Dr. Lerche KG

Certificate of Analysis

Opti-Count® – 10^6 ml^{-1}

Product Number: 1-04406101 and 1-04406106

Reference Material

Number Concentration 400 nm Polystyrene Particles in Aqueous Suspension

	Certified Value (ml^{-1})	Uncertainty[2] (ml^{-1})
Number Concentration[1]	1.06×10^6	0.95×10^5

[1] Determined by a liquid laser counting device (LUMiSpoc®, LUM GmbH, Berlin Germany) with a DAkkS-accredited method following ISO 17025:2018. Device setup according to ISO 21501-2:2019. The certified value is from the unweighted mean of means from the characterization study. The certified value is traceable to SI units.

[2] The uncertainty value provided here is representative of the expanded combined uncertainty with a coverage factor k = 2.8 and comprised of the uncertainties from characterization, homogeneity, short-term stability, and long-term stability. This corresponds to a level of confidence of about 95 %, estimated in accordance with ISO/IEC Guide 98-3:2008 and ISO Guide 35:2017.

Expiration of Certificate: This certificate is valid for 12 months after the issuance date provided below.

Batch Number: 1-04406-XXX

Issuance Date: XXX

Indicative Values		
	Indicative Value[3] (nm)	Uncertainty[4] (nm)
Particle Size $x_{16,0}$	406.6	11.8
Particle Size $x_{50,0}$	410.8	11.9
Particle Size $x_{84,0}$	414.1	12.0

[3] Determined by a liquid laser counting device (LUMiSpoc®, LUM GmbH, Berlin Germany) with a DAkkS-accredited method following ISO 17025:2018. Device setup according to ISO 21501-2:2019. The indicative values are from the unweighted mean of means from the characterization study. The indicative values are traceable to SI units via daily calibration with standard particles (Applied Microspheres GmbH).

[4] The indicative values uncertainties are an estimate of the expanded combined uncertainty for $x_{16,0}$, $x_{50,0}$, and $x_{84,0}$ quantiles with a coverage factor k = 2.1, 2.4, and 2.2 respectively and comprised of the uncertainties from characterization, homogeneity, short-term stability, and long-term stability. This corresponds to a level of confidence of about 95 %, estimated in accordance with ISO/IEC Guide 98-3:2008 and ISO Guide 35:2017.

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

Additional Information		
$\bar{x}_0$	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 at 405 nm, 25°C	1.62(36)[7]	
Refractive Index at 589 nm, 25°C	1.59	
pH	8.0	

[5] Values provided by the particle manufacturer (Applied Microspheres GmbH) except when otherwise clarified.

[6] Number-weighted properties of mater batch of Opti-Count® particles by TEM, provided by Applied Microspheres GmbH, calculated for 1422 particles from 36 images.

[7] X. Zhang, J. Qiu, X. Li, J. Zhao, L. Liu. Complex refractive indices measurements of polymers in visible and near-infrared bands. *Appl. Opt.* **59**, 2337-2344 (2020).

Description of Material

Opti-Count® is a reference material comprised of spherical monomodal carboxylic acid surface functionalized polystyrene particles in an aqueous buffered suspension. A single unit of Opti-Count® is approximately 1 ml of suspension within 1 ml plastic vial with a screw cap. The liquid medium is a surfactant-free Tris-buffer liquid. Development of the reference material followed ISO 17034:2016 and performed at Dr. Lerche KG ISO 17025:2018 accredited laboratories.

Intended Use

Primarily used to validate, evaluate, and qualify methodology performance, and to calibrate and check the performance of liquid laser particle counting and sizing instruments in regards to the number concentration at the nanoscale (less than 1 µm). Calibration and performance checks are possible – for the given quantiles – for the number-weighted size distribution.

Instructions for Handling and Storage

The handling of Opti-Count® particles should be in accordance with the Materials Safety Data Sheet and are only valid when used in the recommended way. The material should be used as is from the bottle. Before opening the vial, it should be gently inverted several times (at least 10 times) to ensure the homogeneity of the suspension. If some suspension is still present in the upper portion of the cap, it can be removed by gently tapping the top of the vial with the forefinger while holding the vial upright. The minimum amount of sample to be used is 32 µl. When using vials, they should be left unclosed as short as possible.

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Store Opti-Count® particle suspensions upright in the original plastic bottles at room temperature (20 ± 5 °C) and away from direct sunlight and sources of heat. Vials should avoid being frozen, as this may compromise the integrity of the material.

Values are only certified within 24 hours of opening the vials. Dr. Lerche KG cannot be held responsible for changes that happen during storage of the material at the customer's premises, especially of opened samples.

Monitoring: The stability of values for Opti-Count® particles will be monitored on a regular basis as part of Dr. Lerche KG's reference materials stability testing program. Customers will be informed of any significant changes in the material if discovered.

Metrological Traceability Statement: The assessment value of particle number concentration and number-weighted size distribution are traceable to the SI units as described in the technical report.

Commutability: The commutability of this RM has not been assessed.

A detailed technical report describing the analysis procedures and the treatment of the analytical data used to certify Opti-Count® particles is available upon request or can be downloaded from the Opti-Count® website at www.opti-count.com.

Prof. Dr. Dr. Dietmar Lerche
Managing Director

Dr. Lerche KG
Wagner-Régeny-Str. 16
12489 Berlin, Germany