NO LONGER PLATE FAILURES

in your QC department

Simplify your workflow with AcZon's nanoparticle technology

Quality control in pharmaceutical manufacturing processes

Why immunoassays matter

A key challenge faced daily by the pharmaceutical industry is the need to verify, throughout the production process, the purity and quality of drugs and biological products, as well as to evaluate their effectiveness and safety by monitoring changes in the immune response and the expression of specific biomarkers. These checks are usually performed using immunoassays, the most common of which is the ELISA test.

The challenge of conventional ELISA

This assay is carried out on a plate and is based on the property of antibodies to bind specifically to an antigen. With this analysis, it is possible to detect the presence of antibodies against a specific antigen in a plasma sample (as in vaccine production), or to evaluate the production of certain molecules by an organism undergoing treatment (such as cytokines in the study of possible adverse reactions).

Issues of conventional reagents

As mentioned above, up today, the most common used immunoassay is ELISA whose validity is universally recognized by scientific community. Unfortunately, those tests suffer from low sensitivity and fail to detect small quantities of analyte (leading to **false negatives**), or they yield positive results due to non-specific signals caused by low stability due to reagent degradation (**false positives**).

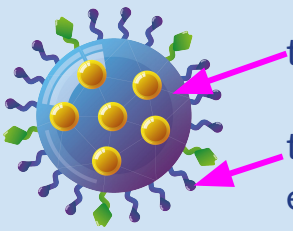
The ultimate outcome is a high failure rate in testing, which forces the rejection of a large number of plates and results in production delays. This significantly increases production costs, creating economic loss for the company.

To overcome these limitations of traditional ELISA tests

To overcome these limitations of traditional ELISA tests, AcZon has developed a new line of reagents — **NanoLISA & NanoLISA-F** — using its proprietary silica nanoparticle-based technology. These reagents have unique features that deliver results incomparably superior to those obtained with conventional reagents currently on the market.

Nanoparticle technology

Nanomaterials are known to bring advantages to many sectors, including life sciences. AcZon has developed a proprietary technology that uses core-shell silica nanoparticles as the foundation of a new class of high-performance reagents. AcZon's fluorescent nanoparticles consist of two compartments:



the **core** (a silica matrix hosting fluorescent molecules)

the **shell** (a PEG coating that ensures solubility in aqueous environments and conjugation with various biomolecules)

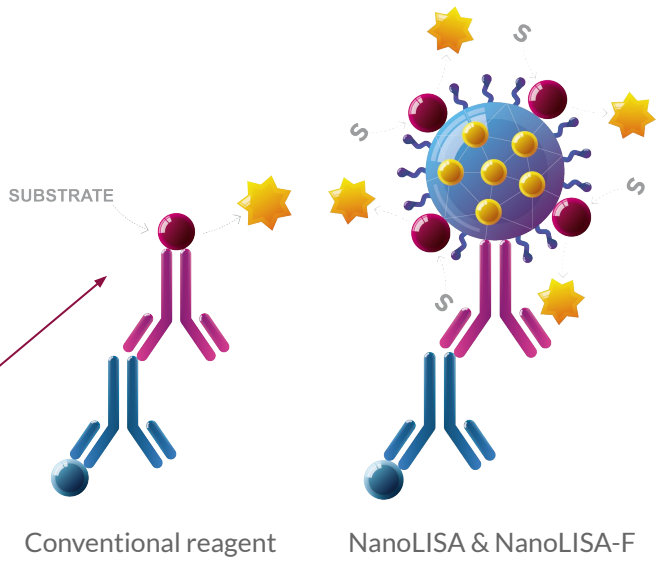
The size of the nanoparticles is finely controlled during synthesis and ranges from 10 to 35 nm. Inside the core, multiple fluorescent molecules are embedded and protected from the environment, resulting in a stronger, more stable signal over time. This provides significant advantages in flow cytometry (higher stain index, brightness, and reduced spillover).

One of the key advantages of this innovative technology is the concentrative effect of the nanoparticles.

Thanks to their spherical shape, a significantly higher number of enzymes (phosphatase or peroxidase) can be bound to the shell per antibody unit, significantly increasing the success rate of immunoassays.

NanoLISA & NanoLISA-F

As illustrated in the image, conventional reagents bind only a small number of **enzyme** molecules per antibody.



Sensitivity

Instead, the same antibody, through amplification enabled by the spherical shape of nanoparticles, can bind many more enzyme molecules. This translates into much greater sensitivity and drastically reduces the number of **false negatives**.

Stability

Moreover, AcZon's proprietary silica nanoparticle technology, which underpins the construct, provides high temporal stability. Combined with AcZon's purification and quality control process (AcZon know-how), this drastically reduces the number of **false positives**.

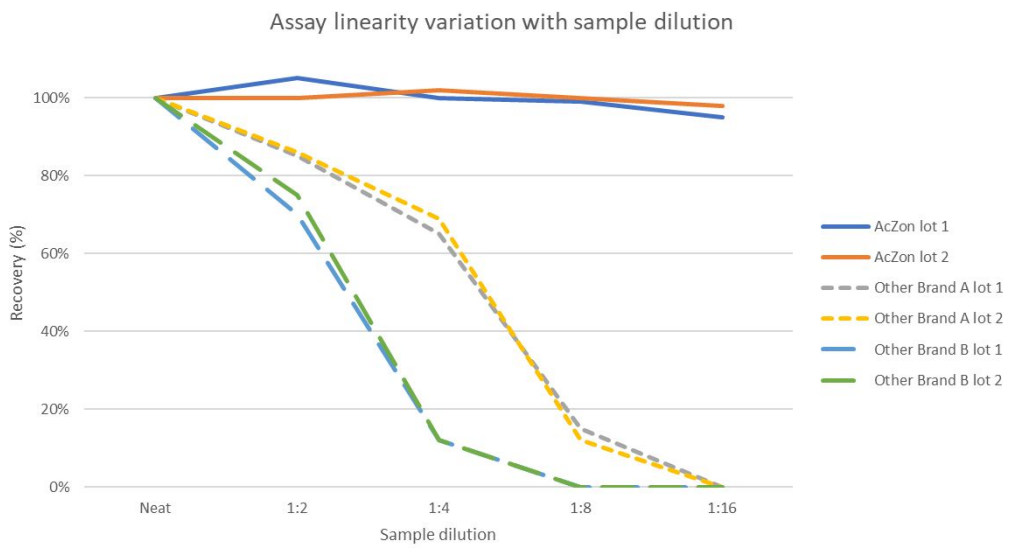
Furthermore, the intrinsic fluorescence of the nanoparticle allows for an additional detection method using a single reagent. The stability of the construct also eliminates the need for periodic reagent retitration.

Results that speak for themselves

Product	Failures	At time 0	After 6 months	After 12 months	After 18 months
AcZon	**False positive**	**5%**	**4%**	**5%**	**5%**
	False negative	**5%**	**4%**	**4%**	**5%**
Others	False positive	15%	20%	30%	Need to retitrate
	False negative	15%	22%	31%	Need to retitrate

The reduction in the ELISA plate failure rate during production processes, thanks to **AcZon reagents**, is tangible and significant, especially over time.

The spherical shape of the nanoparticles — the core innovation behind **NanoLISA & NanoLISA-F** — enables a higher number of enzymes to be bound per antibody unit, ensuring a significantly lower limit of detection (LOD) than the industry average.



Human plasma spike samples (not coagulated with EDTA) were serially diluted and tested for interleukin concentration. The accuracy gained through the use of AcZon NanoLISA is evident compared to competitors.

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