

Table of Contents

I. Intended Use.....1
 II. Principle.....1
 III. Material Supplied.....1
 Bead Size.....1
 Surface Activation.....1
 Binding Capacity.....1
 IV. Product Use.....1
 V. Recommendations for Testing.....2
 MagSi-STA.....2
 Assay Buffers.....2
 Additional Materials Needed.....2
 VI. Customization.....2
 VII. Bulk quantities.....2
 VIII. Technical Data.....2
 IX. Additional Information.....2
 Disclaimer.....2
 Order Information.....2

I. Intended Use

MagSi-STA beads are suitable for numerous In Vitro Diagnostics (IVD) applications, including immunoassays. The MagSi-IVD trial kit is intended for evaluation of different MagSi-STA beads for assay development, and includes MagSi-STA beads with various physical and chemical properties in order to find the best suitable bead for your specific application.

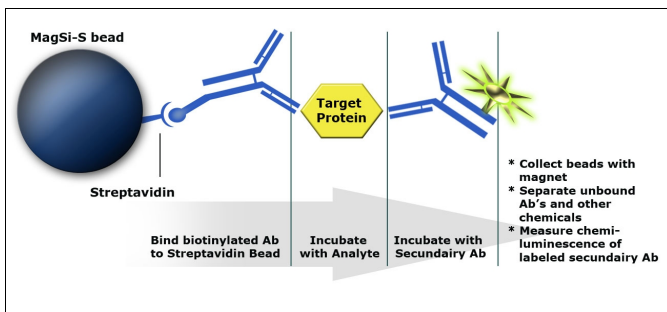


Fig.1: Principle of immunoassay based on MagSi-STA beads

II. Principle

MagSi-STA beads are added to a sample containing biotinylated molecules. The biotinylated molecules will bind to the beads during a short incubation. The complex is separated from the sample using a magnet and can be used analyte capture.

Binding of molecules onto MagSi-STA is based on the strong non-covalent interaction between streptavidin and biotin ($K_a = 10^{15} M^{-1}$). Biotin is easily conjugated to various molecules and inexpensive biotinylated products are sold by many companies. MagSi-STA beads are coated with recombinant streptavidin (53 kDa) with shortened N- and C-terminus for improved solubility and accessibility of the sites. Albumin binding sites are eliminated for optimal specificity.

All MagSi beads included 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 readout and enhances the assay sensitivity and dynamic range. Therefore, MagSi-STA beads are suitable for any assay, regardless of read out method used. The silica matrix ensures product stability over a wide pH range and at high ionic strength conditions.

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 ($\pm 10\%$). For some 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.

The streptavidin surface coating can be controlled with low variation for a broad range of desired binding capacities (up to 8000 pmol free biotin/mg beads, with $\pm 10\%$) to ensure optimal reproducibility for your applications.

III. Material Supplied

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

| Product | Art.No. | Bead size | Surface activation | Free biotin binding capacity (pmol/mg) |
|------------------|---------|-------------|--------------------|--|
| MagSi-STA 600 | MD20001 | 600 nm | Carboxylated | 3500-5000 |
| MagSi-STA 600 BI | MD22001 | 600 nm | Carboxylated | 6000-6800 |
| MagSi-STA 1.0 L | MD09001 | 1.0 μm | Carboxylated | 1200-2000 |
| MagSi-STA 1.0 | MD05001 | 1.0 μm | Carboxylated | 3500-5000 |
| MagSi-STA 1.0 TL | MD28001 | 1.0 μm | Tosylated | 1200-2000 |
| MagSi-STA 1.0 TS | MD32001 | 1.0 μm | Tosylated | 3500-5000 |
| MagSi-STA 3.0 L | MD36001 | 3.0 μm | Carboxylated | 700-1200 |
| MagSi-STA 3.0 TL | MD40001 | 3.0 μm | Tosylated | 500-900 |

MagSi-STA beads are supplied as a suspension containing 10 mg magnetic beads per mL, in PBS (pH 7.4). The products contain 0.05% Tween20 and 0.05% sodium azide as preservative. The MagSi-IVD trial kit contains 8 x 1 mL of each MagSi-STA product as described in Table 1.

Bead Size

MagSi-STA beads are available in sizes of 600 nm, 1.0 μm and 3.0 μm . The sedimentation time of 600 nm beads has been optimized and is approx. 4 times compared to 1.0 μm beads. This allows e.g. long incubation times without shaking/mixing etc. MagSi-STA beads with a diameter of 3.0 μm have stronger magnetic properties and will separate approx. 3x faster compared to 1.0 μm under the same conditions.

Surface Activation

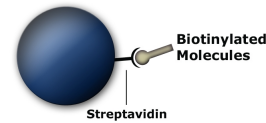
Two types of surface activation for streptavidin coating are included in our kit . Carboxyl-activation is used for higher binding capacities of MagSi-STA beads. Tosyl-activation is typically used for lower binding capacities. Tosyl-activated beads are also more hydrophobic than carboxyl-activated beads. Because of differences in hydrophobicity, the type of surface activation may also influence the sensitivity of the assay.

Binding Capacity

The optimal binding capacity of streptavidin coated magnetic beads depends on the sensitivity requirements of an assay. In this kit, beads with different binding capacities are included, covering the total range of free biotin binding capacities of competitor beads currently used in the market, and even more. It is intended to find the bead with the optimal binding capacity for your specific application.

IV. Product Use

This product is stable for at least 1 year after purchasing date when stored at 2-8°C (for bulk deliveries of MagSi-STA products, a shelf-life of 3 years is guaranteed). Store in well closed vial and in upright position to prevent drying of the beads, because this may result in a decrease of activity. Do not freeze the product! Vortex well before use. Wash the beads to remove preservatives that could interfere with your application. For washing, use the same volume as initially taken from the MagSi-STA vial or more.



V. Recommendations for Testing

MagSi-STA

- It is strongly recommended 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 VII, chapter "customization").
- Assay performance is influenced by bead characteristics as well as the total amount of beads used, so it is recommended to vary bead volumes during your feasibility testing.

Assay Buffers

Optimal binding specificity is obtained by selecting a suitable assay buffer. The following buffers have been proven to be suitable for MagSi-STA beads:

- PBST with BSA:**
 1X PBS with 0.05% Tween20 and 0.1% BSA will eliminate most non-specific adsorption of antibody/antigen to the surface of MagSi-STA (note: BSA often contains traces of immunoglobulins which may interfere in your assay → the use of a recombinant (animal-free) albumin is recommended).
- Polyvinylpyrrolidone:**
 When using Tosyl-activated streptavidin beads ("TS" and "TL"), 1-2% PVP (polyvinylpyrrolidone, MW~10,000) can be added to the assay buffer to decrease non-specific adsorption.

Additional Materials Needed

- Mixer/vortex to mix samples and resuspend beads
- Magnetic separator

VI. 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 by MagnaMedics' product development team. Our development of magnetic beads for IVD-use is focused on optimizing all relevant physical/chemical parameters. This customization approach will make your assay development more efficient, faster and cost-efficient.

Table 2: Examples of product optimization offered by MagnaMedics

| Parameter | Product optimization options |
|---|---|
| Dynamic binding capacity (mean / variation) | Coupling chemistry |
| Suspension time | Size / Magnetic content / storage buffer |
| Separation speed | Size / Magnetic content / storage buffer |
| Non-specific interaction | Adjusting functionalized surface / blocking agent |
| Optical density | Size |

Other assay parameters can be optimized upon request.

VII. Bulk quantities

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

VIII. Technical Data

Table 3: Physical specifications of MagSi-STA

| Product Name | MagSi-STA | | |
|-------------------------|--|--------------------------|-------------------------|
| | 600 | 1.0 | 3.0 |
| Mean size | 600 nm | 1.0 µm | 3.0 µm |
| Concentration | 10 mg/mL | | |
| | beads/mL | | |
| | 8 - 20 · 10 ⁹ | 6 - 12 · 10 ⁹ | 1 - 3 · 10 ⁹ |
| Supplied product volume | 2 mL, 10 mL, 100 mL | | |
| Material | Magnetic silica beads with activated surface | | |
| Magnetic content | 40% | 60% | 60% |
| Size Distribution | D5-D95 | | |
| | 500 - 900 nm | 0.7 - 1.4 µm | 0.6 - 10.0 µm |
| Storage | 2-8°C | | |

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 | Description | Art.No. |
|-----------------------|--|---------|
| MagSi-IVD trial kit | Selection kit of MagSi-beads for evaluation in IVD applications | MD50001 |
| MM-Separator M12 + 12 | Magnetic separator for 1.5 and 2 mL microtubes, manual use | MD90001 |
| MM-Separator M96 | Magnetic separator for 96-well microplates, manual use | MD90002 |
| MM-Separator 96 SBS | Magnetic separator for 96-well microplates, for automated sample processing | MD90005 |
| MM-Separator 384 SBS | Magnetic separator for 384 well microplates, for automated sample processing | MD90006 |

AMSBIO | www.amsbio.com | info@amsbio.com

UK & Rest of the World
 184 Park Drive, Milton Park
 Abingdon, UK
 T: +44 (0)1235 828 200
 F: +44 (0) 1235 820 482

North America
 1035 Cambridge Street,
 Cambridge, MA 02141
 T: +1 (617) 945-5033 or
 T: +1 (800) 987-0985
 F: +1 (617) 945-8218

Germany
 Bockenheimer Landstr. 17/19
 60325 Frankfurt/Main
 T: +49 (0) 69 779099
 F: +49 (0) 69 13376880

Switzerland
 Centro Nord-Sud 2E
 CH-6934 Bioggio-Lugano
 T: +41(0) 91 604 55 22
 F: +41(0) 91 605 17 85