Reference Material Report

Certification of the number concentration of nanoscale polystyrene particles:

Opti-Count® - 400 nm - 10^6 and 10^8 ml^{-1}

Dr. Matthew A. Hood
Principal Scientist at Dr. Lerche KG and LUM GmbH

1. Contents

2. Abstract

Accurate, traceable, and standardized particle characterization has become increasingly critical for ensuring regulatory compliance and scientific reproducibility in the field of nanomaterials. A key gap has persisted in the validation and standardization of measurements for particle number concentration and number-weighted size distribution — parameters essential for the characterization of nanoparticles. The introduction of tools such as the LUMiSpoc® single particle optical counter and the development of Opti-Count® reference materials directly address this need by enabling traceable, validated number-based measurements.

Opti-Count® reference materials are aqueous particle suspensions produced in accordance with ISO 17034:2016 [1] and the relevant statistical analysis – ISO Guide 35 and ISO ISO/IEC Guide 98-3:2003 (GUM) [2, 3], ensuring the competence and quality required for reference materials. Opti-Count® were developed in collaboration with Applied Microspheres GmbH, who formulated the polystyrene particles that are suspended in a buffered aqueous medium. Each unit is supplied in a plastic vial containing approximately 1 ml of the particle suspension.

The reference materials are certified for particle number concentration based on measurements performed using a liquid laser particle counters. A characterization study was performed through an interlaboratory comparison (ILC) between two laboratories: LUM GmbH and Dr. Lerche KG. The latter is ISO/IEC 17025:2017 [4] accredited to by DAkkS. LUM GmbH followed procedures aligned with the guidelines set by Dr. Lerche KG to ensure consistent quality across measurements.

An assessment of the between-unit homogeneity and stability under transport and storage conditions was conducted according to ISO 17034. Data evaluation included regression and outlier analysis; from which any suspicious results were investigated for technical anomalies. No data points were excluded unless a substantiated technical cause for the deviation was identified.

The certified values for number concentration are accompanied by uncertainty budgets accounting for contributions from potential inhomogeneity, short- and long-term instability, and the intermediate precision and measurement biases seen during the characterization analysis. Additionally, indicative values for the number-based particle size distribution at 16, 50, and 84% quantiles were derived from the same assessment and are provided with uncertainties.

Opti-Count® particles are intended for the calibration and performance evaluation of liquid laser particle number concentration measurement methods, supporting the broader adoption of metrologically sound practices in nanoparticle analysis for both quality control and regulatory applications.

Dr. Lerche KG
office@lerche-biotec.com
Tel: +49 - (0)30 - 67 80 60 50
Wagner-Régeny-Str. 16, DE - 12489 Berlin

3. Introduction

Background

Engineered nano- and submicron-materials (ENMs) have become integral to the advancement of modern technologies, with applications spanning energy storage, healthcare, semiconductors, food, personal care, and environmental monitoring. Their unique size-dependent properties — such as increased reactivity, improved strength, and novel electrical or optical behaviors — are made possible by their high surface-area-to-volume ratios and customizable chemistries. These features enable the design of next-generation products, but they also introduce complexities in measurement, standardization, and risks to safety and the environment.

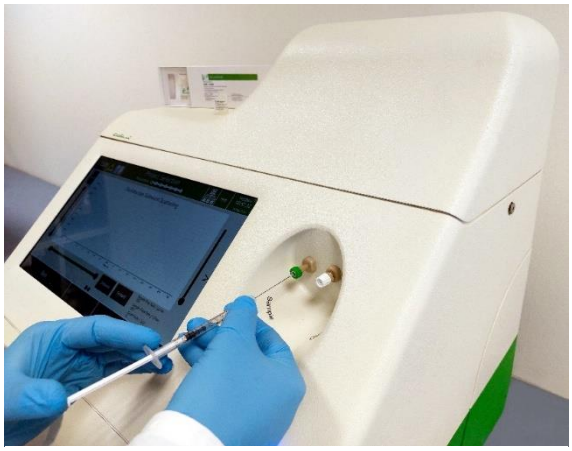


Figure 1: Injecting Opti-Count® reference material particles into a LUMiSpoc® for method validation. ©LUM GmbH

As the use of ENMs continues to rapidly expand, regulators and industries alike are facing a common challenge: the lack of standardized, traceable reference materials (RMs) for reliable measurement and validation. Regulatory frameworks increasingly require detailed characterization of number-weighted particle size distributions and number concentration, to assess exposure risks and ensure product compliance. However, the absence of well-defined RMs — especially in the nanoscale range — hampers consistency across laboratories, undermining efforts in both quality control and regulatory monitoring.

RMs are critical tools that allow stakeholders to validate analytical methods, ensure comparability of results, and build confidence in measurement data. They support compliance with national and international regulations by enabling traceable, repeatable, and defensible measurement methods. Despite their importance, current RMs do not address the need to have number concentrations values for particles less than 1 µm — a size range in which there exists potentially critical toxicological and environmental risks.

Opti-Count® was developed by Dr. Lerche KG and LUM GmbH in collaboration with Applied Microspheres GmbH. This report outlines the measurement studies performed at Dr. Lerche KG to elucidate an estimation of the complete uncertainty budget. Opti-Count® reference materials were developed in accordance with the principles and technical requirements of ISO 17034:2016, using a DAkkS-accredited method paired with the LUMiSpoc® single-particle optical counter and sizer. The process includes a rigorous uncertainty evaluation, resulting in an expanded combined uncertainties of less than 10% including sources of uncertainty from characterization, batch inhomogeneity, delivery stability (i.e. short-term stability), and storage stability (i.e. long-term stability). While measured in particles per ml the method has been validated so that the volume is traceable to the SI unit of gram. The particle size is traceable to the SI unit of nanometer. This RM is intended to support metrologically sound practices and the standardization of particle number-based measurements in liquid laser particle counting and sizing techniques.

Dr. Lerche KG
office@lerche-biotec.com
Tel: +49 - (0)30 - 67 80 60 50
Wagner-Régeny-Str. 16, DE - 12489 Berlin

Highlight of Opti-Count® Reference Material Properties

Opti-Count® particles are first-of-their-kind commercially available number concentration reference materials in the nanoscale size range for validation and calibration of analytical methods and quality assurance protocols.

- 400 nm
- Available as concentration of either 10^6 or 10^8 ml^{-1}
- Aqueous Suspension
- Electrostatic Stabilized Surface Functionality
- Surfactant-Free
- Should be Stored at Room Temperature

Choice of Material

An ideal particle system was identified for the development of Opti-Count® particles. This system consists of monomodal, spherical polystyrene particles with a nominal median particle diameter of 400 nm. The materials are idyllic for setting reference points in calibrating devices used in quality control and regulatory reporting. 400 nm was selected as it fits into a well-defined region with low false counts (based on analysis by the LUMiSpoc® and ISO 21501-2:2019) and having excellent signal-to-noise ratio. Choice of material focused on minimizing all sources of uncertainty during the counting of particles. Opti-Count® particles are dispersed in a buffered aqueous suspension and are surfactant-free so that they are accessible to many relevant measurement methods in industrial and pharmaceutical areas. Stability is maintained via surface functionalization with carboxylic acid resulting in electrostatically stable particles in suspension at pH 8. An anti-microbial has been added to ensure the shelf-life of the batches.

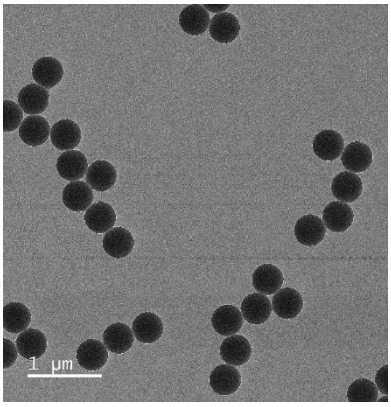


Figure 2: Transmission electron microscopy image of Opti-Count® particles. ©Applied Microspheres GmbH

Table 1: Technical information for the precursor material that forms the basis of Opti-Count® RMs.

Property	Specification
Composition	Polystyrene
Nominal Diameter	400 nm
Shape	Spherical
Surface Functionality	Carboxylic Acid
Density	1.05
Refractive Index at 405 nm[5]	1.62(36)
pH	8
Buffer Type	Tris(hydroxymethyl)aminomethane

LUMiSpoc® - Single Particle Light Scattering Technique

Measurement Principle

Single-particle counting techniques, in which particles pass individually through a measurement zone, are particularly well-suited for determining both number-weighted particle size distributions and particle number concentrations. Flow

Dr. Lerche KG
office@lerche-biotec.com
Tel: +49 - (0)30 - 67 80 60 50
Wagner-Régeny-Str. 16, DE - 12489 Berlin

cytometry is one such technique that detects particles using light scattering or fluorescence as they pass single-file through a laser beam. Traditionally, flow cytometers have been used for analyzing larger particles — such as cells — in biological applications. Recent technological advancements have significantly expanded their capabilities. One such advancement is the development of an optimized version of a flow cytometer: the LUMiSpoc® [6]. The LUMiSpoc® is specifically designed to measure a wide range of particle sizes and concentrations without the need to change membranes, detectors, or tubing.

Key Highlights of the LUMiSpoc® Single Particle Optical Counter and Sizer

The advantages of the innovative LUMiSpoc®, for the characterization of nanoscale particles include:

1. Single particle detection in concentration from 10^3 – 10^9 ml^{-1}
2. No need to change hardware to adjust for different concentrations and sizes
3. Precise measurement of number-based particle size distribution and number concentration
4. Ability to count up to 10 000 particles every second
5. High sensitivity in the nanometer and submicron size range with ability to measure down to 40 nm under specific conditions and up to 5 microns

The LUMiSpoc® is a single-particle optical counter and sizer based on SPLS Technology® (Single Particle Light Scattering Technology). It is optimized to detect the intensity of light scattered by individual nano- and micro-sized particles in both forward and sideward (90°) directions. Particles are injected as a dispersion and hydrodynamically focused into a narrow stream by controlling the relative flow rates of the sample and sheath liquids, which are adjustable by the user. Pressure differences ensure that the sample liquid is centered within the flow cell. When a particle enters the measurement zone it scatters the incident light, which is then detected by a photodetector and converted into an electric pulse. The height of this pulse is proportional to the intensity of the scattered light. The number of particles is determined from the number of detected extinction events above a selectable threshold intensity. Further analysis allows that the classified intensities be converted into a number-weighted particle size distribution density by fitting the collected data to a model that uses the angle of detection and dispersions refractive indices to determine sizes, based on Mie theory.

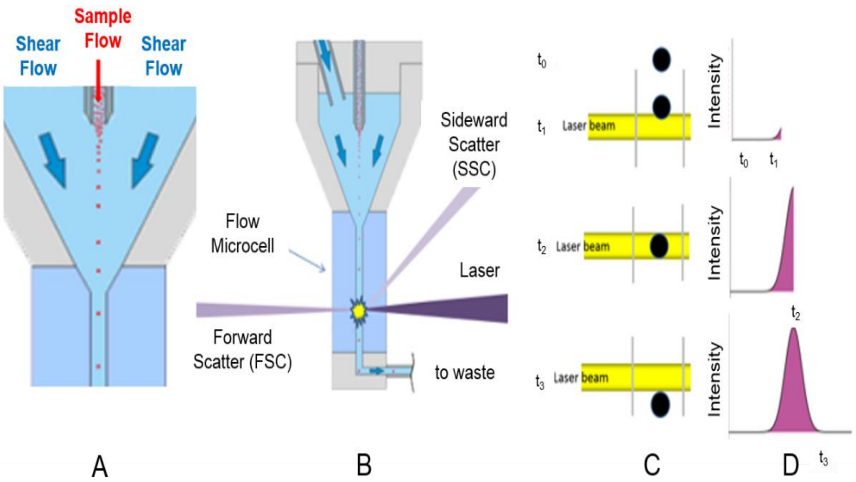


Figure 3: Representative 2D picture of the measured light intensity as particles flow through the measurement beam. A) Hydrodynamic focusing of sample by application of a sheath flow around the sample flow. B) Scattering of light in the sidewards and forwards direction when light interacts with particles in the flow microcell. C and D) Show how signal intensity is measured as well as signal width/area as a particle passes through the laser beam. ©LUM GmbH

Determining the Absolute Number Concentration

By default, the data is shown as a sidewards vs. forwards scattering intensity 2D curve. A 3rd dimension is a color-scaled "heat map" of the number of particles counted with the matching intensities.

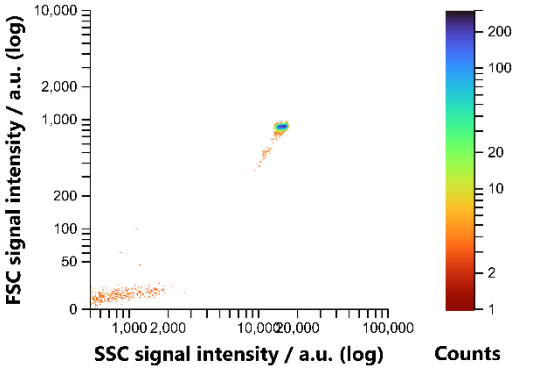


Figure 4: Exemplary 2D signal intensity data for 10^6 ml^{-1} Opti-Count® particles. A polygonal gate is selected around the visible signals which are to be counted and used for the number concentration.

The signal of interest is gated by selecting a set region around the 2D image. In this way only the gated signal is counted, thus minimizing the effects of contamination on the number concentration determination. This method was applied to Opti-Count® particles, for exemplary data see Figure 4. At higher concentrations coincidence can occur resulting in intensities being detected beyond the primary particle. Post-analysis of coincidence can be correct for by gating around the coincidence and factoring by the number of particles in each coincidence, resulting in more accurate number concentration determination.

Determining a Number-based Size Distribution

The LUMiSpoc® is calibrated daily. A calibration particle is used in order to ensure the signal intensities are accurately aligned with a particle size. A NIST traceable calibration particle – 738 nm ± 14 nm (k = 2) polystyrene particle (Applied Microspheres GmbH, Mainz) – is injected into the LUMiSpoc® and used to align the device and set the calibration point for the day. Subsequent measurements are compared to the intensities measured for the calibration particles. Using the 2D

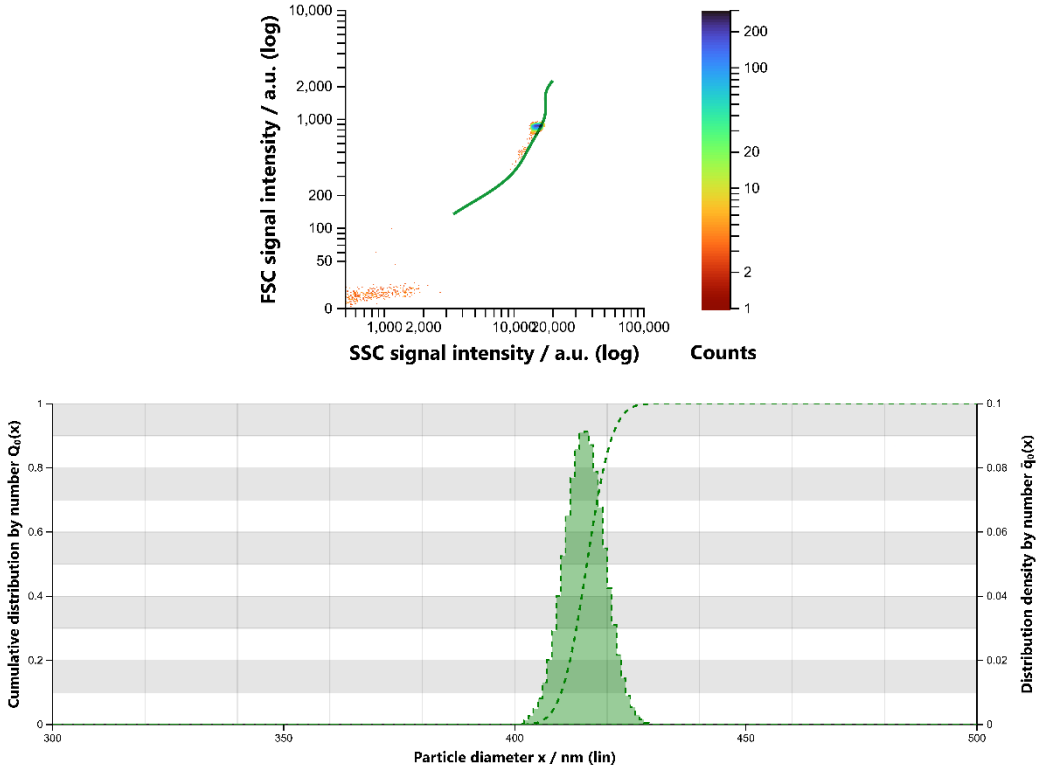


Figure 5: Top) Exemplary 2D SSC vs. FSC data for 10^6 ml^{-1} Opti-Count® particles with the green curve representative of spherical particles between 300 and 500 nm modeled based on Mie theory and the input parameters. Bottom) A fit of the number-weighted cumulative and density particle size distribution calculated from the intensities data.

SSC vs. FSC detector scattering intensity data a size-range curve is modelled based on material parameter inputs – refractive indices for sample particles, the calibration particles, and the continuous phase – provided by the user. Using a model based on Mie theory, a size-range curve is created to which the 2-D scattering intensity data is fit, providing a number-based size distribution (Q_0 and q_0) where q_0 is $Q_0 \cdot dx^{-1}$ (shown in Figure 5).

4. Development of an RM

Initial challenges in the development of Opti-Count® particles

The development of a RM is a complex and time-intensive process, significantly more demanding than the production of general material standards. The complexity of number concentration for nanoscale materials is much greater due to inherent contamination risks. Preliminary work was performed to minimize the effects of these challenges on the final product. Before initiating full production, a particle selection phase was conducted using preliminary batches. This phase aimed to optimize the measurable range — balancing measurement duration with minimized uncertainty — through a series of volumetric dilutions ranging from 10^5 to 10^9 ml^{-1}. Based on these feasibility studies and a market overview of available measurement technologies, two target concentrations were selected: 10^6 and 10^8 ml^{-1}. At these concentrations, the stability of the measurands can be significantly affected by particle adsorption to vial walls over time. Additional challenges include pH changes due to CO_2 absorption from ambient air, and contamination or particle loss due to tribological effects between the suspension liquid and container surfaces. The selection of a plastic vial material, the particle system, and measurement methods were all made with these issues in mind.

Processing

The primary measurand of Opti-Count® RMs is the particle number concentration while secondary measurands are the quantiles of the number-weighted particle size distribution. A master batch of Opti-Count® particles was developed by Applied Microspheres GmbH, from which subsequent batches intended for commercial production were diluted to the target concentrations and separated into vials. Particles are electrostatically stabilized in Tris-buffered aqueous suspensions – which was filtered through 50 nm pores prior to dilution of the master batch.
Prior to full-scale production, the consistency and quality of the dilution process were evaluated over two days using 10 vials. Based on the success of this evaluation, production batches of 10^6 ml^{-1} and 10^8 ml^{-1} by Applied Microsphere GmbH were prepared and delivered to Dr. Lerche KG. 1 ml of each homogenized suspension was dispensed into plastic vials. Vials were tightly sealed with screw caps to ensure sample integrity.

Homogeneity Study

Equivalence within units of a production batch for a RM is critical in ensuring that the certified value is applicable for any unit of the batch, therefore ISO 17034:2016 requires quantification of the between-unit variation via a homogeneity study.

Within-Unit Inhomogeneity and Minimum Sample Size Study

The within-unit inhomogeneity is correlated to the minimum sample size. The minimum sample size is the minimum amount of sample that is, for a given measurand, representative of the whole unit and thus should be used in an analysis. Using sample amounts equal to or above the minimum sample size guarantees the certified value within its stated uncertainty.
Measurements of the production batches of Opti-Count® RMs took place under different standard operating procedures that were selected based on the concertation of particles and therefore have different minimum sample sizes, see Table 2.
The total volume injected into the LUMiSpoc® is greater than the measured volume. A recommendation to inject 250 µL of dispersion for a single measurement with LUMiSpoc® includes a quantity that is 3 times larger than the volume of the

sample tubing in order to ensure that previous sample is fully flushed out. The sample loop is 80 µl in size. Before measuring a preliminary quantity of sample is required to reach the measurement zone so a representative sample is used for the particle count determination. After this and based on the choice of SOP, a minimum sample volume that is actually measured can be calculated.

Table 2: Measurement parameters as basis for minimum sample size.

	Repeat Sample Volume	Repeats per Measurement	Minimum Sample Size
10^6 ml^{-1}	8.0 µl	4	32 µl
10^8 ml^{-1}	0.3 µl	10	3.0 µl

The selection of the SOPs was based on experience and count statics based on Poisson distribution. Both minimum sample volumes guarantee that there are over 10 000 individual particles counted per injection, which would correspond to a count relative statistical uncertainty of ca. 2 % [7]. The importance of statistically relevant counts of particles has been highlighted recently for electron microscopy and indicated that it was necessary that 100s if not 1000s of particle are necessary to count depending on the granulometric nature of the particle [8].

Between-Bottle Inhomogeneity

Determination of the homogeneity requires that the number of units measured should be no less than 10 units or $\sqrt[3]{n_{units}}$ where n_{units} is the production size of a batch, whichever is smaller. Based on the batch size for Opti-Count® 10 units were measured for between-bottle inhomogeneity determination. Vials were measured in triplicate (3 subsamples per vial). The 10 units were selected based on a random stratified scheme representative of the total sample size. Units were measured using the LUMiSpoc® under concentration specific SOPs (see Table 3), which were held constant throughout all measurements.

Table 3: Standard operating procedure for measuring Opti-Count® particles using the LUMiSpoc® at two different concentrations.

	10^6 ml^{-1}	10^8 ml^{-1}
Laser Power (405 nm)	50 mW	50 mW
Trigger Threshold (sidewards direction)	500 bins	500 bins
PMT Voltage	500 V	500 V
Sheath Flow Rate (µl·min^{-1})	1000	1000
Sample Flow Rate (µl·min^{-1})	2.000	0.300
Measurement Time per Repeat (min)	4	1

Units were selected randomly, gently redispersed, and injected into the LUMiSpoc® with a 1 ml plastic syringe. The homogeneity study took place under repeatability conditions, that is measured by the same device within the same day. The measurand was plotted versus the measurement sequence to check for any analytical drift present in the device and a linear regression was performed to check for any significant trends at a 95% confidence interval.
Correction of even non-significant trends improves the separation of unit inhomogeneity uncertainty analysis from method uncertainty and therefore correction was performed by subtraction via:

$$x^*_i = x_i - (\mathrm{b} \cdot \mathrm{i}) \qquad \text{Eq. 1}$$

Where the corrected measurand value (x^*_i) is the measured value (x_i) minus the slope b from the linear regression and the position in the measurement sequence, i.

Dr. Lerche KG
office@lerche-biotec.com
Tel: +49 - (0)30 - 67 80 60 50
Wagner-Régeny-Str. 16, DE - 12489 Berlin

The measurement sequence corrected data was then evaluated according to the vial fill order. Data was evaluated for outliers from the mean and outliers in the variance based on Grubbs' and Cochrane C tests, respectively. Both tests were performed with a confidence interval of 99%. No data points were removed based on the analysis as no technical errors were observed during the measurements.
The normality of the data were visually evaluated based on the skew and kurtosis using box-plots.

Homogeneity Uncertainty

Between-unit inhomogeneity was quantified by performing a one-way analysis-of-variance (ANOVA) on the corrected data. ANOVA allows for the separation of the within-bottle variation (s_{within}) from the between-bottle variation (s_{bb}). Following the recommendations and protocols set out by Linsinger, et. al [9] a check for the hidden between-bottle homogeneity when within-bottle homogeneity is large (u^*_{bb}) was performed. The following equations were used for the determination of uncertainty due to inhomogeneity of the batches.

$$s_{wb} = \sqrt{MS_{within}} \quad \text{Eq. 2}$$

$$u_{bb} = s_{bb} = \sqrt{\frac{MS_{between} - MS_{within}}{n}} \quad \text{Eq. 3}$$

$$u^*_{bb} = \sqrt{\frac{MS_{within}}{n}} \sqrt[4]{\frac{2}{v_{MS_{within}}}} \quad \text{Eq. 4}$$

The relative uncertainties for the measurands were determined by dividing the calculated absolute uncertainties by the mean value of the measurand. A summary of the uncertainties is provided in the following tables.

Table 4: Relative uncertainties from the homogeneity studies of the number concentration.

	$s_{wb,rel}$ (%)	$s_{bb,rel}$ (%)	$u^*_{bb,rel}$ (%)	$u_{bb,rel}$ (%)
10^6 ml^{-1}	3.20	0.25	**0.34**	0.25
10^8 ml^{-1}	2.53	0.34	**0.82**	0.34

Table 5: Relative uncertainties from the homogeneity studies for the 16% quantile of the number-weighted size distribution($x_{16,0}$).

	$s_{wb,rel}$ (%)	$s_{bb,rel}$ (%)	$u^*_{bb,rel}$ (%)	$u_{bb,rel}$ (%)
10^6 ml^{-1}	0.12	0.14	0.04	**0.14**
10^8 ml^{-1}	0.2	-	**0.06**	-

Table 6: Relative uncertainties from the homogeneity studies for the 50% quantile of the number-weighted size distribution ($x_{50,0}$).

	$s_{wb,rel}$ (%)	$s_{bb,rel}$ (%)	$u^*_{bb,rel}$ (%)	$u_{bb,rel}$ (%)
10^6 ml^{-1}	0.09	0.04	0.03	**0.04**
10^8 ml^{-1}	0.05	0.02	0.02	**0.02**

Dr. Lerche KG
office@lerche-biotec.com
Tel: +49 - (0)30 - 67 80 60 50
Wagner-Régeny-Str. 16, DE - 12489 Berlin

Table 7: Relative uncertainties for homogeneity studies for the 84% quantile of the number-weighted size distribution($x_{84,0}$).

	$s_{wb,rel}$ (%)	$s_{bb,rel}$ (%)	$u^*_{bb,rel}$ (%)	$u_{bb,rel}$ (%)
10^6 ml^{-1}	0.12	0.04	0.04	**0.04**
10^8 ml^{-1}	0.06	0.03	0.02	**0.03**

The uncertainty due to inhomogeneity of the batches uses either the relative u^*_{bb} or u_{bb} depending on which is larger, highlighted in bold in the previous tables.

Stability Studies

Stability testing is necessary to establish the effect conditions for storage, as well as transport, have on the measurands of the RMs. During transport, especially in summer, temperatures up to 60 °C can be reached, and stability under these conditions must be demonstrated if the RMs are to be transported without any additional cooling. Time and temperature were expected to have the greatest influence on the stability of the dispersions. Stability testing provides an indication of the deviations that occur from the given certified values. The stability is broken down into two main sources: the first is the extreme conditions that can be expected during transport to customers, i.e. the short-term stability. The second is related to the storage of the batches at a favorable temperature for a given time period, i.e. the long-term stability.

Short-term Stability - Transport Stability

A short-term stability study was conducted over a period of two weeks using an isochronous experimental design [10]. This approach minimizes uncertainty associated with measurement reproducibility, providing a more accurate assessment of the uncertainty arising solely from short-term stability effects. Samples were stored at different temperature conditions for varying durations. At each time point, a subset of samples was transferred from the elevated temperature conditions to reference conditions (room temperature), effectively "freezing" the degradation status of the material. This strategy allows the degradation process to be halted, enabling all samples to be analyzed simultaneously under repeatability conditions. Samples for short-term stability studies were randomly chosen based on a stratified design. A typical isochronous study for Opti-Count® proceeded as follows:

- 12 vials were placed in an oven pre-set to 60°C ± 2°C.
- 4 additional vials were stored at room temperature (20°C ± 5°C), representing Day 0 (reference condition).
- At Days 4, 8, and 14, four vials were removed from the oven and transferred to room temperature storage alongside the Day 0 samples.
- After Day 14, all 16 vials were stored at room temperature until measurement.
- All vials were measured in duplicate – 2 subsamples per vial – in a random order using the LUMiSpoc® on the same day to ensure repeatability (i.e., 32 datapoints).

Data analysis of the short-term uncertainty proceeded as such: Grubb's and Cochrane C tests for outliers was applied to the dataset. Normality was evaluated using box-plots similar to the homogeneity test. Measurements were analyzed via linear regression analysis to correct for any potential influence of measurement order on the results and corrected (see Eq. 1). A second regression of the corrected data against the elapsed time at 60°C – a total of 4 time points were measured over the 2 weeks including reference time 0. As some measurements displayed a trend that was not statistically the same as 0 it was decided to use both Eq. 5 and Eq. 6 to determine the uncertainty of the regression and the uncertainty in the value with time determined by Eq. 7 [11].

Dr. Lerche KG
office@lerche-biotec.com
Tel: +49 - (0)30 - 67 80 60 50
Wagner-Régeny-Str. 16, DE - 12489 Berlin

$$u_{sts,rel} = \frac{RSD}{\sqrt{\sum(t_i - \bar{t})^2}} * \frac{t_{tt}}{\sqrt{k}} \quad \text{Eq. 5}$$

$$u_{deg,rel} = \frac{b}{\sqrt{3}} * \frac{t_{tt}}{\bar{y}} \quad \text{Eq. 6}$$

$$u_{sts,comb,rel} = \sqrt{u^2{}_{sts,rel} + u^2{}_{deg,rel}} \quad \text{Eq. 7}$$

Where t_{tt} is the chosen limit of transport at 60°C which was 7 days, RSD is the relative standard deviation of the measured values, $\bar{t}$ is the average days, and t_i is the different days represented in the measurement. RSD is the relative standard deviation of all stability measurements. The value is divided by $\sqrt{k}$, where k is the number of repeat units (ie. injections) per time point, which totals 8 injections per time point or 32 total injections.

Table 8: Relative uncertainties for short-term stability studies for number concentration.

RM	$s_{sts,rel}$ (%)
10^6 ml^{-1}	1.06
10^8 ml^{-1}	3.58

Table 9: Relative uncertainties for short-term stability studies for 16% quantile of number-weighted size distribution ($x_{16,0}$).

RM	$s_{sts,rel}$ (%)
10^6 ml^{-1}	0.26
10^8 ml^{-1}	0.08

Table 10: Relative uncertainties for short-term stability studies for number-weighted median diameter ($x_{50,0}$).

RM	$s_{sts,rel}$ (%)
10^6 ml^{-1}	0.09
10^8 ml^{-1}	0.10

Table 11: Relative uncertainties for short-term stability studies for 84% quantile of number-weighted size distribution ($x_{84,0}$).

RM	$s_{sts,rel}$ (%)
10^6 ml^{-1}	0.11
10^8 ml^{-1}	0.09

Long-term Stability - Storage Stability

The long-term stability is an estimate of the uncertainty associated with the shelf-life of the material. Based on previous experience measuring low particle concentrations over long storage times, it was decided that “real-time” long-term stability tests should be taken regularly; monthly. Due to the fact that reproducibility conditions is now included into the value, it is accepted that the u_{lts} will be an overestimate, however this was deemed acceptable. No measurement regression correction can take place as has been the case in the previous two uncertainty analysis.
Vials were stored upright at room temperature (20 ± 5 °C), away from direct sunlight.

Dr. Lerche KG
office@lerche-biotec.com
Tel: +49 - (0)30 - 67 80 60 50
Wagner-Régeny-Str. 16, DE - 12489 Berlin

Analysis was performed similarly to the short-term stability with the uncertainty in the slope during the long-term stability measurements estimated as:

$$u_{lts} = \frac{RSD}{\sum(t_i - \bar{t})^2} * \frac{t_{sl}}{\sqrt{k}} \quad \text{Eq. 8}$$

$$u_{deg,rel} = \frac{b}{\sqrt{3}} * \frac{t_{sl}}{\bar{y}} \quad \text{Eq. 9}$$

$$u_{lts,comb,rel} = \sqrt{u^2{}_{lts,rel} + u^2{}_{deg,rel}} \quad \text{Eq. 10}$$

Where t_{sl} refers to the desired shelf-life (e.g. 12 months at room temperature).

Table 12: Relative uncertainties for long-term stability studies for number concentration.

RM	$s_{lts,rel}$ (%)
10^6 ml^{-1}	2.00
10^8 ml^{-1}	2.17

Table 13: Relative uncertainties for long- studies for 16% quantile of number-weighted size distribution ($x_{84,0}$).

RM	$s_{lts,rel}$ (%)
10^6 ml^{-1}	0.74
10^8 ml^{-1}	0.25

Table 14: Relative uncertainties for long- studies for 50% quantile of number-weighted size distribution er ($x_{50,0}$).

RM	$s_{lts,rel}$ (%)
10^6 ml^{-1}	0.60
10^8 ml^{-1}	0.44

Table 15: Relative uncertainties for long- studies for 84% quantile of number-weighted size distribution ($x_{84,0}$).

RM	$s_{lts,rel}$ (%)
10^6 ml^{-1}	0.67
10^8 ml^{-1}	0.44

Short- and long-term stability tests previously performed at 4°C – inside of a refrigerator, but results displayed no significant difference to the values at reported over the timeframes evaluated. Due to the increased thermal energy at higher temperature typically associated with better colloidal stability, we recommend storage at room temperature. No additional temperature control is required during shipping based on these results as well as experience with shipping of similar products.

Stability Monitoring

After value assignment and during the life-time of the product the stability of the RM batches will be regularly monitored. The monitoring frequency has been set as quarterly.
Customers will be notified of any significant deviation from the previously measured stability behavior along with a retraction of the certified values, should such a deviation be observed, and the RM will be removed from sale.

Characterization Studies - ILC

Material characterization tests refer to the process of determining the property value(s) of a RM. Dr. Lerche KG has organized a small-scale interlaboratory comparison (ILC). Laboratories at LUM GmbH and Dr. Lerche KG, both of whom have demonstrated expertise in particle measurement using the LUMiSpoc® system and follow protocols for data management according to ISO 17025. LUM GmbH is not accredited to ISO 17025, however accreditation is not a requirement for the ILC and the participants from LUM GmbH are employed as expert consultants and are trained by Dr. Lerche KG. The characterization protocol was designed to reflect intermediate precision conditions, incorporating variability between operators, days, and instruments, therefore reducing the influence of bias on results.
Each laboratory received three units from each Opti-Count® batch, with instructions how to analyze subsamples per unit on three separate days based on the measurement protocol outlined in Table 16. Instructions to participants were provided on how to measure and how to analyze the data. Gate areas were recommended for the number concentration, but participants were asked check if their signals laid within the gated area. If some deviation was observed, then participants were asked to make small alterations to the gated area, but to attempt to not make it significantly different then the values provided. Vials were selected via a random stratified design over the entire batch size.

Table 16: Measurement protocol for ILC.

	Day 1	Day 2	Day 3
Measurement 1	Calibration Particle	Calibration Particle	Calibration Particle
Measurement 2	Vial 1 Subsample 1	Vial 2 Subsample 1	Vial 3 Subsample 1
Measurement 3	Vial 1 Subsample 2	Vial 2 Subsample 2	Vial 3 Subsample 2
Measurement 4	Vial 1 Subsample3	Vial 2 Subsample 3	Vial 3 Subsample 3
Measurement 5	Vial 1 Subsample 4	Vial 2 Subsample 4	Vial 3 Subsample 4

ILC Characterization Analysis

The data was collected and centralized by the ILC organizers. A summary of the data can be found in Tables 17-24. Evaluation of outliers from the mean and outliers from the variance based on Grubbs' and Cochrane C tests were performed, respectively. Both tests were performed with a confidence interval of 99%. The normality of the data was visually evaluated using box-plots.

Table 17: Number concentration values for 10^6 ml^{-1} measured during ILC.

Lab	1.c ml^{-1}	2.c ml^{-1}	3.c ml^{-1}	4.c ml^{-1}	5.c ml^{-1}	6.c ml^{-1}	7.c ml^{-1}	8.c ml^{-1}	9.c ml^{-1}	10.c ml^{-1}	11.c ml^{-1}	12.c ml^{-1}
LSp1	1.06	1.05	1.06	1.04	1.05	0.99	1.02	1.04	1.01	1.01	1.01	1.07
LSp2	1.09	1.08	1.08	1.08	1.06	1.10	1.11	1.09	1.05	1.07	1.06	1.06

Table 18: Particle size for the 16% quantile of the number-weighted particle size distribution measured during ILC of 10^6 ml^{-1}.

Lab	1.$x_{16,0}$ nm	2.$x_{16,0}$ nm	3.$x_{16,0}$ nm	4.$x_{16,0}$ nm	5.$x_{16,0}$ nm	6.$x_{16,0}$ nm	7.$x_{16,0}$ nm	8.$x_{16,0}$ nm	9.$x_{16,0}$ nm	10.$x_{16,0}$ nm	11.$x_{16,0}$ nm	12.$x_{16,0}$ nm
LSp1	402.0	401.2	400.9	400.6	403.0	403.1	403.1	403.1	411.4	410.7	410.0	409.5
LSp2	407.5	407.6	407.4	407.5	407.9	407.8	407.4	408.6	408.8	409.3	409.7	409.7

Table 19: Particle size for the 50% quantile of the number-weighted particle size distribution measured during ILC of 10^6 ml^{-1}.

Lab	1.$x_{50,0}$ nm	2.$x_{50,0}$ nm	3.$x_{50,0}$ nm	4.$x_{50,0}$ nm	5.$x_{50,0}$ nm	6.$x_{50,0}$ nm	7.$x_{50,0}$ nm	8.$x_{50,0}$ nm	9.$x_{50,0}$ nm	10.$x_{50,0}$ nm	11.$x_{50,0}$ nm	12.$x_{50,0}$ nm
LSp1	406.1	405.8	405.3	405.1	407.0	406.9	407.0	406.9	415.3	414.9	414.5	414.2
LSp2	411.4	411.6	411.7	411.7	412.4	412.3	412.5	413.0	412.6	413.1	413.3	413.5

Dr. Lerche KG
office@lerche-biotec.com
Tel: +49 - (0)30 - 67 80 60 50
Wagner-Régeny-Str. 16, DE - 12489 Berlin

Table 20: Particle size for the 84% quantile of the number-weighted particle size distribution measured during ILC of 10^6 ml^{-1} .

Lab	1.$x_{84,0}$ nm	2.$x_{84,0}$ nm	3.$x_{84,0}$ nm	4.$x_{84,0}$ nm	5.$x_{84,0}$ nm	6.$x_{84,0}$ nm	7.$x_{84,0}$ nm	8.$x_{84,0}$ nm	9.$x_{84,0}$ nm	10.$x_{84,0}$ nm	11.$x_{84,0}$ nm	12.$x_{84,0}$ nm
LSp1	409.7	409.4	409.0	408.8	410.3	410.0	410.0	409.9	418.2	417.9	417.9	417.7
LSp2	414.8	414.9	415.2	415.3	415.8	415.8	416.3	416.4	415.8	416.0	416.3	416.7

Table 21: Number concentration values for 10^8 ml^{-1} measured during ILC.

Lab	1.c ml^{-1}	2.c ml^{-1}	3.c ml^{-1}	4.c ml^{-1}	5.c ml^{-1}	6.c ml^{-1}	7.c ml^{-1}	8.c ml^{-1}	9.c ml^{-1}	10.c ml^{-1}	11.c ml^{-1}	12.c ml^{-1}
LSp1	1.05	1.05	1.01	1.01	1.03	1.01	0.98	0.99	1.01	1.08	1.03	0.99
LSp2	0.92	1.06	1.08	1.08	0.93	1.06	1.08	1.06	0.93	1.03	1.05	1.05

Table 22: Particle size for the 16% quantile of the number-weighted particle size distribution measured during ILC of 10^8 ml^{-1}.

Lab	1.$x_{16,0}$ nm	2.$x_{16,0}$ nm	3.$x_{16,0}$ nm	4.$x_{16,0}$ nm	5.$x_{16,0}$ nm	6.$x_{16,0}$ nm	7.$x_{16,0}$ nm	8.$x_{16,0}$ nm	9.$x_{16,0}$ nm	10.$x_{16,0}$ nm	11.$x_{16,0}$ nm	12.$x_{16,0}$ nm
LSp1	403.2	403.2	403.2	403.0	401.6	401.3	400.8	400.2	408.6	408.8	408.8	408.5
LSp2	406.1	405.9	405.8	405.8	401.9	402.6	402.9	403.1	408.8	409.2	409.3	409.2

Table 23: Particle size for the 50% quantile of the number-weighted particle size distribution measured during ILC of 10^8 ml^{-1}.

Lab	1.$x_{50,0}$ nm	2.$x_{50,0}$ nm	3.$x_{50,0}$ nm	4.$x_{50,0}$ nm	5.$x_{50,0}$ nm	6.$x_{50,0}$ nm	7.$x_{50,0}$ nm	8.$x_{50,0}$ nm	9.$x_{50,0}$ nm	10.$x_{50,0}$ nm	11.$x_{50,0}$ nm	12.$x_{50,0}$ nm
LSp1	406.5	406.5	406.5	406.2	404.8	404.4	404.0	403.4	412.0	412.0	412.0	411.9
LSp2	409.4	409.0	409.1	409.0	404.9	405.7	406.1	406.3	412.1	412.5	412.6	412.5

Table 24: Particle size for the 84% quantile of the number-weighted particle size distribution measured during ILC of 10^8 ml^{-1}.

Lab	1.$x_{84,0}$ nm	2.$x_{84,0}$ nm	3.$x_{84,0}$ nm	4.$x_{84,0}$ nm	5.$x_{84,0}$ nm	6.$x_{84,0}$ nm	7.$x_{84,0}$ nm	8.$x_{84,0}$ nm	9.$x_{84,0}$ nm	10.$x_{84,0}$ nm	11.$x_{84,0}$ nm	12.$x_{84,0}$ nm
LSp1	409.3	409.3	409.3	409.1	407.6	407.2	406.8	406.1	414.8	414.8	414.8	414.7
LSp2	412.0	411.8	411.7	411.7	407.5	408.3	408.8	408.9	414.8	415.3	415.4	415.3

A one-way ANOVA was performed on the collected values and the results were entered into to Eq. 11.

$$s^2 = {s^2}_{between} + \frac{{s^2}_{within}}{n} \qquad \text{Eq. 11}$$

Where ${s^2}_{between}$ is the deviation between groups (between labs) and the deviation within groups (within the lab) and n is the number of samples measured (ie. 12 = 4 subsample * 3 days)[12].
The uncertainty from the characterization study is then the standard error of the ILC according to the following equation:

$$u_{char} = \frac{s}{\sqrt{p}} \qquad \text{Eq. 12}$$

where p is the number of laboratories that participated, which here was 2.

Dr. Lerche KG
office@lerche-biotec.com
Tel: +49 - (0)30 - 67 80 60 50
Wagner-Régeny-Str. 16, DE - 12489 Berlin

Table 25: Summary of results for measurands during the ILC for 10^6 ml^{-1}.

Measurand	n	Statistical Values			
		Mean	s (%)	$s_{between}$ (%)	s_{within} (%)
Number Concentration (10^6 ml^{-1})	12	1.06	2.97	2.91	2.14
$X_{16,0}$ (nm)	12	406.6	0.59	0.55	0.75
$x_{50,0}$ (nm)	12	410.8	0.58	0.54	0.74
$X_{84,0}$ (nm)	12	414.1	0.60	0.57	0.71

Table 26: Summary of results for measurands during the ILC for 10^8 ml^{-1}.

Measurand	n	Statistical Values			
		Mean	s (%)	$s_{between}$ (%)	s_{within} (%)
Number Concentration (10^8 ml^{-1})	12	1.02	1.55	0.75	4.72
$X_{16,0}$ (nm)	12	405.1	0.25	0.09	0.8
$x_{50,0}$ (nm)	12	408.3	0.27	0.16	0.78
$X_{84,0}$ (nm)	12	411.1	0.25	0.13	0.78

The assigned values of the measurands were determined from the ILC as the mean of means.

Value Assignment

A certificate for RMs and CRMs may contain three classes of assigned values:

- *Certified values*: Meet the highest standards of accuracy. A full uncertainty budget is estimated following ISO 17034 and ISO Guide 35. Certified values for an RM can be used for method validation, calibration, and quality control measures.
- *Indicative values*: Provided where the uncertainty is considered too large to allow full certification. Indicative values can be used for statistical quality control, provided that homogeneity and stability have been assessed.
- Additional material information values: Supplied where homogeneity and stability have not been determined. These values may still be useful in certain measurement processes but should be used with caution.

All efforts have been made to produce Opti-Count® particles under the same conditions as a CRM would require.

Certified Value - Number Concentration

The certified value for particle number concentration was determined as the unweighted mean of the means from the accepted datasets obtained in a two-laboratory characterization study. These certified values were assigned for the production batches at 10^6 and 10^8 ml^{-1} based on the SOP listed in Table 3 for particle liquid laser counting devices.
It should be noted that the certified values apply to particle liquid laser light counting techniques. Other analytical methods may yield different results due to differences in detection principles, sensitivities, or response to particle properties.

Dr. Lerche KG
office@lerche-biotec.com
Tel: +49 - (0)30 - 67 80 60 50
Wagner-Régeny-Str. 16, DE - 12489 Berlin

Combined Uncertainty

The combined standard uncertainty (u_c) associated with the assigned values of a RM is calculated by combining the relevant individual relative uncertainty components previously identified and estimated. Specifically, the assigned uncertainty includes contributions from characterization (u_{char}), potential between-unit inhomogeneity (u_{bb}), potential degradation during transport (u_{sts}), and degradation during storage (u_{lts}). These contributions were combined according to:

$$u_c = [u_{char}^2 + u_{bb}^2 + u_{sts}^2 + u_{lts}^2]^{1/2} \quad \text{Eq. 13}$$

This is the square root of the sum of the variances of each contributing source of uncertainty. Additional components may be included in the uncertainty budget if they are considered to have a significant influence. For number concentration, it is assumed that any unaccounted sources of uncertainty are captured within the intermediate precision of the ILC and the long-term stability analysis conducted under real-time conditions.

Indicative Value – Number-weighted Particle Size Distribution

The indicative values represent the unweighted mean of means from the ILC. The uncertainties provided followed the same procedure as for the number concentration, however in addition included the uncertainty in the value for the SI unit-traceable calibration particle.

$$U_c = 2 \cdot u_c = 2 \cdot \left[u_{char}^2 + u_{bb}^2 + u_{sts}^2 + u_{lts}^2 + u_{calibration}^2\right]^{1/2} \quad \text{Eq. 14}$$

Expanded Combined Uncertainty

The combined uncertainty represents only a single standard deviation that has a confidence interval around the certified value of ca. 68%. Therefore, it is common practice to determine an expanded combined uncertainty through the use of a coverage factor, k. The value of k is determined by the Student's t-distribution based on the degrees of freedom. For the above described analyses the degrees of freedom are large for all analyses except the characterization analysis which has only 1 degree of freedom, because only 2 laboratories participated. The main sources of uncertainty come from the stability studies as well as the characterization analysis and it is therefore necessary to apply the Welch-Satterthwaite approximation equation to determine a coverage factor associated with the effective degrees of freedom for the entire uncertainty budget. The final coverage factor k for each measurand was determined. With this the distribution around the certified value is increased from a single standard deviation to an expanded confidence interval of 95%, that is $U_c = k \cdot u_c$.

Summary of Values

Table 27: Summary of results Opti-Count® RM 10^6 ml^{-1}.

Measurand	Value	u_{char} %	u_{bb} %	u_{sts} %	u_{lts} %	$u_{calibration}$ %	k	U_c %
Number Concentration (ml^{-1})	1.06	2.10	0.34	1.06	2.00	-	2.8	9.0
$X_{16,0}$ (nm)	406.6	0.42	0.14	0.26	0.74	0.95	2.1	2.9
$x_{50,0}$ (nm)	410.8	0.41	0.04	0.09	0.60	0.95	2.4	2.9
$X_{84,0}$ (nm)	414.1	0.43	0.04	0.11	0.67	0.95	2.2	2.9

Dr. Lerche KG
office@lerche-biotec.com
Tel: +49 - (0)30 - 67 80 60 50
Wagner-Régeny-Str. 16, DE - 12489 Berlin

Table 28: Summary of results Opti-Count® RM 10^8 ml^{-1}.

Measurand	Value	u_{char} %	u_{bb} %	u_{sts} %	u_{lts} %	$u_{calibration}$ %	k	U_c %
Number Concentration (ml^{-1})	1.02	1.10	0.82	3.58	2.17	-	2	9.0
$X_{16,0}$ (nm)	405.1	0.18	0.06	0.08	0.25	0.95	2.4	2.4
$x_{50,0}$ (nm)	408.3	0.19	0.02	0.10	0.44	0.95	2	2.2
$X_{84,0}$ (nm)	411.1	0.18	0.03	0.08	0.44	0.95	2	2.2

Additional Material Information

The particles used in the development of Opti-Count® RMs have been characterized with transmission electron microscopy (TEM) by Applied Microspheres GmbH and possess statistically valuable particle size information from the master batch. The number-weighted size distribution of the particles has been calculated based on analysis of 36 images. Neither homogeneity nor stability analysis were performed. Additional useful information regarding material properties is provided.

Table 29: Summary of results for Opti-Count® RM provided by Applied Microspheres GmbH.

	Value	Unit
Number of Particles Measured*	1422	
Mean Size*	423.7	nm
Standard Deviation*	6.6	nm
Standard Error*	10.6	nm
$x_{10,0}$ *	420.0	nm
$x_{50,0}$*	425.6	nm
$x_{90,0}$*	428.4	nm
Particle Density	1.05	$g \cdot cm^{-3}$
Refractive Index @ 405 nm, 25°C	1.62(36)[X]	
Refractive Index @ 589 nm, 25°C	1.59	
pH	8	

* Values provided by Applied Microspheres for data collected by Transmission Electron Microscopy (TEM) from 36 images.

[X] Value from X. Zhang, et al., *Appl. Opt.,* **59**, (2020), p. 2337-2344.

5. Metrological Traceability

The metrological traceability of the values of a RM is necessary for comparability of data to a common unit. Metrological traceability of a RM is not necessary. However, all attempts were made to establish the traceability of the number concentration and number-weighted particle size. Metrological traceability of a certified value should be established via an unbroken chain of calibrations. Both measurands of Opti-Count® particles are traceable to SI units. Traceability of the number concentration by LUMiSpoc® can be associated to the two values that make up the measurand, i.e. counts per ml. This can be broken down into an electronic signal component that is calibrated – as are many cytometers – using a quantiFlash device, and a volume component. The volume is set by a sample syringe pump, which was calibrated by gravimetric determination and calibrated weights at the metrological institute PTB (Berlin, Germany). The measurand of

particle size, which are based on fitting of the scattering profiles to a Mie model, are calibrated daily to a known calibration particle as described previously.

6. Value Commutability

Commutability when applied to an RM is related to the ability to commute/transfer the certified value to different measurement techniques that possess the same measurand. The commutability of this RM has not been assessed.

7. Usage

The Opti-Count® RMs are designed for evaluating the performance of a dispersions number concentration particularly in regards to liquid laser particle counting instruments. They may be used to verify measurement accuracy and serve as quality control materials within standardized measurement procedures.
Handling Instructions:

- Re-dispersion: Before use, re-disperse the contents by gently inverting the vial at least 10 times. Do not shake vigorously, as this may cause bubble formation or particle aggregation.
- Sampling: When extracting a sample, use a clean, syringe or pipette. Avoid introducing any foreign materials or contaminants into the suspension.
- Storage Conditions: Store Opti-Count® RMs at room temperature (20 ± 5 °C). Do not freeze or expose to direct sunlight or excessive heat.

Once a vial has been opened, the certified values are valid for up to 24 hours, assuming proper handling and storage. Stability beyond this time frame has not been evaluated, and the risk of contamination or deviations from the certified value increases significantly after opening.
Dr. Lerche KG assumes no responsibility for any changes to the material if the vial is not used within the 24-hour period or if it is stored or handled under conditions other than those specified above.

8. Acknowledgements

The author would like to thank the participation of colleagues at LUM GmbH and Applied Microspheres GmbH in the synthesis, packaging, and measuring of the RMs in this report.
In particular, the author would like to thank the work of Elia Wollik (LUM GmbH) for participating in the ILC and providing technical advice and Bárbara Riera Roussett (Applied Microspheres GmbH) for supporting the particle technical expertise. Additionally, Dr. Susan Strohschein-Lerche for organizational efforts and technical discussion.

9. Declaration

This document was written with the support of artificial intelligence in the restructuring of sentences. All factual information was written by the author and checked after AI editing for correctness.

10. References

1. International Organization for Standardization ISO, *ISO 17034: 2016; General requirements for the competence of reference material producers*. 2016.
2. International Organization for Standardization ISO, *ISO GUIDE 35: 2017; Reference materials — Guidance for characterization and assessment of homogeneity and stability*. 2017. p. 105.

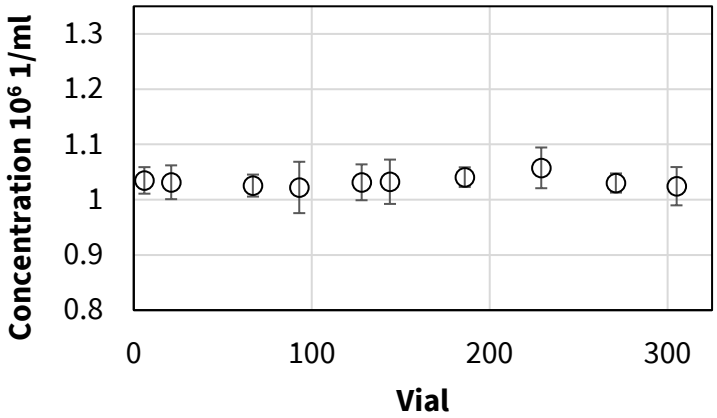
3. Joint Committee for Guides in Metrology, *Evaluation of measurement data - Guide to the expression of uncertainty in measurement*. 2008. p. 120.
4. Deutsches Institut für Normung DIN, *DIN EN ISO/IEC 17025:2018-03 Allgemeine Anforderungen an die Kompetenz von Prüf- und Kalibrierlaboratorien*. 2018. p. 65.
5. Zhang, X., et al., *Complex refractive indices measurements of polymers in visible and near-infrared bands.* Applied Optics, 2020. **59**(8): p. 2337-2344.
6. Hussels, M., et al., *Instrument with an ultra-wide dynamic detection range for the optical counting and sizing of individual particles in suspensions.* Review of Scientific Instruments, 2024. **95**(2).
7. Kammel, M., A. Kummrow, and J. Neukammer, *Reference measurement procedures for the accurate determination of cell concentrations: present status and future developments/Referenzmessverfahren für die genaue Bestimmung von Zellkonzentrationen: Status und zukünftige Entwicklungen*, in *LaboratoriumsMedizin*. 2012. p. 25.
8. Wouters, C., et al., *Assessing particle count in electron microscopy measurements of nanomaterials to support regulatory guidance.* Scientific Reports, 2025. **15**(1): p. 11803.
9. Linsinger, T.P., et al., *Homogeneity and stability of reference materials.* Accreditation and Quality Assurance, 2001. **6**(1): p. 20-25.
10. Linsinger, T.P.J., et al., *Planning and combining of isochronous stability studies of CRMs.* Accreditation and Quality Assurance, 2004. **9**(8): p. 464-472.
11. Linsinger, T.P., et al., *Estimating the uncertainty of stability for matrix CRMs.* Fresenius' journal of analytical chemistry, 2001. **370**(2): p. 183-188.
12. van der Veen, A.M., et al., *Uncertainty calculations in the certification of reference materials 4. Characterisation and certification.* Accreditation and Quality Assurance, 2001. **6**(7): p. 290-294.

Dr. Lerche KG
office@lerche-biotec.com
Tel: +49 - (0)30 - 67 80 60 50
Wagner-Régeny-Str. 16, DE - 12489 Berlin

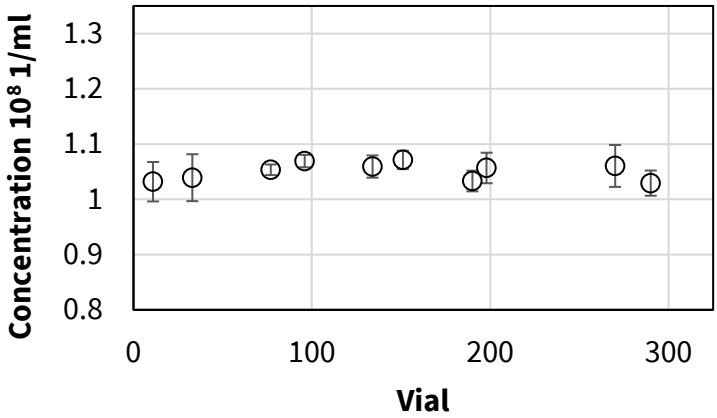
11. Annex

All error bars represent the standard deviation of each data point. Absolute values measured during analysis of the uncertainties not corresponding to the ILC Characterization analysis may not necessarily agree with the certified values.

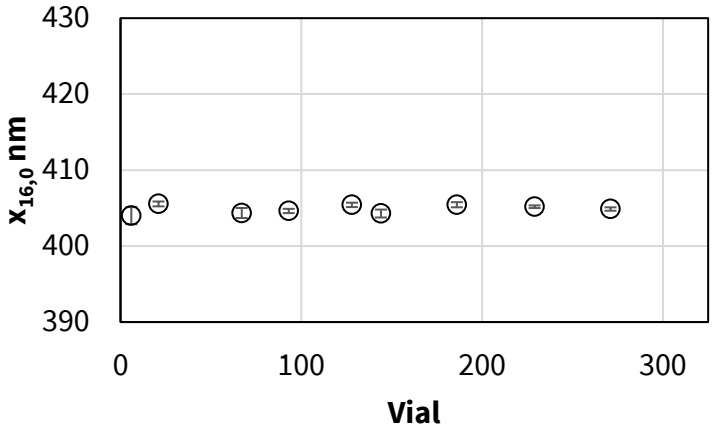
Homogeneity Analysis – Number Concentration 10^6 ml^{-1}

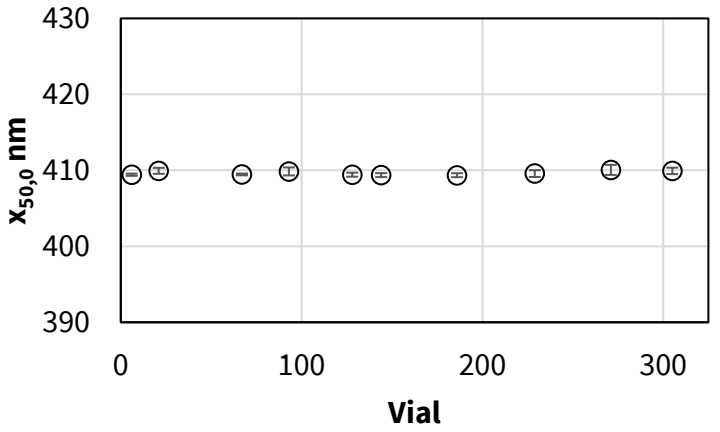


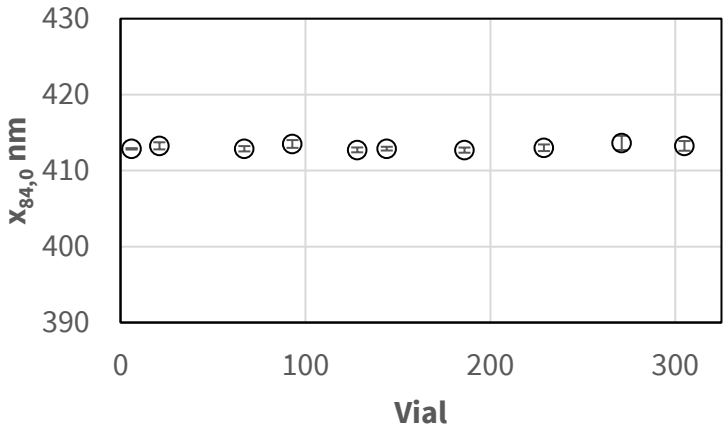
Homogeneity Analysis – Number Concentration 10^8 ml^{-1}



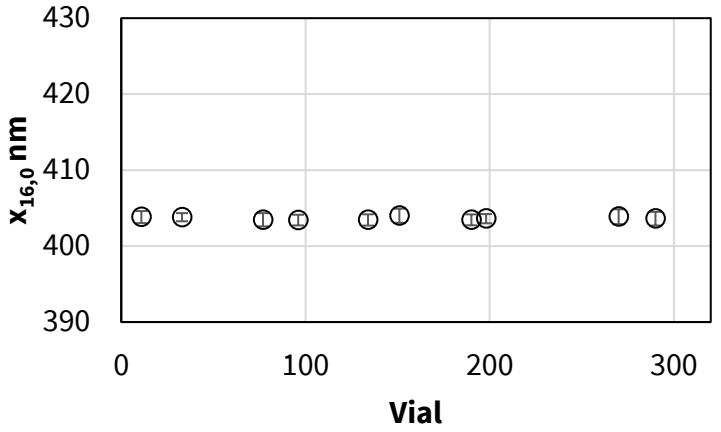
Homogeneity Analysis – Number-weighted Particle Size Quantiles for 10^6 ml^{-1}

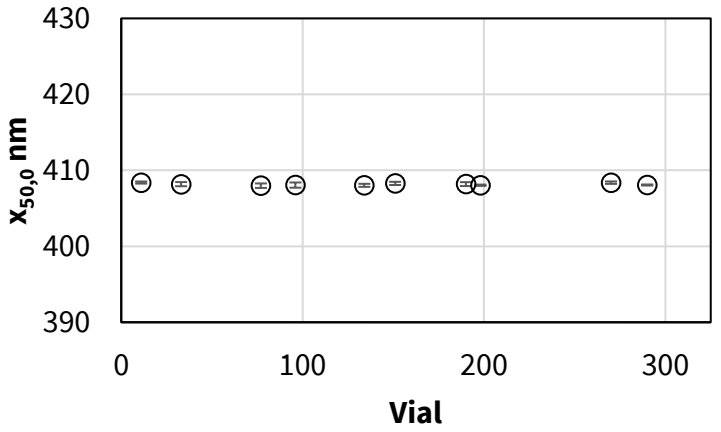


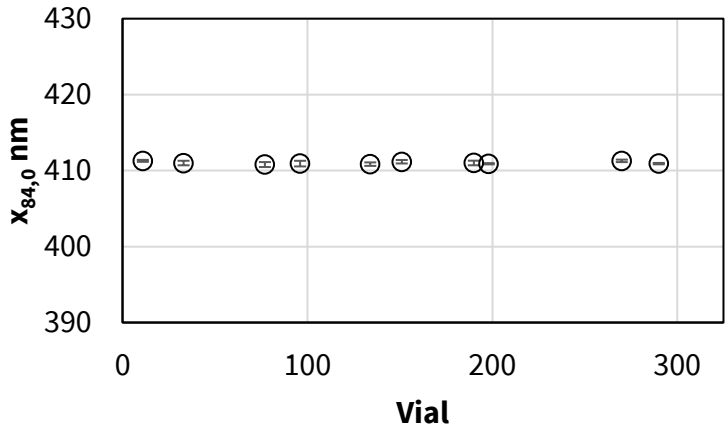




Homogeneity Analysis – Number-weighted Particle Size Quantiles for 10^8 ml^{-1}

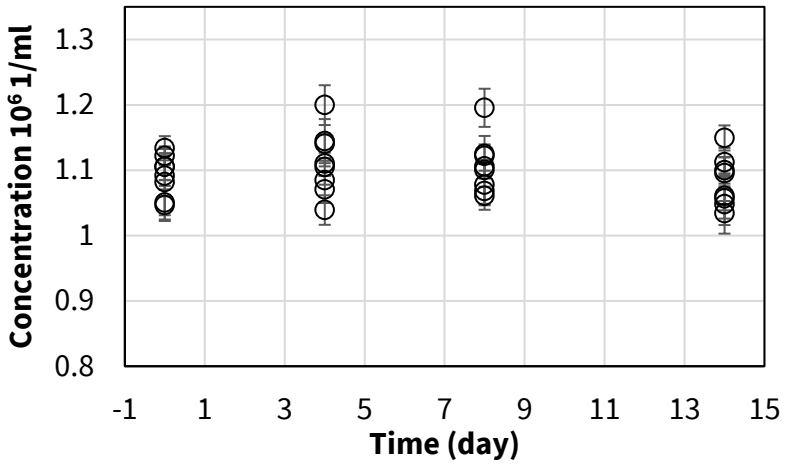




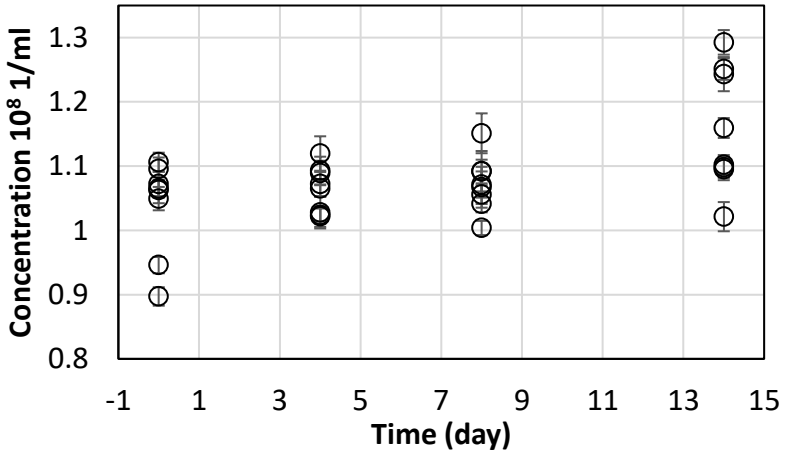


Dr. Lerche KG
office@lerche-biotec.com
Tel: +49 - (0)30 - 67 80 60 50
Wagner-Régeny-Str. 16, DE - 12489 Berlin

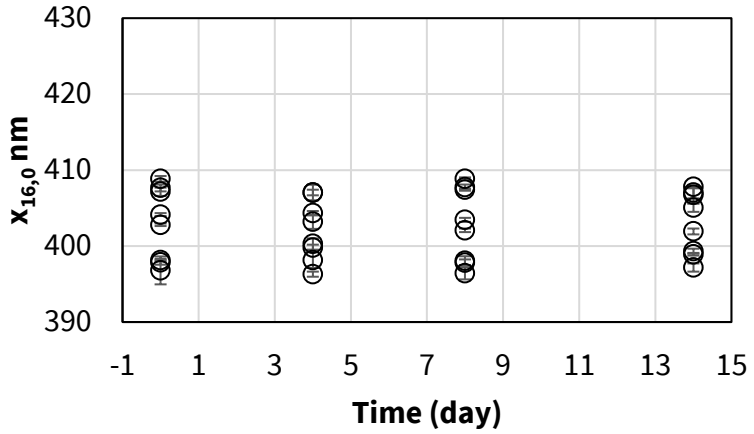
Short-term Transport Stability Analysis – Number Concentration 10^6 ml^{-1}

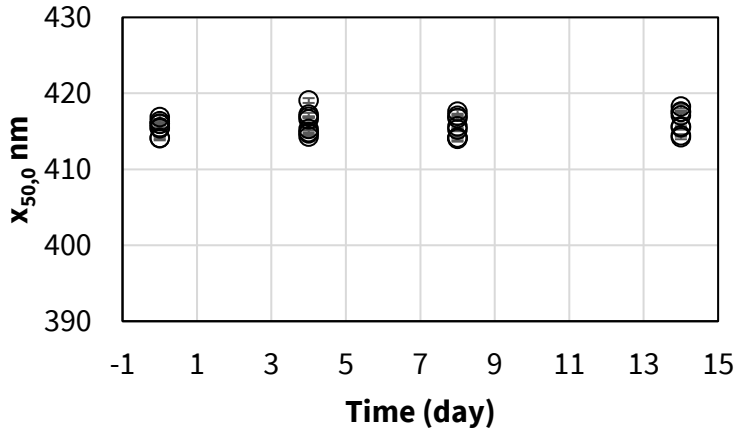


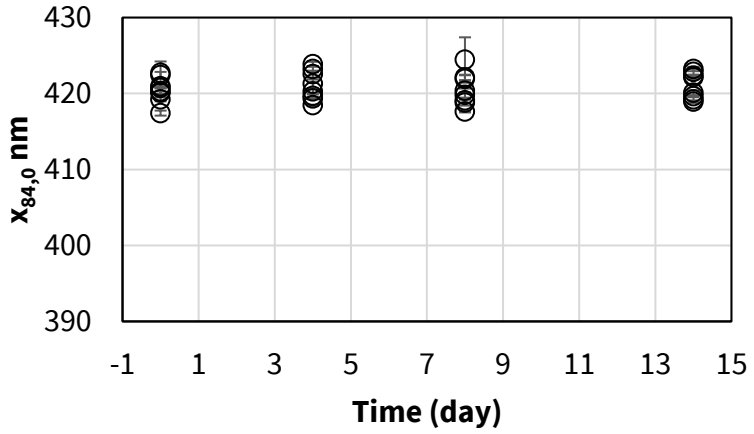
Short-term Transport Stability Analysis – Number Concentration 10^8 ml^{-1}



Short-term Transport Stability Analysis – Number-weighted Particle Size Quantiles for 10^6 ml^{-1}

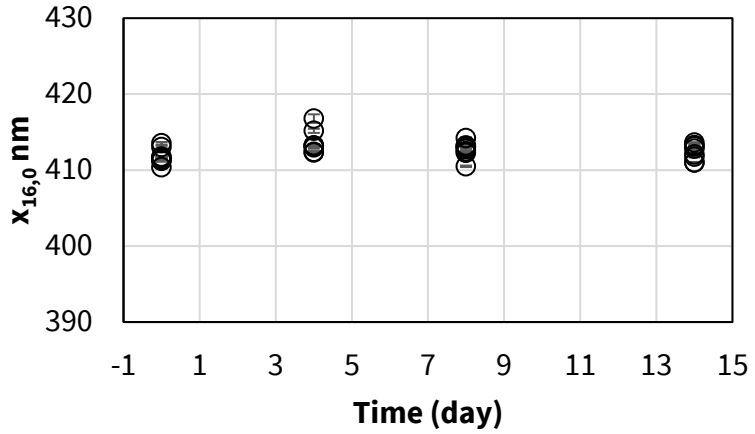


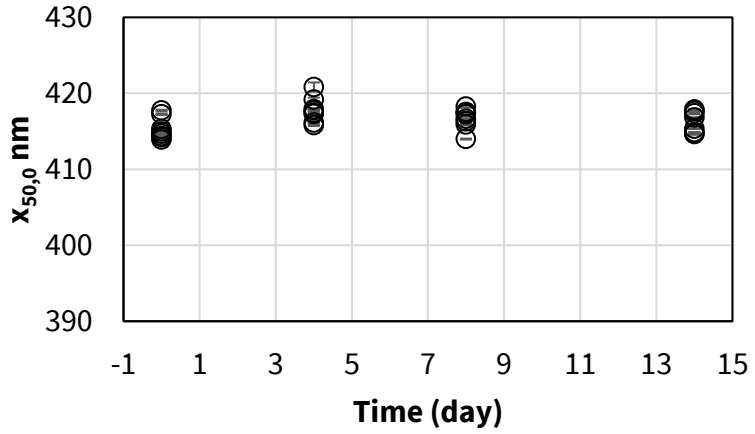


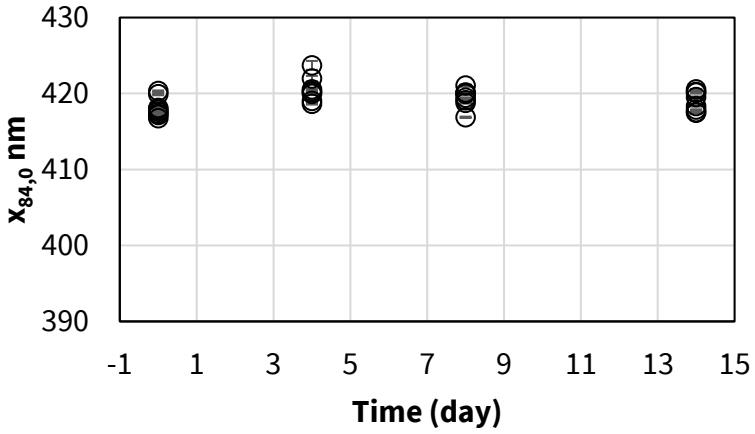


Dr. Lerche KG
office@lerche-biotec.com
Tel: +49 - (0)30 - 67 80 60 50
Wagner-Régeny-Str. 16, DE - 12489 Berlin

Short-term Transport Stability Analysis – Number-weighted Particle Size Quantiles for 10^8 ml^{-1}

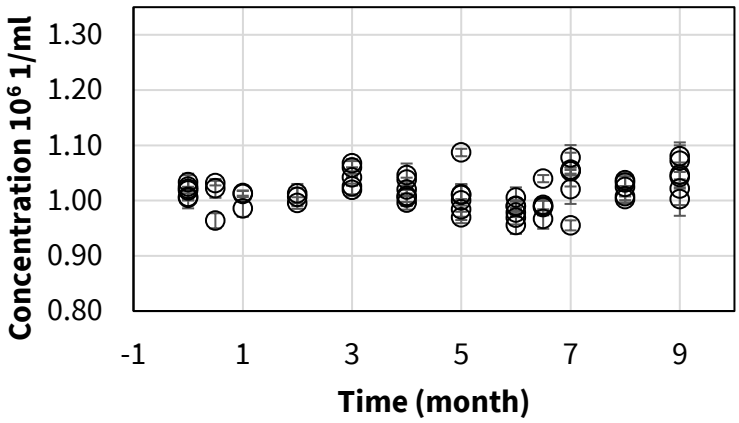




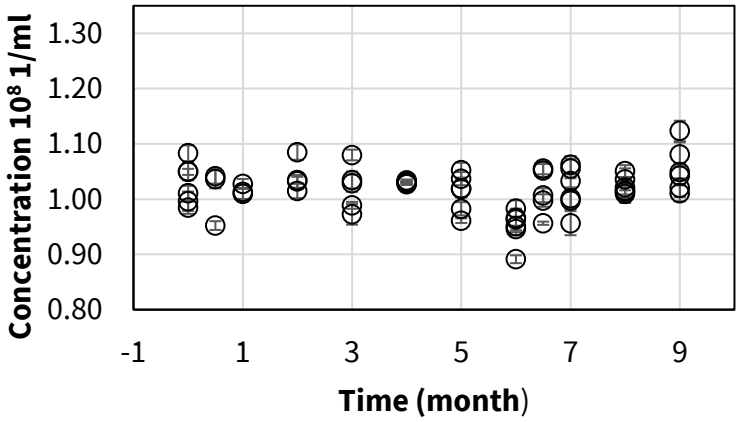


Dr. Lerche KG
office@lerche-biotec.com
Tel: +49 - (0)30 - 67 80 60 50
Wagner-Régeny-Str. 16, DE - 12489 Berlin

Long-term Storage Stability Analysis – Number Concentration 10^6 ml^{-1}

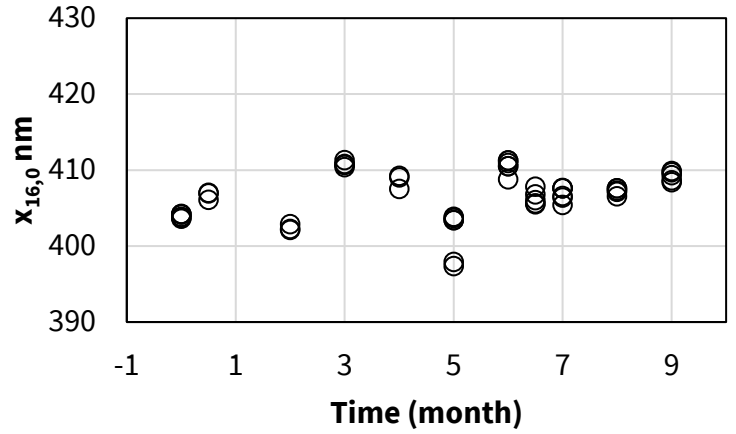


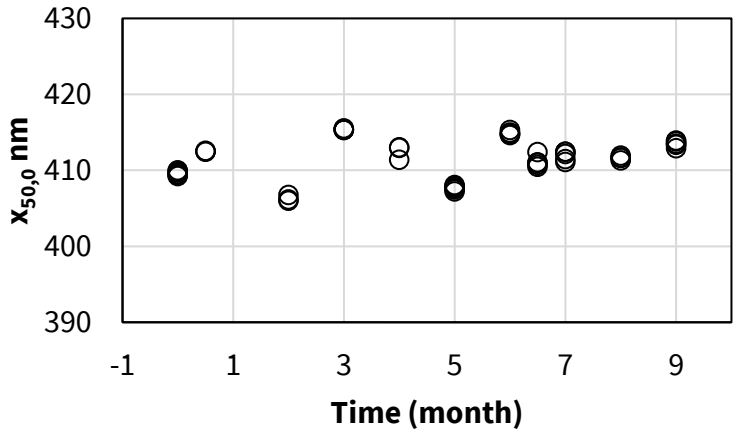
Long-term Storage Stability Analysis – Number Concentration 10^8 ml^{-1}

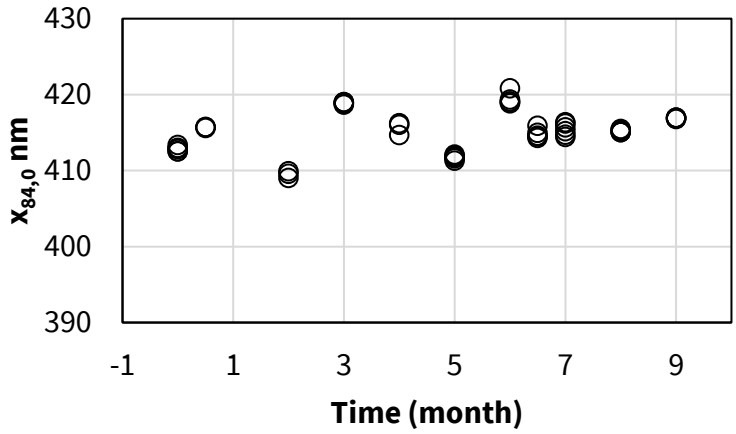


Dr. Lerche KG
office@lerche-biotec.com
Tel: +49 - (0)30 - 67 80 60 50
Wagner-Régeny-Str. 16, DE - 12489 Berlin

Long-term Storage Stability Analysis – Number-weighted Particle Size Quantiles for 10^6 ml^{-1}

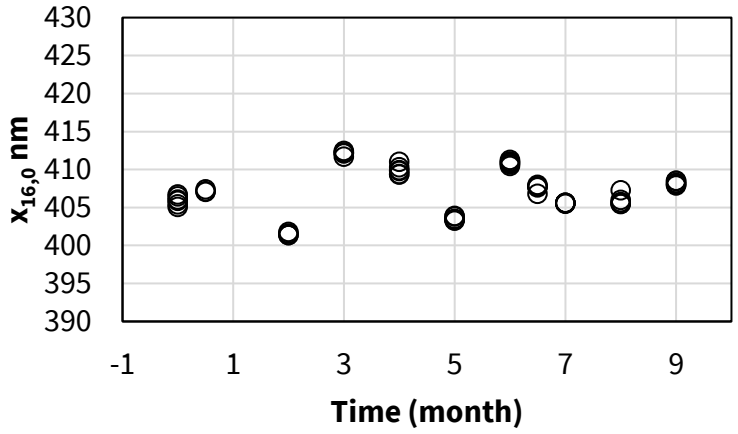


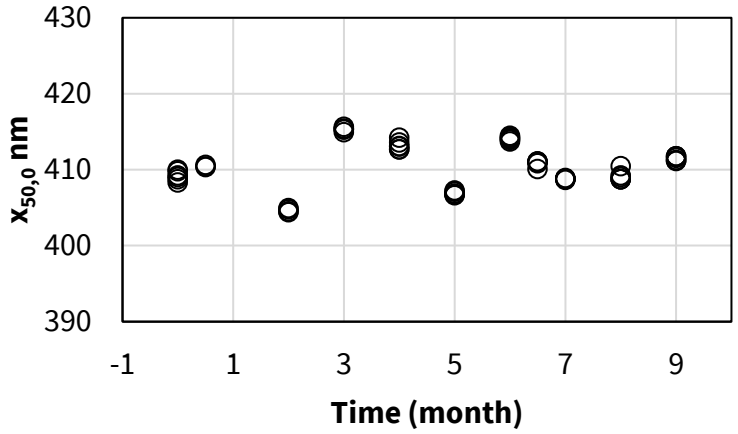


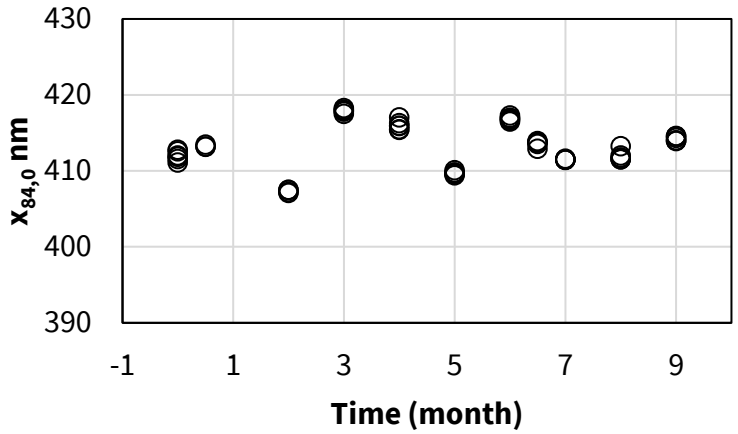


Dr. Lerche KG
office@lerche-biotec.com
Tel: +49 - (0)30 - 67 80 60 50
Wagner-Régeny-Str. 16, DE - 12489 Berlin

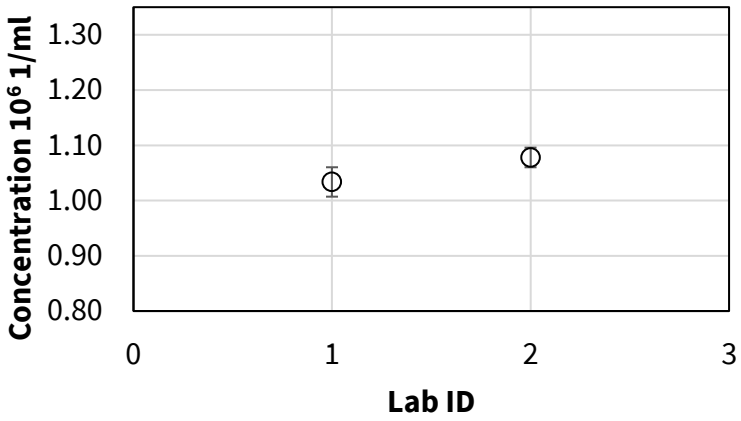
Long-term Storage Stability Analysis – Number-weighted Particle Size Quantiles for 10^8 ml^{-1}



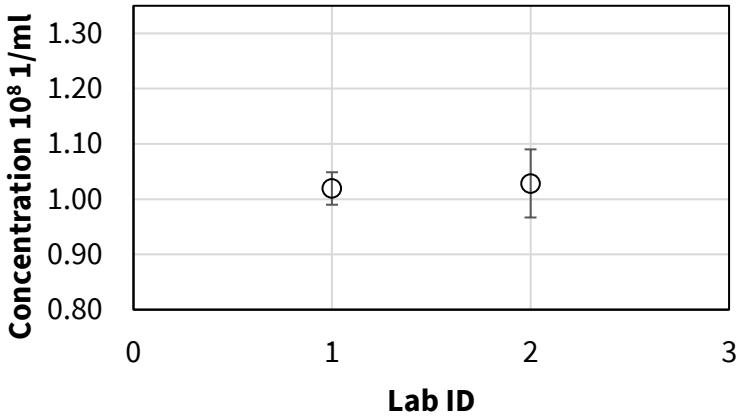




ILC Characterization Analysis – Number Concentration 10^6 ml^{-1}

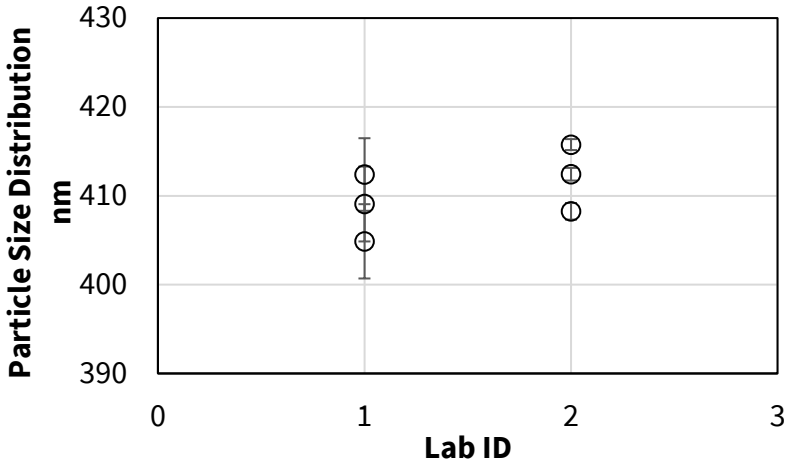


ILC Characterization Analysis – Number Concentration 10^8 ml^{-1}

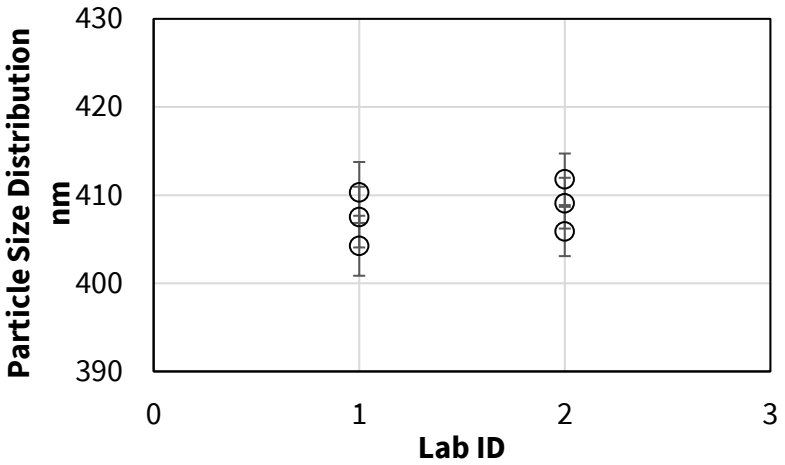


Dr. Lerche KG
office@lerche-biotec.com
Tel: +49 - (0)30 - 67 80 60 50
Wagner-Régeny-Str. 16, DE - 12489 Berlin

ILC Characterization Analysis – Number-weighted Particle Size Quantiles for 10^6 ml^{-1}



ILC Characterization Analysis – Number-weighted Particle Size Quantiles for 10^8 ml^{-1}



Dr. Lerche KG
office@lerche-biotec.com
Tel: +49 - (0)30 - 67 80 60 50
Wagner-Régeny-Str. 16, DE - 12489 Berlin