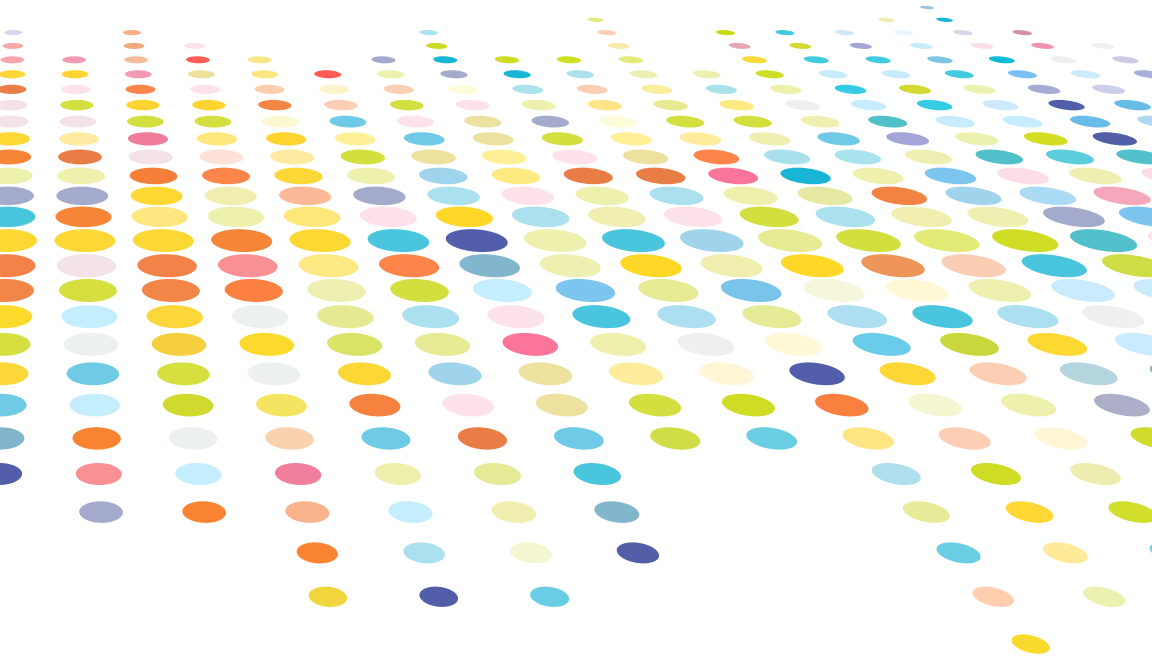
Bangs Labs

DIAGNOSTIC REAGENT DEVELOPMENT



ABOUT

Bangs Laboratories, Inc. has supplied microspheres to diagnostic companies, instrument manufacturers and researchers in the life sciences for 35 years. Our synthesis capabilities encompass silica and superparamagnetic microspheres, as well as traditional polymer compositions. While we offer many versions of our core products to meet our customers' needs, we also offer custom dyeing, coating and surface modification of microspheres. Contact us and let us put our decades of real-world experience to work for you.

LOCATIONS

Bangs is part of the Ott Scientific family of companies. With corporate locations around the world, we are ready to meet your global needs.

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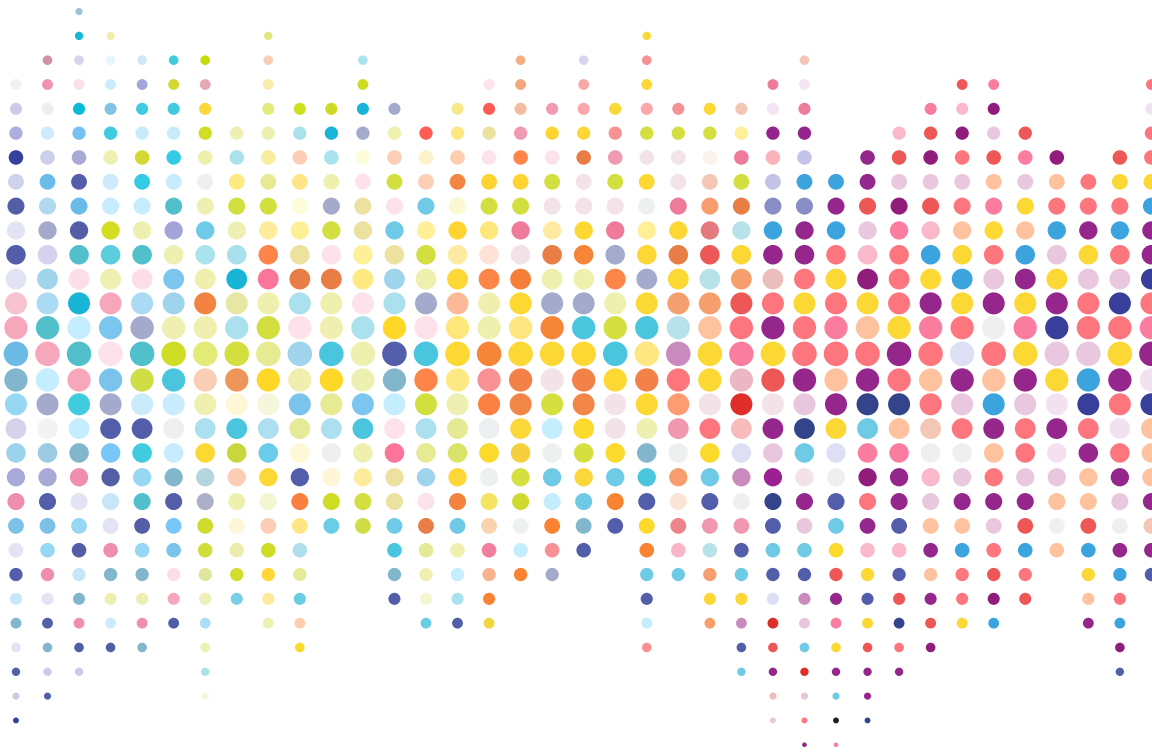
QUALITY

Bangs Laboratories' Quality Management System has been certified by NQA to comply with **ISO 13485:2016** for the design, manufacture, processing and distribution of microspheres and related products.

We hope you enjoy our guide to
Microsphere Reagent Development
and invite you to contact us with any questions
or to discuss your specific requirements.

See our complete library of data sheets, protocols, curated references, presentations and TechNotes at
BangsLabs.com



I. DIAGNOSTIC APPLICATIONS

Microspheres are routinely used as solid phase reagents in diagnostics and bioseparations, and for assay and instrument standardization. Many different types of spheres are available to address the diverse and evolving needs of the industry—polymer, silica and magnetic compositions, with different surface chemistries in a range of sizes. Beads offer a large specific surface area for binding, and permit efficient capture and isolation of target. They are highly amenable to automation and miniaturization, which has been important for traditional uses, and essential for applications necessitating portability.

This is an overview of the many varieties of microspheres that are suitable for the development of diagnostic reagents, and also showcases our capabilities for custom and OEM manufacturing.

TEST & ASSAY FORMATS

TURBIDIMETRIC ASSAYS

The assay of clinically-relevant analytes is important for treating critical medical conditions such as cardiovascular disease, thrombosis, bacterial infections and active inflammatory conditions. Turbidimetric assays permit the rapid and quantitative assessment of the patient's condition, and the development of particle-enhanced versions has been known to increase sensitivities by 10- to 100-fold.

Bangs Laboratories offers carboxylated and plain polystyrene ("latex") microspheres in the submicron diameters (0.05µm – 0.5µm) that are widely used for turbidimetric reagent development. The different surfaces support both covalent and adsorption protocols, allowing for the highly tailored coatings that are important to agglutination reactions. Additionally, our synthesis capabilities permit the manufacture of reproducible lots at the scales needed by OEM customers. *See TN304, Light-Scattering Assays* and our *Turbidmetric Assay brochure.*

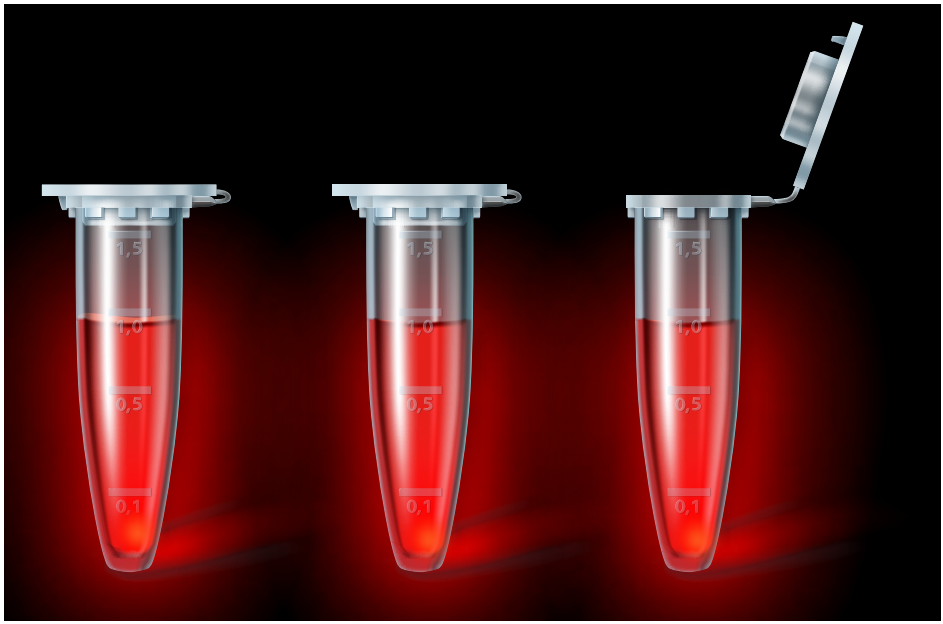
Catalog Number	Description	Nominal Bead Size (µm)
PC02001 - PC03001	PS - COOH	≤0.50
PS02001 - PS03001	PS	≤0.50

LATERAL FLOW TESTS

Dyed submicron microspheres are commonly used as the mobile phase in lateral flow tests. Vibrant colors permit visual detection of test results, and fluorescent versions such as Eu(III) spheres may be used with specialized readers for POC applications. Our Europium Chelate Sampler Pack is available for Lateral Flow Test development.

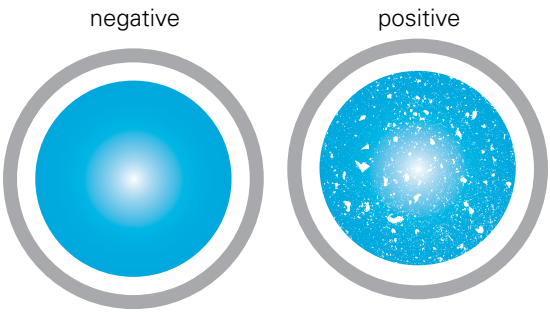
See TN303, Lateral Flow Tests.

Catalog Number	Description	Nominal Bead Size (µm)
DC**001 - DC**002 (*color specific)	Dyed PS - COOH	≤0.50
DS**001 - DS**004 (*color specific)	Dyed PS	≤0.50
FCEU001 - FCEU004	Europium Chelate (PS - COOH)	0.10, 0.20, 0.30, 0.40
21960	Europium Chelate Sampler Pack (PS - COOH)	0.10, 0.20, 0.30, 0.40



BEAD ELISAS

Bead-ELISAs have been developed using various types of microspheres, including micron-range polymer, magnetic or submicron polymer spheres. They offer increased surface area over traditional microplate ELISAs, and magnetic spheres, with their suitability for automation, provide additional benefits with respect to reagent processing and assay performance. *See TN301, Immunological Applications.*



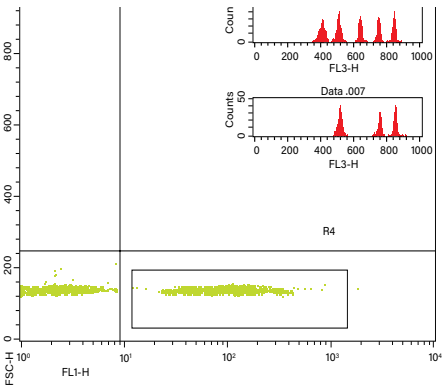
LATEX AGGLUTINATION TESTS (LATs)

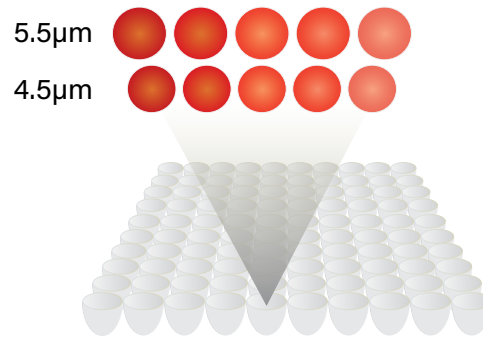
In the classic LAT, beads are coated with antigen for the detection of antibody in serum or blood. If present, the antibody bridges antigen-coated microspheres, causing agglutination. Positive results are visually apparent as the homogeneous, milky white suspension takes on a grainy or sandy appearance. Undyed “white” spheres are often spotted on black cards, and dyed spheres may be applied to slides or white cards. *See TN301, Immunological Applications.*

Catalog Number	Description	Nominal Bead Size (µm)
PC02008 - PC04001	PS - COOH	0.20 - 1.0
DC**001 - DC**004 (*color specific)	Dyed PS - COOH	0.20 - 1.0

SUSPENSION ARRAYS

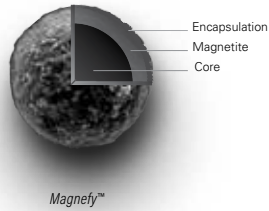
Bead-based flow cytometric assays feature populations of microspheres coated with different ligands to interrogate multiple targets within a single sample. Our QuantumPlex™ kits provide a general platform for multiplexed assay development on standard flow cytometers (488nm or 633nm Ex). Microsphere populations in 5-bead kits are encoded with different intensities of Starfire Red™, and the two size kits (4.4µm, 5.5µm) may be combined to extend the array to a 10-plex. QuantumPlex™M kits feature highly uniform 6µm magnetic microspheres. *See PDS 215 and TN205.*





Through selective gating in the fluorescent reporter channel, the "positive" populations may easily be isolated. The dot plot above shows the results of a sample stained for four analytes. The sample contained two of the four analytes.

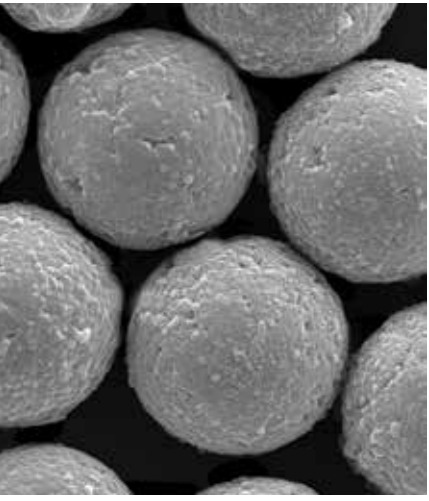
Catalog Number	Description	Nominal Bead Size (µm)
235, 238, 239	QuantumPlex™ COOH	4.4, 5.5
250	QuantumPlex™M COOH	~6
215, 218, 219	QuantumPlex™ Streptavidin	4.4, 5.5
252	QuantumPlex™M Streptavidin	~6



MAGNETIC PARTICLE ASSAYS

Our magnetic particle offerings permit the development of reagents that are uniquely suited to the highly specific demands of proprietary analyzers used for molecular and immunoassays. Bangs' comprehensive line of magnetic particles allows us to address the unique requirements of a multitude of assay systems, with options for particle diameter, surface functionality, morphology, magnetic separation profile and other characteristics. The magnetic particle table below provides general particle recommendations for consideration.

		ProMag® HP COOH	ProMag® HP SA	ProMag® COOH	ProMag® SA	Magnefy™ COOH	Magnefy™ SA	Magnefy™ Mach I	BioMag® COOH	BioMag® SA	COMPEL™ COOH	COMPEL™ SA
Assays	Chemiluminescence	●	●	●	●	●	●	●	●			
	Immuno	●	●	●	●	●	●	●	●	●	●	●
	Molecular	●	●	●	●	●	●	●			●	●
	Flow cytometric										●	●

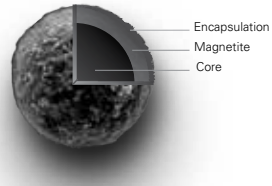


CHEMILUMINESCENCE ASSAYS

The high sensitivities, broad dynamic ranges, simple instrumentation and rapid results that characterize chemiluminescence assays make them well-suited to quantitative measurement of low analyte concentration in immuno- and molecular diagnostic applications. Whether developing assays for fully automated or laboratory-built analyzers, there are many design elements to consider, including assay format, sensitivity, emitter / luminescence system, and solid phase. *See facing table for bead offerings.*

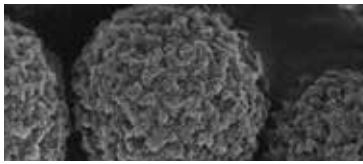
MOLECULAR ASSAYS

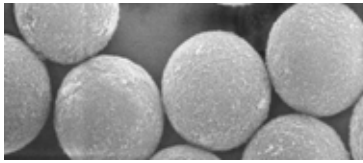
Like immunoassays, molecular diagnostics rely on a wide range of reporters and assay formats. Our *Assay Development* brochure provides general particle characteristics for consideration, and our Magnetic Sampler Packs feature a selection of particles that will allow you to conduct side-by-side comparisons in the lab. We are also adept at helping investigators navigate the particle landscape to select candidates for screening based on the specific context (test / assay format, instrument parameters and other design criteria), and invite you to contact us with your questions regarding particle use in your diagnostic application.

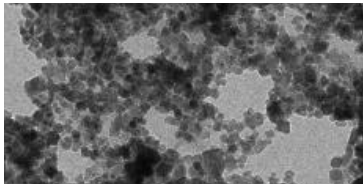


Magnefy™


ProMag HP


ProMag


COMPEL

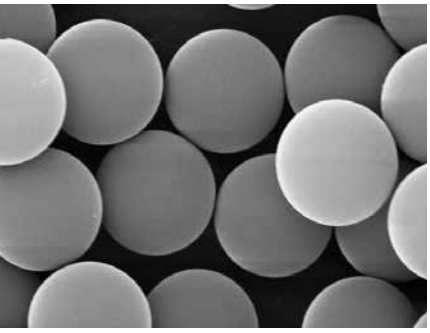

BioMag

Catalog Number	Description	Nominal Bead Size (µm)
MFY0002, MFYS1N	Magnefy™ (COOH & SA)	1.0 µm
MFYM001	Magnefy™ Mach I (COOH)	1.0 µm
BP618, BP628	BioMag® Plus (COOH & SA)	1.5 µm
PMC1N, PMS1N	ProMag® 1 series (COOH & SA)	1.0 µm
PMA3N, PMC3N, PMS3N	ProMag® 3 series (COOH, NH_2 & SA)	3.0 µm
PMC3HP, PMS3HP	ProMag® HP (COOH & SA)	3.0 µm
21940	**Carboxyl Magnetic Sampler Pack Includes:** MFY0001, Magnefy™ 1 COOH - 5mL (5% solids) 50mg/mL, PMC1N, ProMag Series 1 COOH - 5mL (2.5% solids) 25mg/mL, PMC3HP, ProMag HP 3µm COOH - 5mL (2.5% solids) 25mg/mL, BP618, BioMagPlus COOH - 5mL (2% solids) 20mg/mL	
21950	**Streptavidin Magnetic Sampler Pack Includes:** MFYS1N Magnefy 1 SA (1% solids), PMS1N, ProMag 1 Series - 1mL (1% solids), PMS3HP, ProMag HP 3µm - 1mL (1% solids), BP628, BioMagPlus - 2mL (5mg/mL)	

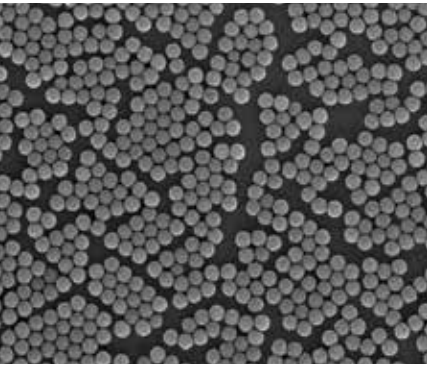
II. MICROSPHERE SELECTION

There are many varieties of microspheres available, so it is important to think about the demands of the assay when selecting a base bead. Physical and optical properties should be considered in the context of handling and detection, and thought should be given to requirements for diameter and size distribution, composition, surface chemistry, and any other needed properties.

Size	Composition	Surface chemistry	Special properties
Diameter Uniformity / distribution	Density Refractive index Hydrophobicity / -philicity Nonspecific binding Autofluorescence	Reactive groups Level of functionalization Charge	Visible dye / fluorophore Superparamagnetic



Scanning Electronic Microscopy image of silica microspheres (4.14µm).



ProMag® 3µm magnetic microspheres

DIAMETER

Microsphere size may be crucial for optimal assay performance, or it may be secondary to other characteristics. Considering traditional diagnostic methods, the test or assay format commonly dictates particle size, such as the use of very small spheres (~0.1 - 0.4µm) to ensure satisfactory wicking in lateral flow tests, or the use of larger, cell-sized spheres (~4 - 10µm) for bead-based flow cytometric assays.

In magnetic separations, particularly those involving capture and elution of target, the exact size of the magnetic particle may be of little importance provided that the particles are in some general size range, and offer desired separation characteristics. *See TN102A* for more on our magnetic particle lines.

Diameter also determines surface area. Small-diameter spheres present more surface area per unit weight, while larger spheres present more surface area per bead. Size also affects ease of handling, processing considerations (such as separation methods [centrifugation, dialysis, filtration]), and the amount of reagent needed for coating.

Physical and Optical Properties of Microsphere Matrices

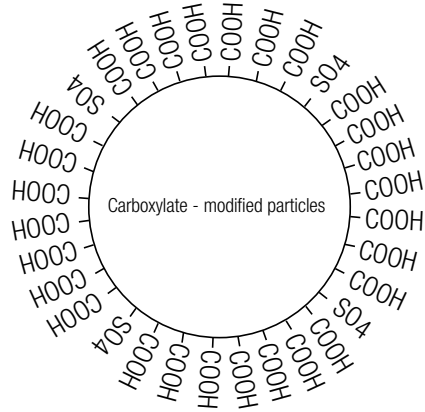
COMPOSITION	REFRACTIVE INDEX (589nm)	DENSITY (g/cm^3)	SOFTENING POINT (˚C)
PS	1.59	1.05	95
PMMA	1.49	1.19	105
Silica	1.43-1.46*	2.0*	>>1000

** Determined using representative samples. Other values are as reported in the literature for bulk polymer or silica.*

COMPOSITION

Common microsphere compositions include polystyrene (PS), polymethyl methacrylate (PMMA) and silica. These materials possess different physical and optical properties, which may present advantages or limitations for different applications.

Polymer beads are generally hydrophobic, and as such, have high protein binding abilities. However, they often require the use of some surfactant (e.g. 0.01-0.1% Tween® 20 or SDS) in the storage buffer to ensure ease of handling. During synthesis, functional monomers may be co-polymerized with styrene or methyl methacrylate to develop beads with surface reactive groups. Functional groups may be used in covalent binding reactions, and also aid in stabilizing the suspension.



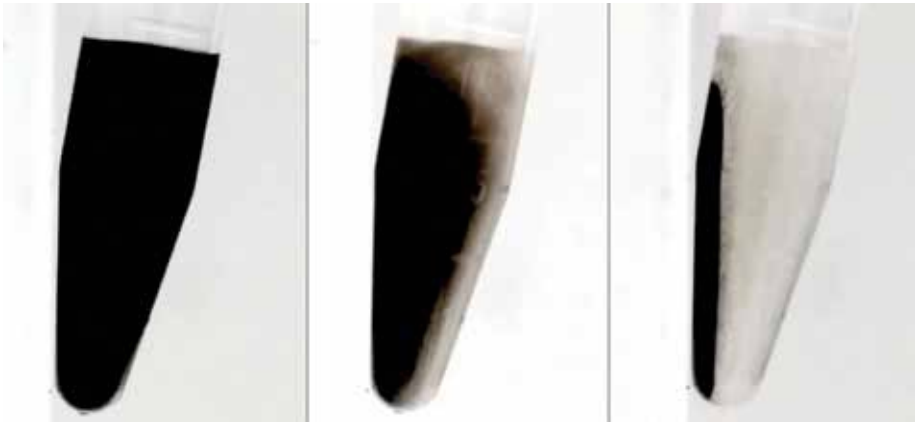
Silica microspheres are inherently hydrophilic and negatively charged. Consequently, aqueous silica suspensions rarely require use of surfactants or other stabilizers. Carboxyl- and amine-functionalized silica spheres are available for use in common covalent coating protocols, and plain silica microspheres may be modified using a variety of silanes to generate functional groups or alter surface properties.

We manufacture
POLYSTYRENE (PS)
POLYMETHYL METHACRYLATE (PMMA)
MAGNETIC
SILICA
with a variety of surfaces and coatings!

Magnetic bead composition determines settling and magnetic separation profiles, which have implications for assay parameters, such as incubation times for binding and elution steps, buffer changes, etc. Most importantly, the magnetic bead composition impacts specific / nonspecific binding characteristics, and background signal arising from the particle itself. These factors have a direct impact on the sensitivity and dynamic range of the assay.

To facilitate particle selection and optimization, we have assembled Magnetic Sampler Packs featuring our most popular carboxyl (COOH) and streptavidin (SA) particles. See datasheets for additional product details.

Catalog Number	Description
21940	Carboxyl Magnetic Sampler Pack Includes: MFY0002, Magnefy™ 1 COOH - 5mL (5% solids) 50mg/mL, PMC1N, ProMag Series 1 COOH - 5mL (2.5% solids) 25mg/mL, PMC3HP, ProMag HP 3µm COOH - 5mL (2.5% solids) 25mg/mL, BP618, BioMagPlus COOH - 5mL (2% solids) 20mg/mL
21950	Streptavidin Magnetic Sampler Pack Includes: MFYS1N, Magnefy 1 SA (1% solids) PMS1N, ProMag 1 Series - 1mL (1% solids), PMS3HP, ProMag HP 3µm - 1mL (1% solids), BP628, BioMagPlus - 2mL (5mg/mL)



Magnetic Separation

SCAN THE QR CODE TO VIEW THE MAGNETIC SEPARATION IN REAL-TIME ON OUR YOUTUBE CHANNEL.

OTHER PROPERTIES

Many applications in the life sciences demand added properties, such as fluorescence or a visible color, or iron oxide inclusions for magnetic separations. Polymer spheres (and polymer-based magnetic spheres) may be internally dyed via organic solvent swelling, and many standard products are available. Dye concentrations can be adjusted to produce beads with different intensities to meet special needs, such as QuantumPlex™ for multiplexed flow cytometric assays.

Microsphere selection for various test and assay formats

TEST / ASSAY FORMAT	BEAD SIZE	BEAD TYPE	COATING STRATEGY	DETECTION STRATEGY	DOC.
Turbidimetric	50 µm – 500 µm	Undyed	Covalent	Turbidimetry	TN304
Magnetic Chemiluminescence	1 - 5 µm	Various	Covalent	Luminescence	PDS743
Flow cytometric (suspension array)	2 µm – 15 µm	QuantumPlex™ QuantumPlex™M (encoded populations for multiplexing) or Non-fluorescent (simplex or multiplex with different bead sizes)	Covalent or streptavidin / biotin	Flow cytometer	TN305
Bead "ELISA"	1 - 3 µm	ProMag®, ProMag® HP	Covalent	Spectrophotometer	TN301
Lateral Flow	0.1 µm – 0.4 µm	Dyed Fluorescent or Europium Chelate	Covalent or adsorption	Visual or Automated Reader (absorbance, fluorescence)	TN303
Dipstick	0.1 µm – 0.4 µm	Dyed (visible)	Covalent or adsorption	Visual	TN303
Latex Agglutination Test (LAT)	0.2 µm – 1.0 µm	Undyed or visibly dyed	Covalent or adsorption	Visual (may be microscope-assisted)	TN201 TN301

III. COATING & BLOCKING

Microspheres are coated with ligand, such as antibodies, oligonucleotides, peptides, etc. for use in diagnostic applications. Coatings are typically optimized to achieve desired specific activity, while minimizing nonspecific interactions. Consideration should also be given to the required stability, development time frame and budget, and the specific ligand to be coated. These factors will aid in determining the most fitting coating strategy for both short- and long-term objectives. Standard microsphere products support three basic coating strategies: adsorption, covalent coupling and affinity ligand.

COATING

ADSORPTION

Adsorption relies primarily on hydrophobic interactions between the biomolecule and the polymer particle. Such coatings are fairly simple, involving incubation of the microspheres with the purified ligand. However, as adsorption relies on the formation of multiple attachment points between the molecule and particle, this strategy is typically reserved for use with proteins and plain polystyrene spheres. Adsorption is generally not suitable for hormones, peptides or nucleic acids in hybridization-based applications, and protein adsorption to hydrophilic silica is expected to be less efficient and stable than it is for polymer. *See TN201 and TN204.*

COVALENT COUPLING

Covalent coupling results in the permanent attachment of the ligand to the functionalized (e.g. carboxyl or amine) microsphere. It can provide needed stability when developing a commercial reagent and for multiplexed assays where analyte-specific bead populations are mixed. Additionally, specialized chemical linkers may be employed to address steric effects or to optimally orient the molecule. Although covalent binding protocols often involve a higher level of optimization than other approaches, coupling kits, such as PolyLink (Cat # PL01N) are available to simplify the process. *See TN205 and PDS 644.*

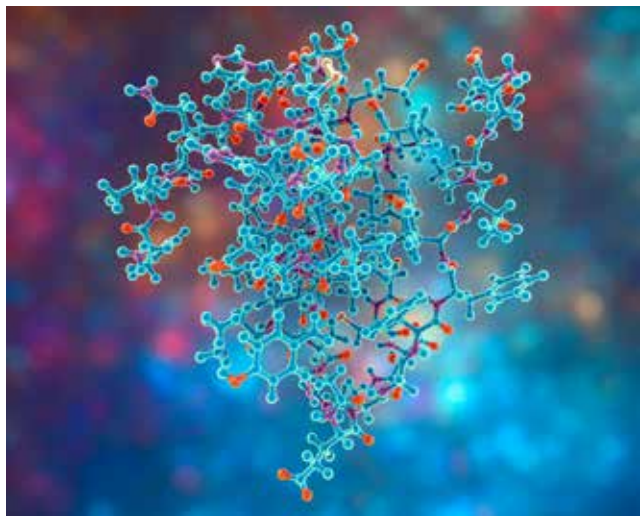
AFFINITY BINDING

Affinity binding is a straightforward method for immobilizing primary antibodies or biotinylated molecules. Proteins A and G and Fc-specific antibody coatings permit the directed immobilization of primary antibodies. Streptavidin is used extensively for the binding of biotinylated molecules, such as antibodies, peptides and oligonucleotides. *See TN101 and TN302.*

It is important to note that each binding strategy has benefits and limitations, which should be weighed in the context of study objectives and the demands that will be placed on the finished reagent. See *TN204 and TN205* for sample coating protocols and additional discussion of crosslinking reagents and specialized immobilization strategies.

Typical Coating Strategies for Common Biomolecules

BIOMOLECULE	TYPICAL COATING STRATEGY	NOTES
Peptides	Covalent Streptavidin / Biotin	End-point attachment to preserve the activity of the peptide
Nucleic acids	Covalent Streptavidin / Biotin	End-point attachment to permit hybridization with target sequence
Proteins (e.g. antibodies)	Covalent Adsorption	Common proteins are generally large enough that multi-point attachment and nonspecific orientation do not compromise activity. However, linkers or spacers (covalent or SA/B) may be employed to address steric effects or sub-optimal orientation.



BLOCKING

Blocking is generally conducted to deter nonspecific binding, improve bead handling, and optimize activity by spacing out surface-immobilized ligand. Blockers may contribute charge groups and prevent hydrophobic interaction with biomolecules.

Common protein blocking molecules include BSA (or other albumin), irrelevant IgG, casein and gelatin. Surfactants or synthetic polymers may also be used as blockers, either in a specific blocking step or as additions to the storage buffer. Blocking may be conducted concurrently following ligand immobilization, and blockers are often included in the microparticle reagent storage buffer.

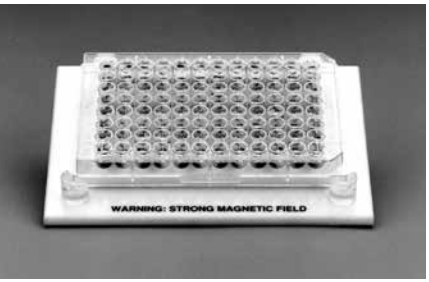
Care should be taken to select blockers that won't interfere with the reaction or activity of the ligand, either through nonspecific binding to active regions or masking due to size. For example, small molecules such as sugars can enter the binding pocket of streptavidin and serve to block biotin binding, while large proteins such as BSA could interfere with accessibility to peptides coatings, etc. Blocking molecules, themselves, can also be a source of nonspecific binding.

PROTEINS		**DETERGENTS**		**SYNTHETIC POLYMERS**	
BSA	69kD	Triton-X 100 Non-ionic (Cat.# AA014)	625 Da	Polyacrylic acid (PAA)	2kD – 50kD
Ovalbumin	45kD	Tween 20 Non-ionic (Cat.# AA016)	1227 Da	Polyethylene glycol (PEG)	2kD – 5kD
Irrelevant IgG	150kD	SDS Anionic (Cat.# AA018)	288 Da	Polyvinyl pyrrolidone (PVP)	
Casein	23kD				
Gelatin	50 - 100kD				

IV. BUFFERS

Microparticle buffers should be suitable for both the ligand and the task at hand. A generic biologic buffer such as PBS or PBS-Tween® may be utilized for bead washes prior to coating, while more specific / complex buffers will typically be used for microparticle coating, storage and use. See *TSD 0300, Buffers* for our range of prepared microsphere buffers and suspending solutions (BUFF1 – BUFF6, SOLN1), and *TN204/TN205* for additional buffers and recipes.

PURPOSE	BUFFER CONSIDERATIONS
Pre-washes	Remove residuals Normalize environment Should not contain additives that will compete with ligand for the bead surface
Coating	Provides conditions needed for the reaction (such as pH for EDAC activation of COOH groups) Provides conditions that are optimal for the ligand (pH, concentration, etc.) Potential inclusion of blocker
Storage	Provides conditions that are optimal for the ligand (pH, concentration, etc.) Inclusion of additives that promote stability, e.g. blocker, detergent, antimicrobial agent
Assay	Composition promotes high specific binding, low nonspecific binding for the specific assay system



Cat # MS003, BioMag 96-well plate magnetic separator

Cat # AA002, Vivaspin® concentrators for 20nm-500nm nanoparticles

WASHING

Washes are conducted as needed to normalize the buffer system, remove residuals that could interfere with ligand coating or activity, and transition microspheres through sequential steps of coating or use protocols.

A single wash may consist of:

- microsphere separation / settling (centrifugation);
- supernatant removal;
- re-suspension of microspheres in buffer;
- with ~2-3 repetitions performed for a given wash step.

Rare earth or electromagnetic separators are used to perform washes for superparamagnetic microspheres; see our *Biomagnetic Separator* brochure for options including single- and multi-tube and 96-well plate magnetic separators.

For non-magnetic microspheres, the wash method(s) should be selected with both microsphere size and throughput in mind. Centrifugation is commonly used for microspheres 0.5µm+, while centrifugal filter devices*, dialysis or cross-flow filtration is typically employed for smaller (<0.5µm) diameters. (*Cat. AA022, Vivaspin® 2mL Ultrafiltration Device) *See TN203, Washing Microspheres* for more information.

Sample protocols for benchtop (7.3cm rotation radius) centrifuge, all ~5min.

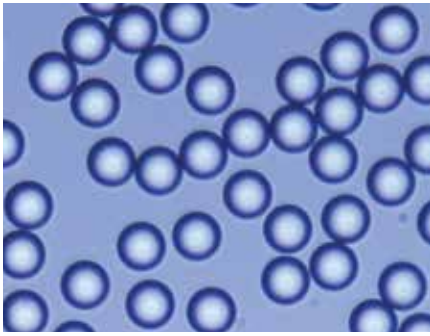
BEAD TYPE	DIAMETER RANGE	RELATIVE CENTRIFUGAL FORCE (xG)	SPEED (RPM)
polymer	> 0.5 µm	6500 - 14000	8925 - 13100
	> 1.0 µm	3000 - 5500	6060 - 8210
	> 5.0 µm	1300 - 3000	3990 - 6060
silica	> 0.5 µm	3000 - 5500	6060 - 8210
	> 1.0 µm	1300 - 3000	3990 - 6060
	> 5.0 µm	750 - 1300	3030 - 3990
protein/Ab-coated	> 0.5 µm	8000 - 11000	9900 - 11610
	> 1.0 µm	5500 - 8000	8210 - 9900
	> 5.0 µm	2000 - 5500	4950 - 8210

AGGREGATION

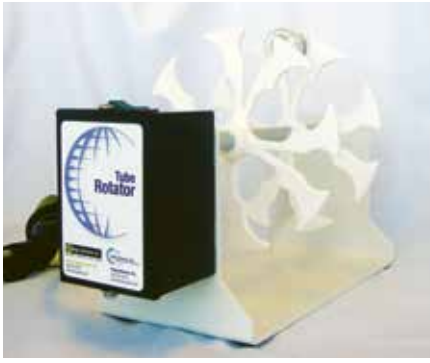
Common polymer matrices (PS, PMMA) are generally hydrophobic, and as such, have both a high capacity for protein loading and a tendency to flocculate in aqueous systems. Consequently, polymer bead suspensions often contain surfactant (e.g. 0.01 – 0.1% Tween® 20 or SDS) to aid in particle wetting and promote ease of handling.

Rolling / rotation are often used as a matter of course (e.g. for bottle storage, or in preparation for bead use) to keep suspensions well-dispersed, and to address instances of slight or transitory aggregation. Careful bath or probe sonication may be used as needed to treat more persistent aggregation (15 - 30s bath, 8 - 10s probe). *See TN202, Microsphere Aggregation,* for additional tips, and *PDS 699* (Cat. ROTAT) for details of our Tube Rotator.

The hydrophilic matrices possessed by silica and some of our magnetic microspheres are less prone to aggregation, though the same strategies may be adapted for use with them or with coated microspheres if stickiness or aggregation is observed.



Well-dispersed 10µm PS spheres



Tube rotator (Cat # ROTAT)

VI. MICROSPHERE CHARACTERIZATION & QC

Bangs Laboratories conducts a battery of analytical tests to ensure that products meet our standard specifications, and to support custom and OEM manufacturing needs. Testing includes (as appropriate for the product line or application):

- Diameter / size distribution
- Surface titration
- Binding capacity
- Concentration / % solids
- Microbial testing
- Microscopic examination

Additional specialized testing is performed for certain product lines to support specific applications:

- Fluorescence
- Autofluorescence
- Absorbance
- Chemiluminescence
- Exposed iron
- Magnetic response time
- Coating uniformity / surface group distribution

We invite you to contact us regarding your specific OEM manufacturing and testing needs.

VII. MICROSPHERE STORAGE & STABILITY

Our uncoated plain, COOH and NH_2 microspheres are considered to be chemically inert, and will be stable indefinitely (years) provided that they are stored and handled properly, i.e. refrigerated storage to safeguard against growth of opportunistic microorganisms, and avoidance of extreme conditions that would cause degradation of the bead matrix.

As general rules:

- polymer microspheres should not be exposed to extreme heat or organic solvents;
- fluorescent microspheres should remain in the as-supplied opaque bottle to safeguard against photobleaching;
- pH extremes (e.g. <4.5, >8.5) should be tested to ensure compatibility;
- suspensions should be stored at 2 - 8 C˚ to deter microbial growth;
- suspensions should not be frozen due to the risk of irreversible aggregation;
- bottles should be stored upright and tightly closed.

The stability of finished reagents that you develop will depend on the specific coating, buffer system and storage conditions. Stability testing should be conducted as appropriate to ensure needed performance.

We are pleased to review specific scenarios for both uncoated microspheres and coated reagents with our customers, and invite you to contact us for discussion of buffer systems, handling practices, storage conditions and QC testing.

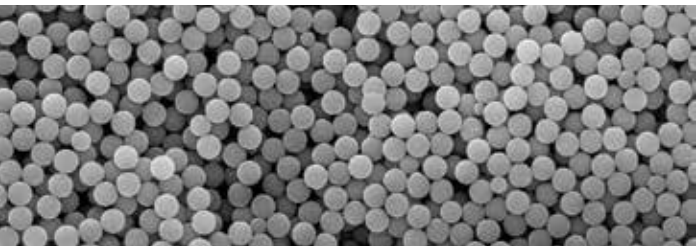
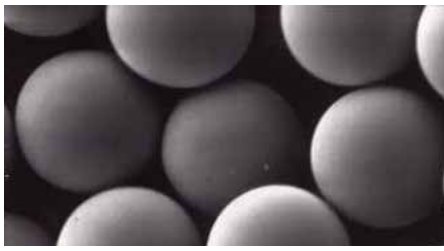
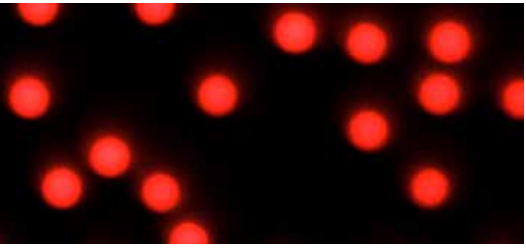
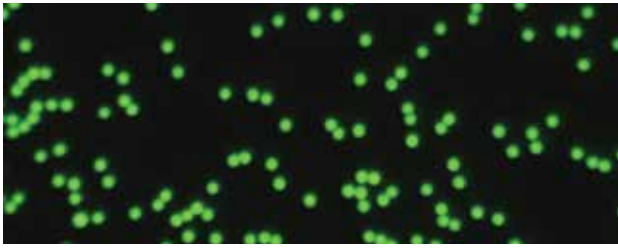
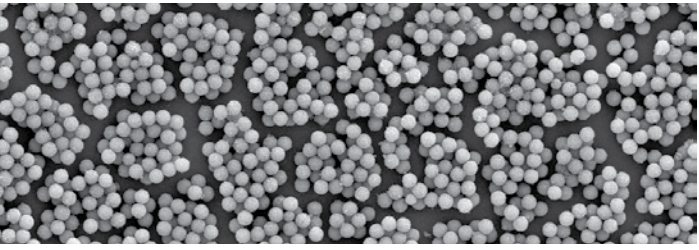
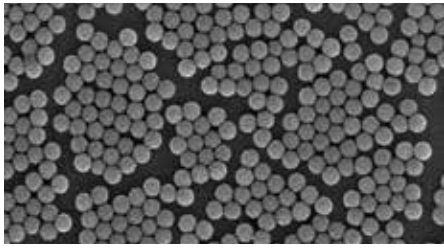
VIII. TRANSFER FROM R&D TO MANUFACTURING

The transfer of reagent production from research to commercial scale is not an insignificant endeavor. We understand scale-up and transfer processes, and invite you to talk with us about:

- Conducting a coating protocol review to ensure efficiency and reproducibility;
- Scaling up the coating protocol, including amounts of reagents, timing of additions, mixing and separation methods, etc.;
- Reviewing raw material (microparticle) specifications to ensure that they are reasonable and robust;
- Availability of multiple validation Lots of the base microparticle.

For our OEM customers, we offer custom services & bulk manufacturing including synthesis, coating, dyeing, mixtures, dilution, drying, packaging and package inserts. We welcome inquiries regarding these and other types of projects.

Please contact us to learn how we may be of assistance in formulating solutions to meet your specific requirements.

We are here for you; let us know how we can be of help.

Orders may be placed via phone (317-570-7020 or 800-387-0672), website or email (info@bangslabs.com). Or if you'd prefer, you can also place orders directly with one of our international distributors. Please visit BangsLabs.com for our complete catalog of products and technical support library.

Let's Connect!

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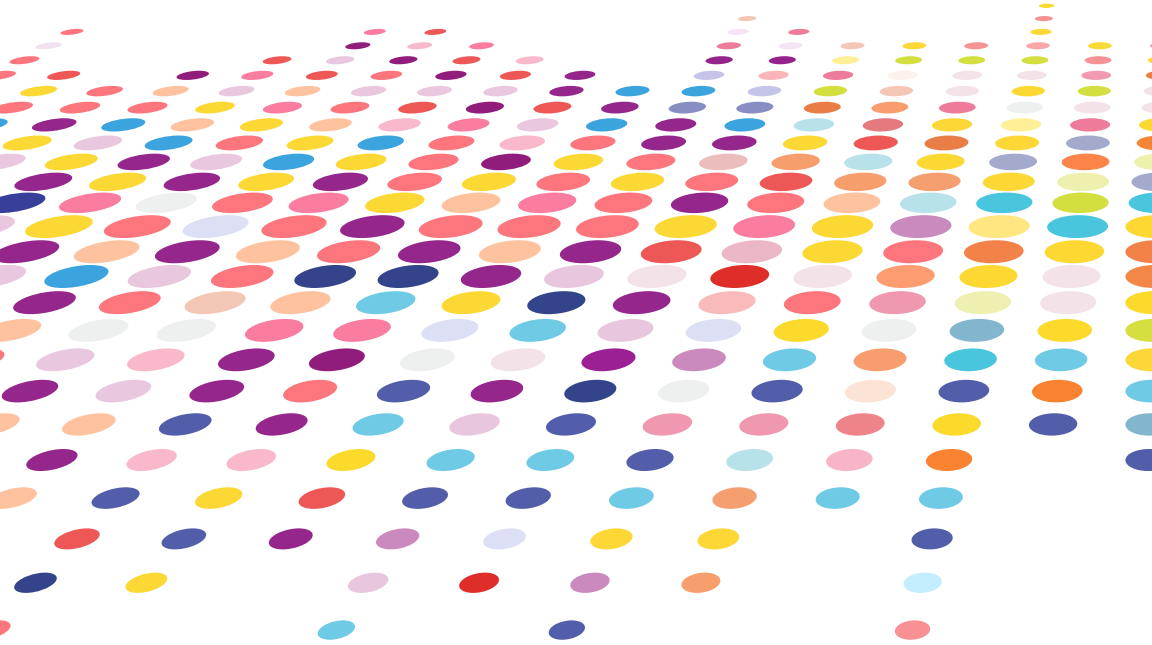

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