For use in quality control/manufacturing process only.

Density Reference Standard Beads (DRSB)

Batch A

Version: 68

Content Version: May 2025

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.

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.)

$$\mathbf{FF\ (new)} = \frac{FF\ (new_1) + FF\ (new_2)}{2}$$

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

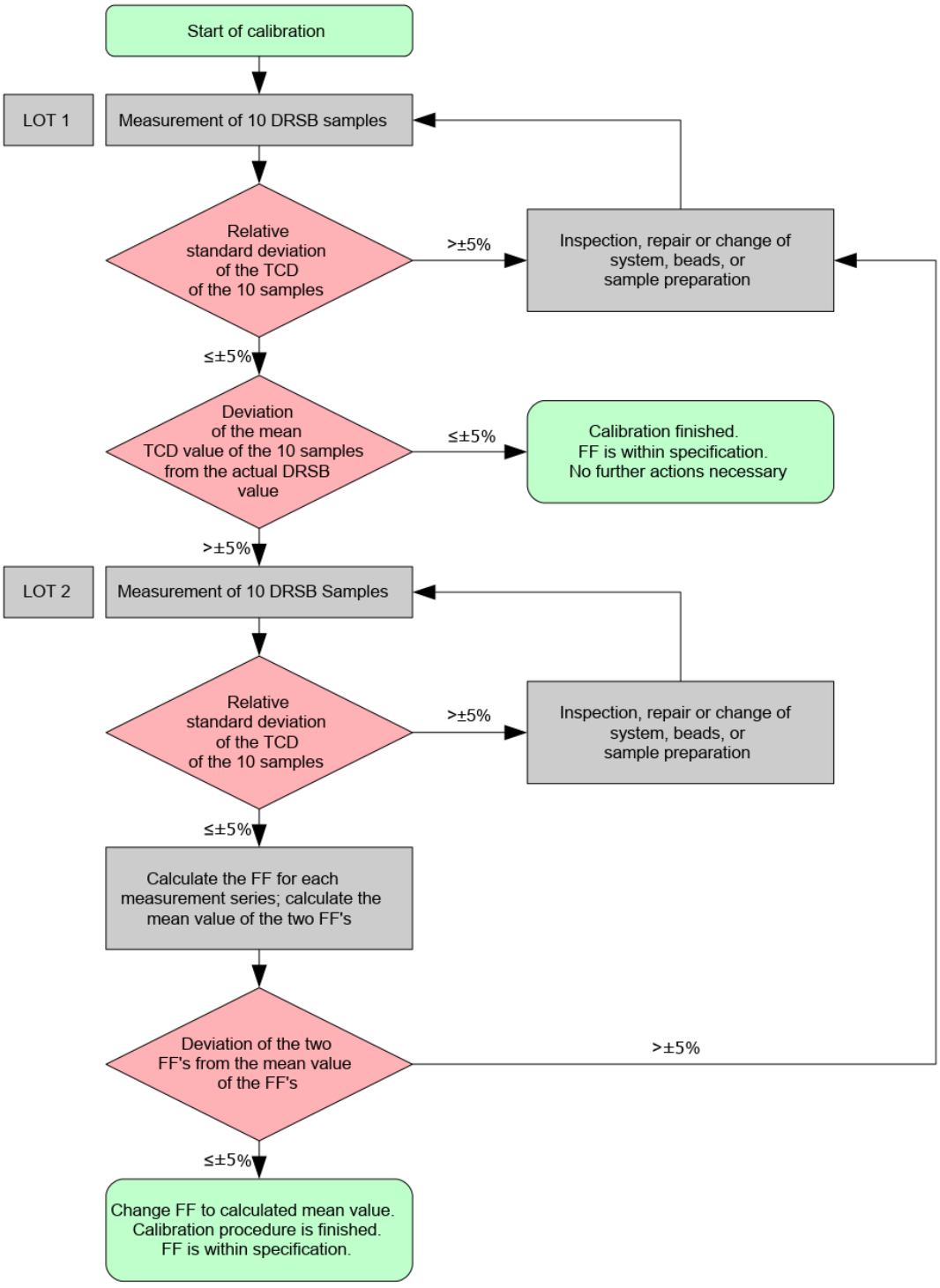

Fig. 1: Calibration of Cedex HiRes Analyzer

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**.

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4. Lot-Specific Data

Density Reference Standard Beads, Batch A	
REF	06 422 659 001
	68
valid for LOT	57130117
	Aug 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*

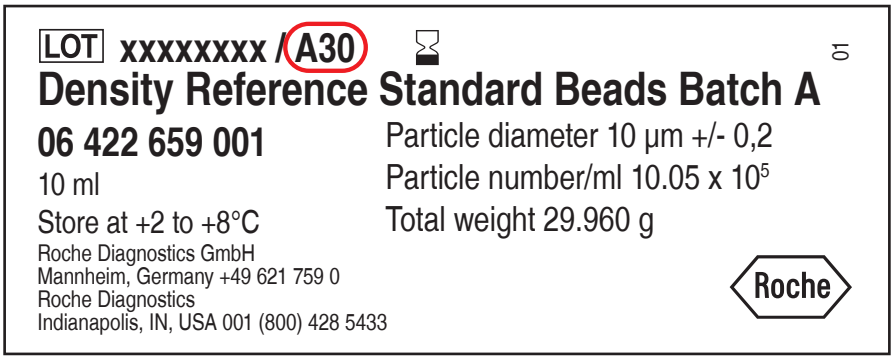

Fig. 2: Example of how to find the bottle number on the bottle label. The bottle number is circled.

ID-Nr. LOT 57130117	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A1	9.93	29.984	
A2	9.92	30.500	
A3	10.02	31.170	
A4	10.11	30.162	
A5	10.02	28.976	
A6	10.15	31.070	
A7	10.19	30.044	
A8	10.12	30.107	
A9	10.06	29.984	
A10	10.13	30.078	
A11	10.16	30.181	
A12	10.14	30.109	
A13	9.98	30.239	
A14	9.98	30.350	
A15	10.19	31.148	
A16	10.13	30.125	
A17	10.17	30.098	
A18	9.96	30.068	
A19	10.11	30.112	
A20	10.09	30.050	
A21	9.96	29.998	
A22	10.09	30.082	
A23	10.03	30.126	
A24	10.03	30.055	
A25	9.96	30.646	
A26	10.09	30.052	
A27	10.06	30.325	
A28	10.10	30.012	
A29	10.15	32.137	
A30	10.07	30.150	
A31	10.11	30.104	
A32	10.13	30.849	
A33	10.13	30.076	
A34	10.06	30.116	
A35	9.98	30.089	
A36	10.01	30.192	
A37	10.06	30.296	
A38	10.17	30.391	
A39	10.09	30.199	
A40	10.00	31.367	
A41	10.11	30.306	
A42	10.08	30.312	

ID-Nr. LOT 57130117	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A43	9.95	30.552	
A44	10.14	30.113	
A45	9.93	30.511	
A46	10.19	30.021	
A47	10.12	30.202	
A48	10.11	30.271	
A49	10.04	30.492	
A50	10.04	30.421	
A51	9.97	30.464	
A52	9.98	30.418	
A53	10.13	30.105	
A54	9.94	30.253	
A55	10.05	30.333	
A56	10.02	31.242	
A57	9.88	30.363	
A58	9.85	30.487	
A59	9.95	30.415	
A60	9.97	30.125	
A61	10.09	30.302	
A62	9.98	30.551	
A63	10.06	31.074	
A64	9.93	30.366	
A65	10.06	30.498	
A66	10.11	30.336	
A67	10.15	30.160	
A68	10.14	30.217	
A69	9.92	31.208	
A70	9.93	30.242	
A71	10.15	30.422	
A72	10.01	30.271	
A73	9.97	30.280	
A74	10.10	30.072	
A75	10.05	30.298	
A76	10.10	30.221	
A77	10.02	30.219	
A78	10.16	30.318	
A79	10.12	31.218	
A80	10.06	30.251	
A81	10.16	29.943	
A82	10.11	30.311	
A83	10.11	30.405	
A84	10.14	30.428	

4. Lot-Specific Data

ID-Nr. LOT 57130117	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A85	9.98	30.345	
A86	10.03	30.520	
A87	10.06	30.288	
A88	10.11	30.394	
A89	10.16	30.447	
A90	9.99	30.256	
A91	10.05	30.390	
A92	10.12	31.249	
A93	10.17	30.328	
A94	9.97	31.300	
A95	10.11	30.393	
A96	10.06	30.337	
A97	10.07	30.568	
A98	10.07	29.233	
A99	10.07	30.327	
A100	9.98	30.363	
A101	10.01	31.396	
A102	10.06	30.020	
A103	9.99	29.951	
A104	10.07	30.102	
A105	10.06	30.006	
A106	10.16	30.393	
A107	9.96	30.116	
A108	10.09	30.454	
A109	10.07	30.392	
A110	10.15	30.234	
A111	10.00	30.244	
A112	9.90	30.290	
A113	10.09	30.292	
A114	10.13	30.353	
A115	10.13	31.308	
A116	10.14	31.261	
A117	9.96	30.208	
A118	9.98	30.219	
A119	10.03	30.509	
A120	10.01	30.231	
A121	10.02	30.511	
A122	10.00	30.181	
A123	10.12	30.181	
A124	10.14	30.437	
A125	10.18	30.201	
A126	10.03	30.429	

ID-Nr. LOT 57130117	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A127	9.98	30.557	
A128	10.04	30.218	
A129	9.98	30.187	
A130	10.03	30.542	
A131	9.97	30.230	
A132	10.11	30.217	
A133	9.90	30.178	
A134	10.08	29.953	
A135	10.08	30.138	
A136	9.99	30.488	
A137	10.01	30.211	
A138	10.14	30.159	
A139	10.01	30.151	
A140	10.13	29.952	
A141	10.04	30.085	
A142	10.05	30.332	
A143	10.13	30.324	
A144	9.96	30.227	
A145	10.03	30.216	
A146	10.18	30.447	
A147	9.90	30.220	
A148	9.97	30.594	
A149	9.94	30.312	
A150	10.06	30.397	
A151	9.93	30.166	
A152	10.02	30.255	
A153	10.13	30.550	
A154	10.04	30.067	
A155	10.02	30.044	
A156	9.96	30.401	
A157	9.95	30.532	
A158	9.99	30.457	
A159	10.02	30.185	
A160	10.02	30.021	
A161	9.95	30.183	
A162	10.03	30.149	
A163	10.07	30.051	
A164	10.05	30.180	
A165	10.03	30.281	
A166	10.06	30.495	
A167	9.96	30.985	
A168	9.86	30.074	

ID-Nr. LOT 57130117	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A169	10.07	30.070	
A170	10.04	30.098	
A171	10.13	30.169	
A172	10.12	30.038	
A173	10.01	30.386	
A174	10.02	30.123	
A175	10.09	30.217	
A176	10.07	30.101	
A177	10.21	29.837	
A178	10.00	30.240	
A179	10.15	29.775	
A180	10.04	30.076	
A181	9.92	30.598	
A182	9.98	30.366	
A183	10.07	30.024	
A184	9.99	30.061	
A185	9.96	30.254	
A186	9.98	30.592	
A187	9.94	30.074	
A188	9.98	30.367	
A189	10.02	30.305	
A190	9.94	30.262	
A191	10.09	30.019	
A192	10.11	30.245	
A193	10.02	30.175	
A194	9.95	31.554	
A195	9.99	29.990	
A196	10.05	30.452	
A197	9.98	30.135	
A198	10.05	30.200	
A199	10.10	30.020	
A200	9.99	30.233	
A201	10.04	30.087	
A202	10.06	29.614	
A203	9.94	30.038	
A204	9.92	30.163	
A205	9.96	30.442	
A206	9.99	30.054	
A207	9.99	29.733	
A208	9.87	29.836	
A209	9.92	30.021	
A210	9.95	30.315	

ID-Nr. LOT 57130117	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A211	10.02	29.749	
A212	10.03	29.867	
A213	9.99	29.850	
A214	9.94	29.850	
A215	10.03	29.645	
A216	10.01	30.884	
A217	10.05	29.708	
A218	10.09	30.023	
A219	10.11	29.911	
A220	9.99	29.853	
A221	9.92	30.047	
A222	9.96	30.926	
A223	9.99	29.927	
A224	9.96	30.787	
A225	10.01	29.794	
A226	10.00	30.916	
A227	10.13	30.895	
A228	10.05	31.202	
A229	10.12	31.235	
A230	10.04	30.947	
A231	10.02	30.938	
A232	10.01	30.730	
A233	10.11	29.837	
A234	10.01	30.971	
A235	10.10	30.919	
A236	10.13	30.730	
A237	10.01	30.852	
A238	10.01	31.201	
A239	10.01	29.718	
A240	9.96	31.007	
A241	10.02	29.748	
A242	10.08	29.840	
A243	9.95	30.929	
A244	10.04	29.820	
A245	9.96	29.716	
A246	10.13	29.781	
A247	10.18	29.870	
A248	10.10	29.790	
A249	9.94	30.069	
A250	9.95	29.670	
A251	10.05	29.677	
A252	10.05	29.727	

4. Lot-Specific Data

ID-Nr. LOT 57130117	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A253	10.07	29.795	
A254	10.00	29.985	
A255	9.99	29.859	
A256	9.97	30.021	
A257	10.01	29.758	
A258	10.07	29.800	
A259	10.14	30.176	
A260	9.96	29.990	
A261	9.98	29.637	
A262	10.07	29.673	
A263	10.08	29.783	
A264	10.03	29.857	
A265	9.97	30.136	
A266	10.16	29.687	
A267	9.98	30.078	
A268	9.97	30.072	
A269	10.13	30.436	
A270	10.09	29.808	
A271	10.08	29.700	
A272	9.98	30.134	
A273	10.04	29.826	
A274	10.03	29.644	
A275	9.93	29.859	
A276	10.14	29.645	
A277	10.01	29.704	
A278	10.04	29.818	
A279	9.97	29.706	
A280	10.02	29.586	
A281	10.13	29.669	
A282	10.03	29.711	
A283	9.99	29.795	
A284	9.97	29.782	
A285	9.99	29.734	
A286	10.00	29.706	
A287	9.91	29.802	
A288	9.98	29.704	
A289	10.07	29.860	
A290	10.04	29.776	
A291	10.08	29.732	
A292	9.98	29.685	
A293	10.01	29.688	
A294	10.06	29.715	

ID-Nr. LOT 57130117	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A295	10.03	29.701	
A296	10.07	29.744	
A297	10.02	29.646	
A298	9.99	29.604	
A299	10.12	29.734	
A300	9.90	29.796	
A301	10.02	29.830	
A302	10.02	29.750	
A303	10.09	29.795	
A304	10.14	29.785	
A305	10.01	29.802	
A306	10.06	29.811	
A307	10.07	29.799	
A308	10.01	30.178	
A309	9.97	31.011	
A310	9.97	29.853	
A311	10.06	29.744	
A312	9.94	29.766	
A313	10.03	31.068	
A314	9.93	29.857	
A315	10.15	29.918	
A316	10.10	29.862	
A317	9.97	29.812	
A318	9.96	31.151	
A319	10.00	29.777	
A320	9.94	29.905	
A321	10.11	29.820	
A322	10.01	29.818	
A323	9.97	29.801	
A324	10.02	29.758	
A325	9.92	29.840	
A326	9.93	30.118	
A327	10.03	31.002	
A328	9.99	29.861	
A329	10.01	29.916	
A330	9.96	29.718	
A331	10.03	29.751	
A332	10.00	29.805	
A333	10.05	30.155	
A334	10.09	29.867	
A335	10.03	29.727	
A336	10.01	29.811	

ID-Nr. LOT 57130117	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A337	9.98	31.288	
A338	10.02	29.778	
A339	9.98	29.881	
A340	10.01	29.802	
A341	10.01	29.944	
A342	10.00	29.832	
A343	9.90	30.084	
A344	10.02	30.985	
A345	9.96	29.868	
A346	10.02	30.103	
A347	9.93	29.791	
A348	9.93	29.748	
A349	9.94	29.781	
A350	9.97	31.245	
A351	10.08	29.793	
A352	9.95	29.858	
A353	10.10	29.843	
A354	9.95	29.813	
A355	9.98	29.770	
A356	10.02	29.816	
A357	10.12	29.855	
A358	10.04	29.826	
A359	10.07	29.868	
A360	9.92	29.881	
A361	10.07	29.794	
A362	9.93	29.756	
A363	9.95	29.760	
A364	9.92	29.898	
A365	10.02	29.799	
A366	9.96	30.815	
A367	9.98	29.844	
A368	10.04	30.249	
A369	10.06	29.779	
A370	10.02	29.824	
A371	9.92	29.799	
A372	10.00	29.918	
A373	10.09	30.999	
A374	10.01	29.750	
A375	9.92	29.807	
A376	10.03	29.712	
A377	9.91	29.731	
A378	9.97	29.874	

ID-Nr. LOT 57130117	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A379	9.92	29.852	
A380	9.89	29.779	
A381	10.05	29.870	
A382	10.06	29.799	
A383	9.93	29.945	
A384	9.95	29.837	
A385	10.10	29.693	
A386	9.88	29.843	
A387	10.06	29.825	
A388	10.15	29.719	
A389	10.03	29.737	
A390	9.97	29.847	
A391	10.01	29.856	
A392	9.99	29.794	
A393	10.05	30.007	
A394	10.07	29.772	
A395	9.91	29.746	
A396	10.04	29.811	
A397	10.05	29.849	
A398	9.97	30.060	
A399	9.99	29.765	
A400	10.04	30.156	
A401	10.02	30.078	
A402	9.92	30.227	
A403	9.89	30.104	
A404	9.97	30.144	
A405	9.94	30.048	
A406	9.87	30.130	
A407	9.94	30.176	
A408	9.98	30.162	
A409	9.85	30.036	
A410	10.01	30.185	
A411	9.98	30.124	
A412	10.01	30.095	
A413	9.99	30.060	
A414	9.95	30.211	
A415	9.93	30.149	
A416	9.90	30.223	
A417	10.04	30.258	
A418	9.96	31.196	
A419	10.01	30.180	
A420	10.01	30.159	

4. Lot-Specific Data

ID-Nr. LOT 57130117	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A421	10.00	30.163	
A422	9.96	30.154	
A423	10.16	30.213	
A424	9.89	30.079	
A425	9.97	30.176	
A426	10.09	30.019	
A427	9.93	30.086	
A428	9.97	30.129	
A429	10.01	30.067	
A430	9.93	30.044	
A431	10.02	30.052	
A432	10.11	30.104	
A433	9.99	30.106	
A434	9.95	30.038	
A435	9.88	29.972	
A436	9.92	30.255	
A437	9.85	30.520	
A438	9.99	30.100	
A439	10.07	30.125	
A440	9.93	30.130	
A441	10.07	30.156	
A442	10.00	30.327	
A443	9.94	30.091	
A444	9.96	30.178	
A445	9.93	30.227	
A446	9.96	30.154	
A447	9.99	31.028	
A448	9.95	30.111	
A449	10.02	30.150	
A450	10.00	30.222	
A451	10.05	30.219	
A452	10.00	30.098	
A453	9.99	30.081	
A454	9.95	30.136	
A455	10.15	30.055	
A456	9.96	30.105	
A457	9.99	30.178	
A458	10.02	30.183	
A459	10.05	30.065	
A460	10.03	30.167	
A461	10.12	30.150	
A462	9.97	30.099	

ID-Nr. LOT 57130117	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A463	9.92	30.204	
A464	10.05	30.166	
A465	9.91	30.080	
A466	10.02	30.183	
A467	9.90	30.070	
A468	9.98	30.018	
A469	9.95	30.167	
A470	9.87	30.181	
A471	9.96	30.085	
A472	10.02	30.144	
A473	10.06	30.156	
A474	10.02	30.267	
A475	10.07	30.102	
A476	9.92	30.044	
A477	10.01	30.116	
A478	9.97	30.012	
A479	10.03	30.132	
A480	10.07	30.109	
A481	9.93	30.104	
A482	10.01	30.155	
A483	9.97	30.049	
A484	9.99	30.120	
A485	9.97	30.054	
A486	10.09	30.150	
A487	10.13	30.042	
A488	9.97	30.170	
A489	10.05	30.227	
A490	10.01	30.144	
A491	9.92	30.132	
A492	10.10	31.132	
A493	9.87	30.238	
A494	9.92	30.332	
A495	9.98	30.055	
A496	10.01	30.108	
A497	9.98	30.132	
A498	10.00	30.069	
A499	10.09	30.046	
A500	10.04	30.151	
A501	9.95	30.066	
A502	10.13	30.005	
A503	10.00	30.034	
A504	10.09	30.144	

ID-Nr. LOT 57130117	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A505	10.13	30.141	
A506	10.03	30.130	
A507	9.87	30.097	
A508	10.01	30.182	
A509	10.15	29.275	
A510	10.11	30.168	
A511	10.10	30.084	
A512	10.09	30.015	
A513	9.97	30.145	
A514	9.96	30.094	
A515	10.09	30.098	
A516	10.10	30.136	
A517	10.17	30.137	
A518	10.00	30.230	
A519	9.91	30.178	
A520	9.99	30.101	
A521	10.06	30.140	
A522	10.15	30.088	
A523	9.99	30.151	
A524	9.99	30.091	
A525	10.12	30.183	
A526	10.05	30.118	
A527	10.11	30.095	
A528	9.91	30.107	
A529	10.07	30.158	
A530	9.98	30.233	
A531	10.04	30.076	
A532	10.11	30.000	
A533	10.19	30.098	
A534	9.99	30.142	
A535	10.02	30.180	
A536	9.95	30.142	
A537	10.00	30.107	
A538	10.04	30.104	
A539	10.16	30.130	
A540	10.07	30.055	
A541	10.07	30.134	
A542	10.04	30.143	
A543	9.91	30.065	
A544	10.06	30.139	
A545	9.98	30.156	
A546	10.11	30.037	

ID-Nr. LOT 57130117	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A547	9.99	30.054	
A548	10.07	30.154	
A549	9.92	30.392	
A550	10.12	30.254	
A551	10.13	30.158	
A552	9.98	30.152	
A553	10.09	30.044	
A554	9.98	30.124	
A555	10.04	30.476	
A556	10.05	30.066	
A557	10.00	30.142	
A558	10.03	30.102	
A559	10.01	30.145	
A560	10.02	30.129	
A561	10.02	30.174	
A562	9.97	30.116	
A563	10.08	30.417	
A564	10.05	30.500	
A565	10.01	30.023	
A566	10.00	30.119	
A567	10.05	30.227	
A568	10.07	30.110	
A569	9.94	30.098	
A570	9.89	31.150	
A571	9.92	30.044	
A572	10.12	30.096	
A573	10.11	30.001	
A574	10.13	30.216	
A575	10.11	30.107	
A576	10.11	30.068	
A577	9.94	30.191	
A578	10.05	30.212	
A579	10.03	30.655	
A580	10.02	30.163	
A581	10.01	30.147	
A582	10.05	30.181	
A583	9.89	30.080	
A584	9.86	30.122	
A585	10.05	30.121	
A586	10.08	30.061	
A587	10.06	29.992	
A588	10.03	30.093	

4. Lot-Specific Data

ID-Nr. LOT 57130117	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A589	10.02	31.072	
A590	9.99	30.049	
A591	10.13	30.157	
A592	10.15	29.989	
A593	9.95	30.017	
A594	10.00	30.123	
A595	10.05	30.109	
A596	10.12	30.046	
A597	10.06	30.099	
A598	9.98	30.044	
A599	10.08	30.134	
A600	10.02	30.134	
A601	10.11	29.881	
A602	10.07	29.750	
A603	9.94	29.802	
A604	10.05	29.706	
A605	10.00	29.783	
A606	10.08	29.937	
A607	10.07	29.778	
A608	10.04	29.886	
A609	10.04	29.840	
A610	10.07	29.820	
A611	10.03	29.799	
A612	10.00	29.712	
A613	9.91	29.881	
A614	10.01	29.795	
A615	10.00	29.819	
A616	9.99	29.784	
A617	10.07	29.740	
A618	10.02	29.770	
A619	9.97	29.785	
A620	9.95	29.781	
A621	10.03	29.708	
A622	10.05	29.660	
A623	10.15	29.789	
A624	10.04	29.714	
A625	10.10	29.788	
A626	10.06	29.854	
A627	9.95	29.752	
A628	10.04	29.789	
A629	9.91	30.739	
A630	10.07	30.075	

ID-Nr. LOT 57130117	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A631	9.96	29.843	
A632	10.02	29.819	
A633	9.98	29.840	
A634	10.02	29.888	
A635	10.10	29.834	
A636	10.03	29.844	
A637	10.01	29.790	
A638	9.96	29.775	
A639	9.99	29.846	
A640	10.06	29.699	
A641	10.05	29.752	
A642	10.02	29.772	
A643	10.00	29.786	
A644	9.99	29.697	
A645	9.99	29.702	
A646	9.88	29.533	
A647	10.15	29.782	
A648	9.96	29.716	
A649	9.98	29.757	
A650	10.03	29.728	
A651	9.90	29.762	
A652	10.06	29.751	
A653	10.07	29.336	
A654	10.05	29.974	
A655	10.12	29.670	
A656	10.07	29.749	
A657	10.01	29.844	
A658	10.06	29.762	
A659	10.03	29.838	
A660	9.98	29.740	
A661	10.02	29.802	
A662	10.09	29.681	
A663	10.14	29.823	
A664	10.00	29.803	
A665	9.97	30.152	
A666	10.07	29.778	
A667	10.10	29.850	
A668	9.98	29.928	
A669	10.01	29.996	
A670	10.03	29.730	
A671	10.08	29.674	
A672	10.08	29.824	

ID-Nr. LOT 57130117	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A673	10.13	29.714	
A674	10.09	29.820	
A675	10.05	29.658	
A676	10.12	29.790	
A677	9.99	29.806	
A678	10.10	29.644	
A679	10.10	29.806	
A680	9.95	29.872	
A681	10.01	29.801	
A682	10.01	29.729	
A683	10.13	29.749	
A684	10.00	29.872	
A685	9.97	29.804	
A686	10.11	29.804	
A687	10.09	29.853	
A688	10.06	29.694	
A689	10.14	29.712	
A690	10.08	30.070	
A691	9.97	29.774	
A692	10.03	29.861	
A693	10.09	29.973	
A694	10.10	29.847	
A695	10.00	29.878	
A696	9.96	29.643	
A697	10.11	29.840	
A698	10.06	29.923	
A699	10.10	29.734	
A700	10.07	31.552	
A701	10.16	29.788	
A702	10.14	30.285	
A703	10.02	30.114	
A704	9.94	30.617	
A705	10.08	29.765	
A706	10.05	29.897	
A707	10.12	29.763	
A708	10.04	29.812	
A709	9.95	30.212	
A710	10.02	30.704	
A711	9.88	30.575	
A712	10.15	30.087	
A713	10.04	30.496	
A714	10.18	29.843	

ID-Nr. LOT 57130117	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A715	10.05	33.219	
A716	10.12	30.064	
A717	10.05	29.798	
A718	10.11	29.736	
A719	10.03	30.178	
A720	10.13	30.113	
A721	10.14	30.352	
A722	10.03	29.765	
A723	10.00	29.889	
A724	10.18	30.209	
A725	10.11	30.297	
A726	10.06	30.265	
A727	10.11	30.143	
A728	10.12	30.045	
A729	10.10	29.882	
A730	10.06	29.801	
A731	9.91	29.814	
A732	10.07	29.918	
A733	9.99	30.065	
A734	10.07	30.083	
A735	9.85	30.264	
A736	10.01	29.969	
A737	9.96	30.089	
A738	10.06	29.687	
A739	9.93	30.784	
A740	10.01	29.759	
A741	9.95	30.103	
A742	9.98	29.773	
A743	10.03	30.224	
A744	9.92	29.887	
A745	9.98	30.127	
A746	9.95	30.110	
A747	9.98	30.083	
A748	10.09	29.597	
A749	10.10	30.044	
A750	9.93	30.095	
A751	10.11	30.142	
A752	10.00	29.808	
A753	9.90	30.199	
A754	9.90	29.775	
A755	9.99	29.933	
A756	10.06	29.741	

4. Lot-Specific Data

ID-Nr. LOT 57130117	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A757	10.07	30.140	
A758	9.99	29.683	
A759	10.00	30.124	
A760	10.11	29.881	
A761	10.02	30.242	
A762	10.14	29.900	
A763	10.06	30.156	
A764	9.91	29.895	
A765	10.14	29.946	
A766	10.13	29.823	
A767	9.96	30.228	
A768	10.09	30.618	
A769	9.96	30.084	
A770	10.14	30.794	
A771	9.96	29.787	
A772	9.98	29.911	
A773	10.03	29.864	
A774	9.98	29.405	
A775	9.99	30.859	
A776	10.11	30.213	
A777	9.96	30.024	
A778	9.97	30.089	
A779	10.11	29.942	
A780	9.98	30.082	
A781	9.99	29.801	
A782	10.05	30.073	
A783	9.93	29.719	
A784	10.08	30.312	
A785	9.98	29.933	
A786	9.94	30.007	
A787	9.90	29.867	
A788	9.94	29.860	
A789	10.01	30.151	
A790	10.10	30.161	
A791	9.91	31.114	
A792	9.89	29.946	
A793	9.93	29.831	
A794	9.91	29.745	
A795	9.90	29.901	
A796	10.05	30.265	
A797	9.86	29.740	
A798	10.06	30.034	

ID-Nr. LOT 57130117	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A799	10.06	29.715	
A800	10.11	29.806	
A801	10.06	30.804	
A802	10.06	31.240	
A803	10.10	31.646	
A804	10.05	31.004	
A805	9.99	31.033	
A806	10.15	30.992	

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