For use in quality control/
manufacturing process only.

Density Reference Standard Beads (DRSB)

Version 46

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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. 57130087

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 57130087	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B1	10.07	30.077	
B2	10.08	29.764	
B3	10.02	29.788	
B4	9.85	30.061	
B5	9.90	30.021	
B6	10.16	29.737	
B7	10.14	30.045	
B8	10.05	29.648	
B9	10.05	29.831	
B10	9.87	29.792	
B11	10.21	29.969	
B12	10.24	29.808	
B13	9.89	29.723	
B14	10.06	29.704	
B15	9.97	29.911	
B16	10.16	29.882	
B17	9.89	29.897	
B18	9.94	29.943	
B19	10.08	29.816	
B20	10.05	29.910	
B21	9.97	29.893	
B22	9.84	30.326	
B23	10.07	29.731	
B24	9.98	29.960	
B25	10.06	29.564	
B26	9.99	29.883	
B27	10.08	29.640	
B28	10.04	29.893	
B29	9.92	30.053	

ID-Nr. LOT 57130087	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B30	9.99	29.857	
B31	9.98	29.870	
B32	10.01	29.739	
B33	9.98	29.824	
B34	10.16	29.363	
B35	9.90	30.043	
B36	10.12	29.388	
B37	9.97	29.858	
B38	10.00	29.580	
B39	9.93	29.839	
B40	10.07	30.052	
B41	10.04	29.564	
B42	9.97	30.239	
B43	10.24	29.501	
B44	10.08	29.987	
B45	10.05	30.456	
B46	10.11	30.142	
B47	10.01	29.619	
B48	10.06	29.741	
B49	10.09	29.998	
B50	10.06	29.676	
B51	10.18	29.777	
B52	10.08	29.916	
B53	10.04	29.852	
B54	10.05	29.728	
B55	10.00	29.904	
B56	10.11	30.202	
B57	9.92	30.032	
B58	10.11	29.681	

ID-Nr. LOT 57130087	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B59	10.13	29.452	
B60	10.01	29.770	
B61	10.00	30.219	
B62	9.96	29.851	
B63	9.90	29.766	
B64	10.02	29.836	
B65	10.14	29.866	
B66	10.14	29.901	
B67	10.03	29.447	
B68	10.09	30.038	
B69	9.98	29.807	
B70	10.16	29.858	
B71	9.88	29.663	
B72	9.98	29.616	
B73	10.05	29.475	
B74	10.04	30.003	
B75	9.95	29.694	
B76	9.89	29.568	
B77	10.15	29.892	
B78	10.11	30.003	
B79	9.97	29.895	
B80	9.90	30.147	
B81	10.05	29.760	
B82	10.15	30.170	
B83	9.99	29.570	
B84	10.00	29.660	
B85	9.87	30.072	
B86	9.86	29.784	
B87	9.98	29.719	

ID-Nr. LOT 57130087	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B88	10.06	30.079	
B89	9.93	29.666	
B90	10.03	29.977	
B91	10.04	29.920	
B92	9.89	29.509	
B93	10.10	29.680	
B94	9.92	30.006	
B95	9.96	29.612	
B96	9.93	29.646	
B97	9.89	29.761	
B98	10.12	29.812	
B99	9.90	29.774	
B100	10.03	29.632	
B101	10.07	29.719	
B102	10.14	29.711	
B103	10.15	29.809	
B104	10.15	29.869	
B105	10.08	29.697	
B106	9.80	29.761	
B107	10.01	29.752	
B108	10.06	29.681	
B109	10.17	29.769	
B110	10.05	29.819	
B111	9.98	29.534	
B112	9.96	29.742	
B113	9.83	29.743	
B114	9.97	29.673	
B115	10.17	29.781	
B116	10.11	29.768	

ID-Nr. LOT 57130087	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B117	10.09	29.687	
B118	9.84	30.382	
B119	10.09	29.781	
B120	10.14	29.699	
B121	10.07	29.614	
B122	10.07	29.781	
B123	10.06	29.682	
B124	10.08	29.678	
B125	10.17	29.674	
B126	9.85	29.742	
B127	10.18	29.865	
B128	10.14	29.708	
B129	10.03	29.593	
B130	10.15	29.627	
B131	10.20	29.490	
B132	10.13	29.848	
B133	9.98	29.996	
B134	10.15	29.848	
B135	10.00	29.795	
B136	10.13	29.737	
B137	10.06	29.773	
B138	10.22	29.632	
B139	10.05	29.715	
B140	10.00	29.819	
B141	10.07	30.143	
B142	10.14	30.071	
B143	10.15	29.744	
B144	10.13	29.682	
B145	10.04	29.656	

ID-Nr. LOT 57130087	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B146	10.13	29.638	
B147	9.97	29.673	
B148	10.13	29.818	
B149	9.86	29.771	
B150	10.19	29.944	
B151	9.97	29.669	
B152	10.02	29.640	
B153	10.15	29.711	
B154	10.05	29.559	
B155	10.02	29.636	
B156	10.08	29.656	
B157	10.08	29.742	
B158	10.08	29.484	
B159	10.21	29.676	
B160	10.12	29.762	
B161	10.14	29.605	
B162	10.07	29.774	
B163	9.85	29.809	
B164	10.12	29.751	
B165	10.12	30.147	
B166	10.09	29.672	
B167	10.08	30.243	
B168	10.13	29.717	
B169	10.04	29.686	
B170	10.06	29.559	
B171	10.08	29.395	
B172	10.08	29.520	
B173	10.03	29.710	
B174	9.97	29.808	

ID-Nr. LOT 57130087	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B175	9.91	29.608	
B176	10.09	29.775	
B177	10.05	29.957	
B178	10.02	29.738	
B179	9.93	29.754	
B180	10.03	30.064	
B181	10.08	29.962	
B182	10.09	29.749	
B183	10.02	29.794	
B184	9.96	29.648	
B185	10.15	29.722	
B186	9.92	29.660	
B187	10.15	29.795	
B188	10.13	29.691	
B189	10.02	29.751	
B190	10.00	29.773	
B191	10.09	29.934	
B192	9.96	29.885	
B193	10.07	29.786	
B194	10.07	29.867	
B195	10.02	29.827	
B196	10.17	29.711	
B197	9.89	29.816	
B198	10.13	29.784	
B199	10.03	29.722	
B200	10.05	30.026	
B201	10.09	29.809	
B202	10.04	30.060	
B203	10.04	30.109	

ID-Nr. LOT 57130087	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B204	10.10	29.777	
B205	10.18	29.606	
B206	10.02	29.868	
B207	10.10	30.078	
B208	10.05	29.995	
B209	9.99	29.770	
B210	10.10	29.850	
B211	10.13	30.087	
B212	10.08	29.788	
B213	9.98	29.821	
B214	10.10	29.777	
B215	10.08	30.138	
B216	10.04	30.034	
B217	10.15	30.021	
B218	10.12	29.550	
B219	10.11	29.672	
B220	9.94	30.113	
B221	10.02	29.503	
B222	10.15	29.754	
B223	10.10	29.743	
B224	10.11	29.675	
B225	10.05	29.766	
B226	10.09	29.702	
B227	9.94	29.702	
B228	10.06	29.466	
B229	10.06	30.063	
B230	9.92	29.929	
B231	10.10	29.808	
B232	10.12	29.724	

ID-Nr. LOT 57130087	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B233	10.06	29.857	
B234	10.02	29.737	
B235	10.11	30.012	
B236	10.08	29.643	
B237	10.00	30.074	
B238	10.13	29.779	
B239	10.03	29.855	
B240	10.12	30.039	
B241	10.13	29.902	
B242	10.05	30.101	
B243	10.13	29.813	
B244	10.02	29.923	
B245	9.97	30.272	
B246	9.98	29.997	
B247	9.91	29.672	
B248	10.02	29.771	
B249	10.11	29.530	
B250	9.93	29.829	
B251	10.04	29.903	
B252	9.94	29.826	
B253	10.01	29.642	
B254	10.13	29.430	
B255	10.13	29.917	
B256	10.02	29.637	
B257	10.06	29.577	
B258	10.02	29.944	
B259	10.02	29.880	
B260	10.03	29.820	
B261	10.05	30.952	

ID-Nr. LOT 57130087	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B262	9.96	29.961	
B263	9.91	29.883	
B264	9.97	29.641	
B265	9.98	29.518	
B266	10.09	29.788	
B267	10.06	29.723	
B268	10.08	29.494	
B269	10.08	29.681	
B270	10.10	29.845	
B271	10.01	29.979	
B272	9.95	29.606	
B273	10.00	29.394	
B274	10.07	29.641	
B275	9.91	29.808	
B276	10.09	29.882	
B277	9.92	29.686	
B278	10.00	29.588	
B279	9.97	29.506	
B280	10.11	29.900	
B281	9.99	29.590	
B282	10.05	29.931	
B283	10.06	29.754	
B284	10.09	29.946	
B285	10.07	29.613	
B286	10.05	29.664	
B287	10.10	29.616	
B288	10.02	29.682	
B289	10.09	29.890	
B290	9.92	29.594	

ID-Nr. LOT 57130087	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B291	10.01	29.827	
B292	10.01	29.528	
B293	9.95	29.861	
B294	10.08	29.756	
B295	10.04	29.863	
B296	10.01	29.924	
B297	10.04	29.892	
B298	10.09	30.070	
B299	10.06	29.961	
B300	10.01	29.927	
B301	10.04	29.814	
B302	10.08	29.994	
B303	10.05	30.136	
B304	10.05	30.168	
B305	9.94	30.111	
B306	10.04	29.924	
B307	10.07	29.961	
B308	10.00	30.036	
B309	9.99	29.815	
B310	10.14	30.041	
B311	10.12	30.080	
B312	10.14	29.963	
B313	10.06	30.017	
B314	10.20	29.916	
B315	10.20	29.865	
B316	10.12	29.846	
B317	10.18	29.821	
B318	10.21	29.952	
B319	10.19	29.741	

ID-Nr. LOT 57130087	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B320	10.07	29.962	
B321	10.04	29.876	
B322	10.09	29.792	
B323	10.12	29.867	
B324	10.13	29.993	
B325	10.19	29.781	
B326	10.04	29.886	
B327	10.07	30.032	
B328	9.94	30.025	
B329	9.92	29.830	
B330	9.93	29.950	
B331	10.10	29.964	
B332	10.09	29.925	
B333	10.15	29.965	
B334	10.08	29.847	
B335	10.09	29.869	
B336	10.09	29.871	
B337	10.00	29.900	
B338	10.00	29.626	
B339	10.06	29.918	
B340	10.07	29.803	
B341	10.14	29.832	
B342	10.04	29.799	
B343	10.04	29.999	
B344	10.08	29.955	
B345	10.07	29.942	
B346	10.07	30.015	
B347	10.06	29.883	
B348	9.97	29.998	

ID-Nr. LOT 57130087	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B349	10.05	30.029	
B350	10.06	30.213	
B351	10.04	29.819	
B352	10.12	29.969	
B353	10.05	29.925	
B354	10.11	30.036	
B355	9.98	30.140	
B356	10.11	29.843	
B357	9.91	29.864	
B358	10.08	29.902	
B359	10.01	29.935	
B360	10.01	29.838	
B361	9.97	29.910	
B362	10.17	29.960	
B363	10.13	29.802	
B364	10.03	29.769	
B365	10.11	29.820	
B366	10.01	29.858	
B367	9.99	29.899	
B368	10.07	29.880	
B369	10.01	30.003	
B370	9.98	29.918	
B371	9.96	29.867	
B372	10.08	30.000	
B373	9.98	30.072	
B374	10.12	29.999	
B375	9.92	29.883	
B376	10.04	30.067	
B377	10.13	29.810	

ID-Nr. LOT 57130087	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B378	9.99	29.960	
B379	9.98	29.946	
B380	9.99	29.893	
B381	10.04	29.939	
B382	10.08	30.113	
B383	10.02	29.915	
B384	10.01	30.043	
B385	10.09	29.951	
B386	10.03	29.926	
B387	10.02	29.984	
B388	10.02	30.043	
B389	9.91	30.020	
B390	9.86	30.014	
B391	10.09	29.965	
B392	10.02	30.071	
B393	10.05	29.963	
B394	9.93	30.030	
B395	9.99	29.955	
B396	9.97	30.091	
B397	9.94	29.959	
B398	10.08	29.955	
B399	10.11	29.962	
B400	10.04	30.039	
B401	9.99	29.548	
B402	10.08	30.003	
B403	10.10	29.953	
B404	10.15	30.123	
B405	10.06	29.869	
B406	10.13	29.838	

ID-Nr. LOT 57130087	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B407	10.13	30.094	
B408	10.01	29.946	
B409	10.09	29.985	
B410	10.03	29.972	
B411	10.07	29.892	
B412	10.00	29.817	
B413	10.14	30.002	
B414	10.08	29.917	
B415	10.01	29.990	
B416	10.06	30.114	
B417	10.06	29.835	
B418	10.06	29.853	
B419	10.08	30.072	
B420	10.15	29.983	
B421	10.09	29.931	
B422	9.87	30.086	
B423	10.00	29.942	
B424	9.99	29.726	
B425	10.17	29.981	
B426	10.19	30.069	
B427	9.99	30.003	
B428	10.20	30.179	
B429	10.02	29.902	
B430	10.14	30.034	
B431	10.02	29.938	
B432	10.05	29.971	
B433	10.05	29.971	
B434	9.90	29.833	
B435	10.11	29.816	

ID-Nr. LOT 57130087	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B436	10.06	29.954	
B437	9.97	29.887	
B438	10.05	29.929	
B439	10.00	29.593	
B440	10.07	29.965	
B441	10.09	29.966	
B442	9.97	30.144	
B443	10.01	29.975	
B444	10.01	29.841	
B445	10.07	29.924	
B446	9.89	29.990	
B447	10.10	29.981	
B448	10.07	30.196	
B449	9.95	30.001	
B450	10.07	30.044	
B451	10.05	29.986	
B452	10.11	29.952	
B453	10.02	30.045	
B454	10.08	29.928	
B455	10.11	30.008	
B456	9.96	30.937	
B457	9.98	29.853	
B458	9.94	29.966	
B459	10.10	30.165	
B460	10.14	30.059	
B461	10.04	30.079	
B462	9.88	30.130	
B463	10.12	29.917	
B464	10.21	29.850	

ID-Nr. LOT 57130087	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B465	10.03	29.944	
B466	10.06	29.892	
B467	9.82	29.994	
B468	9.97	30.116	
B469	10.18	29.904	
B470	10.20	30.102	
B471	10.23	29.990	
B472	10.10	29.851	
B473	10.19	29.820	
B474	10.17	29.881	
B475	10.03	29.774	
B476	10.07	30.230	
B477	10.12	29.993	
B478	10.10	29.742	
B479	10.15	29.824	
B480	9.93	30.024	
B481	10.05	29.963	
B482	10.08	30.093	
B483	10.07	30.121	
B484	10.08	29.823	
B485	10.02	30.049	
B486	10.04	29.842	
B487	10.09	29.753	
B488	10.00	30.032	
B489	10.08	29.777	
B490	10.17	29.757	
B491	10.02	30.145	
B492	10.08	29.881	
B493	9.98	29.860	

ID-Nr. LOT 57130087	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B494	9.86	30.098	
B495	10.05	29.911	
B496	9.94	29.890	
B497	9.91	29.738	
B498	9.93	30.047	
B499	9.99	30.064	
B500	10.04	29.826	
B501	10.02	29.823	
B502	9.93	29.883	
B503	10.05	29.893	
B504	10.10	29.964	
B505	9.96	30.052	
B506	10.04	29.870	
B507	9.97	30.043	
B508	9.90	29.766	
B509	10.04	29.721	
B510	9.99	29.740	
B511	10.10	29.687	
B512	10.05	29.875	
B513	10.05	29.614	
B514	9.99	29.604	
B515	9.98	29.758	
B516	9.88	29.483	
B517	9.92	29.584	
B518	9.98	29.574	
B519	9.93	29.833	
B520	10.02	30.177	
B521	10.08	30.139	
B522	10.03	29.718	

ID-Nr. LOT 57130087	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B523	10.10	29.929	
B524	10.17	29.720	
B525	10.18	29.492	
B526	10.11	29.551	
B527	10.00	30.244	
B528	10.01	30.508	
B529	10.09	29.676	
B530	9.99	29.450	
B531	10.22	29.814	
B532	9.85	30.176	
B533	10.09	29.690	
B534	10.00	29.933	
B535	10.09	29.903	
B536	10.02	29.408	
B537	10.06	29.662	
B538	10.11	29.955	
B539	9.93	29.692	
B540	10.03	29.621	
B541	10.12	29.576	
B542	10.04	29.619	
B543	10.13	29.782	
B544	10.00	29.588	
B545	10.07	29.779	
B546	10.05	29.627	
B547	10.09	29.599	
B548	10.06	29.662	
B549	10.13	30.006	
B550	10.18	29.631	
B551	9.92	29.587	

ID-Nr. LOT 57130087	Concentration Particle number/ml (10^5)	weight (g)	Bottle received
B552	9.97	29.447	
B553	10.01	29.780	
B554	10.17	29.666	
B555	10.08	29.614	
B556	10.10	29.853	
B557	10.10	30.006	
B558	10.12	29.631	
B559	10.13	29.841	
B560	10.00	29.624	

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

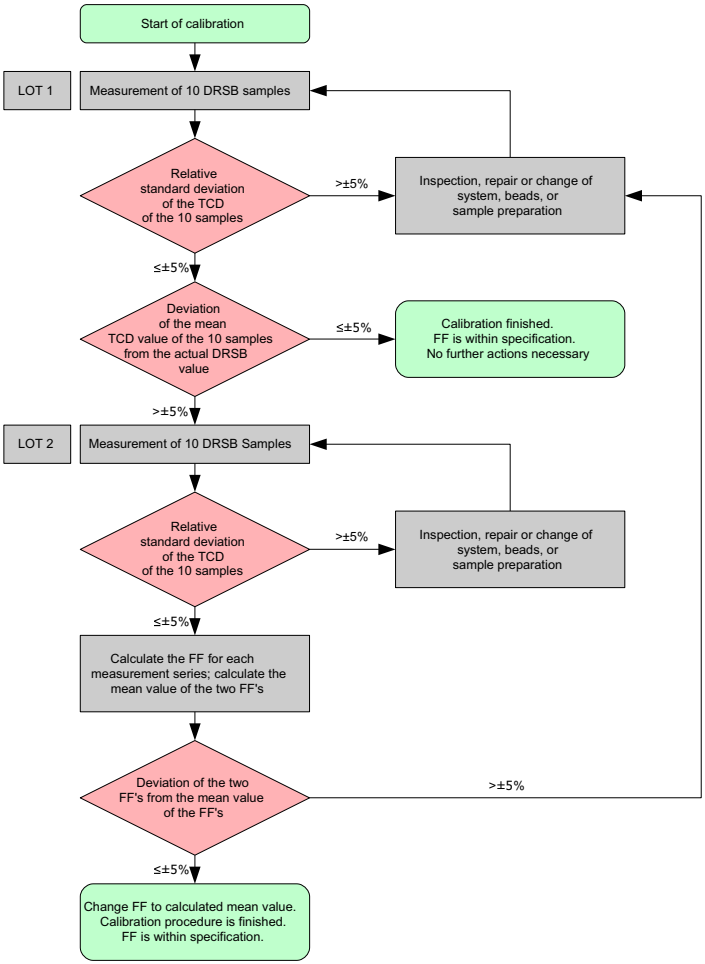

Fig. 2: Calibration Cedex HiRes Analyzer

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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