For use in quality control/manufacturing process only.

Density Reference Standard Beads (DRSB)

Batch A

Version: 67

Content Version: December 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.

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

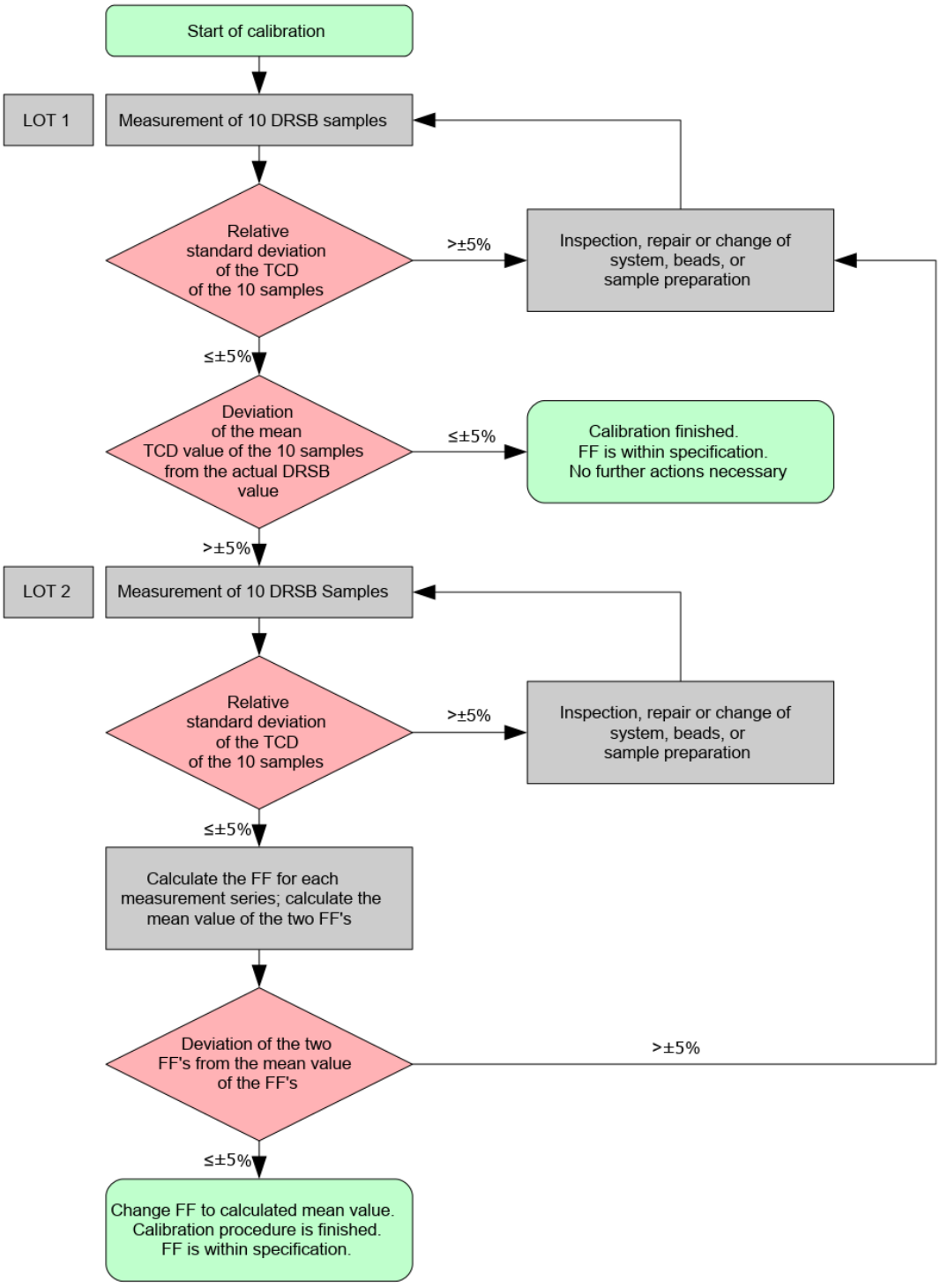

Fig. 1: Calibration of Cedex HiRes Analyzer

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**.

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4. Lot-Specific Data

Density Reference Standard Beads, Batch A	
REF	06 422 659 001
	67
valid for LOT	57130111
	Mar 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*

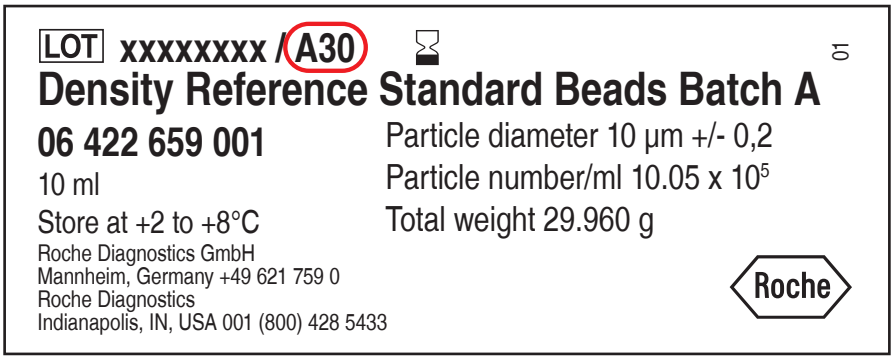

Fig. 2: Example of how to find the bottle number on the bottle label. The bottle number is circled.

ID-Nr. LOT 57130111	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A1	10.05	31.055	
A2	10.12	31.228	
A3	9.94	30.945	
A4	10.02	31.084	
A5	10.11	31.240	
A6	10.00	30.897	
A7	10.02	30.941	
A8	10.03	31.251	
A9	9.89	30.914	
A10	9.93	31.203	
A11	9.96	31.221	
A12	9.95	31.171	
A13	10.02	31.357	
A14	10.03	31.410	
A15	10.05	30.842	
A16	10.09	30.947	
A17	10.05	30.870	
A18	10.09	30.889	
A19	9.91	31.077	
A20	10.06	31.414	
A21	10.08	31.075	
A22	10.08	31.255	
A23	10.08	31.195	
A24	10.07	31.009	
A25	10.07	31.511	
A26	10.12	30.963	
A27	9.96	30.810	
A28	9.96	30.979	
A29	10.05	31.335	
A30	9.97	31.239	
A31	9.95	30.949	
A32	10.11	31.098	
A33	10.02	31.284	
A34	10.12	31.240	
A35	10.05	31.203	
A36	10.07	30.920	
A37	10.02	30.930	
A38	10.03	31.204	
A39	10.01	31.129	
A40	10.04	31.141	
A41	10.14	30.810	
A42	9.92	31.570	

ID-Nr. LOT 57130111	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A43	10.09	31.333	
A44	10.08	31.426	
A45	10.02	31.173	
A46	10.16	31.223	
A47	9.97	31.362	
A48	10.04	31.424	
A49	10.04	31.042	
A50	10.13	31.255	
A51	10.10	31.046	
A52	9.95	31.533	
A53	10.05	31.170	
A54	10.02	31.166	
A55	9.99	31.624	
A56	10.14	31.000	
A57	10.05	31.330	
A58	10.02	31.633	
A59	9.95	31.118	
A60	10.05	31.620	
A61	10.17	30.931	
A62	9.97	31.043	
A63	9.96	31.250	
A64	10.11	31.156	
A65	9.89	31.170	
A66	10.05	31.166	
A67	9.99	31.302	
A68	10.08	31.120	
A69	10.11	31.400	
A70	10.03	31.134	
A71	9.99	31.324	
A72	10.11	31.021	
A73	10.16	31.065	
A74	9.92	31.245	
A75	9.94	31.418	
A76	10.03	31.527	
A77	10.04	31.319	
A78	10.06	31.489	
A79	9.96	31.155	
A80	10.02	31.240	
A81	10.02	31.046	
A82	10.11	30.868	
A83	10.18	31.135	
A84	10.01	31.131	

4. Lot-Specific Data

ID-Nr. LOT 57130111	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A85	10.07	31.134	
A86	10.14	30.992	
A87	10.07	31.337	
A88	9.93	31.094	
A89	10.09	30.832	
A90	10.01	30.966	
A91	9.96	31.476	
A92	10.08	31.069	
A93	10.05	30.897	
A94	9.94	31.340	
A95	10.08	31.357	
A96	10.10	31.007	
A97	9.91	31.274	
A98	10.08	31.068	
A99	10.11	31.509	
A100	9.97	31.491	
A101	10.06	30.892	
A102	10.14	31.671	
A103	10.04	31.135	
A104	10.04	31.262	
A105	10.08	31.599	
A106	10.07	30.895	
A107	10.04	30.985	
A108	9.97	30.851	
A109	10.07	30.992	
A110	10.10	30.829	
A111	10.12	31.203	
A112	9.95	31.021	
A113	10.09	30.876	
A114	9.93	31.189	
A115	9.90	30.998	
A116	9.97	31.211	
A117	9.94	30.736	
A118	10.00	31.074	
A119	9.98	30.989	
A120	9.90	30.872	
A121	10.13	30.837	
A122	9.95	31.076	
A123	9.97	31.023	
A124	9.98	30.872	
A125	9.93	31.124	
A126	10.05	31.020	

ID-Nr. LOT 57130111	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A127	10.06	30.872	
A128	10.02	31.103	
A129	9.94	30.971	
A130	10.18	30.805	
A131	10.01	31.038	
A132	9.97	30.979	
A133	10.13	30.915	
A134	10.06	30.924	
A135	10.05	31.015	
A136	10.03	31.193	
A137	10.08	30.956	
A138	9.98	30.966	
A139	10.08	31.164	
A140	10.04	31.262	
A141	10.09	31.159	
A142	10.13	30.931	
A143	10.08	31.086	
A144	10.10	31.089	
A145	10.01	31.068	
A146	10.06	31.096	
A147	10.14	30.896	
A148	10.06	30.877	
A149	10.05	30.996	
A150	10.03	30.843	
A151	10.09	30.960	
A152	10.03	31.036	
A153	10.07	31.056	
A154	10.11	31.108	
A155	10.12	30.980	
A156	10.00	31.163	
A157	10.07	31.126	
A158	10.09	31.182	
A159	10.14	30.973	
A160	9.98	30.876	
A161	10.13	31.087	
A162	10.06	31.350	
A163	10.13	31.192	
A164	10.01	31.424	
A165	10.01	31.195	
A166	10.17	31.052	
A167	10.04	30.727	
A168	10.06	31.024	

ID-Nr. LOT 57130111	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A169	10.06	31.037	
A170	10.00	30.829	
A171	10.09	31.034	
A172	10.06	30.935	
A173	10.05	31.030	
A174	10.08	31.037	
A175	10.09	30.953	
A176	9.92	31.072	
A177	10.09	31.094	
A178	10.01	30.906	
A179	10.09	31.266	
A180	9.95	31.018	
A181	10.11	31.093	
A182	10.03	30.830	
A183	10.12	31.108	
A184	10.05	31.228	
A185	10.11	30.997	
A186	10.06	31.043	
A187	10.07	31.061	
A188	9.99	30.848	
A189	10.10	30.932	
A190	10.10	30.990	
A191	10.02	30.992	
A192	10.10	30.886	
A193	10.05	31.051	
A194	10.11	30.785	
A195	10.09	30.977	
A196	10.00	31.070	
A197	10.13	31.976	
A198	10.07	30.954	
A199	9.99	31.271	
A200	10.05	31.017	
A201	10.00	31.090	
A202	10.15	31.076	
A203	10.01	31.299	
A204	9.98	30.976	
A205	10.04	31.234	
A206	10.20	31.296	
A207	10.07	31.073	
A208	10.09	31.133	
A209	9.88	31.088	
A210	10.11	31.042	

ID-Nr. LOT 57130111	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A211	9.95	30.872	
A212	9.98	31.136	
A213	10.21	31.063	
A214	10.07	30.965	
A215	10.02	30.925	
A216	10.00	31.220	
A217	10.05	31.149	
A218	10.07	31.219	
A219	9.96	31.200	
A220	10.02	31.126	
A221	9.95	30.979	
A222	10.05	31.036	
A223	10.09	31.160	
A224	9.94	30.985	
A225	10.10	31.183	
A226	9.95	31.187	
A227	9.99	31.124	
A228	10.02	30.966	
A229	9.93	31.189	
A230	9.96	31.179	
A231	10.06	31.123	
A232	9.96	31.005	
A233	9.97	31.181	
A234	9.99	31.164	
A235	10.15	31.196	
A236	9.95	30.930	
A237	9.97	31.236	
A238	10.02	30.893	
A239	10.01	30.985	
A240	9.99	31.156	
A241	10.00	30.960	
A242	9.92	31.087	
A243	9.92	30.903	
A244	9.96	31.127	
A245	10.12	31.019	
A246	10.03	31.263	
A247	10.03	30.895	
A248	10.19	30.882	
A249	9.97	31.084	
A250	9.90	31.108	
A251	10.02	30.853	
A252	10.06	30.914	

4. Lot-Specific Data

ID-Nr. LOT 57130111	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A253	10.10	31.081	
A254	10.13	31.224	
A255	9.99	31.147	
A256	10.08	31.116	
A257	10.02	30.934	
A258	10.12	30.952	
A259	10.04	30.890	
A260	9.99	29.924	
A261	9.98	31.189	
A262	9.97	30.918	
A263	9.98	31.129	
A264	10.11	30.889	
A265	10.03	31.183	
A266	10.13	31.187	
A267	10.12	31.038	
A268	10.05	31.058	
A269	10.01	31.269	
A270	10.03	31.181	
A271	10.02	31.148	
A272	10.00	30.847	
A273	10.10	31.120	
A274	10.10	31.232	
A275	10.02	30.910	
A276	10.02	31.244	
A277	9.99	31.094	
A278	10.01	31.096	
A279	10.12	30.866	
A280	9.98	31.068	
A281	10.00	30.952	
A282	10.14	30.941	
A283	9.87	31.170	
A284	10.09	31.055	
A285	9.91	30.978	
A286	10.02	31.071	
A287	9.87	31.031	
A288	9.96	31.094	
A289	10.02	30.916	
A290	10.00	30.993	
A291	9.97	31.005	
A292	10.12	31.143	
A293	9.99	30.909	
A294	10.02	31.170	

ID-Nr. LOT 57130111	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A295	10.03	31.233	
A296	10.07	31.249	
A297	9.99	30.985	
A298	9.95	31.109	
A299	10.09	30.885	
A300	10.01	31.156	
A301	9.99	31.082	
A302	9.90	30.976	
A303	9.98	31.072	
A304	10.05	30.923	
A305	10.03	31.116	
A306	9.96	30.844	
A307	10.05	31.070	
A308	10.03	30.931	
A309	10.03	30.970	
A310	9.92	30.926	
A311	10.07	30.784	
A312	10.10	30.737	
A313	10.06	31.119	
A314	10.06	31.264	
A315	10.09	31.023	
A316	9.96	31.118	
A317	10.05	30.648	
A318	9.98	31.090	
A319	10.03	31.128	
A320	9.96	30.815	
A321	9.97	30.647	
A322	10.01	30.840	
A323	10.00	30.684	
A324	9.91	30.994	
A325	9.92	31.188	
A326	10.09	31.056	
A327	9.95	31.056	
A328	9.92	31.135	
A329	10.02	31.001	
A330	10.03	31.203	
A331	10.09	30.923	
A332	9.99	31.080	
A333	10.06	31.099	
A334	9.96	30.873	
A335	9.99	31.194	
A336	9.97	30.979	

ID-Nr. LOT 57130111	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A337	10.06	31.066	
A338	10.08	31.075	
A339	9.91	30.999	
A340	10.03	31.116	
A341	9.90	31.139	
A342	9.98	31.022	
A343	9.93	30.871	
A344	10.00	30.862	
A345	10.05	30.950	
A346	9.87	30.893	
A347	10.03	30.914	
A348	9.97	30.987	
A349	9.85	30.905	
A350	10.05	31.416	
A351	10.05	30.879	
A352	10.08	31.012	
A353	9.99	31.011	
A354	9.96	30.960	
A355	10.10	31.316	
A356	10.03	30.988	
A357	10.03	30.891	
A358	10.08	31.123	
A359	9.83	31.118	
A360	10.05	31.028	
A361	10.13	31.284	
A362	10.03	31.014	
A363	9.87	30.733	
A364	9.92	30.888	
A365	10.03	30.754	
A366	9.94	30.744	
A367	10.06	31.056	
A368	10.06	31.178	
A369	9.98	30.714	
A370	9.99	31.068	
A371	10.02	30.847	
A372	9.97	31.014	
A373	10.04	30.822	
A374	10.02	30.999	
A375	9.97	30.967	
A376	10.02	30.789	
A377	9.98	31.013	
A378	9.92	30.952	

ID-Nr. LOT 57130111	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A379	9.94	31.047	
A380	9.98	31.148	
A381	10.11	30.938	
A382	10.11	31.013	
A383	10.10	30.917	
A384	10.01	31.163	
A385	9.96	31.150	
A386	10.02	31.075	
A387	10.07	30.874	
A388	10.10	31.026	
A389	10.10	30.903	
A390	9.90	31.144	
A391	9.90	30.818	
A392	9.97	30.784	
A393	9.96	31.326	
A394	10.11	31.050	
A395	10.11	31.377	
A396	9.99	30.998	
A397	9.97	30.488	
A398	9.96	30.949	
A399	9.90	30.883	
A400	9.98	30.900	
A401	9.92	30.968	
A402	10.01	31.068	
A403	10.03	31.243	
A404	10.01	31.038	
A405	9.96	31.226	
A406	9.95	31.087	
A407	10.01	31.160	
A408	10.06	31.259	
A409	10.09	31.132	
A410	10.15	31.034	
A411	10.11	31.024	
A412	10.12	31.395	
A413	9.98	31.635	
A414	9.99	31.361	
A415	10.06	31.251	
A416	10.03	31.341	
A417	9.92	31.299	
A418	9.91	31.644	
A419	10.03	31.307	
A420	9.94	31.556	

4. Lot-Specific Data

ID-Nr. LOT 57130111	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A421	9.97	31.516	
A422	10.09	31.419	
A423	9.93	31.634	
A424	9.99	31.562	
A425	10.14	29.857	
A426	10.05	31.396	
A427	10.00	31.504	
A428	10.09	31.268	
A429	10.05	31.402	
A430	10.14	31.805	
A431	10.13	31.252	
A432	10.04	31.642	
A433	9.95	31.536	
A434	10.14	30.893	
A435	9.87	31.717	
A436	10.07	31.386	
A437	10.01	31.327	
A438	10.15	30.717	
A439	10.05	31.226	
A440	10.01	31.731	
A441	10.08	31.508	
A442	10.03	31.359	
A443	10.01	31.324	
A444	10.07	31.190	
A445	10.04	31.185	
A446	10.06	31.314	
A447	10.01	31.082	
A448	10.10	31.198	
A449	10.06	31.343	
A450	10.08	31.340	
A451	10.03	31.326	
A452	10.07	31.177	
A453	10.16	31.392	
A454	10.03	31.311	
A455	10.10	31.357	
A456	9.95	31.441	
A457	10.17	31.315	
A458	10.14	31.307	
A459	10.18	31.371	
A460	10.05	31.394	
A461	10.11	31.134	
A462	9.97	31.135	

ID-Nr. LOT 57130111	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A463	9.98	31.510	
A464	9.92	30.375	
A465	10.00	31.414	
A466	9.98	31.620	
A467	10.09	31.418	
A468	10.10	31.440	
A469	9.96	31.478	
A470	10.06	31.455	
A471	10.05	31.537	
A472	10.03	31.361	
A473	10.15	31.260	
A474	10.11	31.319	
A475	10.06	31.442	
A476	9.97	31.456	
A477	10.07	31.307	
A478	9.95	31.475	
A479	10.02	31.335	
A480	10.11	31.434	
A481	9.94	31.355	
A482	10.08	31.551	
A483	10.05	31.417	
A484	10.12	31.451	
A485	10.12	31.086	
A486	10.14	31.494	
A487	10.06	31.493	
A488	10.07	31.313	
A489	10.10	31.463	
A490	10.09	31.426	
A491	10.07	31.562	
A492	9.93	31.676	
A493	10.01	31.358	
A494	9.92	31.689	
A495	10.07	31.538	
A496	9.97	31.540	
A497	10.07	31.413	
A498	10.09	31.260	
A499	10.01	31.249	
A500	9.98	31.421	
A501	10.04	31.117	
A502	9.93	31.178	
A503	10.03	31.659	
A504	10.12	31.304	

ID-Nr. LOT 57130111	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A505	9.97	31.229	
A506	9.99	31.109	
A507	9.97	31.370	
A508	10.07	31.414	
A509	10.14	31.189	
A510	10.08	31.256	
A511	9.95	30.899	
A512	10.04	31.363	
A513	9.98	31.299	
A514	10.11	30.912	
A515	9.99	32.100	
A516	9.99	31.408	
A517	10.05	31.195	
A518	10.06	31.470	
A519	10.04	31.328	
A520	10.17	31.098	
A521	10.06	31.433	
A522	9.93	31.205	
A523	9.97	31.812	
A524	9.92	31.255	
A525	9.96	31.399	
A526	10.05	31.548	
A527	10.07	31.312	
A528	9.93	31.728	
A529	10.12	30.060	
A530	10.05	31.153	
A531	10.01	31.641	
A532	10.08	31.071	
A533	10.03	31.654	
A534	9.93	32.334	
A535	9.91	31.359	
A536	10.08	31.432	
A537	10.18	31.312	
A538	9.98	31.871	
A539	9.91	31.631	
A540	9.96	31.957	
A541	10.01	30.232	
A542	9.94	31.309	
A543	10.07	31.046	
A544	10.06	31.387	
A545	10.08	31.213	
A546	10.07	31.299	

ID-Nr. LOT 57130111	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A547	10.04	31.042	
A548	10.04	31.235	
A549	10.04	31.242	
A550	9.99	31.369	
A551	10.00	31.167	
A552	10.10	31.305	
A553	10.00	32.192	
A554	10.01	30.943	
A555	9.96	31.278	
A556	9.99	31.243	
A557	10.05	30.824	
A558	10.08	30.902	
A559	10.07	31.232	
A560	10.05	31.169	
A561	10.07	31.108	
A562	10.07	30.805	
A563	10.11	31.128	
A564	10.06	31.189	
A565	10.08	31.295	
A566	9.99	31.116	
A567	10.15	30.972	
A568	10.19	30.805	
A569	10.05	31.180	
A570	10.08	31.087	
A571	10.12	31.213	
A572	10.13	31.173	
A573	10.06	30.886	
A574	9.94	30.847	
A575	9.94	31.174	
A576	9.99	30.874	
A577	9.98	31.170	
A578	10.05	31.128	
A579	10.03	31.296	
A580	10.02	31.532	
A581	10.10	31.069	
A582	10.12	31.360	
A583	10.08	31.443	
A584	10.07	31.402	
A585	10.08	31.291	
A586	10.14	30.922	
A587	10.13	30.923	
A588	10.16	31.325	

4. Lot-Specific Data

ID-Nr. LOT 57130111	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A589	10.00	32.066	
A590	9.94	31.375	
A591	10.11	31.119	
A592	9.98	31.255	
A593	10.13	31.083	
A594	10.08	31.156	
A595	10.08	31.294	
A596	10.02	30.906	
A597	10.20	31.161	
A598	10.15	31.242	
A599	10.06	30.855	
A600	10.17	31.282	
A601	10.06	31.014	
A602	10.11	31.041	
A603	10.04	30.840	
A604	10.09	31.117	
A605	9.98	31.143	
A606	10.10	30.990	
A607	10.14	31.166	
A608	10.12	30.885	
A609	10.08	31.147	
A610	10.00	30.886	
A611	9.97	30.908	
A612	9.91	31.014	
A613	10.04	31.169	
A614	10.13	31.160	
A615	9.93	30.793	
A616	9.95	31.116	
A617	10.16	31.041	
A618	10.08	30.950	
A619	10.18	30.959	
A620	10.01	31.114	
A621	10.13	31.287	
A622	9.87	31.330	
A623	9.98	31.125	
A624	10.12	31.413	
A625	9.90	32.510	
A626	10.15	30.775	
A627	10.05	30.905	
A628	9.90	31.075	
A629	9.96	31.090	
A630	10.11	31.059	

ID-Nr. LOT 57130111	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A631	9.95	31.106	
A632	10.08	31.169	
A633	9.95	31.360	
A634	9.98	31.557	
A635	9.90	31.493	
A636	10.04	30.748	
A637	10.05	30.971	
A638	10.02	30.995	
A639	9.88	31.168	
A640	10.00	31.004	
A641	9.96	31.003	
A642	9.98	31.192	
A643	9.97	30.923	
A644	9.92	30.933	
A645	10.16	31.689	
A646	10.01	31.365	
A647	10.05	31.323	
A648	9.96	32.378	
A649	10.07	31.118	
A650	9.99	31.131	
A651	10.12	31.425	
A652	10.14	30.976	
A653	10.07	30.915	
A654	10.19	31.154	
A655	10.15	31.061	
A656	10.07	30.668	
A657	10.20	30.942	
A658	10.14	31.038	
A659	10.04	31.053	
A660	10.15	30.862	
A661	10.21	30.965	
A662	10.07	31.360	
A663	10.00	31.258	
A664	9.98	31.350	
A665	10.02	31.246	
A666	10.13	30.743	
A667	10.08	31.452	
A668	10.00	31.322	
A669	9.96	31.423	
A670	10.03	31.373	
A671	10.07	31.385	
A672	10.00	31.265	

ID-Nr. LOT 57130111	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A673	10.04	31.171	
A674	10.13	31.267	
A675	10.03	31.047	
A676	10.06	31.334	
A677	10.01	31.309	
A678	10.02	31.083	
A679	10.11	31.434	
A680	9.99	31.499	
A681	10.13	30.862	
A682	9.99	31.127	
A683	10.16	30.975	
A684	10.11	31.426	
A685	10.11	31.201	
A686	10.11	31.386	
A687	10.08	31.418	
A688	9.95	31.295	
A689	10.03	31.215	
A690	10.08	31.290	
A691	10.01	31.481	
A692	10.10	30.709	
A693	10.01	31.039	
A694	10.07	30.849	
A695	10.11	31.271	
A696	10.06	31.125	
A697	9.94	31.453	
A698	9.97	31.563	
A699	9.98	31.304	
A700	9.99	29.999	
A701	9.97	31.365	
A702	10.05	32.287	
A703	10.08	31.913	
A704	9.99	31.422	
A705	9.97	31.390	
A706	9.99	31.298	
A707	9.89	31.600	
A708	9.98	31.712	
A709	10.02	31.499	
A710	10.10	31.510	
A711	9.92	31.382	
A712	9.91	31.393	
A713	9.96	31.341	
A714	9.93	31.011	

ID-Nr. LOT 57130111	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A715	9.97	31.355	
A716	10.02	31.098	
A717	10.01	31.141	
A718	10.02	30.899	
A719	9.92	30.813	
A720	10.01	31.079	
A721	10.03	31.505	
A722	10.04	31.584	
A723	10.10	31.367	
A724	10.21	31.312	
A725	9.91	31.259	
A726	9.98	31.459	
A727	10.07	31.338	
A728	10.04	31.203	
A729	10.12	31.216	
A730	10.11	32.151	
A731	9.88	31.666	
A732	10.06	31.749	
A733	10.01	31.390	
A734	10.08	31.356	
A735	10.06	31.578	
A736	10.08	31.386	
A737	10.07	31.132	
A738	10.06	31.290	
A739	10.09	31.382	
A740	10.13	31.514	
A741	10.06	31.196	
A742	9.99	31.502	
A743	10.17	30.848	
A744	10.00	31.404	
A745	10.00	31.316	
A746	10.15	30.931	
A747	9.90	31.466	
A748	9.94	31.594	
A749	9.91	31.484	
A750	10.08	31.262	
A751	9.92	31.423	
A752	9.97	31.612	
A753	9.87	31.777	
A754	9.99	31.467	
A755	9.98	31.346	
A756	10.07	31.353	

4. Lot-Specific Data

ID-Nr. LOT 57130111	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A757	10.08	31.447	
A758	10.09	31.336	
A759	10.07	31.474	
A760	10.00	31.345	
A761	10.15	31.186	
A762	10.09	31.459	
A763	10.03	31.681	
A764	9.97	31.434	
A765	10.07	31.566	
A766	10.07	31.299	
A767	10.09	31.393	
A768	10.00	31.463	
A769	10.04	31.626	
A770	10.02	31.614	
A771	9.99	31.521	
A772	10.13	31.622	
A773	9.91	31.307	
A774	9.96	31.199	
A775	10.15	31.393	
A776	10.18	30.963	
A777	10.13	31.442	
A778	9.87	31.589	
A779	10.05	31.404	
A780	10.06	31.316	
A781	10.18	30.940	
A782	10.11	31.009	
A783	10.11	31.347	
A784	9.87	31.318	
A785	10.00	31.450	
A786	10.02	31.484	
A787	9.89	31.252	
A788	9.98	31.206	
A789	10.01	31.373	
A790	9.99	31.463	
A791	10.09	31.330	
A792	10.04	31.399	
A793	10.08	31.245	
A794	10.08	31.444	
A795	9.98	31.490	
A796	9.98	31.292	
A797	9.98	31.839	
A798	10.10	31.572	

ID-Nr. LOT 57130111	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A799	10.15	31.434	
A800	10.11	31.731	
A801	9.97	31.007	
A802	10.11	31.140	
A803	10.14	31.300	

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