric entries should be excluded.

When no data are available, the field for the median value should be empty.

3. Calculation of the number of results that constitute the daily outpatient median

The number of results that were used for calculating the median should be reported.

4. Calculation of daily flagging rates (%-hypo/-hyper)

Flagging rates (in %) should be calculated as $100 \times (\text{number of outpatient results} > \text{or} < \text{laboratory defined limit} / \text{total number of outpatient results})$; <: limit for %-hypo; >: limit for %-hyper; note: the 1st, or most stringent limit should be chosen which, typically, corresponds to the lower and upper limit of the reference interval/normal range.

5. e-mail type

The e-mail sent to STT Consulting should be “text-type”.

6. Receiver site

The receiver site is an e-mail address at STT-Consulting:
dietmar@stt-consulting.com in the laboratory try-out phase
percentile@stt-consulting.com after successful try-out.

7. Structure of the data to be transmitted by e-mail

Data can be transmitted as

- e-mail embedded table
 - e-mail attached EXCEL-file
 - e-mail attached text-file
- (see also examples)

e-mail content:

Sender mail, date sent, receiver mail, Content: Empower Percentile Project, Time produced : 27-09-2013 00:00 - 27-09-2013 23:59; no special arrangement or formatting.

The data should be in a “table” consisting of data-related number of rows with **10 fields, separated by semicolon (;)** (EXCEL: data-related number of rows; 10 columns, no separator):

- 1) Laboratory ID: at least 6 symbols (letter, number, underscore, point,) chosen by the laboratory or already assigned by the laboratory
- 2) Date: dd/mm/yyyy
- 3) Instrument ID: as already assigned by the laboratory
- 4) Outpatient code: 3 letters or as already assigned by the laboratory
- 5) Analyte name: as already assigned by the laboratory
- 6) Unit: as already assigned by the laboratory
- 7) Value of the median (decimal separator = point or comma: 5.1 or 5,1)
- 8) number of results used for calculating the median
- 9) % flagged hypo
- 10) % flagged hyper

Row breaks: by Line feed or Carriage return directly followed by Line feed.

Example:

ABCDEF;27/09/2013;80_AU5822;POL;ALB;g/dl;3.0;69;5;2

20 Analytes (serum or plasma)

Albumin; Alkaline Phosphatase; Alanine aminotransferase (ALT, or GPT); Aspartate aminotransferase (AST or GOT); total-Bilirubin; Calcium; total-Cholesterol; Chloride; C-reactive protein (CRP); Gamma-glutamyl transferase (GGT); Glucose; Potassium; Creatinine; Lactate dehydrogenase (LDH); Magnesium; Sodium; Inorganic phosphor (phosphate); total-Protein; Urea or Bound Urea Nitrogen; Uric acid (urate)

8. Examples

e-mail embedded Table (without *n* and flagging frequencies!!!)

From: ***

Sent: Saturday, 28 september 2013 06:31

To: dietmar@stt-consulting.com

Content: Empower Percentile Project

Time produced : 27-09-2013 00:00 - 27-09-2013 23:59

ABCDEF;27/09/2013;C16000-5;POL;NA;mmol/L;140.9
ABCDEF;27/09/2013;C16000-6;POL;NA;mmol/L;139.4
ABCDEF;27/09/2013;C16000-5;POL;K;mmol/L;4.61
ABCDEF;27/09/2013;C16000-6;POL;K;mmol/L;4.62
ABCDEF;27/09/2013;C16000-5;POL;CL;mmol/L;104.6
ABCDEF;27/09/2013;C16000-6;POL;CL;mmol/L;103.8
ABCDEF;27/09/2013;C16000-5;POL;CA;mmol/L;2.44
ABCDEF;27/09/2013;C16000-6;POL;CA;mmol/L;2.42
ABCDEF;27/09/2013;C16000-5;POL;P;mmol/L;1.09
ABCDEF;27/09/2013;C16000-6;POL;P;mmol/L;1.03
ABCDEF;27/09/2013;C16000-5;POL;MG;mmol/L;0.85
ABCDEF;27/09/2013;C16000-6;POL;MG;mmol/L;0.84
ABCDEF;27/09/2013;C16000-1;POL;UREUM;mg/dl;30.5
ABCDEF;27/09/2013;C16000-2;POL;UREUM;mg/dl;33.3
ABCDEF;27/09/2013;C16000-3;POL;UREUM;mg/dl;32.6
ABCDEF;27/09/2013;C16000-4;POL;UREUM;mg/dl;33.4
ABCDEF;27/09/2013;C16000-1;POL;KREAT;mg/dl;0.82
ABCDEF;27/09/2013;C16000-2;POL;KREAT;mg/dl;0.82
ABCDEF;27/09/2013;C16000-3;POL;KREAT;mg/dl;0.84
ABCDEF;27/09/2013;C16000-4;POL;KREAT;mg/dl;0.82
ABCDEF;27/09/2013;C16000-1;POL;URINZ;mg/dl;5.54
ABCDEF;27/09/2013;C16000-2;POL;URINZ;mg/dl;5.67
ABCDEF;27/09/2013;C16000-3;POL;URINZ;mg/dl;5.39
ABCDEF;27/09/2013;C16000-4;POL;URINZ;mg/dl;5.45
ABCDEF;27/09/2013;C16000-1;POL;PROT;g/L;70.46
ABCDEF;27/09/2013;C16000-2;POL;PROT;g/L;72.88
ABCDEF;27/09/2013;C16000-3;POL;PROT;g/L;71.4
ABCDEF;27/09/2013;C16000-4;POL;PROT;g/L;71.92
ABCDEF;27/09/2013;C16000-1;POL;ALB;g/L;42.87
ABCDEF;27/09/2013;C16000-2;POL;ALB;g/L;36.78
ABCDEF;27/09/2013;C16000-3;POL;ALB;g/L;43.91
ABCDEF;27/09/2013;C16000-4;POL;ALB;g/L;45.31
ABCDEF;27/09/2013;C16000-1;POL;CHOL;mg/dl;202.9
ABCDEF;27/09/2013;C16000-2;POL;CHOL;mg/dl;194.7
ABCDEF;27/09/2013;C16000-3;POL;CHOL;mg/dl;197.1
ABCDEF;27/09/2013;C16000-4;POL;CHOL;mg/dl;194.1
ABCDEF;27/09/2013;C16000-5;POL;BILTOT;mg/dl;0.59
ABCDEF;27/09/2013;C16000-6;POL;BILTOT;mg/dl;0.59
ABCDEF;27/09/2013;C16000-1;POL;AST;U/l;19.8

Driver Protocol, Data Calculation and Transfer to Empower Percentile

ABCDEF;27/09/2013;C16000-2;POL;AST;U/l;19.2
ABCDEF;27/09/2013;C16000-3;POL;AST;U/l;19.3
ABCDEF;27/09/2013;C16000-4;POL;AST;U/l;20.7
ABCDEF;27/09/2013;C16000-1;POL;ALT;U/l;17.9
ABCDEF;27/09/2013;C16000-2;POL;ALT;U/l;17.3
ABCDEF;27/09/2013;C16000-3;POL;ALT;U/l;17.2
ABCDEF;27/09/2013;C16000-4;POL;ALT;U/l;17.2
ABCDEF;27/09/2013;C16000-1;POL;GGT;U/l;25.9
ABCDEF;27/09/2013;C16000-2;POL;GGT;U/l;23
ABCDEF;27/09/2013;C16000-3;POL;GGT;U/l;22.8
ABCDEF;27/09/2013;C16000-4;POL;GGT;U/l;23
ABCDEF;27/09/2013;C16000-1;POL;ALKFOS;U/l;67
ABCDEF;27/09/2013;C16000-2;POL;ALKFOS;U/l;70.1
ABCDEF;27/09/2013;C16000-3;POL;ALKFOS;U/l;67.6
ABCDEF;27/09/2013;C16000-4;POL;ALKFOS;U/l;66.6
ABCDEF;27/09/2013;C16000-1;POL;LDH;U/l;192
ABCDEF;27/09/2013;C16000-2;POL;LDH;U/l;196
ABCDEF;27/09/2013;C16000-3;POL;LDH;U/l;195
ABCDEF;27/09/2013;C16000-4;POL;LDH;U/l;205
ABCDEF;27/09/2013;C16000-5;POL;GLUC;mg/dl;89.7
ABCDEF;27/09/2013;C16000-6;POL;GLUC;mg/dl;91.3
ABCDEF;27/09/2013;C16000-1;POL;CRP;mg/L;1.89
ABCDEF;27/09/2013;C16000-2;POL;CRP;mg/L;1.87
ABCDEF;27/09/2013;C16000-3;POL;CRP;mg/L;1.81
ABCDEF;27/09/2013;C16000-4;POL;CRP;mg/L;2.04

Driver Protocol, Data Calculation and Transfer to Empower Percentile

Text attachment to e-mail

From: ***

Sent: Saturday, 28 september 2013 06:31

To: dietmar@stt-consulting.com

Content: Empower Percentile Project

Time produced : 27-09-2013 00:00 - 27-09-2013 23:59

Filename: Empower Percentile.txt

ABCDEF;27/09/2013;80_AU5822;POL;ALB;g/dl;3.0;69;5;2

ABCDEF;27/09/2013;80_AU5822;POL;CA;mmol/l;2.125;90;10;12

EXCEL attachment to e-mail (without *n* and flagging frequencies!!!)

From: ***

Sent: Wednesday, 13 november 2013 06:18

To: dietmar@stt-consulting.com

Content: Empower Percentile Project

Time produced : 12-11-2013 00:00 - 12-11-2013 23:59

Filename: Empower Percentile.xlsx (or xls)

| | | | | | | |
|--------|------------|-------------|---|-------|--------|-------|
| ABCDEF | 12/11/2013 | VITROS5.1FS | E | Alb | g/L | 42.2 |
| ABCDEF | 12/11/2013 | VITROS5.1FS | E | APase | U/L | 91.5 |
| ABCDEF | 12/11/2013 | VITROS5.1FS | E | Ca | mmol/L | 2.355 |