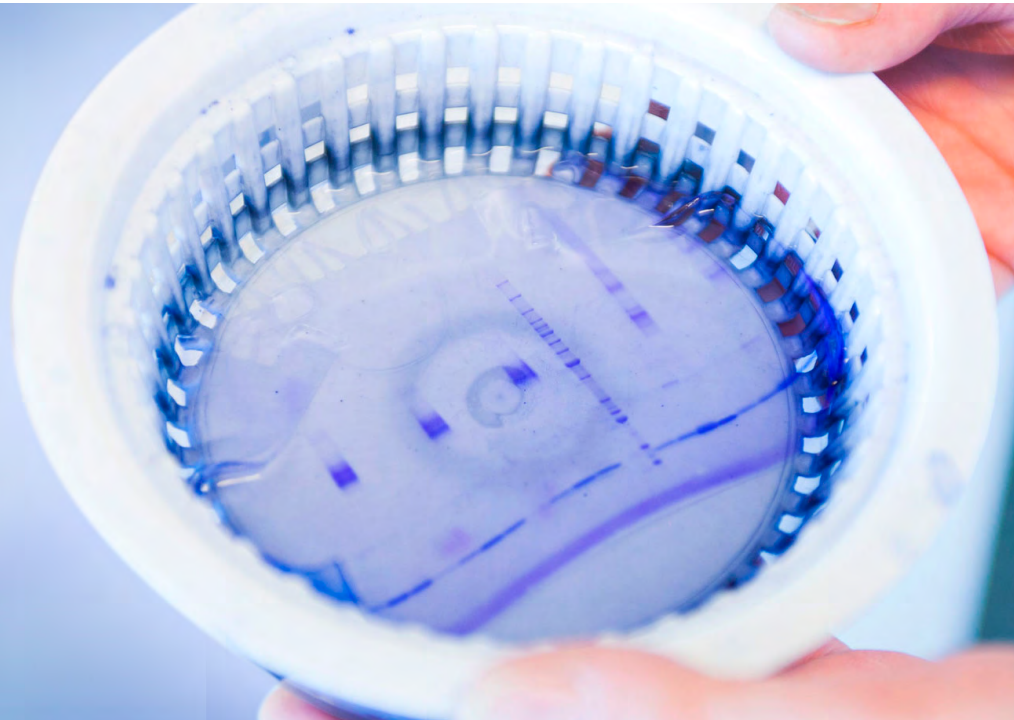


Reliable Components of Successful Clinical Outcomes

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

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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