For use in quality control/
manufacturing process only.

Density Reference Standard Beads (DRSB)

Version 50

Content version: September 2023

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. 57130101

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

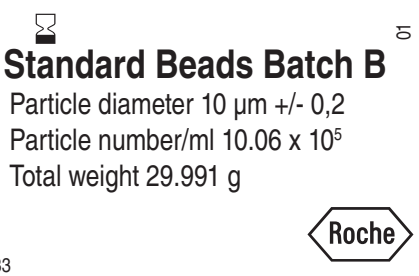

Fig. 1: Example of how to find the bottle number on the bottle label. The bottle number is circled.

ID-Nr. LOT 57130101	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B1	9.98	30.970	
B1	9.98	30.970	
B2	9.91	31.238	
B3	10.06	30.890	
B4	10.01	30.865	
B5	10.09	30.915	
B6	10.06	31.052	
B7	10.10	31.033	
B8	9.94	31.005	
B9	10.14	30.814	
B10	10.09	30.928	
B11	9.92	30.855	
B12	10.02	31.210	
B13	9.95	30.983	
B14	9.99	31.068	
B15	9.87	31.244	
B16	9.90	31.410	
B17	9.91	30.818	
B18	9.94	30.995	
B19	9.94	31.067	
B20	9.93	31.326	
B21	10.08	31.114	
B22	10.04	31.103	
B23	10.16	31.013	
B24	10.07	31.007	
B25	10.01	30.889	
B26	10.00	31.032	
B27	9.95	31.152	
B28	9.91	30.867	

ID-Nr. LOT 57130101	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B29	10.09	30.958	
B30	9.96	30.908	
B31	9.99	30.984	
B32	10.05	30.977	
B33	9.89	31.135	
B34	10.10	31.095	
B35	9.98	30.964	
B36	9.94	31.078	
B37	9.95	31.214	
B38	9.89	31.056	
B39	10.04	31.033	
B40	9.98	30.862	
B41	9.88	31.166	
B42	9.96	31.021	
B43	9.95	30.900	
B44	10.11	30.867	
B45	10.03	31.130	
B46	10.04	31.121	
B47	9.99	30.986	
B48	10.01	31.351	
B49	9.98	31.136	
B50	9.97	31.271	
B51	9.93	31.297	
B52	9.89	31.101	
B53	10.08	31.031	
B54	9.92	31.221	
B55	9.92	31.023	
B56	10.11	31.076	
B57	9.97	30.878	

ID-Nr. LOT 57130101	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B58	9.95	30.799	
B59	9.95	31.087	
B60	9.92	30.936	
B61	10.05	30.861	
B62	10.07	31.118	
B63	10.07	31.116	
B64	9.99	30.908	
B65	9.98	30.911	
B66	10.10	30.971	
B67	9.96	30.981	
B68	9.97	30.959	
B69	9.90	31.115	
B70	9.87	30.889	
B71	10.03	31.368	
B72	10.00	30.882	
B73	9.99	30.952	
B74	10.07	30.905	
B75	9.96	30.834	
B76	9.97	31.044	
B77	9.98	30.896	
B78	9.97	31.026	
B79	10.00	30.951	
B80	9.98	31.220	
B81	9.89	31.038	
B82	10.00	30.970	
B83	9.88	31.132	
B84	10.08	31.129	
B85	10.03	30.923	
B86	10.00	30.930	

ID-Nr. LOT 57130101	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B87	10.06	31.099	
B88	10.04	30.865	
B89	10.00	30.910	
B90	9.97	30.999	
B91	9.96	31.302	
B92	9.95	31.243	
B93	10.07	31.088	
B94	9.94	31.030	
B95	9.96	31.168	
B96	9.97	30.980	
B97	9.93	31.061	
B98	9.90	31.006	
B99	10.10	31.150	
B100	9.98	31.136	
B101	9.98	30.989	
B102	9.93	30.834	
B103	9.97	31.025	
B104	10.00	31.201	
B105	9.99	31.185	
B106	9.91	30.936	
B107	9.87	30.969	
B108	9.95	31.056	
B109	9.99	31.024	
B110	9.95	30.924	
B111	10.03	30.915	
B112	9.97	31.251	
B113	9.97	30.984	
B114	10.02	31.039	
B115	9.90	31.095	

ID-Nr. LOT 57130101	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B116	10.01	31.126	
B117	10.06	31.043	
B118	9.98	31.104	
B119	10.05	30.973	
B120	10.12	30.921	
B121	9.96	30.893	
B122	9.99	31.033	
B123	9.91	31.036	
B124	9.93	31.026	
B125	9.90	31.036	
B126	9.96	31.372	
B127	10.11	30.726	
B128	9.99	30.840	
B129	10.00	31.180	
B130	9.91	31.266	
B131	9.97	30.912	
B132	9.90	31.096	
B133	9.99	31.007	
B134	9.96	31.288	
B135	9.96	31.155	
B136	9.99	31.112	
B137	10.00	30.837	
B138	9.91	31.064	
B139	9.94	30.974	
B140	10.03	31.011	
B141	10.03	31.182	
B142	9.90	31.228	
B143	9.97	30.990	
B144	10.02	31.050	

ID-Nr. LOT 57130101	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B145	9.96	31.164	
B146	9.97	30.810	
B147	9.91	30.922	
B148	9.99	31.118	
B149	10.03	31.036	
B150	10.08	31.071	
B151	10.00	30.988	
B152	10.01	30.960	
B153	9.90	30.965	
B154	10.04	31.022	
B155	9.97	31.230	
B156	10.01	30.984	
B157	10.00	30.886	
B158	10.02	30.931	
B159	10.07	30.995	
B160	9.89	31.220	
B161	10.03	31.018	
B162	9.95	30.968	
B163	10.03	30.963	
B164	10.05	31.048	
B165	10.02	30.952	
B166	10.09	30.983	
B167	9.94	30.986	
B168	9.92	30.979	
B169	9.95	30.942	
B170	9.87	30.846	
B171	10.01	31.086	
B172	9.92	31.056	
B173	10.02	30.871	

ID-Nr. LOT 57130101	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B174	10.07	30.996	
B175	9.96	31.076	
B176	10.04	31.036	
B177	9.91	30.935	
B178	9.99	31.031	
B179	10.07	31.003	
B180	9.93	31.044	
B181	9.89	31.007	
B182	10.00	30.904	
B183	10.13	30.873	
B184	9.98	30.835	
B185	9.99	30.902	
B186	9.93	31.016	
B187	9.91	31.158	
B188	10.00	31.038	
B189	9.93	31.042	
B190	9.93	31.024	
B191	10.03	31.077	
B192	9.93	30.930	
B193	9.89	30.758	
B194	9.95	31.063	
B195	10.08	31.179	
B196	10.02	31.075	
B197	9.98	30.912	
B198	9.98	30.901	
B199	9.96	31.129	
B200	9.99	31.049	
B201	10.04	31.385	
B202	9.96	30.925	

ID-Nr. LOT 57130101	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B203	10.00	29.768	
B204	9.95	31.238	
B205	9.95	30.853	
B206	9.93	31.082	
B207	9.98	31.308	
B208	10.00	31.176	
B209	10.03	30.895	
B210	9.96	31.063	
B211	9.97	31.027	
B212	9.90	31.000	
B213	9.94	31.044	
B214	9.91	31.025	
B215	9.89	30.947	
B216	9.93	31.117	
B217	9.91	31.126	
B218	10.12	30.907	
B219	9.90	31.257	
B220	9.98	31.059	
B221	9.91	30.808	
B222	10.06	30.845	
B223	9.99	31.042	
B224	9.98	31.108	
B225	10.01	30.983	
B226	9.93	31.087	
B227	9.89	30.904	
B228	9.97	31.247	
B229	9.88	31.026	
B230	9.87	30.990	
B231	10.00	31.169	

ID-Nr. LOT 57130101	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B232	9.99	30.927	
B233	9.94	30.946	
B234	9.95	30.957	
B235	9.95	31.247	
B236	9.94	30.992	
B237	9.87	30.975	
B238	9.89	30.892	
B239	9.96	31.156	
B240	9.89	30.895	
B241	10.05	31.096	
B242	9.89	30.945	
B243	9.95	31.039	
B244	9.96	31.021	
B245	9.95	31.084	
B246	9.92	31.066	
B247	9.88	31.056	
B248	10.00	30.979	
B249	10.05	30.901	
B250	9.98	31.271	
B251	9.95	31.009	
B252	10.10	30.927	
B253	10.06	30.973	
B254	10.00	31.005	
B255	10.05	31.043	
B256	10.14	30.930	
B257	9.95	30.996	
B258	10.02	31.012	
B259	10.08	30.926	
B260	9.88	30.923	

ID-Nr. LOT 57130101	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B261	9.92	31.065	
B262	9.95	30.936	
B263	9.89	30.841	
B264	9.92	30.925	
B265	10.04	31.107	
B266	10.06	30.881	
B267	9.91	31.050	
B268	9.88	30.963	
B269	10.01	30.886	
B270	9.92	31.156	
B271	9.99	30.958	
B272	9.91	31.141	
B273	10.03	30.926	
B274	10.06	30.915	
B275	10.05	31.054	
B276	10.07	31.134	
B277	10.09	30.987	
B278	9.95	31.200	
B279	9.89	30.908	
B280	9.93	30.930	
B281	9.90	31.048	
B282	10.01	31.050	
B283	10.02	30.978	
B284	10.04	31.176	
B285	10.01	31.130	
B286	9.89	30.980	
B287	9.89	30.957	
B288	9.99	31.029	
B289	9.94	31.201	

ID-Nr. LOT 57130101	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B290	9.99	31.095	
B291	10.15	30.856	
B292	10.14	31.050	
B293	10.03	31.104	
B294	10.11	31.096	
B295	9.97	30.905	
B296	10.07	31.003	
B297	9.94	31.127	
B298	10.06	29.463	
B299	9.96	30.840	
B300	9.99	31.297	
B301	10.05	30.855	
B302	10.04	30.994	
B303	9.92	31.189	
B304	9.99	31.024	
B305	9.99	31.000	
B306	9.90	31.064	
B307	10.01	30.994	
B308	9.93	31.140	
B309	10.06	31.172	
B310	9.95	31.010	
B311	9.93	30.975	
B312	10.07	30.892	
B313	10.04	31.089	
B314	10.08	30.932	
B315	9.98	30.935	
B316	10.06	31.080	
B317	10.06	29.743	
B318	10.13	31.001	

ID-Nr. LOT 57130101	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B319	10.04	30.872	
B320	10.00	31.003	
B321	10.10	30.925	
B322	10.10	31.043	
B323	10.09	31.006	
B324	9.98	30.988	
B325	9.93	30.937	
B326	9.96	31.057	
B327	9.96	29.608	
B328	9.98	30.864	
B329	9.94	31.006	
B330	10.00	31.112	
B331	10.02	31.021	
B332	9.99	30.920	
B333	10.03	31.052	
B334	10.02	30.875	
B335	10.05	31.160	
B336	10.01	30.936	
B337	9.94	30.944	
B338	10.11	30.839	
B339	9.94	30.985	
B340	9.97	31.169	
B341	10.00	30.985	
B342	10.08	31.099	
B343	9.94	30.880	
B344	9.95	31.040	
B345	9.92	30.828	
B346	9.97	31.136	
B347	9.88	31.023	

ID-Nr. LOT 57130101	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B348	9.97	31.093	
B349	10.06	30.924	
B350	10.03	31.164	
B351	9.98	30.967	
B352	9.98	30.943	
B353	10.09	31.135	
B354	10.02	30.869	
B355	10.02	31.170	
B356	9.93	30.989	
B357	9.94	31.004	
B358	10.04	30.832	
B359	9.89	31.095	
B360	10.04	30.950	
B361	10.00	30.919	
B362	9.89	31.060	
B363	10.01	31.225	
B364	9.88	31.062	
B365	10.02	30.961	
B366	10.04	31.018	
B367	9.88	31.077	
B368	9.91	30.990	
B369	10.14	31.168	
B370	10.15	30.997	
B371	9.97	30.994	
B372	9.96	31.017	
B373	9.94	30.913	
B374	9.93	31.193	
B375	10.07	30.970	
B376	9.99	31.123	

ID-Nr. LOT 57130101	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B377	9.89	31.001	
B378	9.91	30.946	
B379	9.87	30.874	
B380	10.00	31.001	
B381	10.12	31.123	
B382	10.09	31.145	
B383	10.13	30.892	
B384	10.04	30.869	
B385	9.89	30.992	
B386	9.90	30.945	
B387	9.92	31.033	
B388	10.04	30.897	
B389	9.92	31.055	
B390	9.96	30.977	
B391	9.94	30.980	
B392	10.05	30.899	
B393	9.98	30.894	
B394	10.06	30.925	
B395	10.02	30.925	
B396	10.05	30.943	
B397	10.06	31.228	
B398	10.06	30.993	
B399	10.03	31.012	
B400	10.06	31.327	
B401	10.04	30.838	
B402	9.98	30.882	
B403	9.96	31.225	
B404	10.12	30.982	
B405	10.03	30.976	

ID-Nr. LOT 57130101	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B406	9.97	31.188	
B407	9.97	31.126	
B408	9.92	30.806	
B409	9.90	31.089	
B410	9.95	30.995	
B411	10.06	31.136	
B412	10.09	31.016	
B413	10.08	31.099	
B414	9.98	30.943	
B415	10.07	31.078	
B416	10.01	31.069	
B417	9.95	31.047	
B418	9.91	31.007	
B419	9.90	30.915	
B420	9.91	31.267	
B421	10.01	31.088	
B422	10.06	31.116	
B423	9.87	31.172	
B424	9.90	31.159	
B425	9.87	31.070	
B426	9.91	31.063	
B427	9.99	31.151	
B428	10.01	31.026	
B429	9.94	30.926	
B430	10.07	31.079	
B431	10.11	30.958	
B432	10.02	31.133	
B433	9.97	31.443	
B434	10.01	31.302	

ID-Nr. LOT 57130101	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B435	9.97	30.998	
B436	9.90	31.045	
B437	10.02	30.916	
B438	9.94	31.165	
B439	10.01	31.077	
B440	10.00	31.209	
B441	10.11	30.978	
B442	10.01	31.271	
B443	10.08	30.901	
B444	10.02	30.978	
B445	10.06	31.229	
B446	10.10	30.983	
B447	9.91	31.227	
B448	9.92	30.997	
B449	9.91	31.007	
B450	10.06	31.210	
B451	10.00	31.290	
B452	9.94	31.280	
B453	9.87	31.367	
B454	10.01	30.970	
B455	10.05	31.012	
B456	10.08	31.029	
B457	9.90	31.100	
B458	10.08	30.840	
B459	9.92	31.201	
B460	10.02	31.267	
B461	10.07	30.958	
B462	10.10	31.060	
B463	9.93	30.845	

ID-Nr. LOT 57130101	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B464	10.04	31.277	
B465	10.14	30.923	
B466	10.08	31.257	
B467	10.08	30.948	
B468	9.97	31.277	
B469	10.06	30.974	
B470	9.97	30.798	
B471	10.10	31.144	
B472	9.99	31.008	
B473	10.03	30.948	
B474	9.95	30.891	
B475	10.02	30.927	
B476	10.11	30.885	
B477	10.02	31.011	
B478	9.97	30.929	
B479	9.98	31.178	
B480	9.94	31.101	
B481	9.99	30.919	
B482	10.07	31.017	
B483	9.91	31.189	
B484	9.95	30.986	
B485	9.96	30.892	
B486	9.92	30.913	
B487	10.02	30.873	
B488	9.92	31.001	
B489	9.99	30.964	
B490	9.96	30.927	
B491	10.00	31.400	
B492	10.12	31.112	

ID-Nr. LOT 57130101	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B493	9.97	30.971	
B494	10.00	31.019	
B495	9.93	31.058	
B496	9.98	29.687	
B497	9.98	31.251	
B498	10.12	30.308	
B499	9.95	31.069	
B500	10.00	30.972	
B501	10.02	31.071	
B502	9.97	30.798	
B503	9.95	31.161	
B504	9.94	31.216	
B505	9.88	30.816	
B506	10.04	30.973	
B507	10.03	31.227	
B508	10.07	31.133	
B509	9.97	31.313	
B510	10.03	30.821	
B511	9.96	31.022	
B512	10.14	31.007	
B513	10.10	30.864	
B514	10.02	31.019	
B515	9.91	31.161	
B516	9.91	31.241	
B517	10.01	30.877	
B518	10.09	30.843	
B519	10.03	31.201	
B520	10.10	30.948	
B521	9.98	31.006	

ID-Nr. LOT 57130101	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B522	10.04	31.223	
B523	9.89	31.227	
B524	10.05	31.128	
B525	10.09	30.965	
B526	10.07	31.069	
B527	10.06	30.749	
B528	10.14	30.956	
B529	10.07	30.987	
B530	10.06	30.921	
B531	10.10	30.974	
B532	10.09	31.034	
B533	10.10	30.846	
B534	9.92	31.256	
B535	9.94	30.863	
B536	9.95	30.911	
B537	9.90	31.009	
B538	10.06	30.950	
B539	10.03	30.912	
B540	10.06	30.885	
B541	10.00	30.900	
B542	10.05	31.286	
B543	10.01	30.992	
B544	10.06	31.295	
B545	10.07	30.986	
B546	10.15	31.390	
B547	9.96	31.004	
B548	10.02	31.266	
B549	10.01	31.002	
B550	10.15	30.878	

ID-Nr. LOT 57130101	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B551	10.08	31.147	
B552	10.07	31.032	
B553	9.95	31.248	
B554	10.01	30.850	
B555	10.08	30.970	
B556	10.14	30.976	
B557	9.92	30.953	
B558	9.96	31.020	
B559	10.00	31.277	
B560	10.02	30.890	

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

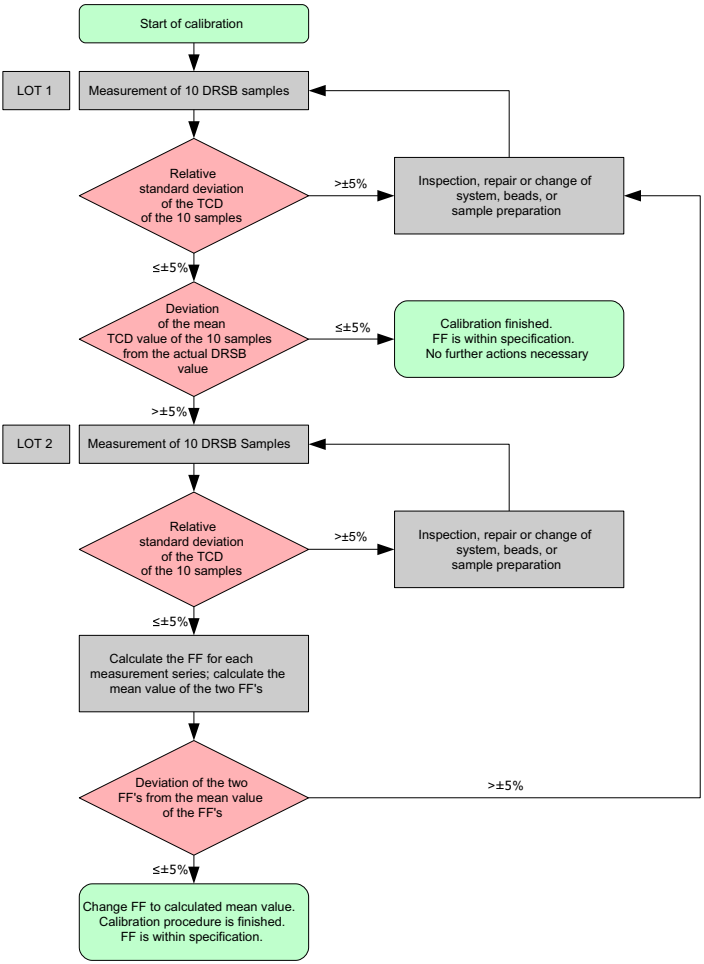

Fig. 2: Calibration Cedex HiRes Analyzer

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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