U.S. Corporate Headquarters
400 Valley Rd.
Warrington, PA 18976
1(800) 523-2575 / (215) 343-6484
1(800)343-3291 fax
info@polysciences.com

Polysciences Europe GmbH
Badener Str. 13
69493 Hirschberg an der Bergstrasse,
Germany
+(49) 06201-845200
+(49) 06201-8452020 fax
info@polysciences.de

Polysciences Asia-Pacific, Inc.
2F-1, 207 DunHua N. Rd.
Taipei, Taiwan 10595
(886) 2 8712 0600
(886) 2 8712 2677 fax
info@polysciences.tw

TECHNICAL DATA SHEET 623

Precision Particles:

NIST Traceable Size Standards

DESCRIPTION

Measurement of microparticle size and size distributions is a critical and challenging task to anyone who is working with micron and sub-micron materials. Many different methods exist to complete this task (Figure 1). As with all analytical techniques, the best choice is application specific. The most critical aspect of microparticle sizing is the use of microparticle size standards. In some cases, the use of a standard is required to verify the correct operation of a sizing instrument; in others, the instrument must be calibrated with a series of size standards before accurate measurements can be produced.

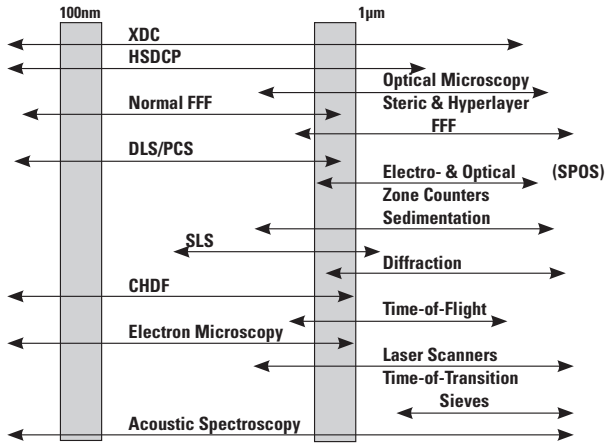
Polysciences provides Precision Particles, a series of NIST traceable polystyrene microparticle size standards that range in size from 40nm to 175µm. Standards are supplied as 1% solids suspensions in de-ionized water with surfactant.

Because of the many different and acceptable sizing techniques used (Figure 1), it is important for the end user to know how Polysciences determines particle size.

Figure 1

COMMERCIALLY AVAILABLE PARTICLE SIZING TECHNIQUES
(Mostly Liquid Suspensions)

XDC = Scanning X-Ray Disc Centrifuge
DCP = High Speed Disc Centrifuge Photosedimentometer
FFF = Field Flow Fractionation
DLS = Dynamic Light Scattering
PCS = Photo Correlation Spectroscopy
SLS = Static Light Scattering
CHDF = Capillary Hydrodynamic Fractionation
SPOS = Single Particle Optical Sensing



QUESTIONS AND ANSWERS

How does Polysciences determine the size and size distribution of Nanobeads, Microbeads and Megabeads?

For sizing the Nanobead (40 to 950 nanometers) and Microbead (1.0 to 9.0 microns) standards, Polysciences uses a Disc Centrifuge (DC) instrument. This analyzer measures particle size distributions, using centrifugal sedimentation within an optically clear spinning disc. The principle involves the relationship between particle diameter size, and the rate of sedimentation. The instrument is calibrated with uniform NIST Standard Reference Materials of known diameters.

For the Megabead (10 to 175 microns) standards, Polysciences uses Single Particle Optical Sensing (SPOS), which is a combination of light extinction and light scattering. Individual particles pass through a small optical sensing region one at a time and produce a detecting pulse. The magnitude of the pulse depends on the size of the particle. The particle size distribution plot of the sample is constructed one particle at a time by comparing the detected pulse heights with a standard calibration curve based on NIST traceable particles of known diameters.

For both methods, the mean diameter size is determined from the major peak.

Why does Polysciences measure particle size using these instruments?

All sizing methodologies have their advantages and disadvantages. There are many different considerations for choosing a sizing method and there is no single "right" method, only a best fit between the method and the application. Because the end users of our Precision Particle Size Standards will be using these methods and others, it is important to note some points about our current methodology:

1. These methods have high resolution while maintaining the ability to "see" a fairly wide size range. This enhances our ability to discriminate between two populations close in size and, at the same time, detect large aggregates and fines.
2. These methods allow statistically meaningful sampling with little user bias. The number of particles measured per sample is greater than 100,000.
3. The sizing measurements obtained are comparable to those obtained by the sizing instruments utilized by end users. While different methodologies will give slightly different answers, these methodologies will agree fairly closely with others.
4. Repeated measures on the same sample give consistent results.
5. Our measurement techniques are made with instruments calibrated and validated with NIST Standard Reference Materials.

How does Polysciences trace the size of their standards to the NIST Standard Reference Particles?

The certified mean diameters of Polysciences' Precision Particle Size Standards are measured by Disc Centrifuge and Single Particle Optical Sensing instruments. Validation of the accuracy of the calibration method is performed using NIST Standard Reference Materials (1690, 1692 and 1961). Traceability of the calibrated mean diameter to NIST Standard Reference Materials is provided through an unbroken chain of measurement using defined procedures and documented uncertainties.

How do the Polysciences NIST Traceable Particle Size Standards compare to those of others?

Historically, very low % CVs (typically 1% or less) have been reported for particle size standards. This may be due to the fact that the particles were measured using electron microscopy techniques. Disadvantages of this method include sampling error due to a statistically small number of particles actually measured, and the possibility of user bias in taking the measurements. Polysciences has found that when these types of samples are measured using our sizing techniques and equipment, the % CVs are often in the range of approximately 2 to 4%. However, it is important to note that these standards are certified for mean diameter only; standard deviations and CVs are provided solely for informational purposes.

As a primary manufacturer of monodisperse particles for FDA-regulated industries, Polysciences must take into consideration the outlying peaks found in many "monodisperse" standards. We employ manufacturing methods to reduce the impact of these outliers. Our refined manufacturing methods enable Polysciences to produce calibration grade particle size standards with a narrower CV than many international standards.

The monodispersity of Polysciences' NIST Traceable Precision Particle Size Standards, as indicated by the coefficient of variation of the mean diameter of the particles in the sample, is comparable and often smaller than those offered by other vendors. In some cases, Polysciences' Precision Particle Size Standards are more monodisperse than the NIST Standard Reference Materials to which they are traced.

IMPORTANT NOTE ON EXPECTED RESULTS

For NIST-Traceable Size Standards, the formal Lot-specific mean diameter is provided on the Certificate of Calibration and Traceability. We do not offer pass / fail criteria as these need to be established by each customer, taking the underlying sizing methodology, software algorithms, historical instrument performance, and sample preparation into consideration.

We anticipate that different values will be returned by different sizing methodologies, though it is often possible to establish a high correlation between them. *See References for information regarding different sizing methodologies.*

We encourage facilities to conduct several runs over time (and of different Lots of size standards, if available), when establishing in-house criteria related to instrument performance. This allows operators to develop a deeper understanding of their instruments (both capabilities and limitations) and to set meaningful QC specifications.

Size Comparison of Representative Lots of Polysciences' NIST Traceable Particle Size Standards with Competitive Products

Source	*Nominal Size*	*Measured Size*[1]	*% CV*
Polysciences	275nm	274[2]nm	2.2
NIST	300nm	266[2]nm	3.2
Polysciences	500nm	512[2]nm	1.8
Competitor	500nm	492[2]nm	2.2
Polysciences	1.0µm	1.01[3]µm	2.6
Competitor	1.0µm	1.01[3]µm	4.3
Polysciences	20.0µm	19.47[3]µm	2.6
Competitor	20.0µm	19.14[3]µm	3.6

Source	*Nominal Size*	*Measured Size*[1]	*% CV*
Polysciences	30.0µm	29.51[3]µm	1.3
NIST	30.0µm	28.41[3]µm	3.2
Polysciences	50.0µm	48.63[3]µm	2.6
Competitor	50.0µm	48.45[3]µm	3.2
Polysciences	100.0µm	102.77[3]µm	2.1
Competitor	100.0µm	98.70[3]µm	2.8

[1] Number Weight Mean Diameter
[2] Measured by Disc Centrifuge
[3] Measured by SPOS

NIST TRACEABLE PRECISION PARTICLE SIZE STANDARDS TABLES

Nanobeads

Catalog #	% Solids	Nominal Size	Size Range	Method[4]
64004-15	1%	40nm	36.0-44.0nm	DC
64005-15	1%	50nm	45.0-55.0nm	DC
64006-15	1%	60nm	55.0-64.0nm	DC
64007-15	1%	70nm	65.0-74.0nm	DC
64008-15	1%	80nm	75.0-84.0nm	DC
64009-15	1%	90nm	85.0-94.0nm	DC
64010-15	1%	100nm	95.0-110.0nm	DC
64011-15	1%	125nm	120.0-130.0nm	DC
64012-15	1%	150nm	140.0-160.0nm	DC
64013-15	1%	200nm	190.0-210.0nm	DC
64014-15	1%	250nm	240.0-260.0nm	DC
64015-15	1%	300nm	285.0-315.0nm	DC
64016-15	1%	350nm	335.0-365.0nm	DC
64017-15	1%	400nm	380.0-420.0nm	DC
64018-15	1%	450nm	430.0-470.0nm	DC

Nanobeads cont.

64019-15	1%	500nm	480.0-520.0nm	DC
64020-15	1%	550nm	530.0-570.0nm	DC
64021-15	1%	600nm	580.0-620.0nm	DC
64022-15	1%	650nm	630.0-670.0nm	DC
64023-15	1%	700nm	680.0-720.0nm	DC
64024-15	1%	750nm	730.0-770.0nm	DC
64025-15	1%	800nm	780.0-820.0nm	DC
64026-15	1%	850nm	830.0-870.0nm	DC
64027-15	1%	900nm	880.0-920.0nm	DC
64028-15	1%	950nm	930.0-970.0nm	DC

[4] *CPS Disc Centrifuge, Model DC24000 (CPS Instruments, Inc.)*

Microbeads

Catalog #	% Solids	Nominal Size	Size Range	Method[5]
64030-15	1%	1.00µm	0.95-1.05µm	DC
64035-15	1%	1.25µm	1.20-1.30µm	DC
64040-15	1%	1.50µm	1.45-1.55µm	DC
64045-15	1%	1.75µm	1.70-1.80µm	DC
64050-15	1%	2.00µm	1.90-2.10µm	DC
64055-15	1%	2.50µm	2.40-2.60µm	DC
64060-15	1%	3.00µm	2.85-3.15µm	DC
64065-15	1%	3.50µm	3.30-3.70µm	DC
64070-15	1%	4.00µm	3.80-4.20µm	DC
64080-15	1%	5.00µm	4.70-5.30µm	DC
64090-15	1%	6.00µm	5.70-6.30µm	DC
64100-15	1%	7.00µm	6.60-7.40µm	DC
64110-15	1%	8.00µm	7.60-8.40µm	DC
64120-15	1%	9.00µm	8.60-9.40µm	DC

[5] *BI-DCP Particle Sizer (Brookhaven Instruments)*

Megabeads

Catalog #	% Solids	Nominal Size	Size Range	Method[6]
64130-15	1%	10.0µm	9.50-10.50µm	SPOS
64140-15	1%	12.0µm	11.50-12.50µm	SPOS
64155-15	1%	15.0µm	14.00-16.00µm	SPOS
64160-15	1%	20.0µm	19.00-21.00µm	SPOS
64165-15	1%	25.0µm	24.00-26.00µm	SPOS
64170-15	1%	30.0µm	28.00-32.00µm	SPOS
64180-15	1%	40.0µm	37.00-43.00µm	SPOS
64190-15	1%	50.0µm	47.00-53.00µm	SPOS
64200-15	1%	60.0µm	57.00-63.00µm	SPOS
64210-15	1%	80.0µm	75.00-85.00µm	SPOS
64220-15	1%	100.0µm	90.00-110.00µm	SPOS
64225-15	1%	125.0µm	115.00-135.00µm	SPOS
64230-15	1%	150.0µm	140.00-160.00µm	SPOS
64235-15	1%	175.0µm	165.00-185.00µm	SPOS

[6] *Accusizer 780 Optical Particle Sizer (Particle Sizing Systems)*

These products are for research use only and are not intended for use in humans or for *in vitro* diagnostic use.

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In The U.S. Fax: 1(800) 343-3291 • (215) 343-0214

In Germany Call: +(49) 06201-845200
In Germany Fax: +(49) 06201-8452020

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