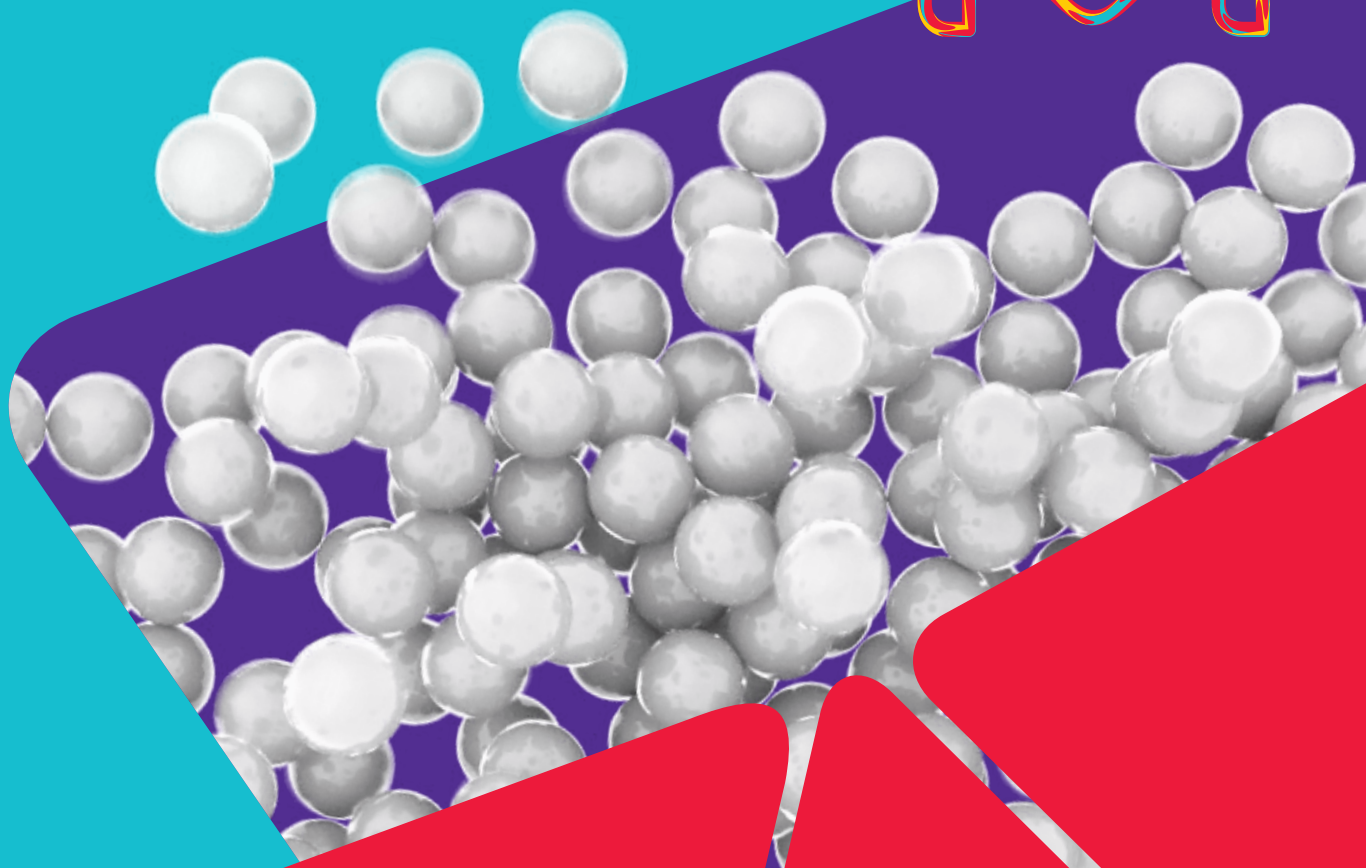
Estapor® Microspheres for Latex Turbidimetry Immunoassay and Agglutination



Sigma-Aldrich®
Lab & Production Materials

committed to you

We are committed to providing our worldwide partners with the highest quality microspheres, service and technical expertise. We provide the components and support you need to manufacture and optimize your diagnostic products.

Offering quality, reliability and choice —
We are your global partner.

For the last 45 years, Estapor® microspheres have been the particle of choice for many Latex Agglutination and Latex Turbidimetry Immunoassay (LTIA) diagnostic test manufacturers. Used globally in millions of assays made by internationally known brands, our microspheres are adapted to both manual and instrumentation-based platforms, are highly characterized, customizable and designed with key features to ideally meet the needs of IVD manufacturers.

Our Features are Your Advantages

Reproducibility:

Estapor® microspheres are polystyrene-based which affords rigidity, dimensional stability, size uniformity and exceptional lot-to-lot reproducibility.

Supply Reliability:

Our state-of-the-art manufacturing facility produces microspheres from gram to industrial (kg) scale facilitating a robust and reliable supply.

Established & Proven:

Supplying a wide range of microspheres to IVD manufacturers for over 45 years, Estapor® offers a recognized and established portfolio of microspheres with proven success.

Technical Support:

Estapor® customers benefit from the extensive knowledge of our dedicated technical team and long-standing microsphere manufacturing experience.

Flexibility:

Estapor® microspheres are compatible for use in manual format as well as most automated platforms and readers on the market.

Enhanced Performance:

Estapor® microspheres are easily dispersed allowing for efficient washing, reduced background and low non-specific binding. Our microspheres do not show significant lot-to-lot variability so you get the performance you pay for, every time!

Estapor® Microspheres for Latex Agglutination and Latex Turbidimetry Immunoassay

Latex Agglutination and Latex Turbidimetric Immunoassays (LTIA) consist of microspheres which are coated with antigens or antibodies that react with a specific biomarker or pathogen. Upon addition of a clinical sample, particle aggregation is triggered in the presence of the specific biomarker to create antibody/antigen – biomarker interactions that result in measurable precipitating complexes. These complexes allow for quick and easy determination of the biomarker concentration through turbidimetry or visual detection of the presence or absence of the biomarker though agglutination. An overview of the basic latex agglutination / latex turbidimetric immunoassay set up is illustrated in **Figure 1** below.

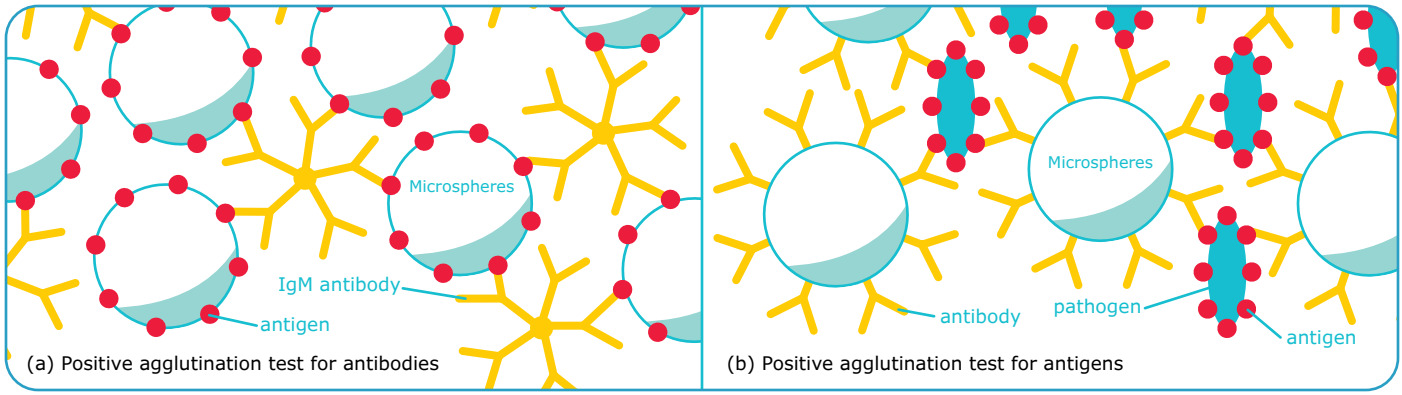


Figure 1 Schematic of latex microspheres bound to either antigens (to detect antibodies) or antibodies (to detect biomarker antigens).

By leveraging the antigen/antibody-particle agglutination with photometric detection, the latex turbidimetric immunoassay has benefits of being highly sensitive and automatable. In these assays (**Figure 2**), the precipitating complexes absorb light such that the transmitted light is inversely proportional to the size/ concentration of particles and can be quantitatively compared to solution standards.

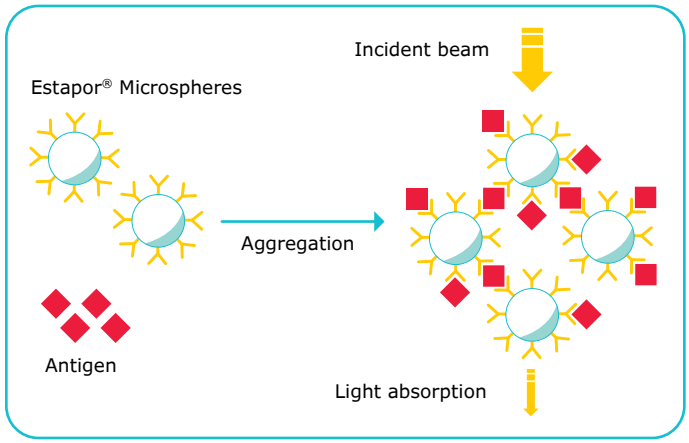


Figure 2 Estapor® LTIA microspheres coated with antibody form insoluble immuno-complexes when mixed with sample containing the corresponding antigen.

Plain Estapor® Microspheres for Latex Turbidimetry Immunoassay

Our standard polystyrene Estapor® microspheres offer a simple and convenient option for the development of a wide range LTIA diagnostic tests. The plain surface of the microsphere is designed to be easily and quickly coated with the antibody or antigen of choice via protein adsorption through hydrophobic and ionic interactions. The simplicity of this conjugation process is a key feature of these microspheres and has attracted many diagnostic test developers whom have successfully utilized these microspheres for several years in a wide variety of LTIAs.

Plain Estapor® Microspheres for LTIA

Product	Diameter (µm)	Cat. No.
K 007	0.050 - 0.080	39431081
K 010	0.081 - 0.125	39469081
K 015	0.126 - 0.175	27712084
K 020	0.176 - 0.225	39430087
K 030	0.276 - 0.325	23690087

Plain Surfactant-free Estapor® Microspheres for LTIA

Our surfactant-free polystyrene microspheres are an excellent choice for diagnostic manufacturers with more stringent requirements. Available in three size options, our surfactant-free range is highly uniform, exhibits high antibody/antigen binding and offers straightforward handling without the use of surfactant.

Product	Diameter (µm)	Cat. No.
KSF 010	0.101 - 0.140	80380104
KSF 015	0.141 - 0.180	80380103
KSF 020	0.181 - 0.220	80380033

Surface Functionalized Estapor® Microspheres for Latex Turbidimetry Immunoassay

Our surface functionalized range of Estapor® LTIA microspheres offers some further options and features. These microspheres undergo copolymerization with carboxyl (-COOH) monomers. The introduction of these highly polar chemical groups to the surface of the microsphere increases the colloidal stability of the subsequent microsphere – antibody/antigen conjugation. In addition, due to their hydrophilic surface, our functionalized microspheres exhibit low levels of non-specific binding.

Keenly aware that one size does not fit all when it comes to diagnostic test development, we offer a wide variety of microsphere sizes ranging from ~50nm to ~250nm, as well as two types of microsphere polymer. All our microspheres are extremely uniform (**Figure 4**) with excellent lot-to-lot reproducibility offering reliability. Microsphere selection will depend on the desired analytical performance and the optical requirements of a particular assay. Our dedicated team of technical specialists are on hand to offer guidance.

Small Carboxyl-Modified Estapor® Microspheres for LTIA

These smaller microspheres and their slower agglutination kinetics within LTIA tests are designed to help mitigate against the 'hook' or 'prozone' effect whereby the effectiveness of antibodies to form immune complexes can be diminished when concentrations of an antibody or an antigen are high. We offer these smaller microspheres in two versions; Styrene-acrylate and Polystyrene. This provides diagnostic developers a further possibility to optimize their assays. Given the high refractive index of the polystyrene microspheres, the particles may exhibit a high degree of scattered light within some assays. On the other hand, styrene-acrylate microspheres display a lower refractive index due to the transparency of the polymer matrix and can thereby be utlized to achieve a higher degree of light intensity within an assay (**Figure 3**).

Product	Diameter (µm)	Surface COOH (µeg/g)	Polymer	Cat. No.
A1 005	0.050 - 0.075	200 - 400	Styrene- acrylate	80380018
A1 010	0.076 - 0.125	20 - 300	Styrene- acrylate	80380020
K1 010	0.130 - 0.190	>300	Polystyrene	39491087
K1 030	0.270 - 0.330	200 - 500	Polystyrene	80380014
PSI 90-21	0.080 - 0.150	100 - 200	Polystyrene	80380012

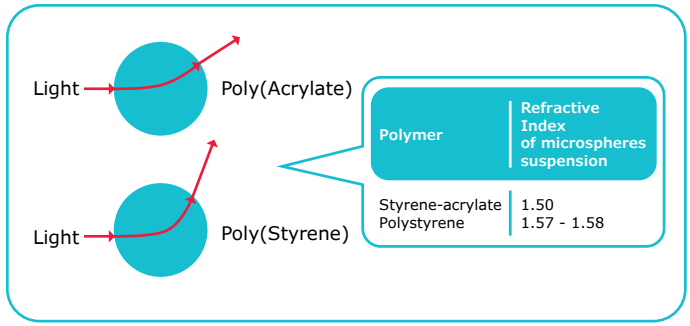


Figure 3 Illustration of the Refractive Index on different microspheres in terms of polymer matrix.

Introducing our IT 250 Carboxyl-Modified Estapor® Microspheres for LTIA

We are proud to launch our new 'IT 250' microspheres. Uniquely developed for LTIA applications, these microspheres exhibit key features making them an ideal choice for diagnostic developers looking for a microsphere that satisfies all key requirements. Combining both a larger size and surface functionalization these microspheres display exceptional performance and are particularly well suited to LTIA tests on clinical samples containing low levels of the analyte of interest. The high sensitivity of these microspheres is achieved by the high antibody/antigen binding efficiency resulting from the COOH surface functionalization as well as their larger size. The increased size of these new microspheres facilitates an increased probability of collision within the sample matrix and thus they achieve faster agglutination with the ability to detect low levels of the biomarker in question. Under an electron microscope these microspheres display a highly uniform appearance which is consistent from lot-to-lot (**Figure 4**).

Our New IT 250 Carboxyl-Modified Estapor® Microspheres for LTIA

Product	Diameter (µm)	Surface COOH (µeg/g)	Polymer	Cat. No.
IT 250	0.220 - 0.275	40 - 100	Polystyrene	80380626

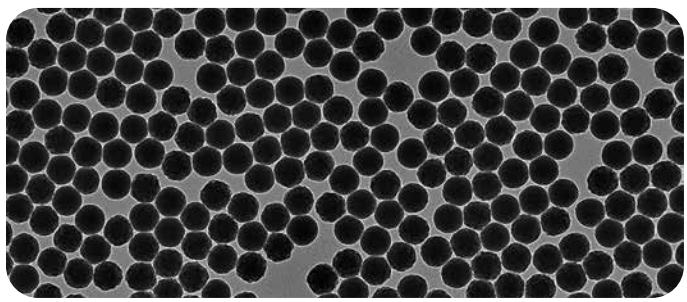


Figure 4 Transmission electron microscopy image of IT 250 microspheres showing highly uniform size and shape.

Estapor® Microspheres for Latex Agglutination

The visual evaluation of the latex agglutination test necessitates different requirements for the microspheres utilized in this application. Since the clinician will read the result by eye, we generally suggest that larger microspheres are used (**Figure 5**). Our latex agglutination range of microspheres are perfectly suited to this application and are also available in functionalized formats. And while larger in size, these microspheres offer the same high level of uniformity and lot-to-lot consistency as our LTIA microsphere offering (**Figure 6**).

Estapor® Microspheres for Latex Agglutination

Product	Diameter (µm)	Surface COOH (µeg/g)	Cat. No.
K 030	0.276 - 0.325	Plain	23690087
K1 030	0.270 - 0.330	200 - 500	80380014
K1 050	0.450 - 0.530	1 - 10	39424086
K 080	0.750 - 0.890	Plain	23692084
K1 080	0.760 - 0.940	1 - 10	23696087

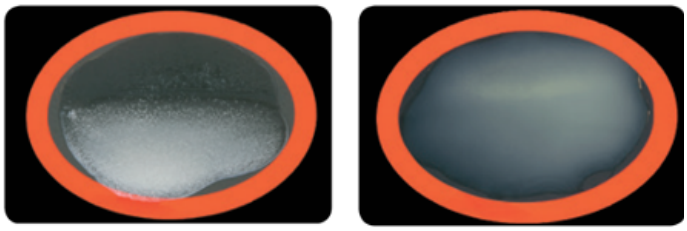


Figure 5 Latex agglutination on a slide using K 080 microspheres, left (+), right (-).

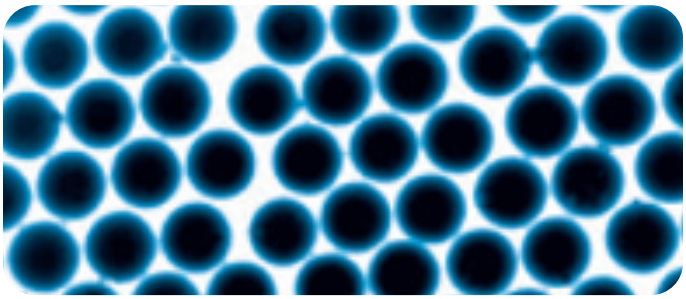


Figure 6 Transmission electron microscopy image of K 080 microspheres showing consistent size and shape.

Quality Assurance You Can Trust

ISO Compliant Manufacturing

Based near Lyon, France our manufacturing site is ISO compliant. Benefiting from over 45 years of microsphere manufacturing experience, our specialized team utilizes state-of-the-art facilities to produce our microspheres to the following standards:

ISO 9001:2015

ISO 14001:2015 (Environmental)

ISO 45001:2018 (Occupational Health and Safety)

Customer plant audits are available upon request.

M-Clarity™ Program

Estapor® Microspheres are classed at MQ-300 in the Life Science harmonized quality system. MQ-300 products offer increased levels of control through a broad range of change notification parameters that meet the needs of markets requiring high quality and consistent components.

Detailed Certificate of Analysis

Each lot of Estapor® Microspheres includes a Certificate of Analysis (CoA) providing assurance that the lot complies with all test specifications and was produced in compliance with documented manufacturing processed and material specifications. On each quality certificate, you will find the specific lot information and QC test data for your product.

Custom Products

In most cases, our standard product offering should fulfil your latex agglutination and latex turbidimetry immunoassay requirements. We do, however, offer custom development services to support demanding applications. Using our state-of-the art facilities, our technical team can provide customized microspheres that will meet your specific needs and requirements. Contact your local account manager to discuss your assay optimization and product customization needs.

Additional Reading

1. Performance of Estapor® Microspheres in a Latex Turbidimetry Immunoassay for C-reactive Protein (CRP). AN7650EN.
2. Estapor® Microspheres for Lateral Flow - Colored, Fluorescent and Magnetic Microspheres for Qualitative and Quantitative Lateral Flow Assays. 2020. BR5965EN.
3. Estapor® Magnetic Microspheres - Critical raw materials for chemiluminescent immunoassays and bio-separation. 2019. BR5442EN.

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Lab & Production Materials

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MerckMillipore.com

For more information, please visit:
MerckMillipore.com/Estapor-Microspheres

To discuss your specific product needs,
please contact your local dedicated Account Manager

Email: **estapor.info@merckgroup.com**

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