immudex
PRECISION IMMUNE MONITORING

Clinical-Grade Dextramer® Reagents

Reliable Components of Successful Clinical Outcomes

Accurate cellular immune monitoring is an increasingly important element of clinical trials and the resulting advances.

The Clinical-Grade Dextramer® reagents ensure efficient, accurate, and reproducible detection and quantification of antigen-specific immune cell responses by flow cytometry under applicable regulatory requirements.

Quality that meets regulatory requirements

Immudex Clinical-Grade Dextramer® reagents meet the quality system requirements for medical devices defined by ISO 13485 and 21 CFR 820 to be used as:

- Components for laboratory-developed tests (LDT)
- Reagents for medical devices governed by CLIA, FDA, and IVDD
- Tools for clinical trials and investigations in accordance with GC(L)P
- Materials for manufacturing and quality control of investigational and commercial pharmaceutical products

Bring the Quality of the Dextramer® Technology into Your Clinical Trial

Explore the benefits of the only MHC multimer manufactured in accordance with quality systems standards:

- Efficient and accurate detection and quantification of T-cell responses
- Meet all the relevant quality standards
- Robust and reliable manufacturing process
- Competent and continuous support from Immudex team

IMMUDEX
www.immudex.com

ORDERING
ordering@immudex.com

CUSTOMER SUPPORT
customer@immudex.com

Robust and Reliable Manufacturing Process

Immudex stands behind every reagent produced with documented evidence of quality, batch consistency, and stability.

With global reach, over 10 years of experience in manufacturing, and time-tested technologies, Immudex provides high-quality cellular immune monitoring solutions.

We focus on clinical objectives, supporting the development of effective strategies for successful clinical outcomes.

Ensuring high-quality from development to production and during use

Immudex Clinical-Grade Dextramer® reagents are developed and manufactured to ensure process robustness and undergo a meticulous check to ensure high-quality.

- 6-12 month shelf life
- In process quality control
- Final quality control
- Product release
- Required regulatory documentation, including certificate of analysis
- Production capability validated by minimum 3 production lots

In addition, change notifications are provided and supplier evaluation, including on-site audit, upon request.

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