For use in quality control/manufacturing process only.

Density Reference Standard Beads (DRSB)

Batch A

Version: 66

Content Version: August 2024

Beads for one-point density calibration.

Cat. No. 06 422 659 001 1 x 10 mL Batch A

Store the product at +2 to +8°C.

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1. General Information

1.1. Contents

Vial / bottle	Label	Batch	Function / description	Content
1	Density Reference Standard Beads	A	Beads for one-point density calibration.	1 bottle, 10 mL

1.2. Storage and Stability

Storage Conditions (Product)

The product is stable at +2 to +8°C until the expiry date printed on the label, when handled as described in these Instructions for Use.
⚠ ***Do not freeze.***

1.3. Additional Equipment and Reagent required

Analyzer and accessories

- Cedex HiRes Analyzer*
- Cedex HiRes Reagent Kit*
- Cedex Sample Cups*

1.4. Applications

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. 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 for the following aspects:
- Particle Size: NIST, USA
- Particle Concentration: Physikalisch-Technische Bundesanstalt, Berlin, Germany

The Density Reference Standard Beads (DRSB) are designed to mimic cell behavior in flow dynamics. Due to their size and optical properties, they will be detected as dead cells by the Cedex HiRes Software.

2. How to Use this Product

2.1. Before you Begin

General Considerations

There is no general advice with regard to how often or how many counts should be done 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.

Acceptance range

Two factors influence the acceptance range for calibration with Density Reference Standard Beads in connection with the Cedex HiRes Analyzer.

Factor	Influenced by
Sample preparation	Mixing, pipetting, and pipette quality (precision, accuracy, service state) have been shown to add approximately 1.5 to 2% to the variability in density measurements.
Measurement precision	▪ Is based on the statistical nature of the measurement process. ▪ Depends on the density of the DRSB used, Cell Type parameter settings, and the level of precision used for the measurement.

Sampling quality

Sampling quality is essential for the evaluation of the status of the instrument. Consider the following:
- Do not freeze the beads; only store beads at +2 to +8°C.
- Acclimate beads to +23 to +27°C prior to use.
- Verify the correct weight of the unopened bottle; see bottle label.
- Use an ultrasonic bath for mixing.
- Rock the bottle gently, including rocking upside down.
- Do not withdraw more than 2 samples from the bottle without remixing.
- Use only calibrated pipettes.
- Only trained staff should perform sample preparation.

Working Solution

Preparation of the DRSB solution

1. Verify that the beads have been stored correctly at +2 to +8°C.

   ⚠ ***Do not freeze the beads.***

2. Verify that the bottle was securely closed before use.
   – Check the weight of the unopened bottle; the correct value is on the bottle label.

3. Allow the beads to acclimate to +23 to +27°C prior to use.

4. Shake the beads using an ultrasonic bath at +23 to +27°C and at the highest available intensity for 5 minutes.

   Cap should be slightly loosened but secured against falling over.

⚠ ***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. Allow the beads to acclimate with occasional mixing at +25°C until the coagulation or crystallization disappears. Alternatively, gently roll the DRSB bottle between the palms of the hands until the coagulation has disappeared. 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.

2.2. Protocols

Checking the FlowFactor (FF)

1. Pipette 1 sample of 0.3 mL DRSB into a Cedex Sample Cup* and immediately run the sample with factory settings for default Cell Type Std. Size.
   – Select the maximum possible setting for “precision”.

2. Mix the DRSB thoroughly, then pipette the next sample of 0.3 mL into a Cedex Sample Cup* and immediately run the sample.

3. Repeat this procedure until 10 samples are processed.

4. Calculate the mean value of the Total Cell Density (TCD) of the 10 samples used.

5. 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 must be checked and the calibration must be repeated.

6. Calculate the deviation of the mean TCD value of the 10 samples used from the actual value which is given as Particle number/ml on the bottle of beads.

7. 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.

8. Close bottle tightly and store beads at +2 to +8°C.

   ⚠ ***Do not freeze the beads.***

   – The current FF is correct and no change is necessary.

9. 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.

10. Calculate the FlowFactor (FF) of each measurement series and the mean value of the two FFs, see section, **Adjusting the FlowFactor**.

11. 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 must be checked and the calibration must be repeated.

12. Calculate the new FF (mean value of the FFs), see section, **Adjusting the FlowFactor**, or follow your company’s requirements.

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, 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, such as the 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.

1. 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.)

$$\mathbf{FF\ (new)} = \frac{FF\ (new_{1}) + FF\ (new_{2})}{2}$$

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2. 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.

FlowFactor calibration

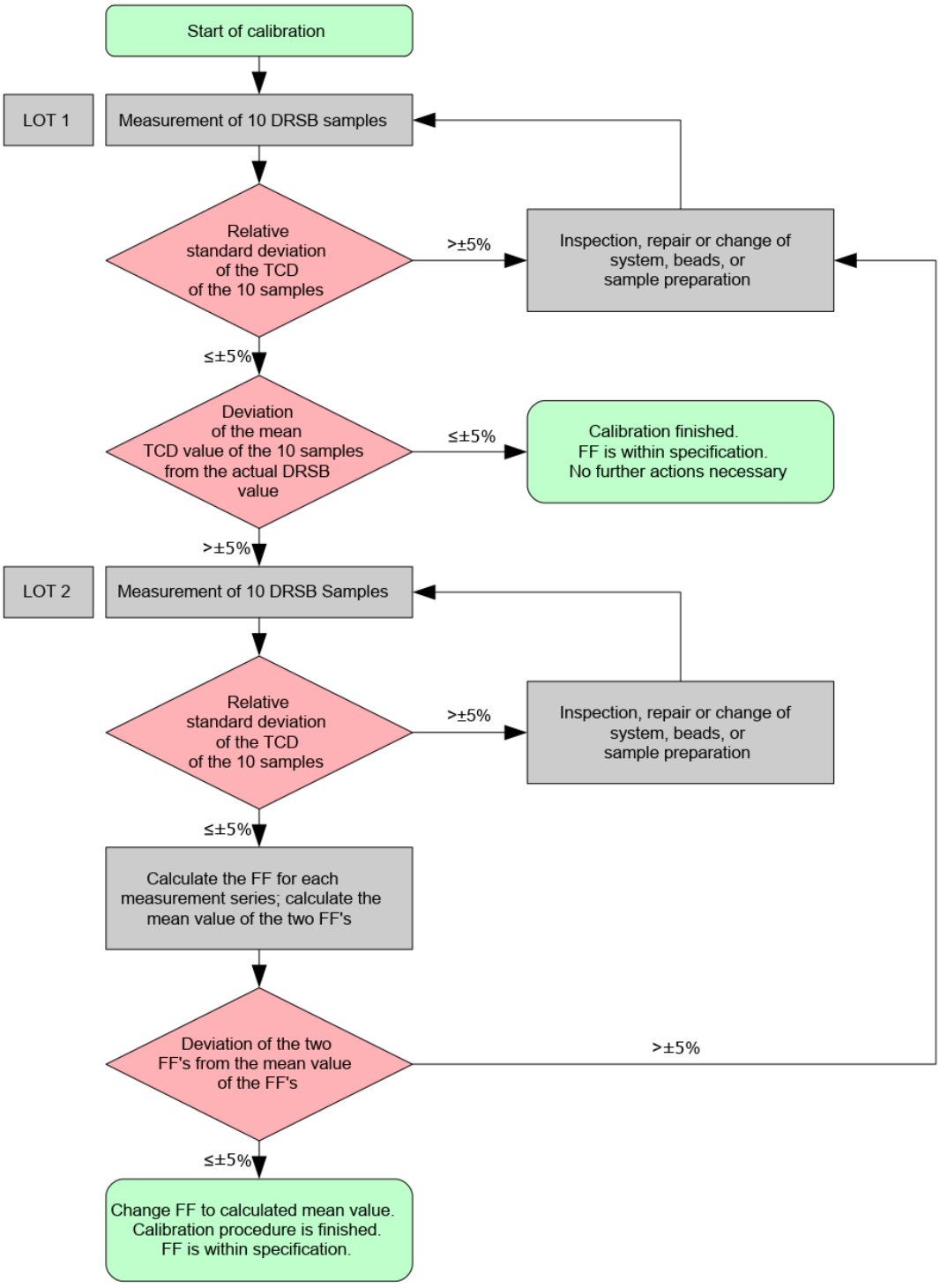

Fig. 1: Calibration of Cedex HiRes Analyzer

3. Supplementary Information

3.1. Conventions

To make information consistent and easier to read, the following text conventions and symbols are used in this document to highlight important information:

Text convention and symbols	
Information Note: Additional information about the current topic or procedure.	
Important Note: Information critical to the success of the current procedure or use of the product.	
① ② ③ etc.	Stages in a process that usually occur in the order listed.
❶ ❷ ❸ etc.	Steps in a procedure that must be performed in the order listed.
* (Asterisk)	The Asterisk denotes a product available from Roche Diagnostics.

3.2. Changes to previous version

Updated to include lot-specific data for new lot.

3.3. Ordering Information

Product	Pack Size	Cat. No.
Consumables		
Cedex Sample Cups	500 cups	05 650 623 001
Instruments		
Cedex HiRes Analyzer	1 instrument	05 650 216 001

3.4. Trademarks

CEDEX is a trademark of Roche.
All other product names and trademarks are the property of their respective owners.

3.5. License Disclaimer

Consult product detail pages at **custombiotech.roche.com** for patent license limitations, if available.

3.6. Regulatory Disclaimer

For use in quality control/manufacturing process only.

3.7. Safety Data Sheet

Please follow the instructions in the Safety Data Sheet (SDS).

3.8. Contact and Support

For additional documentation such as certificates and safety data sheets, please visit **documentation.roche.com**.

Your Roche CustomBiotech Customer Service:

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4. Lot-Specific Data

Density Reference Standard Beads, Batch A	
REF	06 422 659 001
	66
valid for LOT	57130110
	Jan 2026

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

Standard labeling assay

Use this table as follows

1. Print out the table
2. Find the bottle number on the bottle label as shown in Figure 2.
3. 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*

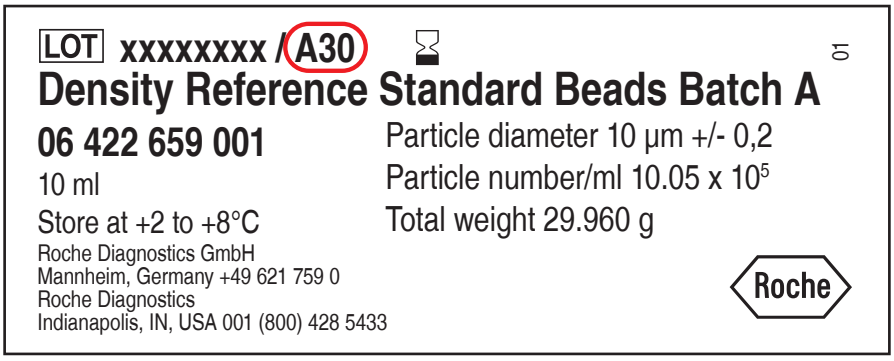

Fig. 2: Example of how to find the bottle number on the bottle label. The bottle number is circled.

ID-Nr. LOT 57130110	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A1	9.95	31.277	
A2	10.11	30.979	
A3	10.13	30.881	
A4	10.00	31.101	
A5	9.93	31.254	
A6	10.00	31.128	
A7	9.97	31.143	
A8	10.08	30.729	
A9	10.07	31.352	
A10	9.94	30.040	
A11	10.08	31.287	
A12	9.96	31.155	
A13	10.06	30.917	
A14	10.05	31.005	
A15	10.04	31.060	
A16	9.98	31.304	
A17	10.09	29.940	
A18	10.07	29.999	
A19	9.99	30.092	
A20	9.99	30.177	
A21	10.01	31.005	
A22	10.15	31.343	
A23	9.94	31.442	
A24	9.90	30.100	
A25	10.01	31.383	
A26	10.00	31.043	
A27	10.04	31.093	
A28	10.00	31.434	
A29	10.03	31.221	
A30	9.93	31.089	
A31	10.00	31.244	
A32	10.07	30.006	
A33	10.08	31.089	
A34	9.93	30.163	
A35	9.92	30.154	
A36	10.03	30.912	
A37	10.07	31.122	
A38	9.95	30.901	
A39	10.10	31.085	
A40	9.97	30.072	
A41	9.99	31.214	
A42	9.96	30.992	

ID-Nr. LOT 57130110	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A43	9.89	31.055	
A44	10.00	31.013	
A45	9.88	31.135	
A46	9.94	30.937	
A47	10.00	31.311	
A48	10.04	30.977	
A49	9.98	31.225	
A50	9.95	31.235	
A51	10.00	30.803	
A52	9.99	31.147	
A53	9.89	30.868	
A54	9.90	31.340	
A55	9.93	30.962	
A56	9.93	31.130	
A57	9.93	31.387	
A58	9.88	31.058	
A59	9.97	31.218	
A60	9.97	31.082	
A61	10.11	31.316	
A62	9.89	31.130	
A63	9.89	31.266	
A64	10.01	30.737	
A65	9.99	31.056	
A66	9.96	31.078	
A67	9.92	31.106	
A68	9.91	30.940	
A69	9.92	30.801	
A70	9.89	31.139	
A71	9.95	30.816	
A72	10.04	31.236	
A73	9.94	31.189	
A74	9.88	31.280	
A75	9.90	31.156	
A76	10.00	30.825	
A77	10.06	30.881	
A78	9.91	31.325	
A79	9.89	31.060	
A80	9.89	31.116	
A81	9.93	31.569	
A82	9.89	30.791	
A83	10.04	31.015	
A84	9.95	31.345	

4. Lot-Specific Data

ID-Nr. LOT 57130110	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A85	9.96	31.236	
A86	9.88	31.133	
A87	10.07	31.090	
A88	9.94	31.086	
A89	9.99	30.718	
A90	9.94	30.908	
A91	9.98	30.903	
A92	9.96	31.144	
A93	10.06	31.014	
A94	10.10	31.134	
A95	9.92	31.202	
A96	10.06	31.078	
A97	9.98	31.273	
A98	10.15	31.142	
A99	9.93	31.455	
A100	9.94	31.378	
A101	10.00	31.216	
A102	10.04	31.086	
A103	10.02	30.975	
A104	10.06	31.266	
A105	10.14	31.068	
A106	9.88	31.049	
A107	10.09	31.036	
A108	10.09	31.154	
A109	9.96	31.127	
A110	9.98	30.931	
A111	9.99	31.097	
A112	9.95	31.312	
A113	9.96	31.292	
A114	10.00	31.257	
A115	9.90	31.308	
A116	9.89	31.346	
A117	9.87	31.247	
A118	10.00	31.301	
A119	9.96	31.113	
A120	9.88	31.228	
A121	10.15	31.360	
A122	9.92	31.402	
A123	10.02	31.025	
A124	9.96	31.041	
A125	9.91	31.350	
A126	9.90	31.320	

ID-Nr. LOT 57130110	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A127	9.92	31.163	
A128	9.97	31.246	
A129	9.95	31.230	
A130	9.94	31.314	
A131	9.93	31.100	
A132	9.87	31.405	
A133	9.95	31.301	
A134	9.88	30.974	
A135	10.05	31.172	
A136	10.03	31.070	
A137	9.86	31.334	
A138	9.87	31.513	
A139	10.01	31.527	
A140	9.90	31.349	
A141	10.05	31.106	
A142	9.96	31.196	
A143	9.95	31.548	
A144	9.98	31.158	
A145	9.93	31.331	
A146	9.93	31.119	
A147	9.90	31.153	
A148	9.94	31.275	
A149	10.05	31.076	
A150	10.13	31.288	
A151	10.00	31.280	
A152	9.97	31.326	
A153	9.98	31.200	
A154	9.98	31.363	
A155	9.90	31.314	
A156	9.92	31.108	
A157	10.12	30.087	
A158	10.04	31.199	
A159	10.03	31.089	
A160	9.99	31.141	
A161	9.98	31.328	
A162	9.99	31.281	
A163	9.90	31.334	
A164	9.91	31.580	
A165	9.92	31.306	
A166	9.93	30.019	
A167	9.94	31.396	
A168	9.89	31.258	

ID-Nr. LOT 57130110	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A169	9.95	31.240	
A170	9.98	29.992	
A171	9.99	31.385	
A172	9.99	31.281	
A173	9.98	31.344	
A174	9.97	31.322	
A175	9.89	31.531	
A176	10.02	31.370	
A177	10.05	31.384	
A178	10.06	31.451	
A179	10.07	31.374	
A180	9.98	31.443	
A181	10.12	31.209	
A182	9.87	31.376	
A183	9.93	31.181	
A184	9.90	31.382	
A185	9.88	31.599	
A186	9.92	31.459	
A187	9.97	31.113	
A188	9.87	31.084	
A189	9.95	31.082	
A190	10.06	30.957	
A191	10.10	31.118	
A192	9.93	30.105	
A193	10.06	30.053	
A194	9.90	30.050	
A195	9.92	30.072	
A196	10.00	31.175	
A197	10.08	31.115	
A198	10.03	31.106	
A199	9.87	31.069	
A200	9.96	31.175	
A201	9.87	30.016	
A202	9.97	29.990	
A203	9.92	30.114	
A204	9.92	30.056	
A205	9.99	30.072	
A206	9.95	29.995	
A207	9.91	30.181	
A208	9.89	30.245	
A209	10.13	31.072	
A210	9.94	30.081	

ID-Nr. LOT 57130110	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A211	9.91	30.012	
A212	9.98	30.139	
A213	10.00	30.100	
A214	9.99	30.042	
A215	9.96	30.057	
A216	9.89	30.002	
A217	9.97	30.041	
A218	10.01	30.095	
A219	10.08	31.617	
A220	9.90	31.157	
A221	9.89	31.433	
A222	9.91	31.141	
A223	9.95	31.718	
A224	10.06	31.400	
A225	9.93	31.371	
A226	9.91	31.381	
A227	10.09	31.530	
A228	9.97	31.092	
A229	9.90	31.141	
A230	9.98	30.989	
A231	10.04	31.384	
A232	10.11	31.306	
A233	9.95	31.113	
A234	9.90	31.108	
A235	10.00	29.970	
A236	9.90	30.004	
A237	9.91	30.043	
A238	10.05	30.128	
A239	10.12	30.098	
A240	10.03	30.088	
A241	9.87	30.991	
A242	9.95	30.180	
A243	9.92	30.071	
A244	9.97	30.099	
A245	9.99	30.165	
A246	9.98	30.088	
A247	9.89	31.121	
A248	9.98	30.087	
A249	10.00	30.063	
A250	9.91	30.140	
A251	9.94	30.062	
A252	9.88	30.138	

4. Lot-Specific Data

ID-Nr. LOT 57130110	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A253	9.91	30.142	
A254	10.06	30.111	
A255	9.93	30.147	
A256	9.95	30.099	
A257	9.88	30.048	
A258	10.08	30.150	
A259	10.06	30.051	
A260	9.93	30.026	
A261	9.89	30.095	
A262	10.15	29.573	
A263	9.90	30.015	
A264	9.92	29.928	
A265	9.92	30.001	
A266	9.95	30.148	
A267	9.92	30.105	
A268	9.88	30.168	
A269	10.10	30.054	
A270	10.10	30.043	
A271	10.01	30.010	
A272	10.05	30.120	
A273	9.95	30.017	
A274	10.07	30.078	
A275	9.93	30.051	
A276	9.88	30.053	
A277	9.89	30.029	
A278	10.03	30.195	
A279	9.92	30.945	
A280	10.08	30.102	
A281	9.99	30.026	
A282	10.12	30.110	
A283	10.08	30.100	
A284	10.08	30.051	
A285	10.07	30.067	
A286	10.00	30.057	
A287	9.99	30.024	
A288	9.93	30.073	
A289	10.03	30.085	
A290	9.97	30.064	
A291	9.98	30.973	
A292	9.95	31.071	
A293	9.91	30.131	
A294	9.97	29.976	

ID-Nr. LOT 57130110	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A295	10.13	30.963	
A296	10.09	29.938	
A297	9.88	30.031	
A298	9.89	30.222	
A299	9.98	31.669	
A300	9.88	31.328	
A301	9.93	30.839	
A302	9.90	30.146	
A303	10.02	30.157	
A304	9.99	30.268	
A305	10.00	30.120	
A306	10.02	31.156	
A307	9.98	31.042	
A308	9.88	30.989	
A309	10.09	30.974	
A310	10.05	31.119	
A311	9.93	31.178	
A312	10.01	30.855	
A313	9.90	31.239	
A314	10.05	31.084	
A315	9.97	30.928	
A316	10.07	31.013	
A317	10.01	31.447	
A318	9.89	31.303	
A319	9.96	31.026	
A320	10.10	31.169	
A321	9.98	31.274	
A322	9.95	31.032	
A323	10.08	31.046	
A324	10.05	30.802	
A325	9.96	31.363	
A326	9.93	31.072	
A327	9.94	31.166	
A328	10.04	31.115	
A329	9.92	30.748	
A330	10.05	30.963	
A331	9.95	30.989	
A332	10.02	30.851	
A333	10.12	31.106	
A334	10.01	30.930	
A335	9.95	31.213	
A336	10.08	31.095	

ID-Nr. LOT 57130110	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A337	9.88	31.342	
A338	10.02	31.181	
A339	9.99	31.095	
A340	9.90	31.227	
A341	10.07	31.062	
A342	10.03	31.085	
A343	9.91	31.133	
A344	9.99	30.985	
A345	10.03	30.913	
A346	10.03	30.646	
A347	9.89	31.037	
A348	9.95	31.138	
A349	9.96	31.242	
A350	10.01	31.201	
A351	9.99	31.395	
A352	10.11	31.203	
A353	9.87	30.899	
A354	9.92	31.300	
A355	9.99	31.327	
A356	9.92	31.044	
A357	9.90	31.195	
A358	10.04	30.902	
A359	10.12	31.243	
A360	9.92	31.140	
A361	10.08	30.931	
A362	10.10	31.080	
A363	10.04	30.760	
A364	10.03	31.045	
A365	9.95	31.298	
A366	10.13	30.954	
A367	9.98	31.029	
A368	10.13	31.041	
A369	9.90	30.750	
A370	10.03	31.100	
A371	10.10	31.172	
A372	10.11	31.136	
A373	9.98	31.286	
A374	10.01	31.139	
A375	10.01	30.906	
A376	10.17	31.301	
A377	10.00	30.872	
A378	10.00	30.992	

ID-Nr. LOT 57130110	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A379	10.04	31.088	
A380	9.99	31.294	
A381	10.16	31.217	
A382	10.01	31.408	
A383	9.98	31.233	
A384	9.95	31.144	
A385	10.07	31.146	
A386	10.09	31.141	
A387	9.99	31.230	
A388	10.15	30.999	
A389	10.16	30.958	
A390	9.94	31.164	
A391	9.98	31.059	
A392	10.07	31.298	
A393	10.16	31.045	
A394	9.95	31.113	
A395	9.99	31.175	
A396	10.10	31.158	
A397	10.08	31.206	
A398	10.03	30.883	
A399	9.94	31.008	
A400	9.93	30.884	
A401	10.10	31.199	
A402	10.07	31.172	
A403	10.09	31.133	
A404	10.07	31.124	
A405	10.07	30.953	
A406	10.08	31.166	
A407	9.92	31.063	
A408	9.94	31.234	
A409	10.12	31.259	
A410	10.16	30.657	
A411	10.05	31.131	
A412	10.13	31.165	
A413	10.04	31.121	
A414	10.00	31.038	
A415	10.01	31.080	
A416	10.13	31.095	
A417	10.05	31.501	
A418	10.13	31.155	
A419	10.08	31.279	
A420	9.92	31.389	

4. Lot-Specific Data

ID-Nr. LOT 57130110	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A421	10.06	31.358	
A422	9.96	31.329	
A423	9.90	31.128	
A424	10.15	31.557	
A425	10.10	31.279	
A426	9.96	31.439	
A427	10.04	31.598	
A428	10.14	31.126	
A429	10.07	31.527	
A430	10.15	31.153	
A431	10.06	31.258	
A432	10.02	31.135	
A433	10.09	31.141	
A434	10.00	31.148	
A435	10.00	31.257	
A436	10.04	31.246	
A437	10.06	31.332	
A438	9.98	31.459	
A439	9.96	31.535	
A440	9.91	31.054	
A441	9.96	31.357	
A442	9.92	31.405	
A443	10.06	31.382	
A444	10.00	31.139	
A445	10.03	31.321	
A446	10.12	31.132	
A447	10.08	31.192	
A448	10.01	31.431	
A449	10.04	31.155	
A450	9.94	31.117	
A451	10.11	31.124	
A452	10.01	31.233	
A453	9.96	31.243	
A454	9.93	31.282	
A455	10.12	30.988	
A456	9.90	31.056	
A457	9.90	31.173	
A458	9.96	31.167	
A459	10.01	31.397	
A460	9.95	31.555	
A461	10.07	31.054	
A462	10.13	31.395	

ID-Nr. LOT 57130110	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A463	9.89	30.993	
A464	9.95	31.197	
A465	9.94	31.050	
A466	10.01	31.419	
A467	10.11	31.321	
A468	10.04	31.215	
A469	9.99	31.383	
A470	9.89	31.540	
A471	10.13	31.454	
A472	10.06	31.164	
A473	10.10	31.288	
A474	10.02	30.983	
A475	9.97	31.294	
A476	10.07	31.312	
A477	10.00	31.058	
A478	10.08	31.096	
A479	9.91	31.255	
A480	9.95	31.091	
A481	10.13	30.873	
A482	10.08	31.546	
A483	10.09	31.008	
A484	10.14	31.323	
A485	10.02	31.183	
A486	10.10	31.056	
A487	10.01	31.351	
A488	10.07	31.289	
A489	10.08	31.147	
A490	10.13	31.212	
A491	10.14	29.987	
A492	10.11	31.041	
A493	10.02	29.993	
A494	10.02	31.124	
A495	10.11	31.594	
A496	9.96	30.031	
A497	10.01	30.206	
A498	10.13	29.894	
A499	10.00	30.134	
A500	9.97	30.080	
A501	10.04	30.357	
A502	10.07	30.036	
A503	10.16	30.003	
A504	9.95	30.034	

ID-Nr. LOT 57130110	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A505	9.93	29.978	
A506	10.04	29.993	
A507	10.01	30.127	
A508	9.90	30.045	
A509	10.07	30.061	
A510	10.00	30.092	
A511	10.05	29.986	
A512	10.08	30.058	
A513	10.05	30.076	
A514	10.02	30.014	
A515	10.14	30.036	
A516	10.10	29.998	
A517	10.13	30.009	
A518	10.00	30.064	
A519	10.15	30.052	
A520	10.08	29.977	
A521	9.90	30.001	
A522	10.13	31.150	
A523	10.01	30.019	
A524	10.13	30.042	
A525	10.06	30.094	
A526	10.07	30.038	
A527	10.01	29.989	
A528	10.07	30.191	
A529	10.10	30.030	
A530	9.94	30.124	
A531	10.09	29.936	
A532	10.01	29.995	
A533	10.11	30.174	
A534	10.00	30.144	
A535	10.07	30.061	
A536	10.09	30.068	
A537	9.99	30.012	
A538	9.95	29.990	
A539	10.11	30.040	
A540	9.98	29.957	
A541	10.13	29.966	
A542	9.96	30.063	
A543	9.89	30.120	
A544	9.93	30.130	
A545	10.01	30.154	
A546	10.04	30.018	

ID-Nr. LOT 57130110	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A547	9.98	30.018	
A548	10.15	30.058	
A549	9.91	29.874	
A550	10.01	29.971	
A551	9.99	30.094	
A552	9.94	30.001	
A553	10.04	29.964	
A554	10.02	30.079	
A555	9.91	30.044	
A556	9.98	30.109	
A557	10.11	29.962	
A558	10.07	30.124	
A559	10.03	30.092	
A560	9.96	30.042	
A561	10.12	29.921	
A562	10.09	30.005	
A563	9.95	30.000	
A564	9.90	30.058	
A565	9.90	30.033	
A566	9.97	30.072	
A567	10.06	30.125	
A568	10.05	30.038	
A569	10.03	30.039	
A570	10.03	30.093	
A571	10.14	29.957	
A572	10.10	30.083	
A573	10.09	31.001	
A574	9.95	30.053	
A575	9.98	30.850	
A576	10.01	30.146	
A577	10.02	30.113	
A578	9.95	30.201	
A579	10.06	31.049	
A580	10.07	30.085	
A581	9.97	30.064	
A582	9.99	30.030	
A583	10.04	29.962	
A584	9.91	29.985	
A585	9.95	29.990	
A586	10.03	29.968	
A587	10.13	30.047	
A588	10.09	29.919	

4. Lot-Specific Data

ID-Nr. LOT 57130110	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A589	9.97	30.012	
A590	10.13	30.035	
A591	10.11	30.694	
A592	10.13	30.884	
A593	10.16	31.287	
A594	10.07	30.748	
A595	10.14	30.897	
A596	10.11	31.144	
A597	9.94	30.742	
A598	9.96	31.230	
A599	9.97	31.144	
A600	10.09	30.776	
A601	10.06	30.780	
A602	10.04	30.762	
A603	10.10	30.702	
A604	10.11	30.582	
A605	9.97	31.010	
A606	10.08	30.998	
A607	9.99	31.217	
A608	10.01	30.876	
A609	10.00	31.043	
A610	9.94	30.863	
A611	9.89	30.963	
A612	10.14	31.213	
A613	9.91	30.940	
A614	9.95	31.112	
A615	9.94	30.802	
A616	9.90	30.976	
A617	9.93	30.692	
A618	9.93	30.853	
A619	10.03	30.653	
A620	9.98	31.244	
A621	10.05	30.558	
A622	10.12	30.894	
A623	10.01	31.003	
A624	10.00	30.823	
A625	10.02	30.977	
A626	9.95	31.326	
A627	10.00	30.656	
A628	9.92	30.969	
A629	9.95	31.031	
A630	10.12	30.531	

ID-Nr. LOT 57130110	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A631	9.98	30.593	
A632	10.07	30.815	
A633	10.16	30.849	
A634	10.11	31.025	
A635	10.05	30.933	
A636	10.14	31.045	
A637	9.97	31.039	
A638	9.90	31.083	
A639	9.98	30.905	
A640	10.03	30.636	
A641	9.93	30.856	
A642	10.01	30.871	
A643	10.11	31.040	
A644	10.06	31.046	
A645	10.11	30.785	
A646	10.02	31.137	
A647	10.11	30.719	
A648	10.06	30.961	
A649	10.04	30.780	
A650	10.06	30.833	
A651	9.92	30.883	
A652	10.01	31.039	
A653	10.05	30.954	
A654	9.88	30.733	
A655	10.05	30.961	
A656	10.02	30.971	
A657	10.07	31.178	
A658	10.07	31.095	
A659	9.89	30.967	
A660	9.88	31.000	
A661	9.96	31.193	
A662	9.98	31.173	
A663	10.08	30.960	
A664	10.05	30.902	
A665	10.13	30.793	
A666	9.93	30.841	
A667	10.09	30.916	
A668	10.02	30.966	
A669	10.02	30.870	
A670	10.05	30.751	
A671	10.10	30.930	
A672	10.06	30.765	

ID-Nr. LOT 57130110	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A673	9.96	30.864	
A674	10.06	30.863	
A675	10.10	30.848	
A676	10.06	30.996	
A677	10.01	30.790	
A678	9.94	30.842	
A679	9.94	30.777	
A680	10.00	31.052	
A681	10.01	31.034	
A682	10.11	30.855	
A683	10.02	30.909	
A684	10.00	31.046	
A685	9.94	30.837	
A686	9.96	31.235	
A687	9.94	31.079	
A688	9.91	31.137	
A689	9.94	31.053	
A690	10.15	31.252	
A691	9.93	31.231	
A692	10.07	31.196	
A693	9.94	31.274	
A694	9.94	31.177	
A695	10.13	30.044	
A696	9.92	30.874	
A697	10.06	30.031	
A698	9.95	30.094	
A699	10.13	30.083	
A700	10.09	30.940	
A701	10.02	30.987	
A702	10.11	30.498	
A703	10.09	31.230	
A704	9.90	30.962	
A705	10.01	31.207	
A706	10.06	30.869	
A707	9.91	30.789	
A708	9.91	30.685	
A709	10.07	30.927	
A710	10.01	30.636	
A711	9.96	30.843	
A712	9.92	31.097	
A713	9.99	30.771	
A714	9.95	31.214	

ID-Nr. LOT 57130110	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A715	10.07	30.842	
A716	9.87	31.247	
A717	9.92	30.955	
A718	10.01	31.019	
A719	9.93	30.868	
A720	9.88	30.978	
A721	9.98	30.942	
A722	9.95	31.184	
A723	9.93	30.983	
A724	10.02	30.612	
A725	9.94	30.949	
A726	10.03	30.789	
A727	9.92	30.783	
A728	9.89	31.061	
A729	10.12	30.713	
A730	9.97	30.837	
A731	9.93	30.922	
A732	9.91	30.817	
A733	9.90	31.053	
A734	10.03	31.039	
A735	10.09	30.967	
A736	10.07	30.913	
A737	10.00	30.911	
A738	9.95	30.976	
A739	9.91	30.954	
A740	10.00	30.899	
A741	9.93	30.825	
A742	10.01	30.995	
A743	9.95	30.893	
A744	9.96	30.945	
A745	10.07	30.906	
A746	10.06	31.084	
A747	10.00	30.864	
A748	10.12	30.837	
A749	10.17	31.056	
A750	10.05	30.855	
A751	10.15	30.909	
A752	10.07	31.025	
A753	10.07	30.498	
A754	10.00	31.040	
A755	10.01	30.874	
A756	9.95	30.798	

4. Lot-Specific Data

ID-Nr. LOT 57130110	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A757	10.11	31.080	
A758	10.05	31.368	
A759	10.08	31.081	
A760	9.94	30.859	
A761	10.10	30.763	
A762	10.12	30.707	
A763	10.02	30.760	
A764	10.07	30.738	
A765	10.03	31.052	
A766	9.94	31.019	
A767	9.96	30.931	
A768	10.12	31.163	
A769	9.97	31.051	
A770	9.87	30.994	
A771	10.05	30.843	
A772	9.93	30.872	
A773	10.03	30.830	
A774	9.90	30.829	
A775	9.97	30.601	
A776	10.01	30.918	
A777	10.07	31.017	
A778	9.94	31.128	
A779	9.95	30.957	
A780	10.13	31.310	
A781	9.98	30.958	
A782	9.94	30.723	
A783	9.91	30.942	
A784	9.94	30.836	
A785	9.89	31.010	
A786	9.99	30.789	
A787	10.01	30.878	
A788	9.90	31.029	
A789	10.00	30.913	
A790	9.88	30.671	
A791	10.08	30.825	
A792	9.90	31.043	
A793	9.97	31.363	
A794	9.98	31.012	
A795	10.04	30.958	
A796	10.17	31.043	
A797	9.96	30.884	
A798	9.92	30.941	

ID-Nr. LOT 57130110	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A799	9.94	31.020	
A800	9.92	30.730	
A801	10.10	30.927	
A802	10.06	30.911	
A803	9.91	31.103	
A804	9.98	31.060	
A805	9.97	31.086	
A806	9.99	31.316	

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