For use in quality control/
manufacturing process only.

Density Reference Standard Beads (DRSB)

Version 59

Content version: March 2022

Beads for one-point density calibration

Cat. No. 06 422 659 001 Batch A

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	06 422 659 001

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. 06 422 659 001, Batch A

Valid for Lot. No. 57130079

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

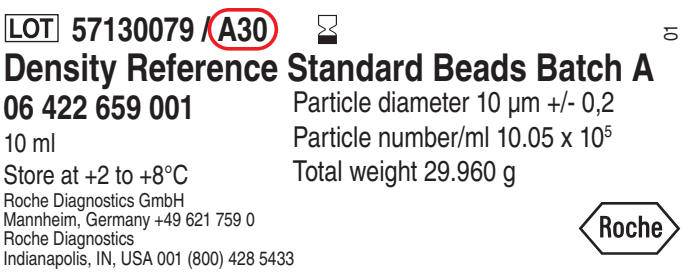

Fig. 1: Example of how to find the bottle number on the bottle label. The bottle number is circled.

ID-Nr. LOT 57130079	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A1	10.04	29.711	
A2	10.21	30.453	
A3	10.23	29.566	
A4	10.01	29.834	
A5	9.98	30.150	
A6	9.87	29.801	
A7	9.83	29.877	
A8	9.94	30.066	
A9	10.10	29.925	
A10	9.99	29.878	
A11	9.92	29.592	
A12	10.06	29.866	
A13	9.90	29.651	
A14	10.04	30.123	
A15	10.07	29.743	
A16	10.07	30.097	
A17	10.19	30.138	
A18	9.84	29.890	
A19	10.07	30.110	
A20	10.27	29.655	
A21	10.19	29.643	
A22	10.21	29.780	
A23	10.12	29.861	
A24	10.07	29.697	
A25	10.30	29.633	
A26	10.24	29.629	
A27	10.12	29.683	
A28	10.18	29.627	
A29	10.00	29.576	

ID-Nr. LOT 57130079	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A30	10.16	29.663	
A31	10.14	29.736	
A32	10.29	29.678	
A33	10.12	29.659	
A34	10.09	29.669	
A35	10.29	30.218	
A36	9.76	29.916	
A37	9.98	29.937	
A38	10.14	29.931	
A39	9.85	29.826	
A40	9.97	29.903	
A41	9.91	30.006	
A42	10.23	29.632	
A43	9.97	29.802	
A44	9.88	29.876	
A45	9.82	30.157	
A46	9.87	30.059	
A47	10.15	29.712	
A48	9.90	29.718	
A49	9.81	29.940	
A50	9.80	30.142	
A51	9.75	29.853	
A52	9.85	29.830	
A53	9.95	29.932	
A54	9.84	29.801	
A55	9.92	29.792	
A56	9.93	30.149	
A57	9.85	29.827	
A58	9.92	29.812	

ID-Nr. LOT 57130079	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A59	9.99	29.984	
A60	9.81	29.901	
A61	10.22	30.126	
A62	9.86	29.884	
A63	9.88	30.042	
A64	10.16	30.030	
A65	10.22	30.075	
A66	10.11	29.980	
A67	9.89	30.096	
A68	10.04	30.007	
A69	10.07	30.096	
A70	9.87	29.905	
A71	10.00	29.911	
A72	9.81	30.090	
A73	10.04	29.794	
A74	9.88	30.103	
A75	9.96	29.921	
A76	9.93	29.895	
A77	9.77	29.785	
A78	10.23	29.943	
A79	10.23	29.687	
A80	9.91	29.901	
A81	10.01	30.135	
A82	10.00	29.944	
A83	10.10	29.689	
A84	9.83	29.772	
A85	10.13	29.960	
A86	9.97	29.788	
A87	10.24	29.814	

ID-Nr. LOT 57130079	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A88	10.16	29.798	
A89	10.07	30.090	
A90	10.20	29.738	
A91	10.08	29.967	
A92	9.91	29.804	
A93	10.06	29.799	
A94	10.02	30.007	
A95	9.79	30.031	
A96	9.97	29.735	
A97	9.94	29.975	
A98	10.12	29.961	
A99	10.00	29.956	
A100	10.01	29.959	
A101	9.97	29.993	
A102	9.94	29.746	
A103	9.91	29.722	
A104	10.04	30.210	
A105	10.01	30.113	
A106	9.98	29.815	
A107	9.82	30.125	
A108	9.91	29.934	
A109	10.13	30.176	
A110	10.05	29.698	
A111	9.88	30.095	
A112	10.21	29.724	
A113	10.21	29.917	
A114	10.01	29.865	
A115	9.88	30.120	
A116	9.81	30.022	

ID-Nr. LOT 57130079	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A117	9.76	29.885	
A118	9.76	30.210	
A119	10.07	29.975	
A120	10.05	29.940	
A121	9.75	29.794	
A122	10.08	30.073	
A123	9.94	30.092	
A124	9.96	30.075	
A125	9.90	29.796	
A126	10.03	30.097	
A127	10.18	30.249	
A128	10.17	30.085	
A129	9.74	29.986	
A130	9.92	29.898	
A131	9.84	29.788	
A132	9.84	29.802	
A133	10.07	30.170	
A134	9.92	30.162	
A135	9.85	29.967	
A136	9.79	30.062	
A137	10.05	29.668	
A138	10.06	29.963	
A139	10.07	30.151	
A140	10.14	29.927	
A141	10.00	30.015	
A142	9.93	30.171	
A143	9.97	29.961	
A144	9.89	29.900	
A145	10.07	29.644	

ID-Nr. LOT 57130079	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A146	10.02	30.099	
A147	9.97	30.196	
A148	10.14	30.062	
A149	10.08	30.079	
A150	10.21	30.203	
A151	10.17	30.213	
A152	10.14	30.354	
A153	10.22	30.095	
A154	10.21	30.120	
A155	10.12	30.047	
A156	9.79	30.181	
A157	10.01	30.267	
A158	9.99	29.949	
A159	9.91	30.014	
A160	9.88	29.952	
A161	9.99	30.146	
A162	9.89	29.818	
A163	10.19	30.179	
A164	10.07	29.881	
A165	9.97	29.861	
A166	9.91	29.904	
A167	10.12	30.032	
A168	10.09	30.020	
A169	10.23	29.949	
A170	9.90	29.785	
A171	10.16	29.938	
A172	9.87	29.816	
A173	9.89	30.109	
A174	9.86	30.065	

ID-Nr. LOT 57130079	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A175	9.97	29.842	
A176	9.91	30.147	
A177	9.97	29.847	
A178	9.82	29.785	
A179	9.99	30.047	
A180	9.93	29.810	
A181	9.80	30.064	
A182	9.82	30.042	
A183	9.98	29.963	
A184	9.81	30.029	
A185	10.12	30.058	
A186	10.04	30.004	
A187	9.91	30.114	
A188	9.99	30.227	
A189	10.03	30.199	
A190	9.84	29.996	
A191	10.14	29.981	
A192	9.90	29.895	
A193	9.93	30.170	
A194	10.03	30.277	
A195	10.00	30.104	
A196	9.86	30.105	
A197	10.16	29.919	
A198	10.25	30.058	
A199	9.89	29.853	
A200	9.89	29.846	
A201	9.90	30.289	
A202	10.16	29.993	
A203	10.16	29.964	

ID-Nr. LOT 57130079	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A204	10.04	30.180	
A205	9.96	29.851	
A206	9.96	30.246	
A207	10.16	30.163	
A208	9.89	29.823	
A209	10.03	30.247	
A210	9.88	29.991	
A211	9.99	29.812	
A212	9.90	29.901	
A213	10.07	30.026	
A214	9.84	30.259	
A215	9.91	30.115	
A216	9.77	29.900	
A217	9.93	29.902	
A218	9.97	29.741	
A219	9.85	29.990	
A220	9.92	30.223	
A221	10.29	30.107	
A222	9.94	30.178	
A223	9.99	29.661	
A224	10.04	30.000	
A225	10.15	30.089	
A226	9.98	29.972	
A227	9.95	29.592	
A228	10.00	30.005	
A229	9.93	30.018	
A230	9.89	29.861	
A231	10.16	29.739	
A232	10.17	29.624	

ID-Nr. LOT 57130079	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A233	9.90	29.744	
A234	9.98	29.926	
A235	9.84	29.802	
A236	9.96	29.714	
A237	9.83	29.776	
A238	9.88	29.873	
A239	9.83	29.638	
A240	9.91	29.698	
A241	9.81	29.805	
A242	9.86	29.883	
A243	9.85	29.847	
A244	10.05	29.520	
A245	9.98	29.828	
A246	9.74	29.909	
A247	10.16	29.823	
A248	9.95	29.806	
A249	9.95	29.945	
A250	9.87	29.890	
A251	9.98	29.940	
A252	10.02	29.918	
A253	9.99	29.862	
A254	9.94	30.260	
A255	10.12	30.024	
A256	10.06	30.240	
A257	9.95	29.774	
A258	10.15	30.234	
A259	10.09	30.113	
A260	10.02	30.111	
A261	9.89	30.155	

ID-Nr. LOT 57130079	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A262	9.95	30.161	
A263	9.83	30.080	
A264	10.05	30.180	
A265	9.76	30.106	
A266	9.85	30.081	
A267	9.83	30.130	
A268	9.94	30.158	
A269	9.92	30.206	
A270	9.86	30.129	
A271	9.99	29.649	
A272	10.01	29.834	
A273	10.00	30.215	
A274	9.71	29.811	
A275	9.89	29.956	
A276	9.87	29.689	
A277	9.97	29.743	
A278	10.14	30.018	
A279	10.02	29.833	
A280	10.13	29.627	
A281	10.17	30.166	
A282	10.06	30.083	
A283	9.92	29.763	
A284	10.10	30.269	
A285	10.29	30.262	
A286	10.15	30.267	
A287	9.96	30.405	
A288	9.90	30.183	
A289	10.05	30.145	
A290	10.05	29.778	

ID-Nr. LOT 57130079	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A291	9.89	30.213	
A292	10.02	30.085	
A293	10.24	30.263	
A294	10.21	30.219	
A295	10.20	30.182	
A296	10.25	30.198	
A297	10.20	30.111	
A298	9.86	30.132	
A299	10.31	30.197	
A300	10.16	30.225	
A301	9.83	30.206	
A302	9.82	30.093	
A303	9.81	30.147	
A304	10.17	30.081	
A305	9.87	30.170	
A306	9.93	30.307	
A307	10.01	29.576	
A308	9.96	30.314	
A309	10.05	30.227	
A310	10.03	30.123	
A311	10.06	29.813	
A312	10.15	30.198	
A313	9.88	30.133	
A314	10.21	30.293	
A315	10.10	30.220	
A316	10.11	30.149	
A317	10.09	29.766	
A318	10.04	30.127	
A319	10.13	29.975	

ID-Nr. LOT 57130079	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A320	10.11	30.227	
A321	9.82	30.123	
A322	10.02	30.152	
A323	9.94	29.724	
A324	9.95	29.851	
A325	9.86	29.833	
A326	10.03	29.903	
A327	9.97	29.644	
A328	9.96	29.690	
A329	9.87	29.789	
A330	9.83	29.727	
A331	9.84	29.640	
A332	9.84	29.690	
A333	10.20	29.812	
A334	10.00	29.736	
A335	10.07	29.863	
A336	9.88	29.817	
A337	9.92	29.641	
A338	10.15	29.809	
A339	10.21	29.886	
A340	9.95	29.943	
A341	10.11	29.707	
A342	9.92	29.736	
A343	10.23	29.613	
A344	10.00	29.719	
A345	10.03	29.660	
A346	9.98	29.816	
A347	9.93	29.475	
A348	9.83	29.869	

ID-Nr. LOT 57130079	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A349	9.95	29.929	
A350	9.89	29.885	
A351	10.04	29.770	
A352	9.83	29.803	
A353	10.15	29.816	
A354	9.97	29.730	
A355	10.15	29.844	
A356	9.94	29.685	
A357	10.02	29.964	
A358	9.93	29.838	
A359	9.91	29.640	
A360	9.94	29.904	
A361	9.99	29.900	
A362	9.94	29.766	
A363	9.87	29.902	
A364	9.94	30.086	
A365	9.97	29.973	
A366	9.92	29.673	
A367	9.92	29.697	
A368	9.95	29.914	
A369	9.99	29.898	
A370	10.06	30.192	
A371	10.08	29.767	
A372	9.94	29.854	
A373	9.93	30.092	
A374	10.09	29.956	
A375	9.88	29.879	
A376	9.92	29.767	
A377	9.97	30.053	

ID-Nr. LOT 57130079	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A378	9.87	29.569	
A379	9.83	29.676	
A380	10.00	29.621	
A381	9.98	29.745	
A382	9.86	30.124	
A383	10.05	29.828	
A384	10.12	29.813	
A385	9.91	29.939	
A386	9.97	29.625	
A387	9.91	29.813	
A388	10.01	29.710	
A389	9.92	29.940	
A390	9.79	29.945	
A391	9.94	29.936	
A392	9.91	30.182	
A393	9.99	29.999	
A394	10.07	29.920	
A395	10.12	29.707	
A396	9.95	30.014	
A397	10.02	29.730	
A398	10.06	29.631	
A399	9.90	29.902	
A400	10.04	29.847	
A401	9.89	29.702	
A402	9.91	29.685	
A403	9.82	29.888	
A404	10.13	30.053	
A405	10.09	29.486	
A406	9.96	29.821	

ID-Nr. LOT 57130079	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A407	10.02	29.672	
A408	9.97	29.685	
A409	9.95	29.694	
A410	9.89	29.833	
A411	9.85	29.880	
A412	10.24	30.194	
A413	10.02	29.793	
A414	9.99	29.638	
A415	9.96	29.710	
A416	9.75	29.712	
A417	9.96	29.992	
A418	9.98	30.201	
A419	9.96	30.144	
A420	9.94	29.842	
A421	10.14	31.375	
A422	9.83	30.260	
A423	9.95	29.750	
A424	9.94	30.002	
A425	9.95	29.766	
A426	10.10	29.859	
A427	9.99	29.623	
A428	10.04	29.697	
A429	9.97	29.687	
A430	9.96	29.806	
A431	9.96	29.648	
A432	9.88	29.837	
A433	10.00	29.750	
A434	9.91	29.927	
A435	9.92	29.729	

ID-Nr. LOT 57130079	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A436	9.91	29.874	
A437	10.06	30.239	
A438	9.94	29.828	
A439	10.03	30.002	
A440	10.10	29.817	
A441	9.89	29.877	
A442	9.96	29.877	
A443	10.06	29.906	
A444	9.92	30.092	
A445	10.10	29.962	
A446	9.87	30.013	
A447	10.00	30.073	
A448	9.92	29.799	
A449	10.11	30.052	
A450	9.87	30.091	
A451	9.85	30.303	
A452	9.91	30.100	
A453	10.09	30.054	
A454	9.88	30.065	
A455	9.89	29.927	
A456	10.02	29.893	
A457	9.87	29.819	
A458	9.90	29.788	
A459	10.06	30.114	
A460	9.81	29.999	
A461	9.98	30.063	
A462	10.16	29.929	
A463	9.88	29.927	
A464	9.86	29.827	

ID-Nr. LOT 57130079	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A465	9.82	29.941	
A466	9.95	29.665	
A467	10.05	29.853	
A468	9.83	30.015	
A469	9.80	29.947	
A470	9.98	29.983	
A471	10.01	29.656	
A472	10.07	30.033	
A473	9.91	29.851	
A474	10.04	30.122	
A475	10.14	29.912	
A476	9.92	29.798	
A477	9.83	29.825	
A478	9.84	29.895	
A479	9.94	29.876	
A480	9.87	29.704	
A481	10.02	29.803	
A482	9.78	29.790	
A483	10.05	29.672	
A484	10.01	29.890	
A485	10.06	29.645	
A486	9.90	30.096	
A487	9.78	30.227	
A488	9.90	29.893	
A489	10.19	29.689	
A490	9.99	29.831	
A491	9.99	29.794	
A492	9.92	29.508	
A493	9.95	29.578	

ID-Nr. LOT 57130079	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A494	9.93	29.720	
A495	9.84	29.937	
A496	10.02	30.112	
A497	9.97	30.161	
A498	10.03	29.492	
A499	10.08	29.782	
A500	9.84	29.663	
A501	10.10	29.506	
A502	10.03	30.014	
A503	9.98	30.025	
A504	9.91	29.806	
A505	9.93	29.899	
A506	9.86	29.631	
A507	9.91	29.702	
A508	9.87	29.527	
A509	9.75	29.991	
A510	9.92	30.160	
A511	9.87	29.777	
A512	9.94	29.625	
A513	9.91	29.795	
A514	9.87	29.761	
A515	9.93	29.761	
A516	9.98	29.870	
A517	9.91	29.872	
A518	10.09	29.903	
A519	9.99	30.171	
A520	9.93	29.940	
A521	9.89	30.004	
A522	9.84	30.168	

ID-Nr. LOT 57130079	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A523	10.16	29.980	
A524	9.99	29.972	
A525	9.99	29.916	
A526	9.93	30.090	
A527	10.02	29.913	
A528	9.99	29.927	
A529	9.97	29.922	
A530	9.79	29.581	
A531	9.86	30.150	
A532	9.89	30.100	
A533	9.89	29.902	
A534	9.93	30.121	
A535	9.83	30.186	
A536	9.90	29.629	
A537	9.98	29.827	
A538	9.86	29.907	
A539	9.85	29.921	
A540	9.88	29.889	
A541	9.96	30.029	
A542	9.97	30.157	
A543	9.86	30.026	
A544	9.88	30.033	
A545	9.77	29.987	
A546	10.00	30.068	
A547	10.09	30.068	
A548	9.99	30.116	
A549	10.00	29.936	
A550	9.94	29.807	
A551	9.83	29.815	

ID-Nr. LOT 57130079	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A552	10.08	30.062	
A553	10.01	29.896	
A554	9.98	29.698	
A555	9.98	29.813	
A556	9.98	30.057	
A557	10.04	29.881	
A558	10.16	29.897	
A559	9.84	29.881	
A560	9.72	30.075	
A561	9.78	29.792	
A562	10.07	29.892	
A563	9.98	29.915	
A564	9.93	29.822	
A565	9.92	29.943	
A566	10.01	30.012	
A567	9.92	29.947	
A568	9.80	29.943	
A569	10.23	30.130	
A570	10.11	29.810	
A571	10.04	29.823	
A572	10.11	29.894	
A573	9.88	29.986	
A574	9.85	30.070	
A575	9.94	29.680	
A576	9.90	30.171	
A577	10.03	30.066	
A578	9.96	29.903	
A579	9.89	29.952	
A580	10.03	29.888	

ID-Nr. LOT 57130079	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A581	9.98	29.849	
A582	10.01	29.710	
A583	9.92	29.854	
A584	10.07	29.936	
A585	10.05	29.871	
A586	10.19	29.865	
A587	10.01	29.956	
A588	10.03	29.915	
A589	10.05	30.129	
A590	10.08	29.766	
A591	10.17	30.174	
A592	10.10	29.829	
A593	10.02	30.123	
A594	10.00	29.702	
A595	9.85	29.869	
A596	10.04	29.612	
A597	9.83	29.850	
A598	10.05	29.846	
A599	9.92	29.864	
A600	10.07	29.725	
A601	10.06	29.808	
A602	9.94	29.789	
A603	10.05	29.883	
A604	10.21	29.991	
A605	10.14	30.127	
A606	9.86	30.001	
A607	10.08	30.008	
A608	10.08	29.774	
A609	10.14	29.895	

ID-Nr. LOT 57130079	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A610	10.13	29.958	
A611	10.15	29.948	
A612	10.13	30.122	
A613	10.07	29.970	
A614	10.02	29.879	
A615	9.85	29.885	
A616	10.22	29.762	
A617	10.16	30.081	
A618	10.23	30.115	
A619	10.11	29.824	
A620	9.96	29.783	
A621	10.23	30.107	
A622	9.99	29.662	
A623	10.05	29.605	
A624	9.98	29.892	
A625	9.94	29.676	
A626	10.16	29.744	
A627	9.94	29.595	
A628	10.00	29.788	
A629	10.02	30.145	
A630	10.07	29.828	
A631	10.08	29.648	
A632	10.02	29.752	
A633	9.94	29.821	
A634	10.07	29.678	
A635	10.09	29.732	
A636	10.12	29.833	
A637	10.22	30.145	
A638	9.96	29.691	

ID-Nr. LOT 57130079	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A639	9.93	30.001	
A640	9.98	30.092	
A641	9.85	29.643	
A642	10.16	29.940	
A643	10.01	29.810	
A644	9.94	29.737	
A645	9.92	29.726	
A646	9.98	29.972	
A647	10.00	29.817	
A648	9.91	29.640	
A649	9.84	29.748	
A650	9.91	29.895	
A651	9.98	29.899	
A652	9.95	29.759	
A653	9.92	29.976	
A654	10.02	29.846	
A655	9.99	29.862	
A656	9.88	29.748	
A657	10.03	29.561	
A658	9.86	29.900	
A659	9.90	29.726	
A660	10.00	29.810	
A661	9.76	29.705	
A662	9.84	29.774	
A663	9.94	29.737	
A664	10.08	29.741	
A665	9.91	29.817	
A666	9.94	29.618	
A667	9.97	29.888	

ID-Nr. LOT 57130079	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A668	9.98	29.721	
A669	9.97	29.668	
A670	10.01	29.712	
A671	9.80	29.841	
A672	10.02	29.633	
A673	10.08	29.749	
A674	10.05	29.614	
A675	9.96	29.602	
A676	9.96	29.558	
A677	9.88	29.786	
A678	9.93	29.719	
A679	9.91	29.720	
A680	9.88	29.605	
A681	10.02	29.816	
A682	9.97	29.720	
A683	9.97	29.770	
A684	10.01	29.733	
A685	9.95	29.907	
A686	9.98	29.778	
A687	9.81	29.806	
A688	10.00	29.798	
A689	9.89	29.540	
A690	9.86	29.743	
A691	10.07	29.657	
A692	10.18	29.982	
A693	9.95	29.659	
A694	9.93	29.851	
A695	10.04	29.672	
A696	9.94	30.093	

ID-Nr. LOT 57130079	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A697	9.98	29.786	
A698	9.90	29.931	
A699	9.78	29.814	
A700	9.87	29.778	
A701	10.10	29.750	
A702	10.08	29.683	
A703	10.12	29.580	
A704	10.04	29.878	
A705	10.08	29.590	
A706	10.00	29.840	
A707	9.95	29.602	
A708	10.11	29.668	
A709	10.04	29.745	
A710	10.02	29.838	
A711	10.05	29.737	
A712	9.99	29.660	
A713	9.92	29.682	
A714	9.87	30.134	
A715	10.04	29.382	
A716	9.90	29.992	
A717	10.14	29.656	
A718	10.01	29.935	
A719	9.97	29.984	
A720	9.97	29.982	
A721	10.09	29.748	
A722	9.89	29.680	
A723	9.84	29.801	
A724	9.94	29.922	
A725	10.02	29.895	

ID-Nr. LOT 57130079	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A726	9.95	29.791	
A727	9.73	29.977	
A728	9.95	29.981	
A729	9.82	30.011	
A730	10.00	29.844	
A731	9.84	29.819	
A732	10.01	29.854	
A733	9.94	29.791	
A734	10.01	30.044	
A735	10.12	29.879	
A736	9.96	29.809	
A737	9.89	30.135	
A738	9.95	29.969	
A739	9.90	29.939	
A740	10.01	30.177	
A741	9.89	29.945	
A742	10.01	30.191	
A743	9.98	29.889	
A744	9.76	29.864	
A745	9.84	29.952	
A746	9.91	30.064	
A747	9.98	29.953	
A748	10.03	29.708	
A749	9.98	30.040	
A750	9.92	29.873	
A751	10.07	30.119	
A752	9.87	29.887	
A753	9.85	29.938	
A754	9.85	29.962	

ID-Nr. LOT 57130079	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A755	9.94	30.039	
A756	10.04	30.079	
A757	9.93	30.153	
A758	10.16	30.070	
A759	9.76	29.850	
A760	9.89	30.104	
A761	9.98	30.102	
A762	10.05	29.601	
A763	9.87	30.056	
A764	10.09	29.942	
A765	9.98	29.918	
A766	9.98	30.002	
A767	10.07	30.130	
A768	9.87	30.028	
A769	9.81	30.063	
A770	9.92	29.960	
A771	10.07	29.877	
A772	9.86	29.906	
A773	10.02	29.995	
A774	9.91	29.913	
A775	10.21	30.134	
A776	10.05	29.844	
A777	10.06	29.933	
A778	10.00	29.816	
A779	9.92	30.009	
A780	9.93	29.697	
A781	9.97	30.134	
A782	9.98	29.851	
A783	10.07	29.955	

ID-Nr. LOT 57130079	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A784	9.96	29.923	
A785	9.93	29.856	
A786	9.82	29.673	
A787	10.15	29.796	
A788	9.77	29.953	
A789	9.94	29.963	
A790	9.79	30.028	
A791	9.88	29.760	
A792	9.99	29.949	
A793	9.80	29.939	
A794	9.96	30.095	
A795	10.00	30.044	
A796	10.06	29.895	
A797	9.97	29.909	
A798	9.89	29.780	
A799	9.89	30.036	
A800	9.85	30.168	
A801	9.86	29.987	
A802	9.86	29.940	
A803	9.99	30.001	
A804	9.94	29.677	
A805	10.00	30.027	

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

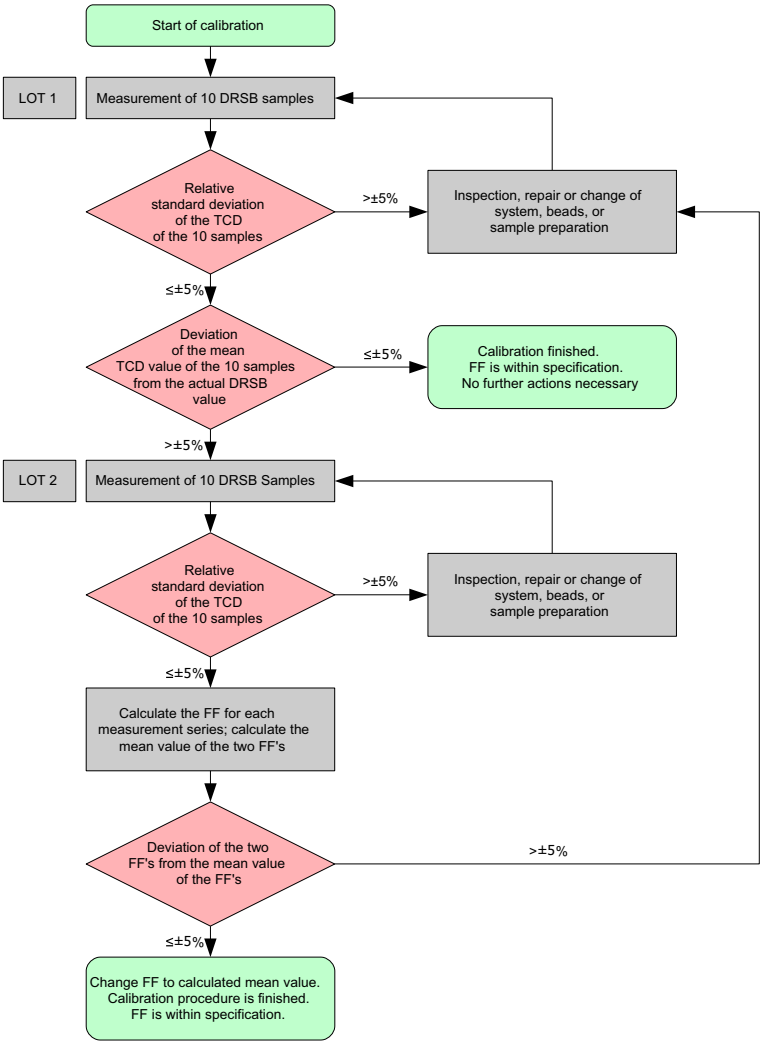

Fig. 2: Calibration Cedex HiRes Analyzer

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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