For use in quality control/manufacturing process only.

Density Reference Standard Beads (DRSB)

Batch A

Version: 65

Content Version: April 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 3
1.1. Contents 3
1.2. Storage and Stability 3
Storage Conditions (Product) 3
1.3. Additional Equipment and Reagent required 3
1.4. Applications 3
2. How to Use this Product 4
2.1. Before you Begin 4
General Considerations 4
Acceptance range 4
Sampling quality 4
Working Solution 4
Preparation of the DRSB solution 4
2.2. Protocols 5
Checking the FlowFactor (FF) 5
Adjusting the FlowFactor 6
FlowFactor calibration 7
3. Supplementary Information 8
3.1. Conventions 8
3.2. Changes to previous version 8
3.3. Ordering Information 8
3.4. Trademarks 9
3.5. License Disclaimer 9
3.6. Regulatory Disclaimer 9
3.7. Safety Data Sheet 9
3.8. Contact and Support 9
4. Lot-Specific Data 10
Standard labeling assay 10

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

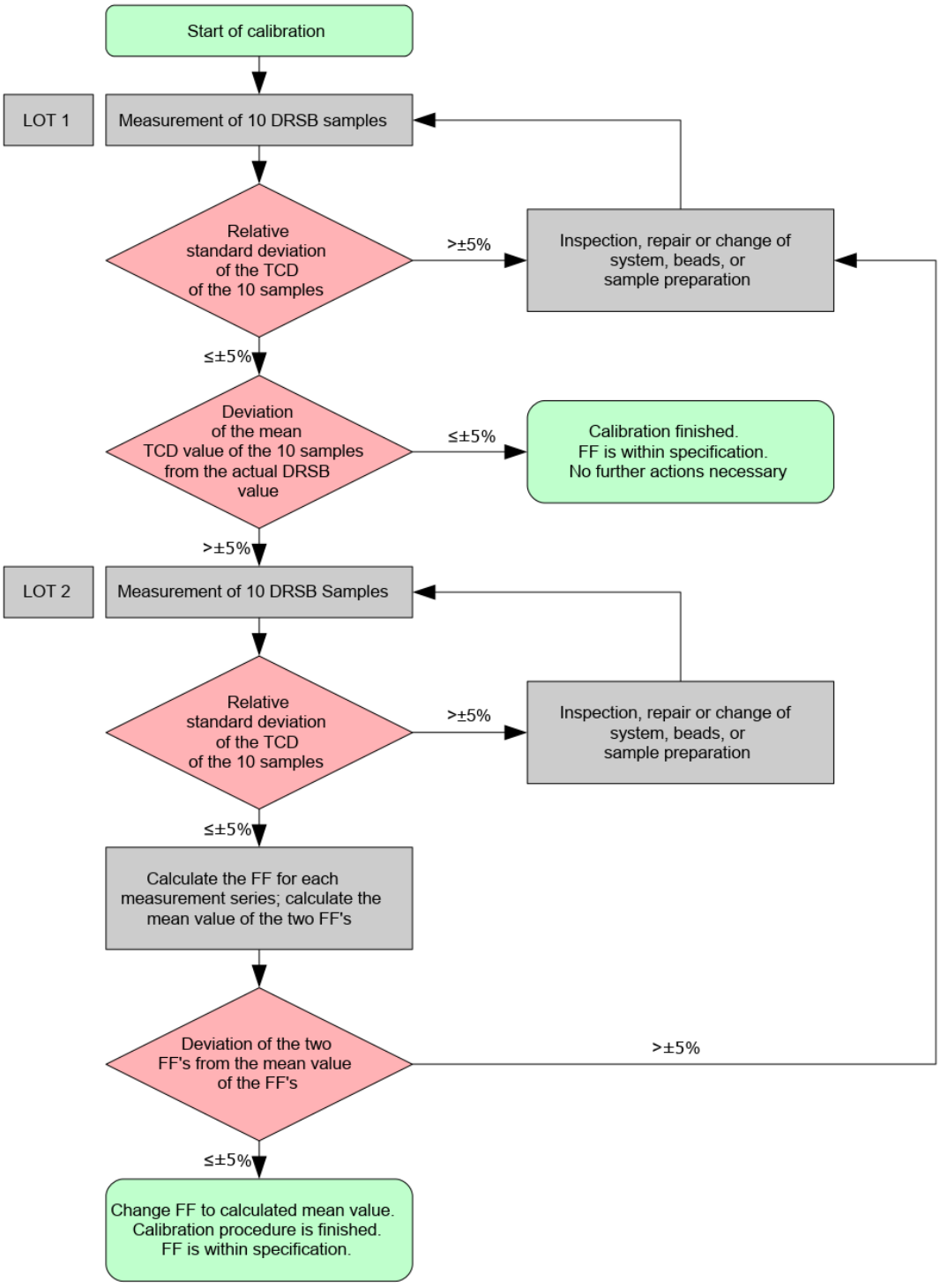

Fig. 1: Calibration of Cedex HiRes Analyzer

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

Layout changes.
Editorial changes.
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
	65
valid for LOT	57130106
	Sep 2025

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*

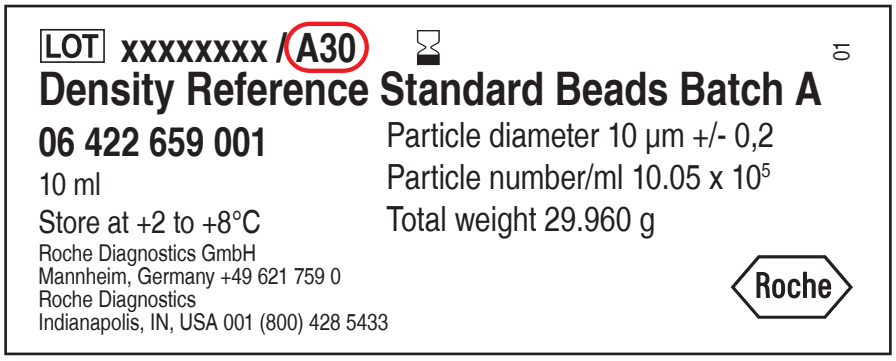

Fig. 2: Example of how to find the bottle number on the bottle label. The bottle number is circled.

ID-Nr. LOT 57130106	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A1	9.933	31.052	
A2	10.045	31.068	
A3	10.043	31.443	
A4	9.980	31.235	
A5	10.145	31.143	
A6	10.020	30.775	
A7	10.010	31.093	
A8	10.138	30.971	
A9	10.098	30.979	
A10	10.038	30.905	
A11	10.153	31.177	
A12	10.013	31.503	
A13	9.983	31.911	
A14	10.030	30.984	
A15	10.060	31.132	
A16	10.060	31.181	
A17	9.955	31.017	
A18	9.923	31.349	
A19	9.960	31.134	
A20	9.983	31.097	
A21	9.965	31.202	
A22	9.903	31.086	
A23	10.060	31.468	
A24	10.045	30.975	
A25	10.090	30.784	
A26	10.090	30.916	
A27	10.035	31.174	
A28	10.035	31.134	
A29	10.075	31.408	
A30	10.118	30.941	
A31	10.053	31.315	
A32	10.033	30.981	
A33	10.038	31.257	
A34	10.030	30.938	
A35	10.060	30.967	
A36	9.973	30.987	
A37	9.990	31.184	
A38	9.983	31.215	
A39	10.040	30.923	
A40	9.918	30.991	
A41	9.955	31.100	
A42	10.020	31.134	

ID-Nr. LOT 57130106	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A43	10.055	31.285	
A44	10.010	31.336	
A45	10.120	30.712	
A46	9.963	30.793	
A47	9.990	30.826	
A48	10.043	31.098	
A49	10.038	31.195	
A50	9.990	30.852	
A51	10.088	31.016	
A52	10.103	31.219	
A53	10.050	31.346	
A54	10.098	31.060	
A55	10.018	30.939	
A56	10.018	31.163	
A57	10.043	31.079	
A58	10.048	31.169	
A59	9.980	30.839	
A60	10.093	30.799	
A61	10.068	31.170	
A62	10.093	31.149	
A63	9.993	30.743	
A64	9.965	30.720	
A65	10.040	30.936	
A66	10.000	30.911	
A67	10.018	31.331	
A68	10.023	30.960	
A69	10.070	31.187	
A70	10.080	31.196	
A71	9.973	31.201	
A72	10.075	31.320	
A73	9.975	31.229	
A74	9.993	30.992	
A75	9.998	30.935	
A76	10.048	31.360	
A77	9.995	31.255	
A78	10.035	31.346	
A79	9.978	30.988	
A80	9.948	31.203	
A81	10.020	31.107	
A82	9.958	31.305	
A83	9.888	30.734	
A84	10.003	31.209	

4. Lot-Specific Data

ID-Nr. LOT 57130106	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A85	9.965	31.248	
A86	10.105	30.750	
A87	9.980	31.241	
A88	10.130	32.148	
A89	9.943	31.069	
A90	10.105	30.831	
A91	9.963	31.117	
A92	9.963	31.129	
A93	9.960	31.089	
A94	10.008	30.856	
A95	10.035	31.181	
A96	9.990	30.915	
A97	10.018	31.145	
A98	10.013	31.137	
A99	9.973	31.183	
A100	10.030	30.825	
A101	9.993	31.033	
A102	10.040	31.033	
A103	9.928	31.049	
A104	10.003	31.103	
A105	10.058	30.985	
A106	9.995	31.264	
A107	10.080	30.635	
A108	10.050	31.218	
A109	10.055	30.815	
A110	10.108	30.991	
A111	10.015	31.170	
A112	10.073	30.960	
A113	10.133	31.107	
A114	10.025	31.250	
A115	10.020	31.079	
A116	10.030	30.688	
A117	10.085	30.970	
A118	10.063	30.750	
A119	9.963	30.789	
A120	10.115	30.968	
A121	10.118	31.522	
A122	9.928	31.562	
A123	10.030	31.129	
A124	9.965	31.169	
A125	10.095	30.710	
A126	10.120	31.221	

ID-Nr. LOT 57130106	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A127	9.985	30.872	
A128	10.063	31.174	
A129	10.098	31.268	
A130	10.135	30.782	
A131	10.068	31.100	
A132	10.015	31.172	
A133	10.065	30.811	
A134	10.080	30.951	
A135	9.988	30.890	
A136	9.940	30.921	
A137	9.978	30.740	
A138	10.030	31.136	
A139	9.973	30.932	
A140	10.050	30.892	
A141	9.935	30.963	
A142	9.943	30.776	
A143	10.123	31.101	
A144	10.045	30.940	
A145	10.083	31.039	
A146	10.060	30.967	
A147	10.080	30.981	
A148	10.183	31.267	
A149	10.098	31.034	
A150	9.935	31.029	
A151	10.175	30.973	
A152	10.008	30.968	
A153	10.018	31.064	
A154	10.065	31.058	
A155	10.028	30.883	
A156	9.955	30.795	
A157	10.120	30.945	
A158	10.080	31.253	
A159	9.995	30.784	
A160	9.988	31.310	
A161	10.100	30.921	
A162	10.148	31.322	
A163	10.120	30.824	
A164	10.058	30.532	
A165	10.088	31.091	
A166	10.090	30.881	
A167	10.000	30.805	
A168	10.065	30.882	

ID-Nr. LOT 57130106	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A169	10.100	31.019	
A170	10.070	30.754	
A171	10.113	30.951	
A172	10.083	31.252	
A173	10.083	31.164	
A174	10.058	31.199	
A175	10.183	31.004	
A176	10.158	30.939	
A177	9.985	31.036	
A178	10.020	31.192	
A179	10.025	31.095	
A180	10.093	31.027	
A181	10.105	30.643	
A182	10.070	30.683	
A183	10.085	30.896	
A184	10.103	30.690	
A185	10.070	31.307	
A186	10.033	30.858	
A187	10.025	30.966	
A188	10.060	30.990	
A189	10.103	30.818	
A190	10.005	31.305	
A191	9.998	31.112	
A192	10.050	31.032	
A193	10.073	31.252	
A194	10.063	30.881	
A195	10.098	30.764	
A196	10.160	31.077	
A197	10.013	30.781	
A198	9.950	30.814	
A199	10.008	31.068	
A200	10.090	30.874	
A201	10.028	30.844	
A202	10.060	30.919	
A203	10.125	30.959	
A204	9.985	30.608	
A205	9.963	30.775	
A206	10.048	30.694	
A207	10.013	30.739	
A208	10.105	31.011	
A209	10.028	31.077	
A210	10.008	31.282	

ID-Nr. LOT 57130106	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A211	10.120	31.296	
A212	10.075	31.195	
A213	10.125	31.362	
A214	10.068	31.082	
A215	10.038	31.020	
A216	10.078	30.704	
A217	10.010	31.045	
A218	10.065	31.276	
A219	10.048	31.339	
A220	10.053	30.778	
A221	10.095	31.238	
A222	10.093	31.033	
A223	10.073	30.815	
A224	10.098	31.078	
A225	10.103	30.459	
A226	10.038	30.923	
A227	10.018	31.061	
A228	10.050	30.980	
A229	10.043	30.960	
A230	10.033	31.023	
A231	9.970	31.315	
A232	9.958	30.671	
A233	10.065	31.281	
A234	10.160	31.031	
A235	9.998	31.151	
A236	10.003	30.828	
A237	9.965	31.010	
A238	9.995	30.876	
A239	10.133	30.897	
A240	10.085	31.006	
A241	10.083	30.538	
A242	10.043	30.654	
A243	10.128	31.103	
A244	10.025	31.457	
A245	10.025	31.022	
A246	9.895	31.023	
A247	9.988	30.737	
A248	9.975	31.196	
A249	10.015	30.905	
A250	10.068	30.685	
A251	10.090	29.752	
A252	10.013	31.034	

4. Lot-Specific Data

ID-Nr. LOT 57130106	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A253	9.838	30.746	
A254	10.158	31.104	
A255	10.090	31.122	
A256	9.978	30.746	
A257	9.920	31.164	
A258	9.900	31.010	
A259	10.073	30.820	
A260	10.093	31.397	
A261	9.948	30.899	
A262	9.975	30.867	
A263	10.025	31.073	
A264	9.973	30.832	
A265	9.953	30.934	
A266	10.043	30.953	
A267	10.030	31.084	
A268	10.080	30.840	
A269	9.930	31.141	
A270	9.975	31.064	
A271	10.015	30.842	
A272	10.088	31.253	
A273	10.060	31.010	
A274	10.025	31.117	
A275	10.013	31.043	
A276	9.905	30.818	
A277	10.125	30.877	
A278	10.045	31.073	
A279	10.003	31.143	
A280	9.963	30.918	
A281	9.993	30.925	
A282	10.053	30.916	
A283	9.948	30.869	
A284	9.928	30.919	
A285	10.023	30.875	
A286	10.008	30.714	
A287	9.980	30.923	
A288	9.925	30.071	
A289	10.058	31.313	
A290	10.005	31.067	
A291	10.078	31.186	
A292	9.978	30.725	
A293	10.023	30.943	
A294	9.943	31.176	

ID-Nr. LOT 57130106	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A295	9.990	30.887	
A296	10.103	31.314	
A297	9.985	30.893	
A298	10.005	30.870	
A299	9.928	30.976	
A300	10.055	30.995	
A301	9.940	31.151	
A302	10.023	30.971	
A303	9.998	30.980	
A304	10.070	29.845	
A305	10.040	30.959	
A306	10.033	31.073	
A307	10.045	30.670	
A308	10.035	30.764	
A309	10.110	30.824	
A310	9.963	30.942	
A311	10.078	30.740	
A312	10.060	30.812	
A313	10.063	31.113	
A314	10.040	30.899	
A315	9.990	30.799	
A316	10.033	31.060	
A317	9.873	30.807	
A318	9.948	31.233	
A319	10.040	31.209	
A320	10.060	31.174	
A321	10.060	31.029	
A322	10.033	30.887	
A323	9.968	30.970	
A324	10.130	31.030	
A325	9.915	30.973	
A326	10.073	30.664	
A327	10.053	30.742	
A328	10.110	31.050	
A329	10.020	31.044	
A330	10.033	30.811	
A331	10.045	31.056	
A332	10.098	30.845	
A333	9.920	30.954	
A334	9.915	30.889	
A335	10.065	30.799	
A336	9.965	31.198	

ID-Nr. LOT 57130106	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A337	10.135	30.905	
A338	9.890	30.814	
A339	10.010	31.066	
A340	9.933	31.127	
A341	10.088	31.103	
A342	10.100	30.829	
A343	10.045	30.776	
A344	10.023	30.759	
A345	10.065	31.004	
A346	9.953	31.035	
A347	10.140	30.727	
A348	9.958	30.844	
A349	10.118	30.704	
A350	9.963	30.878	
A351	9.923	32.056	
A352	9.900	30.944	
A353	9.965	30.926	
A354	9.925	30.803	
A355	10.015	30.957	
A356	10.030	31.012	
A357	10.083	31.023	
A358	10.133	30.706	
A359	9.965	30.810	
A360	10.008	30.873	
A361	9.993	30.719	
A362	9.920	30.826	
A363	9.960	31.023	
A364	9.953	31.071	
A365	9.928	31.009	
A366	10.093	31.059	
A367	9.918	30.936	
A368	9.988	31.221	
A369	9.933	30.892	
A370	10.048	30.945	
A371	10.075	30.933	
A372	10.063	30.859	
A373	10.073	31.109	
A374	9.968	30.908	
A375	10.075	30.971	
A376	10.040	30.685	
A377	10.083	30.688	
A378	10.080	31.000	

ID-Nr. LOT 57130106	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A379	10.105	31.124	
A380	9.923	30.939	
A381	9.928	31.118	
A382	9.933	30.785	
A383	10.043	31.128	
A384	10.050	30.910	
A385	10.143	30.968	
A386	10.045	30.879	
A387	9.945	30.801	
A388	10.058	30.974	
A389	9.988	30.908	
A390	10.035	30.878	
A391	9.958	31.171	
A392	10.088	31.044	
A393	10.088	30.935	
A394	10.078	30.784	
A395	9.985	30.953	
A396	10.018	30.683	
A397	9.940	30.825	
A398	9.968	31.102	
A399	9.880	31.054	
A400	9.990	31.153	
A401	10.030	30.989	
A402	9.965	30.810	
A403	10.013	30.954	
A404	9.985	31.026	
A405	10.105	30.823	
A406	10.075	31.102	
A407	9.963	31.036	
A408	9.965	30.896	
A409	10.175	30.745	
A410	9.865	31.088	
A411	10.050	31.143	
A412	10.020	30.954	
A413	10.038	30.698	
A414	9.938	31.072	
A415	9.973	31.137	
A416	10.085	30.930	
A417	10.055	30.893	
A418	10.143	30.889	
A419	9.928	30.631	
A420	10.050	30.754	

4. Lot-Specific Data

ID-Nr. LOT 57130106	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A421	10.058	31.056	
A422	10.055	31.106	
A423	10.075	31.132	
A424	10.040	30.786	
A425	9.950	30.837	
A426	9.945	31.215	
A427	9.990	30.936	
A428	10.098	30.891	
A429	10.073	31.117	
A430	10.050	31.051	
A431	10.008	30.966	
A432	9.885	30.956	
A433	10.030	30.910	
A434	9.953	30.922	
A435	10.053	30.895	
A436	10.005	30.962	
A437	10.003	31.180	
A438	10.028	30.988	
A439	9.990	31.038	
A440	9.983	31.159	
A441	9.965	31.153	
A442	10.043	30.752	
A443	9.960	30.836	
A444	10.070	31.108	
A445	9.965	31.060	
A446	9.963	30.862	
A447	9.910	31.113	
A448	10.060	31.020	
A449	10.015	31.047	
A450	9.950	30.980	
A451	9.880	31.089	
A452	10.008	31.073	
A453	9.945	31.024	
A454	9.939	31.114	
A455	10.095	31.206	
A456	9.985	31.216	
A457	10.015	31.094	
A458	9.995	30.863	
A459	9.970	31.080	
A460	10.090	31.023	
A461	9.915	30.863	
A462	9.923	31.213	

ID-Nr. LOT 57130106	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A463	9.910	30.774	
A464	9.998	31.070	
A465	9.913	30.991	
A466	10.125	31.129	
A467	9.958	31.279	
A468	10.020	31.145	
A469	9.915	31.182	
A470	10.048	31.311	
A471	9.955	31.079	
A472	10.070	30.935	
A473	10.010	31.143	
A474	10.055	31.285	
A475	10.090	31.132	
A476	9.943	31.073	
A477	9.990	31.034	
A478	10.158	30.909	
A479	10.030	31.158	
A480	10.013	30.710	
A481	9.890	31.282	
A482	9.855	31.029	
A483	9.970	31.320	
A484	9.998	31.055	
A485	10.068	30.976	
A486	10.033	31.142	
A487	10.068	31.190	
A488	10.093	31.060	
A489	9.918	31.230	
A490	9.978	31.194	
A491	9.993	31.155	
A492	10.058	31.179	
A493	9.985	30.744	
A494	10.090	30.978	
A495	10.060	31.208	
A496	10.095	30.924	
A497	9.940	31.001	
A498	10.005	31.292	
A499	10.020	30.936	
A500	9.983	31.147	
A501	10.098	31.126	
A502	10.023	31.024	
A503	10.123	30.964	
A504	10.083	31.075	

ID-Nr. LOT 57130106	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A505	10.030	31.931	
A506	10.115	31.055	
A507	10.120	30.974	
A508	9.983	31.103	
A509	10.048	31.083	
A510	10.033	31.102	
A511	10.025	30.960	
A512	10.028	31.150	
A513	10.015	31.131	
A514	10.033	31.121	
A515	10.095	30.918	
A516	10.020	30.481	
A517	9.918	31.087	
A518	9.863	30.807	
A519	9.983	30.745	
A520	10.065	31.054	
A521	10.073	31.003	
A522	9.923	31.442	
A523	10.060	30.972	
A524	9.910	31.097	
A525	9.915	31.408	
A526	10.038	31.207	
A527	9.945	31.213	
A528	10.025	31.209	
A529	9.975	31.191	
A530	9.950	31.320	
A531	9.963	30.784	
A532	9.953	31.372	
A533	9.968	30.996	
A534	10.155	31.324	
A535	10.025	30.932	
A536	9.990	31.057	
A537	9.975	32.034	
A538	9.983	31.089	
A539	9.995	31.141	
A540	9.938	31.397	
A541	10.005	30.702	
A542	10.043	31.086	
A543	9.958	31.086	
A544	10.018	31.501	
A545	9.880	30.911	
A546	10.020	30.958	

ID-Nr. LOT 57130106	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A547	9.943	31.019	
A548	9.885	31.151	
A549	10.058	31.233	
A550	10.020	31.144	
A551	9.920	31.085	
A552	10.083	30.920	
A553	10.035	30.687	
A554	9.988	31.028	
A555	10.033	31.361	
A556	9.955	31.029	
A557	9.890	31.110	
A558	10.028	30.976	
A559	10.080	31.110	
A560	9.903	31.441	
A561	10.093	31.121	
A562	10.023	31.396	
A563	9.873	31.005	
A564	9.953	31.134	
A565	9.918	30.876	
A566	9.860	31.057	
A567	10.025	31.263	
A568	10.010	31.177	
A569	10.040	30.934	
A570	10.040	31.333	
A571	10.025	30.917	
A572	10.030	31.364	
A573	10.063	30.966	
A574	10.048	31.189	
A575	9.958	31.253	
A576	9.955	31.179	
A577	9.983	31.227	
A578	10.080	31.153	
A579	9.965	31.149	
A580	10.123	31.087	
A581	10.068	31.140	
A582	10.013	30.833	
A583	10.020	31.052	
A584	9.910	31.073	
A585	10.043	31.008	
A586	9.993	31.409	
A587	10.168	31.171	
A588	10.085	30.966	

4. Lot-Specific Data

ID-Nr. LOT 57130106	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A589	9.920	31.023	
A590	9.978	31.374	
A591	10.050	31.417	
A592	10.050	31.227	
A593	10.023	31.362	
A594	10.023	30.904	
A595	9.858	30.880	
A596	9.945	30.913	
A597	9.960	31.303	
A598	10.003	31.459	
A599	10.088	31.432	
A600	9.985	31.395	
A601	10.075	30.896	
A602	10.115	30.938	
A603	9.915	31.050	
A604	9.983	30.848	
A605	9.980	30.874	
A606	10.013	31.356	
A607	10.080	30.912	
A608	9.933	30.775	
A609	10.110	31.559	
A610	9.930	31.015	
A611	10.070	31.034	
A612	10.090	31.385	
A613	10.040	31.220	
A614	9.965	31.145	
A615	9.923	30.954	
A616	10.068	31.146	
A617	10.058	31.025	
A618	9.943	31.261	
A619	9.930	31.173	
A620	9.958	31.148	
A621	9.965	30.911	
A622	9.995	30.720	
A623	9.950	31.150	
A624	10.015	31.010	
A625	9.880	31.283	
A626	10.063	31.080	
A627	10.070	30.807	
A628	9.973	31.223	
A629	9.873	31.075	
A630	10.040	31.269	

ID-Nr. LOT 57130106	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A631	9.973	31.097	
A632	10.025	31.069	
A633	10.095	30.967	
A634	9.913	30.861	
A635	10.073	30.961	
A636	9.980	30.910	
A637	9.993	30.932	
A638	9.968	31.092	
A639	10.045	30.878	
A640	9.930	30.951	
A641	10.038	30.956	
A642	9.953	30.939	
A643	10.003	30.862	
A644	10.078	30.953	
A645	9.933	30.851	
A646	10.053	30.838	
A647	10.103	31.019	
A648	10.065	30.776	
A649	10.115	30.823	
A650	10.045	30.990	
A651	9.988	30.981	
A652	9.925	30.994	
A653	10.095	31.039	
A654	10.060	30.804	
A655	10.045	30.835	
A656	9.965	30.900	
A657	10.013	30.969	
A658	9.993	30.913	
A659	10.090	30.914	
A660	10.070	31.071	
A661	9.958	30.954	
A662	10.008	31.135	
A663	9.930	30.859	
A664	10.013	30.909	
A665	10.085	30.884	
A666	10.063	31.047	
A667	10.055	31.126	
A668	9.985	31.055	
A669	10.050	31.049	
A670	10.133	31.002	
A671	10.048	31.137	
A672	9.905	30.950	

ID-Nr. LOT 57130106	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A673	9.880	30.865	
A674	10.135	30.598	
A675	10.025	30.966	
A676	10.015	31.022	
A677	9.975	31.100	
A678	9.958	30.541	
A679	9.985	31.002	
A680	9.920	31.009	
A681	9.995	30.878	
A682	9.935	30.929	
A683	9.860	30.803	
A684	9.908	30.817	
A685	9.850	31.007	
A686	10.038	31.111	
A687	9.990	31.096	
A688	9.960	31.040	
A689	9.923	31.197	
A690	9.923	31.017	
A691	9.998	30.817	
A692	9.920	31.043	
A693	9.873	31.020	
A694	10.075	31.011	
A695	10.083	33.014	
A696	10.040	30.957	
A697	10.123	30.938	
A698	10.140	31.008	
A699	10.000	31.007	
A700	9.928	31.028	
A701	10.078	31.483	
A702	9.940	30.799	
A703	9.795	31.045	
A704	10.053	30.244	
A705	10.120	31.029	
A706	9.980	30.890	
A707	10.010	30.994	
A708	9.935	31.060	
A709	10.063	30.982	
A710	10.085	30.976	
A711	10.168	31.384	
A712	9.970	31.281	
A713	9.975	31.366	
A714	9.885	31.198	

ID-Nr. LOT 57130106	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A715	10.083	31.001	
A716	9.978	31.282	
A717	10.043	31.344	
A718	10.063	31.025	
A719	10.030	31.168	
A720	10.073	31.390	
A721	9.910	30.931	
A722	9.930	30.902	
A723	9.983	31.228	
A724	10.130	31.059	
A725	10.113	30.558	
A726	10.060	30.970	
A727	10.010	30.997	
A728	9.943	31.418	
A729	10.033	31.128	
A730	10.150	31.212	
A731	10.083	30.961	
A732	10.000	31.450	
A733	10.020	31.173	
A734	10.035	31.171	
A735	9.888	30.884	
A736	9.995	30.962	
A737	10.013	31.347	
A738	9.988	30.093	
A739	9.960	31.323	
A740	10.158	30.891	
A741	9.953	31.384	
A742	10.108	31.319	
A743	9.913	31.364	
A744	10.013	31.233	
A745	9.940	31.001	
A746	9.983	31.193	
A747	9.875	30.840	
A748	9.963	30.794	
A749	9.998	31.264	
A750	10.088	31.185	
A751	10.013	30.889	
A752	10.080	31.067	
A753	9.935	30.977	
A754	9.920	30.861	
A755	10.033	30.831	
A756	9.955	30.892	

4. Lot-Specific Data

ID-Nr. LOT 57130106	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A757	9.878	31.205	
A758	10.048	31.045	
A759	9.988	30.921	
A760	9.928	30.961	
A761	9.983	30.957	
A762	9.948	31.310	
A763	10.075	30.857	
A764	9.968	31.279	
A765	9.993	31.210	
A766	9.855	31.098	
A767	10.030	31.382	
A768	9.943	31.320	
A769	10.038	31.232	
A770	10.043	31.153	
A771	10.003	30.794	
A772	10.028	30.927	
A773	9.923	31.192	
A774	10.025	30.899	
A775	10.005	31.478	
A776	9.910	31.123	
A777	10.110	30.963	
A778	9.943	31.319	
A779	10.023	31.092	
A780	10.023	31.042	
A781	10.040	31.094	
A782	9.965	31.009	
A783	9.905	31.099	
A784	10.035	31.200	
A785	10.090	31.499	
A786	10.010	30.917	
A787	10.173	31.046	
A788	10.088	31.216	
A789	10.015	30.933	
A790	10.000	31.184	
A791	10.013	31.304	
A792	9.990	31.308	
A793	9.908	31.049	
A794	9.965	31.068	
A795	9.918	31.543	
A796	10.013	31.361	
A797	9.955	31.454	
A798	9.908	31.014	

ID-Nr. LOT 57130106	Concentration Particle number/mL (x 10^5)	weight (g)	Bottle received
A799	10.093	31.400	
A800	10.103	30.997	
A801	9.970	31.251	
A802	10.100	31.277	
A803	10.143	31.014	
A804	10.030	30.825	
A805	9.953	31.008	
A806	10.048	31.225	

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