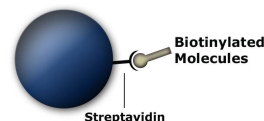


MagSi-IVD trial kit

Product Description



I. Intended Use

MagSi magnetic silica beads are ideal for numerous *In Vitro* Diagnostics (IVD) applications. This MagSi-IVD trial kit allows evaluation of MagSi beads with various physical and chemical properties to find the best suitable product for the desired application. It is addressing this by offering four different streptavidin coated MagSi beads with a ready-to-use surface for assay development using biotinylated molecules, and five COOH- and NH₂-functionalized MagSi beads for own biomolecule coupling.

II. Description of materials

MagSi beads are superparamagnetic spherical beads with a large surface made up by a nanoporous structure. The surface coating is controlled with low variation for a broad range of desired binding capacities (for instance streptavidin; up to 8000 pmol free biotin/mg beads with ±10%) to ensure optimal reproducibility in the applications. The surface chemistry of the products included is suitable for coating of a very broad range of biomolecules and offers flexibility in assay development projects.

Included in this kit are two bead sizes: 600nm and 1µm. The sedimentation time of 600nm MagSi beads has been optimized and is approx. 4 times longer compared to 1.0µm beads. This allows e.g. long incubation times without shaking/mixing etc. MagSi beads with a diameter of 1µm have stronger magnetic properties and will separate approx. 2x faster compared to 600nm in the same conditions; the typical separation time is ≤1 minute using a suitable magnet.

All MagSi beads in this kit consist of a silica matrix*, which does not have luminescent properties like for instance polystyrene. This results in comparatively low background signals in chemiluminescence- and UV/Vis read outs and enhances the assay sensitivity and dynamic range. The silica matrix ensures product stability over a wide pH range and at high ionic strength as well.

*On request, the matrix can be changed to another chemistry.

III. Contents

A) MagSi-STA beads with streptavidin coupled covalently to the surface

MagSi-STA beads can be used with biotinylated molecules. The different types have varying sizes and biotin binding capacities, showcasing the flexibility of the product characteristics.

Table 1: MagSi-STA beads supplied in this MagSi-IVD trial kit

#	Bead type*	Volume	Bead diameter	Biotin uptake [pmol free biotin/mg bead]**
1	MagSi-STA 1.0 Lot: SA10DDMMYY#	1 ml	1µm	4000
2	MagSi-STA 1.0 Lot: SA10DDMMYY#	1 ml	1µm	1250
3	MagSi-STA 600 Lot: SA06DDMMYY#	1 ml	600nm	6400
4	MagSi-STA 600 Lot: SA06DDMMYY#	1 ml	600nm	4000

*All beads are supplied at a concentration of 10 mg/ml

**Lot-specific free biotin binding capacities will be included in kit package

When using small targets (e.g. organic molecules), or free biotin interference is of importance, a free biotin binding capacity around 4000 pmol/mg beads or higher is most suitable (#1,2,4). For larger target molecules a lower free biotin binding capacity (≤4000 pmol/mg beads) can be more suitable due to steric hindrance (#1,3,4). MagnaMedics' production process has been developed for a very flexible but controlled magnetic bead synthesis and streptavidin coating. This process enables MagnaMedics to set the range for biotin binding capacity as narrow as needed (±10%). For the application this is important, because the parameters in play, like bead concentration, total amount of beads and binding kinetics of biotinylated targets, can be set as fixed values in optimizing and validating an IVD assay. MagSi-STA beads are designed for any type of IVD sandwich assay (chemiluminescence-, fluorescence- or colorimetry-based) and can be applied on any IVD instrument platform.

MagnaMedics strongly recommends to test all beads in parallel. The result of this will either define the right product immediately or function as a guide towards a suitable product for the application (see also III, chapter "customization").

B) MagSi-S COOH and MagSi-S NH₂ for own covalent coupling of biomolecules

Functionalized MagSi beads (COOH - and NH₂-coated) are designed for covalent coupling of biomolecules for IVD applications (e.g. streptavidin, antibodies and peptides) using well documented available coupling chemistries (e.g. EDC/NHS). The different surface chemistries of the beads have been developed to offer flexibility towards the type of biomolecule to be coupled, and to minimize non-specific interactions of the end product in the assay application.

Table 2: Functionalized MagSi beads for own biomolecule coupling

#	Bead type*	Volume	Bead diameter
5	MagSi-S COOH 1.0 Lot: CH10DDMMYY#	1 ml	1µm
6	MagSi-S COOH 600, Lot: CH06DDMMYY#	1 ml	600nm
7	MagSi-S COOH 1.0 type II Lot: CL10DDMMYY#	1 ml	1µm
8	MagSi-S NH ₂ 1.0 Lot: NH10DDMMYY#	1 ml	1µm
9	MagSi-S NH ₂ 600 Lot: NH06DDMMYY#	1 ml	600nm

*All beads are supplied at a concentration of 10 mg/ml

Depending on the biomolecule to be coupled and the preferred coupling chemistry, either MagSi-S NH₂ and MagSi-S COOH can be more suitable. For coupling large proteins and antibodies a spacer is included in MagSi-S COOH (#5,6) to assure proper exposure. If a very well defined amount of carboxyl groups is needed, MagSi-S COOH 1.0 type II (#7) is ideal. The density of the functional groups is approx. 300 nmol substrate per mg beads for 1 µm sized beads and 600 nmol substrate per mg beads for 600 nm sized beads.

MagnaMedics strongly recommends to test multiple functionalized bead types for covalent coupling of biomolecules.

IV. Customization

Some IVD assays have requirements which are not covered by standard products in the market. The purpose of this kit is to find the best candidate for your assay application. However, if the products in this kit do not meet the requirements completely, MagnaMedics offers further customization on specific parameters. The initial evaluation of this MagSi-IVD trial kit will serve as a starting point for product optimization for MagnaMedics' product development team. Our development of magnetic beads for IVD-use is focused on optimizing all relevant physical/chemical parameters. The customization approach will make assay development more efficient and economical.

MagSi-IVD trial kit

Product Description

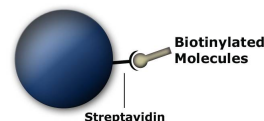


Table 3: Examples of product optimization offered by MagnaMedics

#	Assay parameter	Product optimization options
1	Binding capacity (mean / variation)	Coupling chemistry
2	Suspension time	Size / Magnetic content / storage buffer
3	Separation speed	Size / Magnetic content / storage buffer
4	Non-specific interaction	Adjusting functionalized surface / blocking agent
5	Optical density	Size

- Functionalized beads can also be supplied with alternative chemistries (e.g. CHO, SH etc.)
- Other assay parameters can be optimized upon request

V. Recommendations for Testing

Additional Materials Needed:

- Mixer/vortex to mix samples and re-suspend bead
- Magnetic separators (see table further below)

Buffers:

- MagSi-STA beads are suspended in the optimized MP Buffer. As alternative, a neutral buffer like PBS is recommended. In order to reduce non-specific adsorption, 0.05% Tween 20 or 0.1% BSA can be added.

VI. Evaluation of the MagSi-IVD trial kit

Assay performance is influenced by bead characteristics as well as the total amount of beads used, so it is recommended to vary bead volumes in the tests.

MagSi-STA 1.0 and MagSi-STA 600

The streptavidin densities of the supplied MagSi-STA beads are different per item included. It is recommended to test the beads in parallel, so the optimal free biotin uptake (and streptavidin density) for the assay can be determined. This is important for assay sensitivity and reproducibility, but it can be cost-saving as well.

Functionalized MagSi beads (MagSi-S COOH; MagSi-S NH₂)

Coupling protocols are provided by MagnaMedics on request. The individual client set-up can be analysed for an optimized coupling protocol for your specific IVD assay.

For coupling of antigens, antibodies, proteins and peptides to MagSi beads for IVD assays the following parameters should be considered:

- Chemistry of the ligand on the biomolecule to be coupled
- Size of the biomolecule to be coupled
- Amount of biomolecule to be coupled
- Surface blocking to prevent non-specific interactions in the assay.
- Spacing agent for proper exposure of the coated biomolecule in the assay.

VII. Additional technical data

Table 4: Specifications for 600 nm and 1.0 µm MagSi-beads

Products	As described in II	
Size	600 nm	1.0 µm
Concentration	10 mg/ml	
	beads/ml	
Size Distribution	0.6 - 2 x 10 ¹⁰	6 - 12 x 10 ⁹
	D5 - D95	
Size Distribution	500 - 900 nm	0.7 - 1.4 µm
Magnetic content:	35-45%	> 50%
Buffer additives	MagSi-STA: MP Buffer; MagSi-S COOH: PBS (pH 7.4), 0.05% sodium azide; MagSi-S NH ₂ : water, 0.05% sodium azide	
Storage	Store at 2-8°C	

VIII. Bulk quantities

MagnaMedics offers MagSi beads in bulk quantities up to several litres with the same (or customized) bead specifications as outlined for the products in this kit.

IX. Additional Information

Disclaimer

For R&D use only. Not for drug, household or other uses. Material Safety Data Sheets (MSDS) are available on our website at www.magnamedics.com.

Order Information

Product name	description	Art. No.
MagSi-IVD trial kit	Selection of MagSi-beads for evaluation in IVD applications	MD50001
MM-Separator M12 +12	Magnet for preparation in 1.5-2 ml tubes	MD90001
MM-Separator 96 SBS	Magnet for preparation in 96 well plates, SBS footprint for automation	MD90005
MM-Separator 384 SBS	Magnet for preparation in 384 well plates, SBS footprint for automation	MD90006

MagnaMedics Diagnostics B.V.

Burg. Lemmensstraat 366

6163 JT Geleen

The Netherlands

www.magnamedics.com

E-mail: info@magnamedics.com

tel: +31(0)46 82 00 20 6

fax: +31(0)46 41 06 82 5