immudex®
PRECISION IMMUNE MONITORING

Clinical-Grade Dextramer® Reagents (GMP)

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:

- Measure T cell number, identity and purity during release testing of cellular immunotherapies
- Efficient and accurate quantification of antigen-specific T cells in patients following a therapeutic intervention
- Meet all the relevant quality standards
- Robust and reliable manufacturing process validated by GMP

IMMUDEX
www.immudex.com

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ordering@immudex.com

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customer@immudex.com

Robust and Reliable Manufacturing Process

Immudex® stands behind every reagent produced with rigorous quality control and procedures for every step of the manufacturing process included within our Quality Management System (QMS).

With global reach, over 10 years of experience in manufacturing, and technologies that have stood the test of time, Immudex® provides high-quality precision 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.

- Established shelf-life and expiry date
- In-process quality control
- Final quality control
- Product release
- Required regulatory documentation, including certificate of analysis
- Production validated according to GMP, demonstrating a track record of robust manufacturing

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

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