For use in quality control/
manufacturing process only.

Density Reference Standard Beads (DRSB)

Version 41

Content version: September 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. 57130068

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

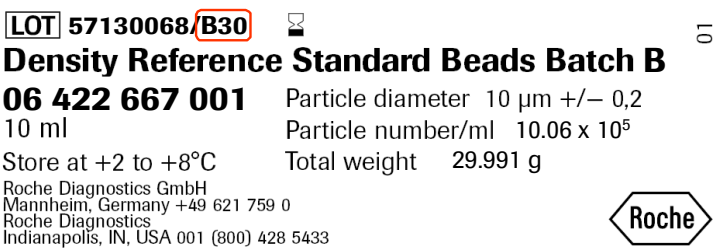

Fig. 1: Example of how to find the bottle number on the bottle label. The bottle number is circled.

ID-Nr. LOT 57130068	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B1	10.20	29.537	
B2	9.95	29.673	
B3	10.00	29.713	
B4	10.12	29.717	
B5	10.14	29.712	
B6	10.06	29.294	
B7	10.14	29.248	
B8	10.16	29.350	
B9	10.16	29.237	
B10	10.05	29.145	
B11	10.13	29.359	
B12	10.14	29.231	
B13	10.04	29.227	
B14	10.09	29.215	
B15	10.03	29.714	
B16	10.13	29.753	
B17	10.03	29.658	
B18	9.96	29.647	
B19	10.15	29.584	
B20	10.02	29.819	
B21	10.12	30.055	
B22	10.14	30.231	
B23	10.14	30.183	
B24	10.07	30.115	
B25	10.04	30.178	
B26	10.11	30.027	
B27	10.13	30.061	
B28	10.02	30.030	
B29	10.07	29.566	

ID-Nr. LOT 57130068	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B30	10.04	29.603	
B31	10.22	30.185	
B32	10.05	29.945	
B33	10.09	30.117	
B34	10.05	29.932	
B35	10.13	30.022	
B36	10.12	30.176	
B37	10.08	30.095	
B38	10.10	30.109	
B39	10.20	29.745	
B40	10.15	30.283	
B41	10.11	29.874	
B42	10.19	30.108	
B43	10.15	29.868	
B44	10.07	30.053	
B45	10.11	30.095	
B46	10.13	29.991	
B47	10.12	30.035	
B48	10.15	30.042	
B49	10.25	29.971	
B50	10.04	30.061	
B51	10.10	30.005	
B52	10.25	30.082	
B53	10.08	30.048	
B54	10.10	29.746	
B55	10.00	30.039	
B56	10.04	29.903	
B57	9.93	30.196	
B58	10.09	30.014	

ID-Nr. LOT 57130068	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B59	10.05	29.640	
B60	10.15	29.592	
B61	10.12	30.022	
B62	10.21	30.007	
B63	10.18	29.821	
B64	10.08	30.016	
B65	10.14	29.908	
B66	10.14	29.511	
B67	10.16	29.445	
B68	10.10	29.569	
B69	10.13	29.662	
B70	9.98	29.608	
B71	10.12	29.871	
B72	10.17	29.955	
B73	10.13	30.135	
B74	10.09	30.136	
B75	10.07	30.082	
B76	10.14	29.578	
B77	10.06	29.531	
B78	10.14	29.148	
B79	9.98	29.638	
B80	10.02	29.547	
B81	10.18	30.015	
B82	10.10	30.024	
B83	10.11	30.045	
B84	10.00	29.853	
B85	10.22	30.053	
B86	10.08	29.688	
B87	10.09	29.470	

ID-Nr. LOT 57130068	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B88	10.02	29.671	
B89	10.06	29.586	
B90	10.14	29.655	
B91	10.06	29.612	
B92	10.19	29.478	
B93	10.08	29.606	
B94	10.13	29.759	
B95	10.05	29.566	
B96	10.14	29.711	
B97	10.01	29.546	
B98	10.01	29.662	
B99	10.09	29.576	
B100	10.18	29.810	
B101	10.03	29.326	
B102	10.07	29.459	
B103	10.07	29.312	
B104	10.00	29.303	
B105	9.97	29.292	
B106	10.04	29.252	
B107	9.99	29.429	
B108	10.04	29.372	
B109	10.09	29.383	
B110	10.13	29.413	
B111	10.12	29.355	
B112	10.13	29.321	
B113	10.24	29.350	
B114	10.16	29.264	
B115	10.04	29.372	
B116	10.11	29.431	

ID-Nr. LOT 57130068	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B117	10.12	29.330	
B118	10.02	29.278	
B119	10.10	29.231	
B120	10.03	29.479	
B121	10.02	29.543	
B122	10.02	29.370	
B123	10.01	29.478	
B124	10.08	29.326	
B125	10.03	29.216	
B126	10.10	29.241	
B127	10.11	29.113	
B128	9.99	29.372	
B129	10.16	29.166	
B130	10.10	29.326	
B131	10.01	29.229	
B132	10.21	29.298	
B133	10.20	29.231	
B134	9.99	29.343	
B135	10.14	29.220	
B136	10.18	29.153	
B137	10.12	29.385	
B138	10.16	29.216	
B139	10.18	29.202	
B140	10.13	29.315	
B141	10.03	29.156	
B142	10.00	29.402	
B143	10.13	29.182	
B144	10.05	29.103	
B145	10.01	29.258	

ID-Nr. LOT 57130068	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B146	10.16	29.327	
B147	9.99	29.162	
B148	10.07	29.262	
B149	10.03	29.225	
B150	10.13	29.295	
B151	10.12	29.344	
B152	10.07	29.167	
B153	10.15	29.270	
B154	10.12	29.276	
B155	10.00	29.103	
B156	10.15	29.231	
B157	10.11	29.320	
B158	10.16	29.244	
B159	9.97	29.275	
B160	10.22	29.302	
B161	10.15	29.290	
B162	10.02	29.464	
B163	10.02	29.389	
B164	10.09	29.228	
B165	10.12	29.633	
B166	10.05	29.369	
B167	10.17	29.166	
B168	10.10	29.259	
B169	10.19	29.348	
B170	10.07	29.212	
B171	10.11	29.099	
B172	10.06	29.251	
B173	10.09	29.278	
B174	10.18	29.697	

ID-Nr. LOT 57130068	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B175	10.19	29.501	
B176	10.10	29.402	
B177	10.01	29.250	
B178	10.11	29.564	
B179	10.06	29.546	
B180	10.05	29.536	
B181	10.09	29.449	
B182	10.13	29.166	
B183	10.01	29.590	
B184	10.00	29.286	
B185	10.14	29.223	
B186	10.03	29.254	
B187	10.07	29.428	
B188	10.04	29.477	
B189	10.03	29.378	
B190	10.00	29.731	
B191	10.13	29.170	
B192	10.07	29.358	
B193	10.04	29.285	
B194	10.05	29.161	
B195	10.08	29.243	
B196	9.99	29.638	
B197	10.22	29.658	
B198	10.01	29.331	
B199	10.07	29.717	
B200	10.12	29.364	
B201	10.08	29.738	
B202	10.06	29.684	
B203	10.14	29.648	

ID-Nr. LOT 57130068	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B204	10.12	29.748	
B205	10.14	29.684	
B206	10.14	29.816	
B207	10.15	29.717	
B208	10.20	29.768	
B209	10.18	29.414	
B210	10.10	29.794	
B211	10.06	29.603	
B212	9.97	29.430	
B213	10.16	29.412	
B214	10.20	29.683	
B215	10.16	29.374	
B216	10.12	29.603	
B217	10.10	29.184	
B218	10.19	29.299	
B219	10.16	29.335	
B220	10.17	29.780	
B221	10.08	29.110	
B222	10.04	29.356	
B223	10.14	29.354	
B224	10.08	29.689	
B225	10.16	29.177	
B226	10.12	29.294	
B227	10.16	29.406	
B228	10.09	29.276	
B229	10.05	29.685	
B230	10.17	29.596	
B231	10.19	29.380	
B232	10.20	29.362	

ID-Nr. LOT 57130068	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B233	10.23	29.361	
B234	10.17	29.402	
B235	10.15	29.314	
B236	10.11	29.446	
B237	10.23	29.250	
B238	10.04	29.320	
B239	10.16	29.415	
B240	10.14	29.385	
B241	10.14	29.198	
B242	10.13	29.429	
B243	10.08	29.523	
B244	10.17	29.639	
B245	10.16	29.607	
B246	9.98	29.735	
B247	10.12	29.560	
B248	10.20	29.388	
B249	10.17	29.746	
B250	10.18	29.839	
B251	10.04	29.591	
B252	10.10	29.618	
B253	10.11	29.431	
B254	10.07	29.381	
B255	10.08	29.324	
B256	10.04	29.389	
B257	10.04	29.280	
B258	10.07	29.271	
B259	10.13	29.324	
B260	10.05	29.391	
B261	10.11	29.385	

ID-Nr. LOT 57130068	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B262	10.08	29.295	
B263	10.12	29.312	
B264	10.10	29.305	
B265	10.13	29.479	
B266	10.13	29.374	
B267	10.20	29.269	
B268	10.04	29.377	
B269	10.13	29.475	
B270	10.15	29.416	
B271	10.22	29.124	
B272	10.15	29.362	
B273	10.03	29.149	
B274	10.11	29.271	
B275	10.13	29.427	
B276	10.06	29.348	
B277	10.10	29.258	
B278	10.03	29.266	
B279	10.05	29.300	
B280	10.16	29.247	
B281	10.19	29.347	
B282	10.13	29.465	
B283	10.05	29.396	
B284	10.06	29.242	
B285	10.12	29.321	
B286	10.17	29.340	
B287	10.07	29.252	
B288	10.10	29.350	
B289	10.20	29.315	
B290	10.11	29.357	

ID-Nr. LOT 57130068	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B291	10.07	29.285	
B292	10.11	29.325	
B293	10.04	29.537	
B294	10.09	29.620	
B295	10.00	29.609	
B296	10.07	29.477	
B297	10.09	29.455	
B298	10.12	29.444	
B299	10.11	29.639	
B300	10.03	29.469	
B301	9.99	29.388	
B302	10.00	29.551	
B303	10.04	29.661	
B304	10.03	29.529	
B305	10.03	29.432	
B306	10.03	29.665	
B307	10.06	29.692	
B308	10.10	29.589	
B309	10.09	29.673	
B310	9.97	29.610	
B311	10.01	29.530	
B312	10.01	29.704	
B313	10.18	29.736	
B314	10.11	29.736	
B315	10.15	29.556	
B316	10.16	29.690	
B317	10.12	29.696	
B318	10.23	29.570	
B319	10.04	29.689	

ID-Nr. LOT 57130068	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B320	10.08	29.902	
B321	10.15	29.500	
B322	9.97	29.773	
B323	9.99	29.650	
B324	10.11	29.605	
B325	10.10	29.637	
B326	10.10	29.647	
B327	10.10	29.677	
B328	10.01	29.636	
B329	10.15	29.634	
B330	10.00	29.480	
B331	10.00	29.546	
B332	10.01	29.712	
B333	10.01	29.672	
B334	9.96	29.574	
B335	9.97	29.759	
B336	10.06	29.764	
B337	10.21	29.691	
B338	10.11	29.691	
B339	10.00	29.629	
B340	10.10	29.790	
B341	10.08	29.504	
B342	10.16	29.675	
B343	10.03	29.593	
B344	10.05	29.711	
B345	10.04	29.690	
B346	10.05	29.377	
B347	9.99	29.557	
B348	10.02	29.635	

ID-Nr. LOT 57130068	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B349	10.12	29.587	
B350	10.08	29.733	
B351	10.05	29.688	
B352	10.12	29.615	
B353	10.19	29.673	
B354	10.13	29.668	
B355	10.07	29.687	
B356	10.13	29.596	
B357	10.12	29.766	
B358	10.08	29.721	
B359	10.07	29.508	
B360	10.07	29.716	
B361	10.07	29.646	
B362	10.12	29.641	
B363	10.12	29.575	
B364	10.15	29.755	
B365	10.00	29.670	
B366	9.97	29.487	
B367	10.03	29.236	
B368	9.96	29.238	
B369	10.04	29.386	
B370	9.99	29.366	
B371	10.10	29.289	
B372	10.10	29.383	
B373	9.93	29.407	
B374	10.02	29.370	
B375	10.03	29.507	
B376	10.04	29.334	
B377	10.08	29.554	

ID-Nr. LOT 57130068	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B378	9.99	29.479	
B379	9.99	29.556	
B380	10.01	29.599	
B381	10.11	29.458	
B382	10.21	29.501	
B383	10.20	29.530	
B384	10.02	29.420	
B385	10.13	29.504	
B386	9.92	29.459	
B387	10.13	29.454	
B388	9.98	29.560	
B389	9.99	29.383	
B390	10.09	29.487	
B391	10.08	29.368	
B392	10.12	29.429	
B393	10.09	29.391	
B394	10.08	29.587	
B395	10.12	29.450	
B396	10.03	29.506	
B397	10.07	29.483	
B398	10.06	29.422	
B399	9.95	29.469	
B400	10.09	29.590	
B401	10.21	29.952	
B402	10.25	29.261	
B403	10.15	29.194	
B404	10.18	29.562	
B405	10.08	29.755	
B406	10.03	29.433	

ID-Nr. LOT 57130068	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B407	10.14	29.477	
B408	10.13	29.369	
B409	10.13	29.375	
B410	10.09	29.515	
B411	10.12	29.423	
B412	10.16	29.416	
B413	10.10	29.240	
B414	10.08	29.508	
B415	10.02	29.582	
B416	10.00	29.491	
B417	10.19	29.320	
B418	9.98	29.443	
B419	9.98	29.441	
B420	10.13	29.412	
B421	10.05	29.294	
B422	10.16	29.295	
B423	10.14	29.400	
B424	9.98	29.392	
B425	10.16	29.362	
B426	10.16	29.356	
B427	10.18	29.659	
B428	10.14	29.332	
B429	10.04	29.318	
B430	10.11	29.456	
B431	10.11	29.569	
B432	10.08	29.473	
B433	10.17	29.413	
B434	10.12	29.284	
B435	10.14	29.290	

ID-Nr. LOT 57130068	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B436	10.13	29.359	
B437	10.17	29.370	
B438	10.18	29.468	
B439	10.10	29.575	
B440	10.09	29.425	
B441	10.15	29.566	
B442	10.14	29.485	
B443	10.11	29.419	
B444	10.04	29.452	
B445	9.99	29.300	
B446	10.12	29.438	
B447	10.04	29.435	
B448	10.09	29.244	
B449	10.05	29.434	
B450	10.02	29.363	
B451	10.04	29.311	
B452	10.05	29.609	
B453	10.06	29.395	
B454	10.07	29.605	
B455	10.05	29.664	
B456	9.94	29.574	
B457	10.10	29.388	
B458	10.06	29.472	
B459	10.02	29.255	
B460	10.03	29.383	
B461	10.07	29.299	
B462	10.08	29.390	
B463	10.00	28.963	
B464	10.00	29.593	

ID-Nr. LOT 57130068	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B465	10.04	29.637	
B466	9.96	29.579	
B467	10.11	29.494	
B468	10.14	29.557	
B469	10.02	29.620	
B470	10.14	29.380	
B471	10.00	29.536	
B472	10.18	29.671	
B473	10.01	29.698	
B474	10.03	29.640	
B475	10.11	29.726	
B476	10.08	29.660	
B477	9.97	29.751	
B478	10.02	29.604	
B479	10.14	29.602	
B480	10.18	29.624	
B481	10.08	29.501	
B482	10.12	29.684	
B483	10.14	29.470	
B484	10.05	29.567	
B485	10.01	29.661	
B486	10.17	29.638	
B487	10.08	29.847	
B488	10.09	29.885	
B489	10.11	29.666	
B490	10.06	29.940	
B491	10.20	29.418	
B492	10.17	29.424	
B493	10.15	29.510	

ID-Nr. LOT 57130068	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B494	10.02	29.309	
B495	10.11	29.528	
B496	9.98	29.456	
B497	10.07	29.551	
B498	10.06	29.306	
B499	10.11	29.160	
B500	10.06	29.215	
B501	10.11	29.496	
B502	10.17	29.156	
B503	10.15	29.460	
B504	10.14	29.402	
B505	10.18	29.353	
B506	10.09	29.452	
B507	10.21	29.356	
B508	10.08	29.272	
B509	10.13	29.379	
B510	10.09	29.385	
B511	10.10	29.421	
B512	10.12	29.588	
B513	10.06	29.508	
B514	10.22	29.522	
B515	10.12	29.108	
B516	10.17	29.839	
B517	10.08	29.718	
B518	10.14	29.246	
B519	10.11	29.135	
B520	10.06	29.380	
B521	10.07	29.344	
B522	10.09	29.436	

ID-Nr. LOT 57130068	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B523	10.11	29.329	
B524	9.97	29.248	
B525	9.98	29.420	
B526	9.97	29.370	
B527	10.11	29.227	
B528	10.16	29.685	
B529	10.15	29.539	
B530	10.24	29.609	
B531	10.10	29.557	
B532	10.07	29.762	
B533	10.19	29.643	
B534	10.15	29.466	
B535	10.02	29.530	
B536	10.01	29.434	
B537	10.05	29.640	
B538	10.05	29.559	
B539	10.09	29.457	
B540	10.21	29.713	
B541	10.21	29.547	
B542	10.08	29.500	
B543	10.18	29.692	
B544	9.98	29.635	
B545	10.08	29.498	
B546	10.06	29.510	
B547	9.95	29.857	
B548	10.05	29.325	
B549	10.18	29.532	
B550	10.10	29.567	
B551	10.17	29.312	

ID-Nr. LOT 57130068	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B552	10.22	29.454	
B553	10.03	29.619	
B554	10.20	29.196	
B555	10.20	29.427	
B556	10.17	29.846	

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

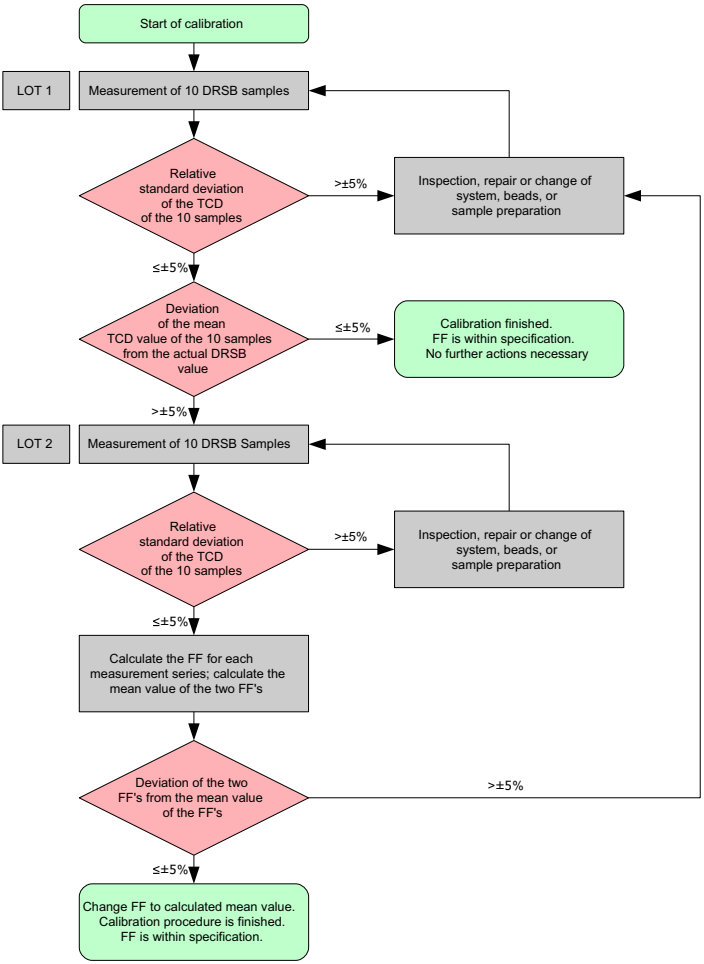

Fig. 2: Calibration Cedex HiRes Analyzer

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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