For use in quality control/
manufacturing process only.

# Density Reference Standard Beads (DRSB)

**Version 43**

Content version: January 2022

Beads for one-point density calibration

**Cat. No. 06 422 667 001** Batch B

**Store Beads at +2 to +8°C**

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# 1. Introduction

The Cedex HiRes Analyzer measures the cell density, also known as concentration, of a cellular suspension, along with its viability status and cell characteristics such as diameter and compactness. In order to check the correct calibration with regard to the density, use the Density Reference Standard Beads instead of an ordinary cell sample.

This product is traceable in the following aspects:

- Particle Size: NIST, USA
- Particle Concentration: Physikalisch-Technische Bundesanstalt, Berlin, Germany

The Density Reference Standard Beads are made to mimic cell behavior in flow dynamics. Due to their size and optical properties, they will appear as dead cells in the Cedex Software.

## Contents

| Content | Volume | Cat. No. |
|---|---|---|
| Beads for one-point density calibration | 10 ml | 06 422 667 001 |

## Storage and Stability

Store Beads at +2 to +8°C.

The product is stable until the expiry date printed on the label, when handled as described in these Instructions for Use.

# 2. How to Use this Product

There is no general advice with regard to how often or how many counts should be done in order to ensure that your analyzer is working correctly. Roche Diagnostics has had good results using the DRSB on a monthly basis, carrying out 10 samples per run with the Cedex HiRes Analyzer.

Two factors influence the acceptance range for calibration with Density Reference Standard Beads in connection with the Cedex HiRes Analyzer.

- **Sample preparation:** Mixing, pipette operation, and pipette quality (precision, accuracy, service state) have been shown in the field to add approximately 1.5 – 2% to the variability in density measurements.
- **Measurement precision is based on the statistical nature of the measurement process.** It depends on the density of the DRSB used, Cell Type parameter settings, and the level of precision used for the measurement.

Sampling quality is essential for the evaluation of the status of the instrument. Special care should be taken to ascertain, for example, that among other factors:

- Beads were not frozen, but stored properly at +2 to +8°C.
- Beads were allowed to acclimate to a temperature of +23 to +27°C prior to use.
- Weight of the unopened bottle is correct (see label on the bottle).
- Ultrasonic bath is used for mixing.
- Bottle is rocked gently, including rocking upside down.
- No more than 2 samples are drawn from the bottle without intermediate remixing.
- Only calibrated pipettes are used.
- Only trained staff are performing the sample preparation.

# 3. Protocol

## 3.1 Preparation of the DRSB solution

- Verify that the beads have been stored correctly at temperatures of +2 to +8°C (BEADS CANNOT BE FROZEN).
- Verify that the bottle was securely closed before use (check the weight of the unopened bottle; the correct value is given on the bottle).
- Allow the beads to acclimate to a temperature of +23 to +27°C prior to use.
- Use an ultrasonic bath at a temperature of +23 to +27°C and at the highest available intensity for 5 minutes (with cap slightly loosened but secured against falling over) to shake the beads.
- Ensure that no beads are sticking to the base or side of the bottle before use.

The DRSB solution contains SDS, which may show signs of some coagulation or crystallization at low temperatures. Crystals and/or signs of coagulation can be removed by allowing the beads to acclimate, with occasional mixing, at +25°C until the coagulation disappears. Alternatively, the DRSB bottle can be gently rolled between the palms of the hands until the coagulation has disappeared. Note that as long as the DRSB solution has been allowed to acclimate to +23 to +27°C, and all steps in this Instructions for Use have been carried out, any remaining coagulation or crystallization will have no effect on the performance or quality of the DRSB solution when used in a Cedex HiRes Analyzer.

### 3.2 Checking the FlowFactor (FF) (see Figure 2)

| | |
|---|---|
| ❶ | Pipet 1 sample of 0.3 ml DRSB into a Cedex Sample cup, and run the sample with factory settings for default Cell Type Std. Size immediately. Select the maximum possible setting for “precision”. |
| ❷ | Mix the DRSB thoroughly, then pipet the next sample of 0.3 ml into a Cedex Sample cup, and run the sample immediately. |
| ❸ | Repeat this procedure until 10 samples are processed. |
| ❹ | Calculate the mean value of the Total Cell Density (TCD) of the 10 samples used. |
| ❺ | Calculate the relative standard deviation of the TCD values of the 10 samples used, and verify that the relative standard deviation is less than or equal to 5%. Otherwise, the Cedex HiRes Analyzer, the beads, or the handling have to be checked and the calibration must be repeated. |
| ❻ | Calculate the deviation of the mean TCD value of the 10 samples used from the actual value (given as Particle number/ml on the bottle of beads). |
| ❼ | Verify that the deviation of the mean TCD value is less than or equal to 5%, or as specified by your requirements, from the actual value given on the bottle for the beads. If the value falls outside of the acceptable range, skip to Step 9. |
| ❽ | Close bottle tightly and store beads at +2 to +8°C (BEADS CANNOT BE FROZEN). The current FF is correct and no change is necessary. |
| ❾ | If the mean value falls out of range, repeat Steps 1 to 5 using a second/different LOT (batch) of Density Reference Standard Beads. Continue with Step 10. |
| ❿ | Calculate the FlowFactor (FF) of each measurement series (see 5.1, “How to Calculate and Change the FlowFactor”), and the mean value of the two FFs. |
| ⓫ | Verify that the deviation of the two FFs from the mean value of the FFs, are less than or equal to 5%. Otherwise, the Cedex HiRes Analyzer, the beads, or the handling have to be checked and the calibration must be repeated. |
| ⓬ | Calculate the new FF (mean value of the FFs); (see 5.1, “How to Calculate and Change the FlowFactor”), or follow your company’s requirements. |

# 4. Lot Specific Data

## Cat. No. 06 422 667 001, Batch B

## Valid for Lot. No. 57130074

In this chapter, you will find lot specific data about your product. The table below provides the following information for each bottle produced for this lot.

Column 1: Bottle No. for the bottle.
Column 2: Actual concentration expressed in particle number/ml for the bottle.
Column 3: Total weight of bottle, including bottle, contents, and label.
Column 4: Check Box for marking which bottle was received.

Use this table as follows:

| | |
|---|---|
| ❶ | Print out the table. |
| ❷ | Find the bottle number on the bottle label as shown in Figure 1. |
| ❸ | Place a check mark in the "Bottle Received" column to mark the specific bottle received for future reference. |

This product is traceable in the following aspects:

- Particle Size: NIST, USA
- Particle Concentration: Physikalisch-Technische Bundesanstalt, Berlin, Germany

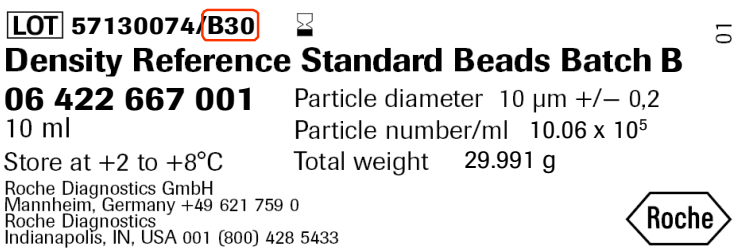


**Fig. 1:** Example of how to find the bottle number on the bottle label. The bottle number is circled.

| ID-Nr. LOT 57130074 | Concentration Particle number/ml ($10^5$) | weight (g) | Bottle received |
|---|---|---|---|
| B1 | 9.98 | 29.576 | |
| B2 | 10.03 | 30.300 | |
| B3 | 10.00 | 30.181 | |
| B4 | 10.05 | 30.104 | |
| B5 | 10.02 | 30.631 | |
| B6 | 10.05 | 29.538 | |
| B7 | 9.96 | 29.660 | |
| B8 | 10.01 | 29.644 | |
| B9 | 9.91 | 29.671 | |
| B10 | 9.98 | 29.666 | |
| B11 | 9.95 | 29.717 | |
| B12 | 9.95 | 29.790 | |
| B13 | 9.97 | 29.508 | |
| B14 | 10.08 | 29.762 | |
| B15 | 9.99 | 29.914 | |
| B16 | 10.04 | 29.987 | |
| B17 | 9.99 | 30.328 | |
| B18 | 10.00 | 29.865 | |
| B19 | 10.01 | 29.952 | |
| B20 | 10.00 | 30.010 | |
| B21 | 10.05 | 29.572 | |
| B22 | 9.99 | 29.606 | |
| B23 | 9.94 | 29.716 | |
| B24 | 9.94 | 29.547 | |
| B25 | 10.05 | 29.595 | |
| B26 | 10.03 | 29.999 | |
| B27 | 9.92 | 29.562 | |
| B28 | 9.96 | 29.765 | |
| B29 | 10.05 | 29.940 | |

| ID-Nr. LOT 57130074 | Concentration Particle number/ml ($10^5$) | weight (g) | Bottle received |
|---|---|---|---|
| B30 | 9.93 | 29.770 | |
| B31 | 10.02 | 30.322 | |
| B32 | 10.00 | 30.008 | |
| B33 | 9.99 | 30.185 | |
| B34 | 10.00 | 29.714 | |
| B35 | 10.02 | 29.926 | |
| B36 | 10.04 | 29.863 | |
| B37 | 10.00 | 29.730 | |
| B38 | 9.97 | 29.726 | |
| B39 | 9.99 | 29.881 | |
| B40 | 9.94 | 29.718 | |
| B41 | 10.03 | 29.654 | |
| B42 | 10.02 | 29.368 | |
| B43 | 10.01 | 29.768 | |
| B44 | 9.99 | 29.824 | |
| B45 | 10.02 | 29.646 | |
| B46 | 9.94 | 29.942 | |
| B47 | 10.03 | 29.550 | |
| B48 | 10.03 | 29.540 | |
| B49 | 9.98 | 29.677 | |
| B50 | 9.99 | 29.654 | |
| B51 | 10.02 | 29.835 | |
| B52 | 10.01 | 29.514 | |
| B53 | 9.95 | 29.675 | |
| B54 | 10.06 | 29.721 | |
| B55 | 10.03 | 29.681 | |
| B56 | 9.97 | 29.673 | |
| B57 | 10.06 | 29.959 | |
| B58 | 10.04 | 29.720 | |

| ID-Nr. LOT 57130074 | Concentration Particle number/ml ($10^5$) | weight (g) | Bottle received |
|---|---|---|---|
| B59 | 9.98 | 29.594 | |
| B60 | 9.96 | 29.689 | |
| B61 | 9.97 | 29.778 | |
| B62 | 10.00 | 29.873 | |
| B63 | 9.93 | 29.547 | |
| B64 | 10.02 | 29.816 | |
| B65 | 10.03 | 30.077 | |
| B66 | 10.04 | 29.995 | |
| B67 | 9.91 | 29.744 | |
| B68 | 9.95 | 29.770 | |
| B69 | 9.99 | 29.646 | |
| B70 | 10.06 | 29.522 | |
| B71 | 9.96 | 29.687 | |
| B72 | 10.03 | 29.673 | |
| B73 | 9.97 | 29.784 | |
| B74 | 10.01 | 29.652 | |
| B75 | 10.05 | 29.698 | |
| B76 | 9.98 | 30.122 | |
| B77 | 9.95 | 29.389 | |
| B78 | 9.97 | 29.645 | |
| B79 | 9.99 | 30.120 | |
| B80 | 9.94 | 29.567 | |
| B81 | 10.04 | 29.626 | |
| B82 | 9.99 | 29.884 | |
| B83 | 10.00 | 29.599 | |
| B84 | 10.02 | 29.541 | |
| B85 | 10.02 | 29.722 | |
| B86 | 9.95 | 29.676 | |
| B87 | 10.05 | 29.787 | |

| ID-Nr. LOT 57130074 | Concentration Particle number/ml ($10^5$) | weight (g) | Bottle received |
|---|---|---|---|
| B88 | 9.92 | 29.699 | |
| B89 | 9.96 | 29.545 | |
| B90 | 9.98 | 29.718 | |
| B91 | 10.04 | 29.554 | |
| B92 | 10.01 | 29.849 | |
| B93 | 9.98 | 30.425 | |
| B94 | 9.98 | 29.660 | |
| B95 | 9.99 | 29.968 | |
| B96 | 9.97 | 29.526 | |
| B97 | 9.98 | 29.558 | |
| B98 | 10.04 | 29.621 | |
| B99 | 9.96 | 29.558 | |
| B100 | 9.94 | 30.014 | |
| B101 | 10.06 | 29.681 | |
| B102 | 9.93 | 29.513 | |
| B103 | 10.07 | 29.521 | |
| B104 | 10.04 | 30.330 | |
| B105 | 10.00 | 29.524 | |
| B106 | 10.04 | 29.635 | |
| B107 | 10.04 | 29.373 | |
| B108 | 10.03 | 30.003 | |
| B109 | 10.06 | 29.527 | |
| B110 | 10.02 | 29.862 | |
| B111 | 10.02 | 29.545 | |
| B112 | 9.98 | 29.612 | |
| B113 | 9.95 | 29.400 | |
| B114 | 10.03 | 29.494 | |
| B115 | 10.04 | 29.865 | |
| B116 | 9.99 | 29.867 | |

| ID-Nr. LOT 57130074 | Concentration Particle number/ml ($10^5$) | weight (g) | Bottle received |
|---|---|---|---|
| B117 | 9.98 | 29.440 | |
| B118 | 9.97 | 29.582 | |
| B119 | 9.97 | 29.679 | |
| B120 | 9.92 | 29.724 | |
| B121 | 9.99 | 29.565 | |
| B122 | 10.03 | 29.717 | |
| B123 | 9.92 | 29.561 | |
| B124 | 9.98 | 29.812 | |
| B125 | 10.00 | 29.921 | |
| B126 | 9.98 | 29.524 | |
| B127 | 10.02 | 29.627 | |
| B128 | 9.99 | 29.674 | |
| B129 | 10.01 | 29.978 | |
| B130 | 9.96 | 29.693 | |
| B131 | 10.00 | 29.607 | |
| B132 | 9.99 | 29.586 | |
| B133 | 10.05 | 29.564 | |
| B134 | 10.04 | 29.490 | |
| B135 | 10.05 | 29.747 | |
| B136 | 9.96 | 29.897 | |
| B137 | 10.04 | 29.842 | |
| B138 | 9.93 | 29.671 | |
| B139 | 10.01 | 29.542 | |
| B140 | 9.94 | 29.692 | |
| B141 | 10.06 | 29.755 | |
| B142 | 9.96 | 29.598 | |
| B143 | 9.96 | 29.641 | |
| B144 | 9.95 | 30.202 | |
| B145 | 9.90 | 30.122 | |

| ID-Nr. LOT 57130074 | Concentration Particle number/ml ($10^5$) | weight (g) | Bottle received |
|---|---|---|---|
| B146 | 9.96 | 30.076 | |
| B147 | 10.14 | 30.085 | |
| B148 | 9.78 | 29.983 | |
| B149 | 9.86 | 30.720 | |
| B150 | 9.91 | 29.731 | |
| B151 | 10.01 | 29.822 | |
| B152 | 9.91 | 30.348 | |
| B153 | 9.94 | 30.703 | |
| B154 | 10.12 | 30.222 | |
| B155 | 9.74 | 30.879 | |
| B156 | 10.07 | 30.700 | |
| B157 | 10.03 | 29.426 | |
| B158 | 10.00 | 29.558 | |
| B159 | 10.11 | 29.517 | |
| B160 | 10.04 | 29.453 | |
| B161 | 10.03 | 29.527 | |
| B162 | 10.20 | 29.416 | |
| B163 | 10.01 | 29.651 | |
| B164 | 10.07 | 29.472 | |
| B165 | 9.88 | 29.580 | |
| B166 | 9.89 | 29.423 | |
| B167 | 9.87 | 29.464 | |
| B168 | 10.07 | 29.527 | |
| B169 | 9.94 | 29.550 | |
| B170 | 9.90 | 29.549 | |
| B171 | 9.82 | 29.725 | |
| B172 | 9.81 | 29.622 | |
| B173 | 9.72 | 29.703 | |
| B174 | 10.10 | 29.639 | |

| ID-Nr. LOT 57130074 | Concentration Particle number/ml ($10^5$) | weight (g) | Bottle received |
|---|---|---|---|
| B175 | 9.80 | 29.598 | |
| B176 | 9.93 | 29.631 | |
| B177 | 10.00 | 29.584 | |
| B178 | 9.72 | 29.787 | |
| B179 | 10.01 | 29.262 | |
| B180 | 9.85 | 29.588 | |
| B181 | 10.23 | 29.506 | |
| B182 | 10.03 | 29.604 | |
| B183 | 10.00 | 29.453 | |
| B184 | 9.84 | 29.693 | |
| B185 | 10.18 | 29.536 | |
| B186 | 10.01 | 29.568 | |
| B187 | 9.98 | 29.514 | |
| B188 | 10.21 | 29.580 | |
| B189 | 9.96 | 29.538 | |
| B190 | 10.07 | 29.618 | |
| B191 | 10.27 | 29.437 | |
| B192 | 10.23 | 29.515 | |
| B193 | 9.92 | 29.571 | |
| B194 | 10.04 | 29.581 | |
| B195 | 9.99 | 29.570 | |
| B196 | 10.06 | 29.316 | |
| B197 | 9.85 | 29.598 | |
| B198 | 10.05 | 29.520 | |
| B199 | 10.05 | 29.508 | |
| B200 | 10.08 | 29.385 | |
| B201 | 10.18 | 29.496 | |
| B202 | 10.29 | 29.133 | |
| B203 | 9.82 | 29.535 | |

| ID-Nr. LOT 57130074 | Concentration Particle number/ml ($10^5$) | weight (g) | Bottle received |
|---|---|---|---|
| B204 | 10.13 | 29.652 | |
| B205 | 9.91 | 29.431 | |
| B206 | 10.06 | 29.584 | |
| B207 | 9.89 | 29.605 | |
| B208 | 9.97 | 29.444 | |
| B209 | 9.89 | 29.649 | |
| B210 | 10.00 | 29.575 | |
| B211 | 10.30 | 29.691 | |
| B212 | 10.13 | 29.402 | |
| B213 | 9.94 | 29.603 | |
| B214 | 10.02 | 29.668 | |
| B215 | 9.94 | 29.625 | |
| B216 | 10.06 | 29.448 | |
| B217 | 9.92 | 29.384 | |
| B218 | 10.14 | 29.782 | |
| B219 | 10.08 | 29.706 | |
| B220 | 10.08 | 29.712 | |
| B221 | 9.74 | 29.656 | |
| B222 | 9.98 | 29.709 | |
| B223 | 10.02 | 29.615 | |
| B224 | 9.89 | 29.730 | |
| B225 | 9.97 | 29.593 | |
| B226 | 9.94 | 29.687 | |
| B227 | 9.90 | 29.566 | |
| B228 | 9.87 | 29.661 | |
| B229 | 9.86 | 29.786 | |
| B230 | 10.02 | 29.745 | |
| B231 | 9.86 | 29.465 | |
| B232 | 9.73 | 29.488 | |

| ID-Nr. LOT 57130074 | Concentration Particle number/ml ($10^5$) | weight (g) | Bottle received |
|---|---|---|---|
| B233 | 9.97 | 29.603 | |
| B234 | 10.20 | 29.515 | |
| B235 | 10.10 | 29.545 | |
| B236 | 10.15 | 29.630 | |
| B237 | 10.17 | 29.623 | |
| B238 | 10.12 | 29.550 | |
| B239 | 9.99 | 29.688 | |
| B240 | 10.03 | 29.557 | |
| B241 | 9.87 | 29.536 | |
| B242 | 9.92 | 29.603 | |
| B243 | 9.91 | 29.310 | |
| B244 | 10.05 | 29.497 | |
| B245 | 9.93 | 29.572 | |
| B246 | 9.96 | 29.476 | |
| B247 | 10.04 | 29.558 | |
| B248 | 10.08 | 29.621 | |
| B249 | 9.93 | 29.569 | |
| B250 | 10.00 | 29.546 | |
| B251 | 10.26 | 29.625 | |
| B252 | 10.09 | 29.520 | |
| B253 | 10.09 | 29.702 | |
| B254 | 9.81 | 29.602 | |
| B255 | 9.96 | 29.709 | |
| B256 | 10.04 | 29.697 | |
| B257 | 10.07 | 29.802 | |
| B258 | 9.94 | 29.599 | |
| B259 | 9.93 | 29.616 | |
| B260 | 10.13 | 29.479 | |
| B261 | 9.85 | 29.733 | |

| ID-Nr. LOT 57130074 | Concentration Particle number/ml ($10^5$) | weight (g) | Bottle received |
|---|---|---|---|
| B262 | 9.93 | 29.476 | |
| B263 | 9.95 | 29.643 | |
| B264 | 9.76 | 29.524 | |
| B265 | 9.92 | 29.710 | |
| B266 | 9.91 | 29.592 | |
| B267 | 10.17 | 29.590 | |
| B268 | 10.17 | 29.618 | |
| B269 | 9.86 | 29.687 | |
| B270 | 9.98 | 29.423 | |
| B271 | 9.99 | 29.612 | |
| B272 | 9.93 | 29.832 | |
| B273 | 10.01 | 29.537 | |
| B274 | 9.94 | 29.599 | |
| B275 | 10.20 | 29.583 | |
| B276 | 10.01 | 29.491 | |
| B277 | 10.06 | 29.606 | |
| B278 | 9.75 | 29.571 | |
| B279 | 9.76 | 29.736 | |
| B280 | 9.91 | 29.688 | |
| B281 | 10.04 | 29.776 | |
| B282 | 9.87 | 29.659 | |
| B283 | 9.91 | 29.676 | |
| B284 | 9.85 | 29.441 | |
| B285 | 9.84 | 29.652 | |
| B286 | 9.87 | 29.636 | |
| B287 | 9.83 | 29.419 | |
| B288 | 10.15 | 29.631 | |
| B289 | 9.75 | 29.843 | |
| B290 | 9.79 | 29.740 | |

| ID-Nr. LOT 57130074 | Concentration Particle number/ml ($10^5$) | weight (g) | Bottle received |
|---|---|---|---|
| B291 | 9.99 | 29.582 | |
| B292 | 10.00 | 29.640 | |
| B293 | 9.92 | 29.689 | |
| B294 | 9.86 | 29.696 | |
| B295 | 9.78 | 29.636 | |
| B296 | 9.93 | 29.468 | |
| B297 | 9.92 | 29.719 | |
| B298 | 9.75 | 29.598 | |
| B299 | 9.88 | 29.819 | |
| B300 | 10.17 | 29.551 | |
| B301 | 10.07 | 29.823 | |
| B302 | 9.95 | 29.632 | |
| B303 | 10.03 | 29.896 | |
| B304 | 9.88 | 29.800 | |
| B305 | 9.85 | 29.708 | |
| B306 | 9.92 | 29.787 | |
| B307 | 9.90 | 29.671 | |
| B308 | 9.78 | 29.945 | |
| B309 | 9.90 | 29.852 | |
| B310 | 9.86 | 29.634 | |
| B311 | 9.85 | 29.665 | |
| B312 | 9.98 | 29.929 | |
| B313 | 9.80 | 29.743 | |
| B314 | 10.07 | 29.570 | |
| B315 | 9.82 | 29.654 | |
| B316 | 9.93 | 29.682 | |
| B317 | 10.17 | 29.584 | |
| B318 | 10.04 | 29.562 | |
| B319 | 10.16 | 29.600 | |

| ID-Nr. LOT 57130074 | Concentration Particle number/ml ($10^5$) | weight (g) | Bottle received |
|---|---|---|---|
| B320 | 10.20 | 29.808 | |
| B321 | 10.23 | 29.783 | |
| B322 | 10.05 | 29.540 | |
| B323 | 7.52 | 29.547 | |
| B324 | 9.99 | 29.692 | |
| B325 | 10.20 | 29.631 | |
| B326 | 10.09 | 29.574 | |
| B327 | 10.16 | 29.643 | |
| B328 | 9.91 | 29.511 | |
| B329 | 9.81 | 29.823 | |
| B330 | 10.00 | 29.648 | |
| B331 | 9.80 | 29.756 | |
| B332 | 9.99 | 29.604 | |
| B333 | 9.93 | 29.680 | |
| B334 | 9.74 | 29.647 | |
| B335 | 9.94 | 29.605 | |
| B336 | 10.06 | 29.323 | |
| B337 | 9.94 | 29.684 | |
| B338 | 10.11 | 29.751 | |
| B339 | 10.02 | 29.532 | |
| B340 | 9.81 | 29.729 | |
| B341 | 9.93 | 29.686 | |
| B342 | 9.99 | 29.753 | |
| B343 | 10.00 | 29.896 | |
| B344 | 9.96 | 29.722 | |
| B345 | 9.87 | 29.653 | |
| B346 | 9.72 | 29.477 | |
| B347 | 10.06 | 29.464 | |
| B348 | 10.24 | 29.626 | |

| ID-Nr. LOT 57130074 | Concentration Particle number/ml ($10^5$) | weight (g) | Bottle received |
|---|---|---|---|
| B349 | 10.09 | 29.669 | |
| B350 | 10.13 | 29.742 | |
| B351 | 10.05 | 29.624 | |
| B352 | 9.87 | 29.563 | |
| B353 | 9.80 | 29.750 | |
| B354 | 10.02 | 29.657 | |
| B355 | 10.07 | 29.686 | |
| B356 | 9.88 | 29.626 | |
| B357 | 10.04 | 29.662 | |
| B358 | 10.04 | 29.653 | |
| B359 | 9.80 | 29.749 | |
| B360 | 9.82 | 29.705 | |
| B361 | 9.97 | 29.354 | |
| B362 | 9.95 | 29.853 | |
| B363 | 9.93 | 29.614 | |
| B364 | 10.07 | 29.730 | |
| B365 | 9.88 | 29.804 | |
| B366 | 10.24 | 29.689 | |
| B367 | 10.07 | 29.613 | |
| B368 | 10.13 | 29.665 | |
| B369 | 10.11 | 29.737 | |
| B370 | 9.84 | 29.428 | |
| B371 | 10.25 | 29.829 | |
| B372 | 9.84 | 29.676 | |
| B373 | 9.93 | 29.716 | |
| B374 | 9.79 | 29.490 | |
| B375 | 9.78 | 29.563 | |
| B376 | 9.89 | 29.669 | |
| B377 | 10.07 | 29.526 | |

| ID-Nr. LOT 57130074 | Concentration Particle number/ml ($10^5$) | weight (g) | Bottle received |
|---|---|---|---|
| B378 | 10.11 | 29.554 | |
| B379 | 10.00 | 29.815 | |
| B380 | 9.94 | 29.838 | |
| B381 | 9.94 | 29.586 | |
| B382 | 9.81 | 29.678 | |
| B383 | 9.85 | 29.608 | |
| B384 | 9.84 | 30.789 | |
| B385 | 9.73 | 29.643 | |
| B386 | 10.04 | 29.798 | |
| B387 | 9.97 | 29.942 | |
| B388 | 9.88 | 29.715 | |
| B389 | 9.79 | 29.848 | |
| B390 | 9.87 | 29.561 | |
| B391 | 10.02 | 29.772 | |
| B392 | 9.99 | 29.633 | |
| B393 | 9.88 | 29.604 | |
| B394 | 9.76 | 29.859 | |
| B395 | 9.86 | 29.707 | |
| B396 | 9.91 | 29.565 | |
| B397 | 9.83 | 29.785 | |
| B398 | 10.00 | 29.651 | |
| B399 | 9.94 | 29.699 | |
| B400 | 9.98 | 29.745 | |
| B401 | 10.11 | 29.647 | |
| B402 | 9.94 | 29.864 | |
| B403 | 10.08 | 29.764 | |
| B404 | 9.79 | 29.576 | |
| B405 | 10.18 | 29.712 | |
| B406 | 9.95 | 29.740 | |

| ID-Nr. LOT 57130074 | Concentration Particle number/ml ($10^5$) | weight (g) | Bottle received |
|---|---|---|---|
| B407 | 10.08 | 29.632 | |
| B408 | 9.88 | 29.546 | |
| B409 | 10.03 | 29.615 | |
| B410 | 10.21 | 29.850 | |
| B411 | 9.76 | 29.714 | |
| B412 | 9.82 | 29.684 | |
| B413 | 9.85 | 29.613 | |
| B414 | 9.90 | 29.663 | |
| B415 | 9.93 | 29.708 | |
| B416 | 9.89 | 29.740 | |
| B417 | 9.89 | 29.585 | |
| B418 | 9.97 | 29.753 | |
| B419 | 9.73 | 29.670 | |
| B420 | 9.80 | 29.770 | |
| B421 | 9.92 | 29.693 | |
| B422 | 9.99 | 29.579 | |
| B423 | 9.97 | 29.536 | |
| B424 | 9.91 | 29.728 | |
| B425 | 10.01 | 29.715 | |
| B426 | 10.05 | 29.776 | |
| B427 | 10.07 | 29.745 | |
| B428 | 10.01 | 29.611 | |
| B429 | 9.96 | 29.479 | |
| B430 | 9.90 | 29.528 | |
| B431 | 9.87 | 29.599 | |
| B432 | 9.98 | 29.626 | |
| B433 | 10.02 | 29.456 | |
| B434 | 9.77 | 29.658 | |
| B435 | 9.73 | 29.661 | |

| ID-Nr. LOT 57130074 | Concentration Particle number/ml ($10^5$) | weight (g) | Bottle received |
|---|---|---|---|
| B436 | 9.92 | 29.631 | |
| B437 | 9.88 | 29.681 | |
| B438 | 9.84 | 29.719 | |
| B439 | 9.81 | 29.604 | |
| B440 | 9.71 | 29.723 | |
| B441 | 9.90 | 29.628 | |
| B442 | 9.97 | 29.724 | |
| B443 | 9.86 | 29.638 | |
| B444 | 9.81 | 29.774 | |
| B445 | 9.95 | 29.681 | |
| B446 | 9.71 | 29.482 | |
| B447 | 9.75 | 29.690 | |
| B448 | 9.98 | 29.735 | |
| B449 | 9.97 | 29.560 | |
| B450 | 10.25 | 29.599 | |
| B451 | 10.01 | 29.486 | |
| B452 | 9.86 | 29.503 | |
| B453 | 10.11 | 29.568 | |
| B454 | 9.94 | 29.507 | |
| B455 | 9.99 | 29.558 | |
| B456 | 9.97 | 29.504 | |
| B457 | 9.94 | 29.494 | |
| B458 | 9.77 | 29.405 | |
| B459 | 9.80 | 29.627 | |
| B460 | 9.82 | 29.584 | |
| B461 | 10.03 | 29.470 | |
| B462 | 9.97 | 29.399 | |
| B463 | 9.84 | 29.388 | |
| B464 | 9.82 | 29.752 | |

| ID-Nr. LOT 57130074 | Concentration Particle number/ml ($10^5$) | weight (g) | Bottle received |
|---|---|---|---|
| B465 | 9.95 | 29.578 | |
| B466 | 10.14 | 29.684 | |
| B467 | 9.97 | 29.882 | |
| B468 | 9.81 | 29.713 | |
| B469 | 9.84 | 29.719 | |
| B470 | 9.92 | 29.835 | |
| B471 | 10.01 | 29.677 | |
| B472 | 9.87 | 29.780 | |
| B473 | 9.82 | 29.889 | |
| B474 | 10.24 | 29.703 | |
| B475 | 9.93 | 29.777 | |
| B476 | 9.83 | 29.565 | |
| B477 | 9.76 | 29.818 | |
| B478 | 10.17 | 29.769 | |
| B479 | 9.88 | 29.752 | |
| B480 | 10.08 | 29.590 | |
| B481 | 9.99 | 29.722 | |
| B482 | 9.77 | 29.706 | |
| B483 | 9.84 | 29.717 | |
| B484 | 9.93 | 29.641 | |
| B485 | 10.28 | 29.770 | |
| B486 | 10.03 | 29.538 | |
| B487 | 10.06 | 29.627 | |
| B488 | 9.95 | 29.856 | |
| B489 | 9.79 | 29.748 | |
| B490 | 9.90 | 29.776 | |
| B491 | 10.07 | 29.757 | |
| B492 | 9.99 | 29.811 | |
| B493 | 9.77 | 29.712 | |

| ID-Nr. LOT 57130074 | Concentration Particle number/ml ($10^5$) | weight (g) | Bottle received |
|---|---|---|---|
| B494 | 9.81 | 29.708 | |
| B495 | 9.86 | 29.725 | |
| B496 | 9.86 | 29.591 | |
| B497 | 10.07 | 29.645 | |
| B498 | 9.86 | 30.305 | |
| B499 | 9.77 | 30.285 | |
| B500 | 9.89 | 29.920 | |
| B501 | 10.12 | 29.711 | |
| B502 | 10.09 | 29.958 | |
| B503 | 10.04 | 29.945 | |
| B504 | 9.94 | 30.025 | |
| B505 | 9.96 | 29.964 | |
| B506 | 9.74 | 30.041 | |
| B507 | 10.02 | 29.882 | |
| B508 | 10.24 | 29.856 | |
| B509 | 9.97 | 29.545 | |
| B510 | 10.12 | 29.582 | |
| B511 | 10.02 | 29.862 | |
| B512 | 9.94 | 29.890 | |
| B513 | 9.85 | 30.075 | |
| B514 | 9.89 | 30.023 | |
| B515 | 9.92 | 30.212 | |
| B516 | 9.87 | 30.149 | |
| B517 | 9.85 | 29.971 | |
| B518 | 9.80 | 29.941 | |
| B519 | 10.01 | 29.725 | |
| B520 | 9.81 | 29.563 | |
| B521 | 9.74 | 29.482 | |
| B522 | 9.76 | 29.462 | |

| ID-Nr. LOT 57130074 | Concentration Particle number/ml ($10^5$) | weight (g) | Bottle received |
|---|---|---|---|
| B523 | 9.86 | 29.579 | |
| B524 | 9.95 | 29.464 | |
| B525 | 9.97 | 29.627 | |
| B526 | 9.90 | 29.471 | |
| B527 | 9.84 | 29.586 | |
| B528 | 9.88 | 29.661 | |
| B529 | 10.03 | 29.750 | |
| B530 | 10.08 | 29.630 | |
| B531 | 9.97 | 29.536 | |
| B532 | 9.99 | 29.689 | |
| B533 | 10.15 | 29.746 | |
| B534 | 9.88 | 29.581 | |
| B535 | 10.02 | 29.676 | |
| B536 | 10.01 | 29.569 | |
| B537 | 10.02 | 29.520 | |
| B538 | 9.91 | 29.849 | |
| B539 | 10.17 | 29.681 | |
| B540 | 10.24 | 29.556 | |
| B541 | 10.10 | 29.520 | |
| B542 | 10.17 | 29.617 | |
| B543 | 10.15 | 29.597 | |
| B544 | 10.02 | 29.552 | |
| B545 | 10.26 | 29.547 | |
| B546 | 10.08 | 29.554 | |
| B547 | 10.31 | 29.472 | |
| B548 | 9.99 | 29.604 | |
| B549 | 10.14 | 29.608 | |
| B550 | 10.26 | 29.605 | |
| B551 | 10.19 | 29.816 | |

| ID-Nr. LOT 57130074 | Concentration Particle number/ml ($10^5$) | weight (g) | Bottle received |
|---|---|---|---|
| B552 | 9.96 | 30.112 | |
| B553 | 10.07 | 29.626 | |
| B554 | 10.11 | 29.499 | |
| B555 | 10.10 | 29.712 | |
| B556 | 10.02 | 29.458 | |
| B557 | 9.97 | 29.688 | |
| | | | |
| B558 | 9.95 | 29.652 | |
| B559 | 10.25 | 29.670 | |
| B560 | 10.00 | 29.613 | |

# 5. Adjusting the FlowFactor

The FlowFactor (FF) is analyzer specific and part of the conversion factor that relates the number of objects detected in the Cedex HiRes Analyzer to the actual density in the analyzed sample.

The conversion factor is linearly dependent on the FlowFactor, thus allowing for the possibility to compute the appropriate setting for this parameter via the comparison of Cedex HiRes Analyzer results versus a known density of a sample (*e.g.*, Density Reference Standard Beads).

Refer to the relevant Cedex HiRes Operator's Manual for the location of the current FlowFactor. The location depends on the installed Software version.

## 5.1 How to Calculate and Change the FlowFactor

❶ Write down the current FlowFactor (FFold) and calculate a new FlowFactor as follows:

$$FF(new_1) = \frac{\text{actual density (according to bottle label)}}{\text{mean value TCD of measurement series 1}} \times FF(old)$$

$$FF(new_2) = \frac{\text{actual density (according to bottle label)}}{\text{mean value TCD of measurement series 2}} \times FF(old)$$

("actual density" is specified as Particle number/ml on the label of the bottle of beads used for the calibration.)

$$\textbf{FF (new)} = \frac{FF(new_1) + FF(new_2)}{2}$$

❷ Refer to the relevant Cedex HiRes Operator's Manual for information about the location of the FlowFactor. Update the FlowFactor in that location based on the result calculated in Step 1.

## 5.2 FlowFactor Calibration

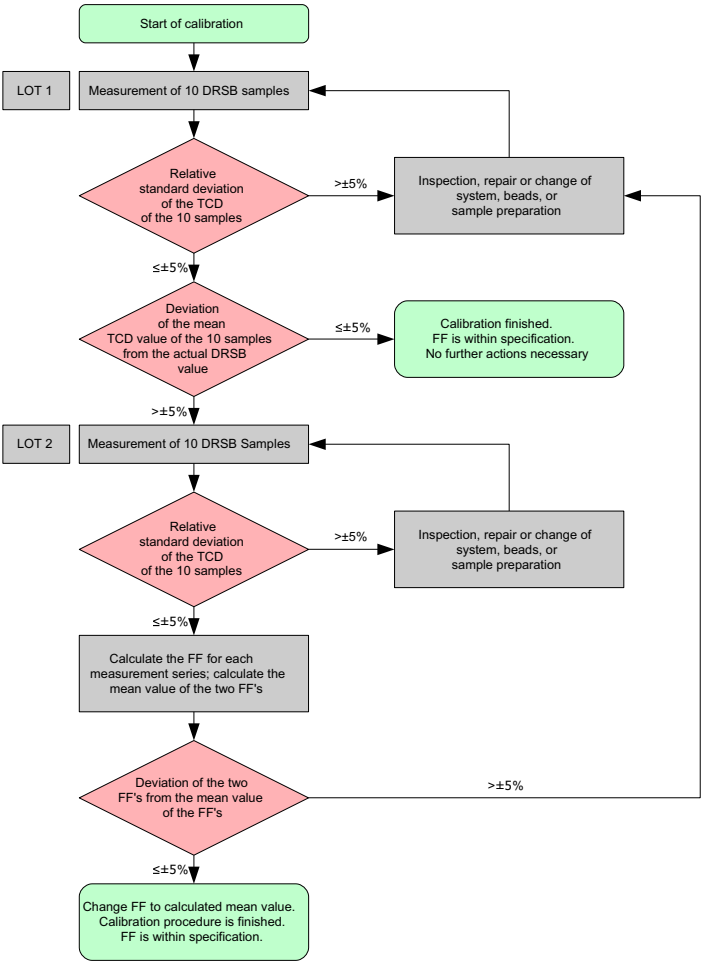


**Fig. 2:** Calibration Cedex HiRes Analyzer

# 6. Supplementary Information

## 6.1 Conventions

### 6.1.1 Text Conventions

To make information consistent and easier to read, the following text conventions are used in this document:

| Text Convention | Usage |
|---|---|
| Numbered stages labeled ①, ②, etc. | Stages in a process that usually occur in the order listed. |
| Numbered instructions labeled ❶, ❷, etc. | Steps in a procedure that must be performed in the order listed. |
| Asterisk * | Denotes a product available from Roche Diagnostics. |

### 6.1.2 Symbols

In this document, the following symbols are used to highlight important information:

| Symbol | Description |
|---|---|
| | Information Note:<br>Additional information about the current topic or procedure. |
| | Important Note:<br>Information critical to the success of the procedure or use of the product. |

## 6.2 Changes to Previous Version

- Updated to include lot-specific data for new lot.

## 6.3 Trademarks

CEDEX is a trademark of Roche.
Other brands or product names are trademarks of their respective holders.

## 6.4 Regulatory Disclaimer

For use in quality control/manufacturing process only.

## 6.5 Contact Support

For additional documentation such as certificates and safety data sheets, please visit documentation.roche.com.

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**For more documentation such as instructions for use and safety data sheets, please visit documentation.roche.com**

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