For use in quality control/
manufacturing process only.

Density Reference Standard Beads (DRSB)

Version 63

Content version: November 2023

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. 57130098

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

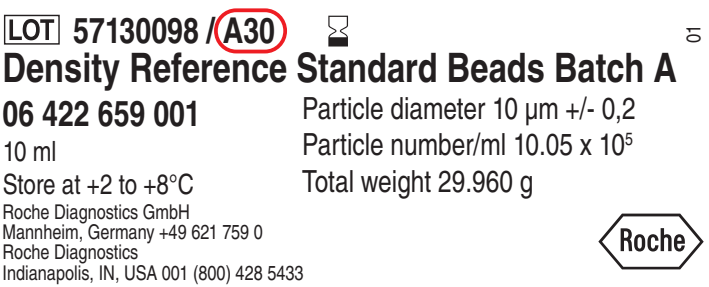

Fig. 1: Example of how to find the bottle number on the bottle label. The bottle number is circled.

ID-Nr. LOT 57130098	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A1	10.03	29.768	
A2	10.03	29.840	
A3	9.98	29.943	
A4	10.07	29.475	
A5	9.96	30.029	
A6	10.11	29.754	
A7	9.89	29.874	
A8	9.89	29.805	
A9	10.07	29.868	
A10	9.91	29.924	
A11	9.86	29.533	
A12	10.10	30.823	
A13	9.91	29.835	
A14	9.97	29.576	
A15	10.09	30.086	
A16	10.06	29.587	
A17	10.07	29.897	
A18	10.01	29.599	
A19	10.03	29.689	
A20	9.90	30.010	
A21	9.93	29.819	
A22	9.94	29.501	
A23	10.14	29.920	
A24	9.96	30.049	
A25	10.03	29.972	
A26	10.17	29.868	
A27	9.89	29.842	
A28	10.00	29.587	
A29	9.89	29.790	

ID-Nr. LOT 57130098	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A30	9.97	29.752	
A31	9.99	29.836	
A32	9.92	29.678	
A33	9.94	30.035	
A34	10.02	29.494	
A35	10.00	29.757	
A36	9.93	31.045	
A37	10.07	29.740	
A38	9.95	29.928	
A39	10.12	30.035	
A40	9.94	29.754	
A41	9.88	29.807	
A42	10.13	29.858	
A43	9.89	29.833	
A44	10.02	30.048	
A45	9.98	29.842	
A46	9.91	30.000	
A47	9.95	29.873	
A48	10.10	29.761	
A49	9.97	29.840	
A50	10.12	29.500	
A51	9.97	29.544	
A52	9.98	29.758	
A53	10.14	29.667	
A54	10.08	29.972	
A55	9.89	29.756	
A56	10.15	31.105	
A57	9.90	29.672	
A58	9.87	29.848	

ID-Nr. LOT 57130098	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A59	9.96	29.566	
A60	10.07	29.841	
A61	9.92	29.640	
A62	9.93	29.876	
A63	9.91	29.667	
A64	9.96	29.871	
A65	9.95	28.739	
A66	10.12	29.519	
A67	9.94	30.736	
A68	10.04	29.679	
A69	9.97	29.527	
A70	9.86	29.761	
A71	9.92	29.433	
A72	9.99	29.911	
A73	9.92	29.826	
A74	9.87	29.866	
A75	9.93	29.682	
A76	9.91	29.859	
A77	9.95	29.514	
A78	9.88	29.755	
A79	9.97	29.637	
A80	9.96	29.490	
A81	9.91	29.675	
A82	10.06	29.876	
A83	9.95	29.793	
A84	10.06	29.959	
A85	9.99	29.528	
A86	9.97	30.948	
A87	9.94	29.929	

ID-Nr. LOT 57130098	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A88	9.99	29.413	
A89	9.94	29.636	
A90	10.06	29.954	
A91	9.96	29.659	
A92	10.10	29.723	
A93	9.88	29.810	
A94	9.92	29.587	
A95	9.98	29.537	
A96	9.99	29.731	
A97	10.09	31.014	
A98	10.06	30.884	
A99	10.04	29.665	
A100	9.98	29.764	
A101	9.94	31.045	
A102	10.11	29.560	
A103	9.94	29.751	
A104	9.94	29.725	
A105	9.91	29.924	
A106	9.94	30.028	
A107	9.89	29.946	
A108	9.90	29.954	
A109	9.87	29.856	
A110	9.89	29.813	
A111	9.93	30.862	
A112	9.90	30.897	
A113	10.06	29.707	
A114	10.07	29.870	
A115	9.91	29.902	
A116	9.97	29.876	

ID-Nr. LOT 57130098	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A117	9.87	29.945	
A118	10.04	29.647	
A119	9.98	29.970	
A120	10.01	29.812	
A121	9.93	29.890	
A122	9.86	29.864	
A123	9.92	29.843	
A124	9.89	29.766	
A125	9.95	29.752	
A126	9.95	29.896	
A127	9.96	29.831	
A128	10.02	30.008	
A129	9.98	29.950	
A130	9.91	29.565	
A131	10.01	29.894	
A132	9.90	29.808	
A133	9.89	29.985	
A134	9.92	30.004	
A135	10.03	29.407	
A136	9.94	30.906	
A137	9.96	29.888	
A138	9.99	29.879	
A139	9.96	29.819	
A140	10.01	30.030	
A141	10.03	31.120	
A142	10.07	29.769	
A143	9.90	29.756	
A144	9.95	29.485	
A145	9.95	30.769	

ID-Nr. LOT 57130098	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A146	9.94	29.963	
A147	10.07	29.995	
A148	10.03	29.876	
A149	9.96	29.820	
A150	10.00	31.082	
A151	10.03	29.924	
A152	10.14	29.828	
A153	9.92	29.814	
A154	9.92	29.776	
A155	9.98	29.931	
A156	9.89	30.125	
A157	9.91	31.027	
A158	10.17	29.890	
A159	9.95	30.009	
A160	9.97	29.507	
A161	10.02	29.672	
A162	10.07	29.911	
A163	9.89	30.161	
A164	9.92	31.009	
A165	9.92	29.973	
A166	9.86	29.974	
A167	10.14	29.676	
A168	9.89	31.191	
A169	9.93	30.030	
A170	10.13	29.837	
A171	9.92	29.739	
A172	9.88	29.928	
A173	9.90	30.079	
A174	9.89	30.006	

ID-Nr. LOT 57130098	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A175	10.00	29.913	
A176	10.01	29.481	
A177	10.01	30.024	
A178	9.91	29.896	
A179	9.87	30.021	
A180	9.94	29.814	
A181	10.04	29.550	
A182	9.97	29.485	
A183	9.96	30.121	
A184	9.93	29.736	
A185	9.99	29.937	
A186	10.07	30.050	
A187	9.96	29.686	
A188	10.02	29.871	
A189	9.96	31.025	
A190	9.87	30.982	
A191	9.94	29.767	
A192	9.99	29.951	
A193	9.89	29.816	
A194	9.90	29.907	
A195	9.89	30.878	
A196	9.91	29.681	
A197	9.97	29.519	
A198	9.98	29.637	
A199	9.96	29.738	
A200	9.92	29.427	
A201	10.08	30.957	
A202	10.18	31.335	
A203	9.99	31.043	

ID-Nr. LOT 57130098	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A204	10.06	31.096	
A205	10.15	30.834	
A206	10.01	31.366	
A207	10.17	30.849	
A208	9.94	31.138	
A209	9.98	30.815	
A210	9.88	30.768	
A211	10.12	30.861	
A212	10.09	30.905	
A213	9.99	31.260	
A214	10.00	30.838	
A215	9.95	31.253	
A216	9.93	30.912	
A217	9.89	31.155	
A218	9.87	31.046	
A219	9.92	30.890	
A220	9.89	31.361	
A221	9.97	30.860	
A222	10.02	30.766	
A223	9.94	31.067	
A224	10.18	30.878	
A225	10.06	30.910	
A226	10.03	30.826	
A227	10.08	30.807	
A228	10.05	30.829	
A229	9.97	30.668	
A230	9.98	30.917	
A231	10.08	30.872	
A232	9.90	30.837	

ID-Nr. LOT 57130098	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A233	9.97	30.900	
A234	9.94	31.114	
A235	9.93	30.839	
A236	10.04	30.857	
A237	10.11	31.067	
A238	9.90	30.855	
A239	10.04	31.100	
A240	9.97	30.986	
A241	10.06	31.234	
A242	10.05	30.965	
A243	9.87	31.152	
A244	9.96	30.893	
A245	10.09	30.869	
A246	9.94	31.015	
A247	10.05	30.849	
A248	10.01	30.913	
A249	9.89	30.901	
A250	9.87	30.991	
A251	9.87	31.239	
A252	9.88	31.003	
A253	9.95	30.745	
A254	10.11	31.351	
A255	9.93	31.027	
A256	9.95	30.868	
A257	10.01	30.911	
A258	10.00	30.946	
A259	10.11	31.126	
A260	10.09	31.138	
A261	10.02	30.851	

ID-Nr. LOT 57130098	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A262	9.92	30.800	
A263	9.93	30.745	
A264	9.92	31.160	
A265	10.10	30.803	
A266	9.88	30.710	
A267	9.92	30.954	
A268	9.96	32.003	
A269	10.08	31.085	
A270	9.91	30.927	
A271	10.09	30.691	
A272	9.89	30.774	
A273	10.04	30.959	
A274	9.96	30.716	
A275	10.01	30.956	
A276	9.88	30.874	
A277	9.99	30.900	
A278	10.15	30.813	
A279	10.04	30.797	
A280	9.89	30.892	
A281	9.95	30.784	
A282	9.94	30.790	
A283	9.96	30.659	
A284	10.05	30.920	
A285	10.03	31.016	
A286	9.97	30.669	
A287	10.16	30.850	
A288	9.93	30.916	
A289	10.02	31.018	
A290	9.96	30.911	

ID-Nr. LOT 57130098	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A291	9.91	31.082	
A292	9.99	31.094	
A293	9.94	31.322	
A294	10.09	29.616	
A295	9.89	30.857	
A296	9.93	30.881	
A297	9.92	31.258	
A298	10.05	29.455	
A299	9.95	31.261	
A300	10.03	29.522	
A301	10.02	29.979	
A302	9.87	30.040	
A303	10.00	29.766	
A304	9.94	29.863	
A305	10.00	30.015	
A306	9.94	29.842	
A307	9.92	29.912	
A308	10.10	30.004	
A309	9.95	29.852	
A310	10.00	29.895	
A311	9.95	29.970	
A312	9.96	29.381	
A313	10.01	29.915	
A314	9.98	30.053	
A315	9.91	29.810	
A316	9.96	29.897	
A317	9.87	29.829	
A318	9.91	29.894	
A319	10.04	30.002	

ID-Nr. LOT 57130098	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A320	9.92	29.868	
A321	9.98	30.062	
A322	10.01	29.929	
A323	10.01	30.071	
A324	9.99	29.799	
A325	10.02	29.967	
A326	10.04	29.898	
A327	9.88	29.967	
A328	10.00	30.003	
A329	9.94	29.724	
A330	9.92	29.979	
A331	9.92	30.123	
A332	9.98	29.932	
A333	9.94	29.806	
A334	9.84	29.885	
A335	9.94	30.076	
A336	9.93	29.713	
A337	9.99	29.640	
A338	9.89	31.002	
A339	9.94	29.852	
A340	9.91	31.004	
A341	9.99	30.944	
A342	9.95	29.718	
A343	10.02	29.827	
A344	9.92	30.035	
A345	9.94	29.779	
A346	10.06	29.768	
A347	9.94	29.915	
A348	9.91	29.850	

ID-Nr. LOT 57130098	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A349	9.93	29.576	
A350	9.96	29.752	
A351	9.93	29.780	
A352	9.90	30.859	
A353	10.04	29.889	
A354	9.96	29.858	
A355	9.90	29.623	
A356	9.90	29.531	
A357	9.92	29.841	
A358	9.93	30.875	
A359	10.01	29.779	
A360	10.02	29.816	
A361	10.01	29.540	
A362	9.87	29.695	
A363	9.88	29.763	
A364	9.95	29.777	
A365	9.90	29.689	
A366	9.94	29.799	
A367	9.88	30.858	
A368	10.14	29.746	
A369	10.06	30.006	
A370	9.90	30.913	
A371	9.96	29.714	
A372	10.13	29.828	
A373	9.93	31.116	
A374	10.10	29.893	
A375	9.89	30.979	
A376	10.13	29.353	
A377	9.91	29.585	

ID-Nr. LOT 57130098	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A378	9.87	29.618	
A379	9.89	29.754	
A380	9.92	30.483	
A381	10.06	29.914	
A382	9.87	29.864	
A383	9.87	29.866	
A384	9.87	29.747	
A385	9.99	29.734	
A386	9.94	29.605	
A387	10.10	31.004	
A388	10.07	29.763	
A389	10.09	29.901	
A390	10.02	29.729	
A391	9.99	29.896	
A392	9.91	29.729	
A393	10.01	29.892	
A394	10.00	29.756	
A395	9.99	29.743	
A396	10.00	29.959	
A397	10.14	29.954	
A398	9.91	29.963	
A399	9.90	29.870	
A400	10.01	29.782	
A401	10.11	30.684	
A402	9.96	29.549	
A403	9.96	29.607	
A404	10.08	31.178	
A405	9.98	29.913	
A406	10.14	30.997	

ID-Nr. LOT 57130098	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A407	9.99	31.351	
A408	10.08	29.793	
A409	10.13	29.813	
A410	9.99	29.843	
A411	10.00	29.733	
A412	9.97	30.959	
A413	10.13	30.931	
A414	9.94	29.799	
A415	10.00	30.843	
A416	10.03	30.935	
A417	10.01	31.045	
A418	10.02	30.805	
A419	9.98	29.704	
A420	9.89	31.018	
A421	9.98	30.876	
A422	10.09	29.643	
A423	9.97	30.695	
A424	10.02	31.104	
A425	10.04	29.846	
A426	9.96	31.223	
A427	9.99	29.703	
A428	9.95	29.864	
A429	9.87	30.911	
A430	10.04	31.077	
A431	10.11	30.972	
A432	9.88	31.126	
A433	10.01	30.060	
A434	10.01	31.057	
A435	9.95	31.002	

ID-Nr. LOT 57130098	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A436	9.90	29.833	
A437	10.04	30.908	
A438	9.87	29.783	
A439	9.97	31.020	
A440	10.07	31.131	
A441	9.96	29.905	
A442	10.16	29.903	
A443	10.06	30.715	
A444	9.95	31.135	
A445	9.89	30.712	
A446	9.95	29.715	
A447	9.88	30.826	
A448	10.00	30.972	
A449	9.99	29.508	
A450	10.07	29.821	
A451	10.02	29.670	
A452	9.88	29.869	
A453	10.08	31.119	
A454	9.92	29.718	
A455	9.96	31.224	
A456	10.10	29.767	
A457	9.89	29.717	
A458	9.92	29.808	
A459	10.04	29.937	
A460	10.05	31.000	
A461	9.93	29.772	
A462	10.01	30.645	
A463	9.87	29.857	
A464	10.07	30.844	

ID-Nr. LOT 57130098	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A465	10.14	29.443	
A466	10.11	29.552	
A467	10.00	29.788	
A468	9.88	29.837	
A469	9.99	31.302	
A470	10.01	29.786	
A471	10.01	29.917	
A472	10.09	29.896	
A473	9.88	31.199	
A474	10.09	30.844	
A475	9.94	29.899	
A476	9.89	29.842	
A477	9.92	29.735	
A478	9.88	29.853	
A479	9.96	29.588	
A480	10.01	30.885	
A481	10.02	29.609	
A482	10.14	29.623	
A483	10.05	29.765	
A484	10.07	31.004	
A485	9.90	30.836	
A486	9.97	29.528	
A487	10.00	30.905	
A488	9.98	29.481	
A489	9.94	30.826	
A490	9.87	31.059	
A491	10.02	30.887	
A492	9.94	31.242	
A493	10.06	30.594	

ID-Nr. LOT 57130098	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A494	10.03	29.861	
A495	10.04	29.819	
A496	9.92	29.831	
A497	9.98	30.954	
A498	9.93	31.045	
A499	10.00	29.748	
A500	10.05	29.828	
A501	9.98	31.066	
A502	10.02	31.087	
A503	9.92	31.059	
A504	9.93	30.898	
A505	10.05	31.019	
A506	9.89	31.111	
A507	10.13	31.390	
A508	9.91	31.081	
A509	10.01	30.977	
A510	9.94	31.039	
A511	9.91	31.021	
A512	9.89	31.245	
A513	10.01	31.394	
A514	10.18	31.268	
A515	9.90	30.927	
A516	10.11	31.176	
A517	10.04	31.065	
A518	10.02	31.236	
A519	9.92	30.991	
A520	9.98	30.871	
A521	10.03	31.163	
A522	10.07	31.383	

ID-Nr. LOT 57130098	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A523	9.90	31.256	
A524	10.04	31.010	
A525	10.02	31.394	
A526	9.97	31.103	
A527	10.01	30.724	
A528	9.96	31.218	
A529	9.91	31.259	
A530	9.90	31.368	
A531	9.96	31.156	
A532	10.03	30.889	
A533	9.89	30.976	
A534	10.01	31.165	
A535	9.93	31.059	
A536	9.97	31.140	
A537	10.12	30.968	
A538	10.00	31.228	
A539	10.00	30.935	
A540	9.94	30.793	
A541	9.97	31.208	
A542	9.97	30.755	
A543	9.95	31.110	
A544	10.17	31.070	
A545	10.06	31.082	
A546	9.95	31.064	
A547	9.90	30.941	
A548	9.97	31.054	
A549	9.98	31.240	
A550	9.89	30.953	
A551	10.13	31.092	

ID-Nr. LOT 57130098	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A552	10.04	31.071	
A553	9.91	31.129	
A554	10.04	31.286	
A555	9.98	31.055	
A556	9.96	30.940	
A557	9.95	31.006	
A558	9.89	30.841	
A559	10.08	30.788	
A560	10.15	31.240	
A561	9.97	30.989	
A562	9.88	31.009	
A563	10.05	30.952	
A564	9.97	30.975	
A565	10.14	31.092	
A566	10.04	31.033	
A567	10.01	30.865	
A568	9.86	30.989	
A569	9.87	31.300	
A570	9.91	31.010	
A571	9.98	31.007	
A572	9.91	31.052	
A573	10.14	31.034	
A574	9.95	31.096	
A575	9.94	31.333	
A576	9.99	31.021	
A577	9.89	31.223	
A578	9.91	31.246	
A579	9.90	30.980	
A580	9.93	31.118	

ID-Nr. LOT 57130098	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A581	10.04	31.023	
A582	10.05	30.957	
A583	9.95	31.096	
A584	9.94	31.198	
A585	10.02	31.139	
A586	9.94	31.275	
A587	9.92	31.000	
A588	9.93	31.017	
A589	10.09	31.048	
A590	9.93	31.095	
A591	9.89	31.243	
A592	10.00	31.103	
A593	9.95	31.295	
A594	9.88	31.165	
A595	10.10	30.999	
A596	9.97	31.197	
A597	9.94	31.036	
A598	9.98	31.144	
A599	9.89	30.879	
A600	9.91	31.012	
A601	10.11	31.242	
A602	9.99	30.980	
A603	9.98	31.073	
A604	9.90	31.198	
A605	9.96	31.368	
A606	9.96	31.077	
A607	9.96	30.768	
A608	9.91	30.749	
A609	10.09	31.200	

ID-Nr. LOT 57130098	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A610	9.93	30.998	
A611	10.01	31.131	
A612	9.93	31.086	
A613	9.97	31.245	
A614	10.06	31.205	
A615	10.03	31.146	
A616	10.12	31.213	
A617	10.09	31.153	
A618	9.93	30.982	
A619	10.00	31.238	
A620	9.95	31.007	
A621	10.02	30.917	
A622	9.97	31.024	
A623	10.05	31.189	
A624	9.92	30.588	
A625	9.88	31.229	
A626	9.93	31.082	
A627	10.06	31.096	
A628	10.06	30.984	
A629	9.91	31.151	
A630	10.00	30.788	
A631	10.01	31.279	
A632	9.89	30.817	
A633	9.96	30.909	
A634	9.87	31.173	
A635	9.95	31.314	
A636	9.87	30.858	
A637	10.03	30.985	
A638	9.98	31.168	

ID-Nr. LOT 57130098	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A639	9.88	31.140	
A640	10.08	30.909	
A641	10.11	31.181	
A642	10.11	31.088	
A643	10.08	31.182	
A644	10.00	31.023	
A645	9.88	30.905	
A646	9.98	31.189	
A647	9.93	31.317	
A648	10.06	31.264	
A649	10.12	31.031	
A650	9.99	31.291	
A651	9.91	31.023	
A652	10.12	31.010	
A653	10.14	30.831	
A654	10.07	31.423	
A655	10.01	30.833	
A656	10.00	30.965	
A657	10.00	30.891	
A658	10.17	31.180	
A659	10.00	31.237	
A660	9.94	31.374	
A661	10.10	31.350	
A662	9.93	31.394	
A663	9.87	31.100	
A664	10.04	31.178	
A665	10.19	30.990	
A666	10.12	31.169	
A667	9.99	31.082	

ID-Nr. LOT 57130098	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A668	10.04	31.258	
A669	10.16	31.293	
A670	10.09	30.181	
A671	10.09	30.983	
A672	10.08	30.870	
A673	10.00	30.945	
A674	9.98	30.939	
A675	10.03	31.026	
A676	10.03	31.402	
A677	9.87	30.904	
A678	9.91	31.231	
A679	10.05	31.073	
A680	9.90	31.060	
A681	9.98	31.197	
A682	9.87	31.080	
A683	9.93	30.858	
A684	9.87	31.159	
A685	9.90	31.253	
A686	10.13	31.011	
A687	10.06	30.940	
A688	10.04	31.057	
A689	10.07	31.015	
A690	10.07	31.260	
A691	9.96	30.919	
A692	9.97	30.894	
A693	10.07	31.114	
A694	9.96	31.145	
A695	10.12	31.168	
A696	10.00	30.992	

ID-Nr. LOT 57130098	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A697	10.12	30.993	
A698	9.88	31.034	
A699	10.16	31.280	
A700	10.10	31.047	
A701	10.18	31.030	
A702	9.93	29.754	
A703	9.98	29.427	
A704	10.05	30.098	
A705	9.94	30.925	
A706	9.97	29.202	
A707	10.06	31.306	
A708	10.10	31.105	
A709	10.07	31.082	
A710	10.14	29.806	
A711	9.96	31.021	
A712	10.04	29.838	
A713	10.04	30.877	
A714	10.15	31.236	
A715	10.06	31.455	
A716	10.00	31.397	
A717	10.08	31.113	
A718	10.09	30.667	
A719	10.09	30.980	
A720	9.88	30.967	
A721	10.03	30.926	
A722	10.01	31.229	
A723	9.98	31.072	
A724	9.94	30.958	
A725	9.94	30.856	

ID-Nr. LOT 57130098	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A726	9.99	30.833	
A727	10.01	30.844	
A728	10.03	31.110	
A729	9.97	30.862	
A730	9.96	31.116	
A731	10.16	31.228	
A732	9.94	31.134	
A733	9.97	30.853	
A734	9.96	30.756	
A735	9.96	30.907	
A736	10.13	30.984	
A737	10.13	31.099	
A738	10.08	30.921	
A739	10.00	30.868	
A740	10.02	30.922	
A741	10.03	30.868	
A742	10.04	31.045	
A743	10.17	30.002	
A744	9.96	30.709	
A745	9.98	31.151	
A746	10.12	31.151	
A747	10.03	31.305	
A748	9.99	31.293	
A749	10.00	31.019	
A750	9.94	30.902	
A751	9.88	30.992	
A752	10.11	30.820	
A753	10.12	30.954	
A754	9.97	29.706	

ID-Nr. LOT 57130098	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A755	10.18	30.975	
A756	10.14	31.132	
A757	10.11	31.302	
A758	10.05	31.123	
A759	10.07	30.887	
A760	9.95	31.029	
A761	10.06	30.811	
A762	10.13	31.074	
A763	9.98	29.996	
A764	9.92	31.020	
A765	9.93	31.050	
A766	10.07	30.836	
A767	9.97	30.931	
A768	10.11	30.975	
A769	10.17	31.082	
A770	10.05	31.195	
A771	9.99	30.683	
A772	10.05	31.344	
A773	10.03	31.092	
A774	10.14	30.200	
A775	9.95	31.106	
A776	10.08	30.988	
A777	9.91	30.892	
A778	10.11	30.767	
A779	9.93	30.796	
A780	9.95	30.718	
A781	10.16	31.071	
A782	9.95	31.135	
A783	10.04	30.939	

ID-Nr. LOT 57130098	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A784	10.09	30.848	
A785	10.03	30.960	
A786	9.99	30.779	
A787	10.07	31.123	
A788	10.04	30.976	
A789	10.14	30.978	
A790	10.04	31.086	
A791	10.08	30.753	
A792	10.11	29.808	
A793	9.99	30.906	
A794	10.12	30.700	
A795	10.14	30.911	
A796	10.04	30.909	
A797	10.08	30.921	
A798	10.00	30.947	
A799	10.02	30.877	
A800	9.99	30.889	
A801	10.03	30.708	
A802	9.98	31.089	
A803	9.92	30.959	
A804	10.12	30.954	
A805	10.07	31.042	

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

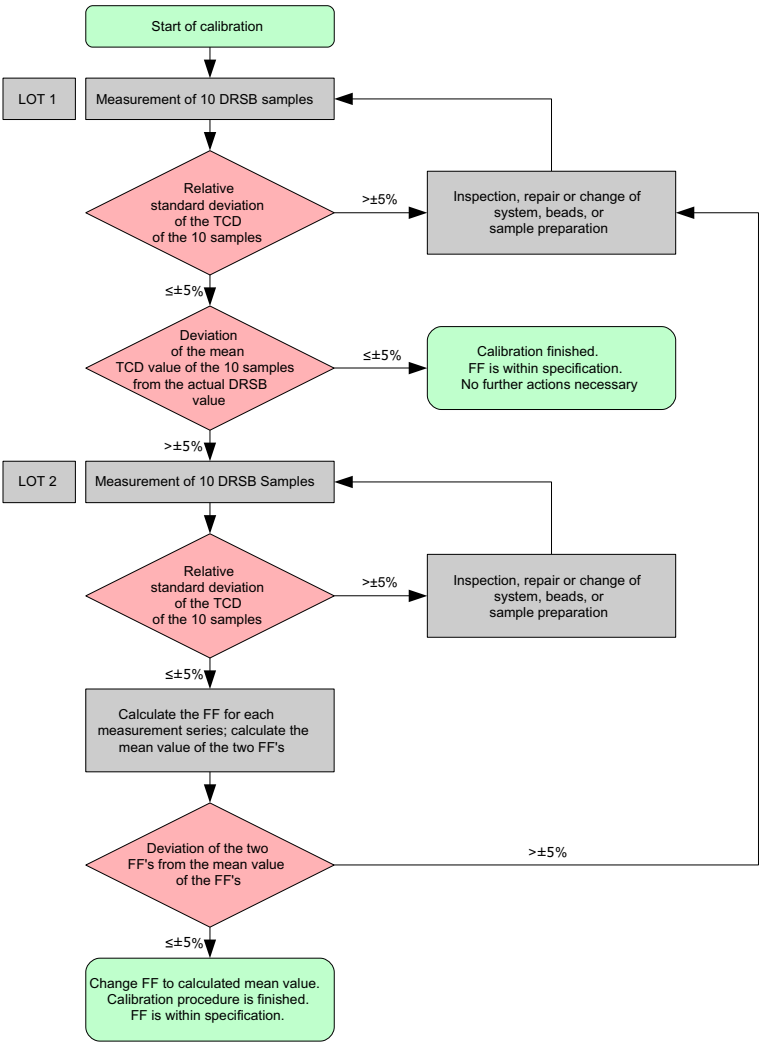

Fig. 2: Calibration Cedex HiRes Analyzer

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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