



news digest #012

MALDI Biotyper® for biopharmaceuticals productions using yeast strains

Diabetes is a chronic disease which, if left untreated, leads to serious damage over time to the heart, blood vessels, eyes, kidneys and nerves. According to the World Health Organization, diabetes was the direct cause of 1.5 million deaths in 2019.¹

People living with type 1 diabetes are unable to produce insulin needed to regulate blood glucose levels. This type constitutes about 5-10% of all cases of diabetes.² By far the more common form is type 2 diabetes, which occurs either when the body becomes resistant to insulin or can't produce enough. Without insulin, blood sugar levels may become too high (hyperglycemia) or too low (hypoglycemia) and cells will start to malfunction. Insulin turns a deadly disease into a manageable one for people living with type 1 diabetes and is essential to reduce the risk of kidney failure and other health issues in people with type 2.

Dietary and lifestyle changes such as long working hours, less physical activity, and unhealthy drinking habits are

leading to a higher prevalence of type 2 diabetes,³ which is set to drive demand for diabetes drugs during the next 10 years. According to market reports, the global insulin drugs market is expected to grow from \$28.82 billion in 2021 to \$32.51 billion in 2022 at a compound annual growth rate (CAGR) of 12.8%,³ making it vital for insulin to be produced quickly and cost-effectively.

Microorganisms for biopharmaceutical production

The most prominent example of diabetes treatment is insulin production using microorganisms. *Saccharomyces cerevisiae* is a species of yeast that has been used extensively to produce recombinant human insulin since the early 1980s and more recently various insulin analogues too. *S. cerevisiae* is the preferred yeast for the commercial production of insulin but other yeasts such as *Pichia pastoris*, *Kluyveromyces lactis*, *Hansenula polymorpha*, and *Yarrowia lipolytica* have also gained huge attention as production yeast or biopharmaceutical protein expression.

Obtaining recombinant proteins using bacterial vectors is a mature and favored method of industrial protein production. Yeast is a preferred host for many heterologous proteins that require modification for their biological activity because they grow vigorously on inexpensive medium and are easy to use for genetic modifications. However, yeast can be contaminated by microorganisms such as bacteria, therefore, rapid and effective quality control is essential before the host yeast enters the production process.

MALDI-TOF for pharmaceutical microbiology laboratories

MALDI-TOF detection allows rapid identification of microorganisms. Scientists at biopharmaceutical labs can start with a microorganism colony and use MALDI-TOF mass spectrometry (MS) to identify the spectrum of ribosomal proteins of bacteria, yeasts and molds in the whole production process. With the Bruker MALDI Biotyper reference libraries covering around 4,700 species, identification can be performed very quickly. The measurement of 96 samples (95 samples plus 1 calibrator) takes only 30 minutes, including sample preparation starting from culture.

The MALDI Biotyper is a trusted, state-of-the-art instrument that offers a cost-effective solution to quality control, particularly when used in combination with classic microbiology or molecular technologies like PCR or sequencing. It can be used in biopharmaceutical production for a variety of applications such as:

- Strain collection control
- Identification of microorganisms in hygiene monitoring
- Quality control of pharmaceutical water
- Contamination monitoring in ingredients, intermediates and finished products
- Research and development

For more information, visit
www.bruker.com/microbiology

Further reading

- Urwyler *et al.*, Advantage of MALDI-TOF-MS over biochemical-based phenotyping for microbial identification illustrated on industrial applications, *Lett Appl Microbiol*, 2016
<https://sfamjournals.onlinelibrary.wiley.com/doi/full/10.1111/lam.12526>
- Madhavan *et al.*, Customized yeast cell factories for biopharmaceuticals: from cell engineering to process scale up, *Microbial Cell Factories*, 2021
<https://microbialcellfactories.biomedcentral.com/articles/10.1186/s12934-021-01617-z>

References

- ¹ Diabetes, World Health Organization, 10 November 2021.
<https://www.who.int/news-room/fact-sheets/detail/diabetes>
- ² Mobasser *et al.*, Prevalence and incidence of type 1 diabetes in the world; a systematic review and meta-analysis, *Health Promot Perspect*, 2020.
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7146037/#:~:text=The%20results%20of%20meta%20analysis,are%20increasing%20in%20the%20world>
- ³ ReportLinker, Insulin Drugs Global Market Report, 2022.
https://www.reportlinker.com/p06245011/Insulin-Drugs-Global-Market-Report.html?utm_source=GNW

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