For use in quality control/
manufacturing process only.

Density Reference Standard Beads (DRSB)

Version 42

Content version: November 2021

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. 57130069

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

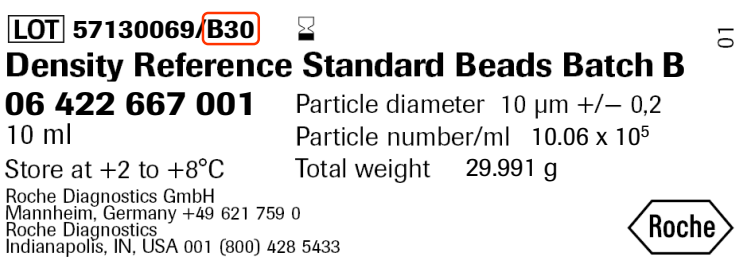

Fig. 1: Example of how to find the bottle number on the bottle label. The bottle number is circled.

ID-Nr. LOT 57130069	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B1	9.99	29.552	B1
B2	9.96	29.231	B2
B3	9.94	29.614	B3
B4	9.98	29.580	B4
B5	10.01	29.556	B5
B6	9.98	29.477	B6
B7	10.06	29.496	B7
B8	9.94	29.650	B8
B9	10.02	29.679	B9
B10	10.01	29.683	B10
B11	10.01	29.712	B11
B12	9.99	29.662	B12
B13	9.97	29.446	B13
B14	9.94	29.684	B14
B15	10.00	29.879	B15
B16	10.02	29.683	B16
B17	9.95	29.856	B17
B18	10.07	29.697	B18
B19	10.00	29.437	B19
B20	9.98	29.538	B20
B21	10.07	29.711	B21
B22	9.94	29.367	B22
B23	9.96	29.510	B23
B24	10.04	29.607	B24
B25	9.94	29.550	B25
B26	9.98	29.801	B26
B27	9.93	29.575	B27
B28	9.91	29.742	B28
B29	9.95	29.368	B29

ID-Nr. LOT 57130069	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B30	9.98	29.812	B30
B31	9.98	29.648	B31
B32	9.98	29.745	B32
B33	9.99	29.638	B33
B34	9.99	29.477	B34
B35	9.98	29.601	B35
B36	9.92	29.714	B36
B37	10.01	29.534	B37
B38	9.93	29.446	B38
B39	9.94	29.668	B39
B40	10.00	29.580	B40
B41	9.95	29.408	B41
B42	10.01	29.688	B42
B43	10.03	29.706	B43
B44	9.90	29.791	B44
B45	10.04	29.581	B45
B46	10.00	29.699	B46
B47	10.02	29.755	B47
B48	9.99	29.630	B48
B49	9.98	29.501	B49
B50	9.94	29.715	B50
B51	9.91	29.702	B51
B52	10.01	29.610	B52
B53	9.99	29.674	B53
B54	10.07	29.563	B54
B55	9.93	29.447	B55
B56	10.00	29.563	B56
B57	9.96	29.485	B57
B58	9.90	29.657	B58

ID-Nr. LOT 57130069	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B59	9.93	29.609	B59
B60	9.99	29.652	B60
B61	10.00	29.429	B61
B62	10.02	29.738	B62
B63	9.99	29.761	B63
B64	9.97	29.579	B64
B65	10.07	29.792	B65
B66	9.97	29.163	B66
B67	10.00	29.657	B67
B68	10.00	29.719	B68
B69	9.99	29.791	B69
B70	9.98	29.757	B70
B71	9.92	29.715	B71
B72	10.03	29.638	B72
B73	9.98	29.584	B73
B74	9.97	29.682	B74
B75	10.02	29.490	B75
B76	10.02	29.631	B76
B77	9.93	29.654	B77
B78	10.01	29.470	B78
B79	9.95	29.723	B79
B80	10.05	29.746	B80
B81	10.05	29.783	B81
B82	9.99	29.395	B82
B83	9.95	29.593	B83
B84	9.99	29.638	B84
B85	10.02	29.514	B85
B86	9.93	29.654	B86
B87	9.99	29.350	B87

ID-Nr. LOT 57130069	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B88	10.05	29.598	B88
B89	10.03	29.667	B89
B90	10.04	29.442	B90
B91	9.96	29.675	B91
B92	10.00	29.550	B92
B93	9.99	29.610	B93
B94	10.03	29.510	B94
B95	10.02	29.578	B95
B96	9.93	29.558	B96
B97	9.96	29.534	B97
B98	10.01	29.432	B98
B99	9.95	29.668	B99
B100	9.92	29.519	B100
B101	10.00	29.852	B101
B102	10.07	29.527	B102
B103	10.02	29.664	B103
B104	9.97	29.420	B104
B105	9.94	29.684	B105
B106	9.93	29.445	B106
B107	9.93	29.689	B107
B108	10.01	29.696	B108
B109	9.95	29.601	B109
B110	10.07	29.577	B110
B111	9.93	29.406	B111
B112	10.01	29.553	B112
B113	10.03	29.502	B113
B114	9.96	29.593	B114
B115	10.01	29.588	B115
B116	9.99	29.721	B116

ID-Nr. LOT 57130069	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B117	10.00	29.825	B117
B118	9.95	29.641	B118
B119	9.95	29.637	B119
B120	10.05	29.802	B120
B121	9.97	29.569	B121
B122	10.00	29.596	B122
B123	10.00	29.770	B123
B124	9.93	29.651	B124
B125	10.00	29.718	B125
B126	9.93	29.684	B126
B127	9.94	29.786	B127
B128	9.98	29.671	B128
B129	10.00	29.547	B129
B130	9.94	29.635	B130
B131	10.01	29.759	B131
B132	10.05	29.545	B132
B133	10.01	29.651	B133
B134	9.94	29.680	B134
B135	9.95	29.792	B135
B136	10.01	29.774	B136
B137	10.00	29.685	B137
B138	9.96	29.640	B138
B139	10.02	29.574	B139
B140	9.94	29.846	B140
B141	9.98	29.337	B141
B142	10.00	29.674	B142
B143	9.95	29.291	B143
B144	9.91	29.406	B144
B145	10.00	29.762	B145

ID-Nr. LOT 57130069	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B146	10.09	29.632	B146
B147	10.05	29.836	B147
B148	9.96	29.802	B148
B149	10.08	29.795	B149
B150	10.02	29.545	B150
B151	9.96	29.490	B151
B152	10.04	29.760	B152
B153	10.02	29.817	B153
B154	9.96	29.556	B154
B155	10.01	29.652	B155
B156	9.97	29.761	B156
B157	10.04	29.481	B157
B158	9.94	29.675	B158
B159	10.01	29.388	B159
B160	10.06	29.606	B160
B161	9.92	29.721	B161
B162	10.01	29.527	B162
B163	9.96	29.431	B163
B164	10.01	29.670	B164
B165	9.96	29.489	B165
B166	9.98	29.692	B166
B167	10.01	29.494	B167
B168	9.98	29.613	B168
B169	10.07	29.502	B169
B170	10.00	29.525	B170
B171	9.98	29.724	B171
B172	9.97	29.616	B172
B173	9.92	29.474	B173
B174	10.00	29.815	B174

ID-Nr. LOT 57130069	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B175	9.93	29.617	B175
B176	9.97	29.578	B176
B177	9.99	29.691	B177
B178	10.02	29.798	B178
B179	9.98	29.585	B179
B180	10.02	29.454	B180
B181	10.06	29.658	B181
B182	9.98	29.515	B182
B183	10.01	29.704	B183
B184	10.05	29.520	B184
B185	10.00	29.731	B185
B186	10.03	29.743	B186
B187	9.95	29.529	B187
B188	9.98	29.444	B188
B189	10.04	29.649	B189
B190	10.02	29.524	B190
B191	10.05	29.560	B191
B192	10.07	29.791	B192
B193	10.00	29.813	B193
B194	10.00	29.514	B194
B195	10.06	29.551	B195
B196	10.03	29.517	B196
B197	10.07	29.464	B197
B198	10.01	29.524	B198
B199	9.96	29.774	B199
B200	10.05	29.610	B200
B201	9.94	29.553	B201
B202	10.01	29.566	B202
B203	9.96	29.493	B203

ID-Nr. LOT 57130069	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B204	9.92	29.644	B204
B205	10.04	29.656	B205
B206	9.99	29.418	B206
B207	9.95	29.467	B207
B208	10.05	29.627	B208
B209	10.05	29.593	B209
B210	10.09	29.466	B210
B211	10.01	29.701	B211
B212	10.01	29.678	B212
B213	9.99	29.648	B213
B214	9.98	29.720	B214
B215	10.00	29.573	B215
B216	10.01	29.692	B216
B217	10.03	29.611	B217
B218	10.00	29.702	B218
B219	10.04	29.707	B219
B220	10.01	29.430	B220
B221	10.09	29.351	B221
B222	9.97	29.658	B222
B223	9.99	29.578	B223
B224	9.93	29.496	B224
B225	9.98	29.553	B225
B226	9.99	29.603	B226
B227	10.08	29.607	B227
B228	10.00	29.691	B228
B229	9.99	29.635	B229
B230	9.98	29.461	B230
B231	9.97	29.786	B231
B232	9.90	29.667	B232

ID-Nr. LOT 57130069	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B233	9.98	29.770	B233
B234	10.05	29.676	B234
B235	9.94	29.592	B235
B236	10.01	29.752	B236
B237	10.01	29.720	B237
B238	9.98	29.672	B238
B239	9.95	29.682	B239
B240	10.04	29.586	B240
B241	10.02	29.670	B241
B242	10.00	29.707	B242
B243	9.95	29.400	B243
B244	10.01	29.406	B244
B245	9.95	29.390	B245
B246	10.00	29.666	B246
B247	9.95	29.321	B247
B248	10.06	29.635	B248
B249	10.03	29.713	B249
B250	10.05	29.691	B250
B251	10.04	29.621	B251
B252	9.99	29.628	B252
B253	9.98	29.626	B253
B254	9.95	29.737	B254
B255	10.00	29.476	B255
B256	10.02	29.393	B256
B257	10.06	29.586	B257
B258	9.96	29.639	B258
B259	10.01	29.741	B259
B260	10.03	29.697	B260
B261	10.06	29.678	B261

ID-Nr. LOT 57130069	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B262	9.97	29.590	B262
B263	10.00	29.506	B263
B264	10.00	29.622	B264
B265	9.96	29.561	B265
B266	10.06	29.647	B266
B267	9.95	29.655	B267
B268	9.95	29.681	B268
B269	9.92	29.734	B269
B270	9.99	29.653	B270
B271	9.99	29.629	B271
B272	10.00	29.536	B272
B273	9.96	29.615	B273
B274	10.09	29.475	B274
B275	9.94	29.695	B275
B276	10.00	29.591	B276
B277	9.96	29.508	B277
B278	9.94	29.677	B278
B279	10.00	29.582	B279
B280	9.92	29.735	B280
B281	10.00	29.626	B281
B282	10.01	29.758	B282
B283	9.99	29.731	B283
B284	9.90	29.394	B284
B285	9.98	29.691	B285
B286	9.91	29.365	B286
B287	10.03	29.691	B287
B288	9.98	29.588	B288
B289	9.99	29.525	B289
B290	10.00	29.356	B290

ID-Nr. LOT 57130069	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B291	10.05	29.573	B291
B292	9.97	29.301	B292
B293	10.02	29.429	B293
B294	9.99	29.719	B294
B295	9.99	29.576	B295
B296	10.00	29.652	B296
B297	10.04	29.621	B297
B298	10.03	29.735	B298
B299	9.93	29.694	B299
B300	10.03	29.698	B300
B301	9.93	29.629	B301
B302	10.02	29.422	B302
B303	9.98	29.540	B303
B304	9.93	29.463	B304
B305	10.02	29.598	B305
B306	10.02	29.550	B306
B307	10.06	29.553	B307
B308	10.01	29.555	B308
B309	9.90	29.477	B309
B310	10.03	29.490	B310
B311	10.02	29.585	B311
B312	9.97	29.783	B312
B313	10.05	29.415	B313
B314	9.96	29.773	B314
B315	9.94	29.463	B315
B316	10.01	29.790	B316
B317	10.01	29.463	B317
B318	9.97	29.378	B318
B319	10.05	29.732	B319

ID-Nr. LOT 57130069	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B320	9.97	29.596	B320
B321	10.02	29.584	B321
B322	10.03	29.353	B322
B323	9.99	29.602	B323
B324	10.09	29.526	B324
B325	9.91	29.664	B325
B326	10.02	29.453	B326
B327	10.01	29.658	B327
B328	10.05	29.508	B328
B329	9.96	29.488	B329
B330	10.02	29.347	B330
B331	10.07	29.511	B331
B332	9.96	29.482	B332
B333	9.99	29.495	B333
B334	9.96	29.557	B334
B335	9.90	29.512	B335
B336	10.00	29.493	B336
B337	9.96	29.458	B337
B338	9.99	29.584	B338
B339	9.97	29.524	B339
B340	10.03	29.523	B340
B341	9.96	29.577	B341
B342	9.96	29.484	B342
B343	9.99	29.501	B343
B344	10.04	29.348	B344
B345	10.05	29.580	B345
B346	10.00	29.596	B346
B347	10.03	29.390	B347
B348	9.93	29.507	B348

ID-Nr. LOT 57130069	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B349	9.98	29.416	B349
B350	10.00	29.510	B350
B351	9.95	29.554	B351
B352	9.96	29.432	B352
B353	9.90	29.453	B353
B354	9.98	29.380	B354
B355	9.94	29.515	B355
B356	9.99	29.608	B356
B357	9.92	29.591	B357
B358	10.06	29.549	B358
B359	10.03	29.576	B359
B360	9.98	29.437	B360
B361	10.02	29.345	B361
B362	9.95	29.410	B362
B363	10.00	29.378	B363
B364	10.07	29.167	B364
B365	10.02	29.420	B365
B366	10.00	29.615	B366
B367	9.99	29.264	B367
B368	9.95	29.551	B368
B369	9.91	29.538	B369
B370	9.94	29.500	B370
B371	10.05	29.501	B371
B372	10.09	29.351	B372
B373	10.04	29.469	B373
B374	10.04	29.649	B374
B375	9.96	29.671	B375
B376	9.91	29.549	B376
B377	9.90	29.701	B377

ID-Nr. LOT 57130069	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B378	9.99	29.616	B378
B379	9.99	29.563	B379
B380	9.95	29.624	B380
B381	9.91	29.385	B381
B382	9.97	29.415	B382
B383	10.01	29.443	B383
B384	9.92	29.392	B384
B385	10.01	29.655	B385
B386	9.95	29.761	B386
B387	10.00	29.688	B387
B388	9.96	29.571	B388
B389	10.01	29.742	B389
B390	10.01	29.498	B390
B391	9.99	29.125	B391
B392	10.01	29.396	B392
B393	9.96	29.489	B393
B394	10.03	29.653	B394
B395	10.04	29.446	B395
B396	10.04	29.590	B396
B397	9.90	29.414	B397
B398	9.92	29.521	B398
B399	9.92	29.730	B399
B400	10.04	29.692	B400
B401	9.92	29.516	B401
B402	9.99	29.530	B402
B403	9.99	29.433	B403
B404	9.99	29.416	B404
B405	10.06	29.535	B405
B406	10.07	29.467	B406

ID-Nr. LOT 57130069	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B407	9.98	29.161	B407
B408	10.01	29.388	B408
B409	10.01	29.364	B409
B410	9.94	29.497	B410
B411	10.03	29.365	B411
B412	9.91	29.483	B412
B413	9.97	29.592	B413
B414	9.91	29.526	B414
B415	10.01	29.554	B415
B416	9.96	29.374	B416
B417	10.04	29.374	B417
B418	10.07	29.382	B418
B419	9.99	29.343	B419
B420	10.09	29.442	B420
B421	10.05	29.604	B421
B422	9.90	29.603	B422
B423	9.99	29.366	B423
B424	9.94	29.759	B424
B425	10.05	29.807	B425
B426	10.04	29.757	B426
B427	9.98	29.882	B427
B428	10.01	29.703	B428
B429	10.00	29.853	B429
B430	9.97	29.836	B430
B431	10.08	29.693	B431
B432	10.05	29.472	B432
B433	9.92	29.689	B433
B434	10.01	29.475	B434
B435	9.96	29.859	B435

ID-Nr. LOT 57130069	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B436	10.05	29.709	B436
B437	9.98	29.589	B437
B438	9.92	29.602	B438
B439	9.98	29.673	B439
B440	10.04	29.693	B440
B441	9.98	29.660	B441
B442	9.94	29.722	B442
B443	9.92	29.810	B443
B444	10.05	29.700	B444
B445	10.01	29.741	B445
B446	9.95	29.628	B446
B447	10.00	29.589	B447
B448	10.06	29.738	B448
B449	10.01	29.754	B449
B450	10.09	29.692	B450
B451	9.94	29.724	B451
B452	10.02	29.421	B452
B453	10.00	29.519	B453
B454	10.01	29.404	B454
B455	10.07	29.541	B455
B456	10.01	29.597	B456
B457	9.95	29.533	B457
B458	10.01	29.073	B458
B459	10.00	29.400	B459
B460	10.06	29.052	B460
B461	10.03	29.447	B461
B462	9.94	29.547	B462
B463	10.02	29.236	B463
B464	9.95	29.258	B464

ID-Nr. LOT 57130069	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B465	10.04	29.386	B465
B466	10.04	29.286	B466
B467	10.00	29.294	B467
B468	9.99	29.557	B468
B469	9.99	29.517	B469
B470	9.98	29.632	B470
B471	9.99	29.770	B471
B472	10.04	29.383	B472
B473	9.95	29.695	B473
B474	10.08	29.290	B474
B475	9.94	29.480	B475
B476	9.95	29.539	B476
B477	10.06	29.213	B477
B478	9.99	29.511	B478
B479	10.05	29.543	B479
B480	10.01	29.195	B480
B481	9.95	29.397	B481
B482	10.03	29.170	B482
B483	9.92	29.367	B483
B484	10.02	29.325	B484
B485	10.00	29.485	B485
B486	10.09	29.426	B486
B487	10.06	29.387	B487
B488	9.90	29.524	B488
B489	10.04	29.288	B489
B490	9.94	29.769	B490
B491	9.97	29.211	B491
B492	10.05	29.158	B492
B493	9.93	29.503	B493

ID-Nr. LOT 57130069	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B494	9.90	29.305	B494
B495	9.94	29.868	B495
B496	9.96	29.608	B496
B497	10.02	29.143	B497
B498	10.07	29.448	B498
B499	10.07	29.197	B499
B500	10.02	29.460	B500
B501	10.08	29.331	B501
B502	9.93	29.456	B502
B503	9.97	29.569	B503
B504	9.90	29.426	B504
B505	9.93	29.413	B505
B506	9.99	29.354	B506
B507	9.92	29.333	B507
B508	9.97	29.481	B508
B509	10.06	29.458	B509
B510	9.98	29.357	B510
B511	10.03	29.411	B511
B512	10.06	29.439	B512
B513	10.03	29.473	B513
B514	9.99	29.764	B514
B515	10.02	29.449	B515
B516	10.01	29.421	B516
B517	9.91	29.488	B517
B518	10.01	29.211	B518
B519	10.03	29.398	B519
B520	9.94	29.395	B520
B521	10.00	29.350	B521
B522	10.01	29.555	B522

ID-Nr. LOT 57130069	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B523	9.90	29.391	B523
B524	9.95	29.504	B524
B525	10.03	29.463	B525
B526	10.01	29.090	B526
B527	10.00	29.259	B527
B528	10.05	29.409	B528
B529	9.95	29.656	B529
B530	9.99	29.302	B530
B531	9.91	29.440	B531
B532	10.03	29.374	B532
B533	9.94	29.202	B533
B534	10.05	29.486	B534
B535	10.06	29.174	B535
B536	9.93	29.387	B536
B537	10.01	29.108	B537
B538	10.03	29.517	B538
B539	10.00	29.400	B539
B540	9.94	29.135	B540
B541	9.91	29.575	B541
B542	10.03	29.397	B542
B543	10.06	29.467	B543
B544	9.95	29.473	B544
B545	9.98	29.397	B545
B546	9.97	29.465	B546
B547	9.93	29.349	B547
B548	9.94	29.244	B548
B549	9.93	29.459	B549
B550	9.97	29.270	B550
B551	9.94	29.535	B551

ID-Nr. LOT 57130069	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B552	9.93	29.674	B552
B553	9.95	29.573	B553
B554	10.02	29.550	B554
B555	9.95	29.620	B555
B556	9.99	29.500	B556

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

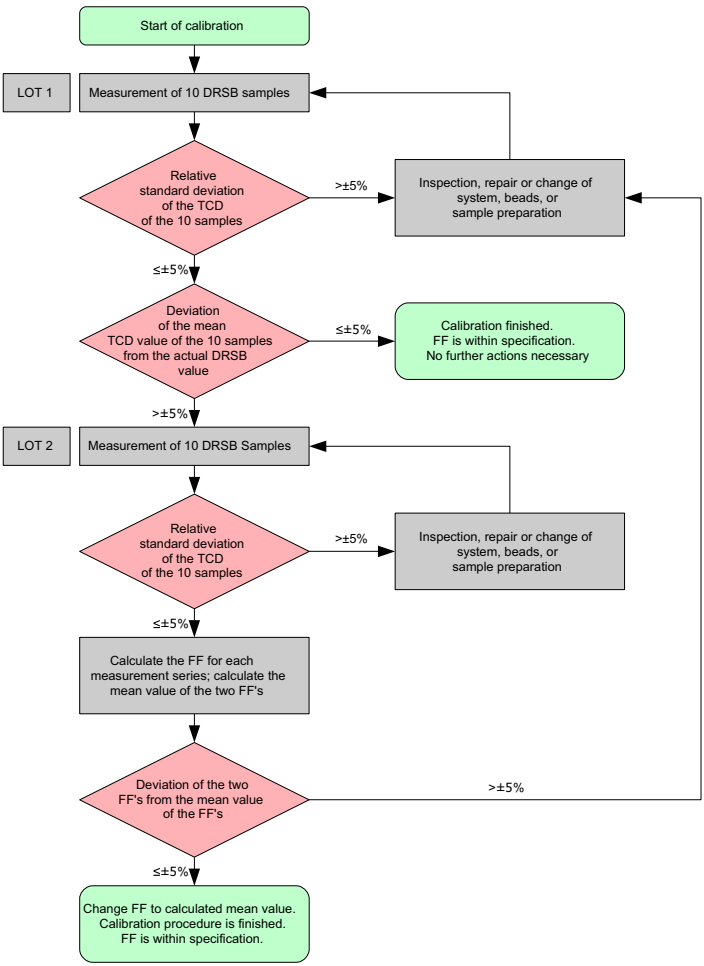

Fig. 2: Calibration Cedex HiRes Analyzer

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: Additional information about the current topic or procedure.
	Important Note: 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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Roche Diagnostics GmbH
Sandhofer Straße 116
68305 Mannheim
Germany

06326056001 ㊷ 1121

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Your Roche CustomBiotech Customer Service

Europe, Middle East, Africa, and Latin America
Phone +49 621 759 8580
Fax +49 621 759 6385
mannheim.custombiotech@roche.com

United States
Phone +1 800 428 5433 (toll-free)
Fax +1 317 521 4065
custombiotech.ussales@roche.com

Canada
Phone +1 450 686 7050
Fax +1 450 686 7012
custombiotech.can@roche.com

Japan
Phone +81 3 6634 1046
Fax +81 3 5479 0585
japan.custombiotech@roche.com

Asia Pacific
Phone +65 6371 6638
Fax +65 6371 6601
apac.custombiotech@roche.com