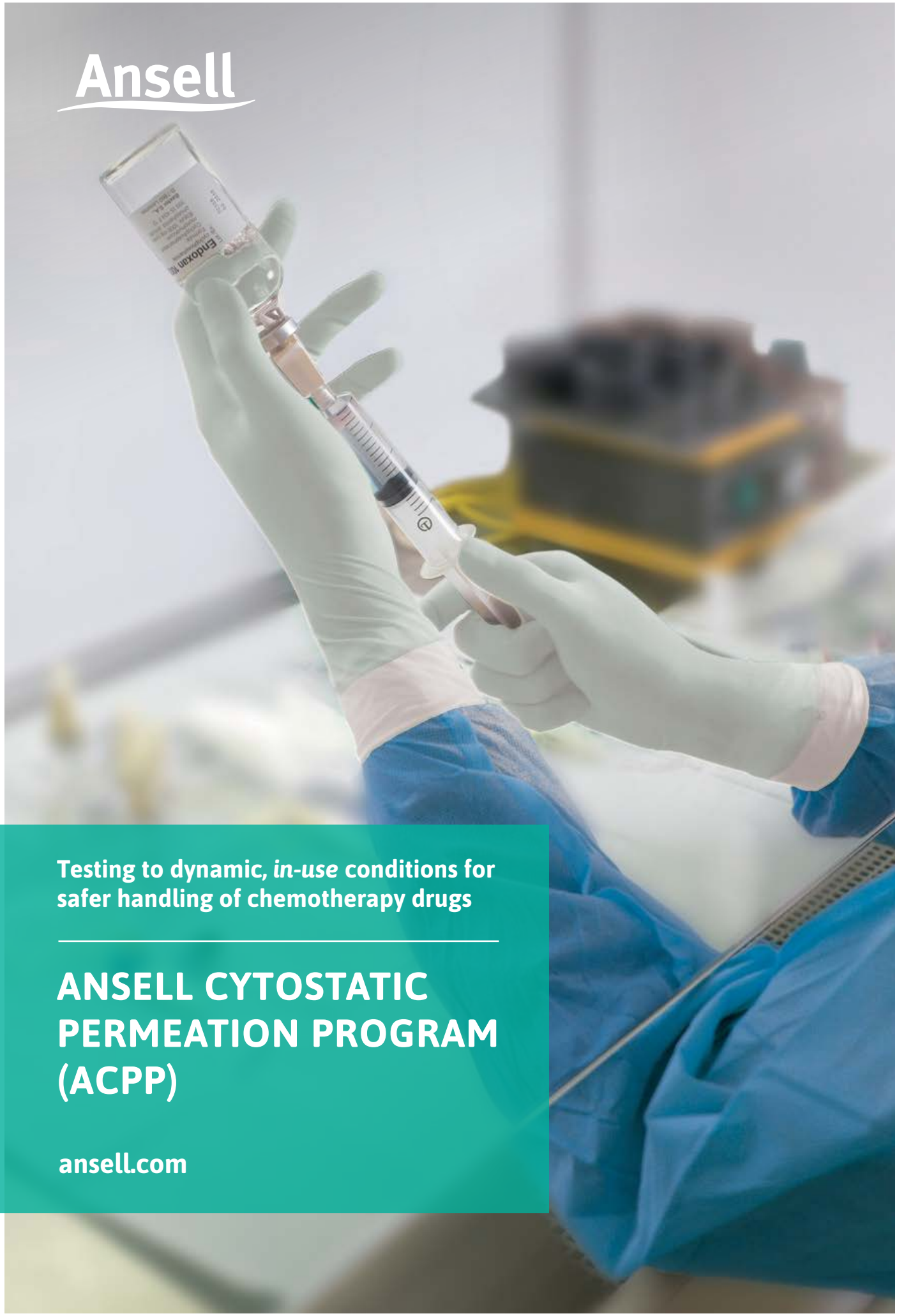

Ansell

Testing to dynamic, *in-use* conditions for safer handling of chemotherapy drugs

ANSELL CYTOSTATIC PERMEATION PROGRAM (ACPP)

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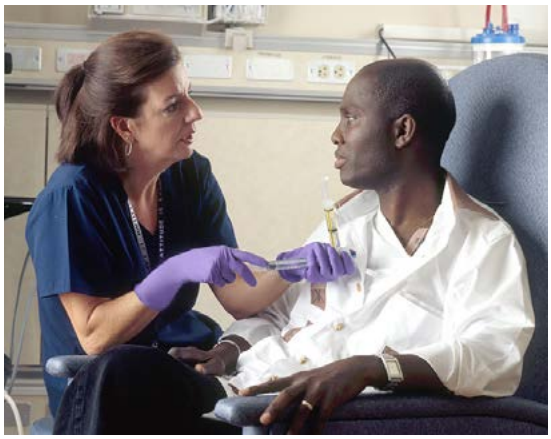
DYNAMIC PERMEATION TESTING FOR GREATER CONFIDENCE AT WORK

As the global incidences of cancer rise, so will the need to ensure the safe handling of chemotherapy drugs in your workplace.

Cancer continues to be on the rise: from **17 million** cases in 2018 to **26 million** in 2040[1]

Figures exclude non-melanomatous skin cancers.



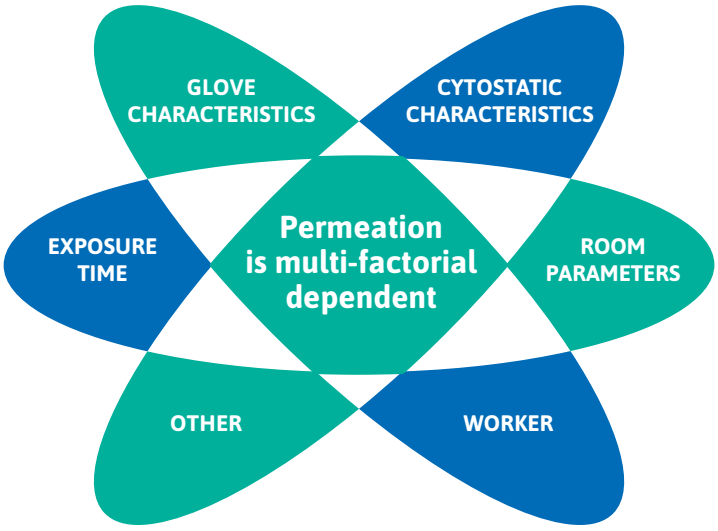
Ansell gloves are tested to EN 16523-1 and ASTM D6978 standards[2], or both, to ensure gloves meet the requirements for safe handling of hazardous drugs and their intended use either as medical devices or personal protective equipment (PPE). *But we don't stop there.*

Ansell's Cytostatic Permeation Program (ACPP), a unique dynamic permeation test, has been designed to give you an added *in-use* perspective of permeation detection to help you select the right glove for safer handling of chemotherapy drugs.

Working conditions are dynamic, so why not test to *in-use* conditions?

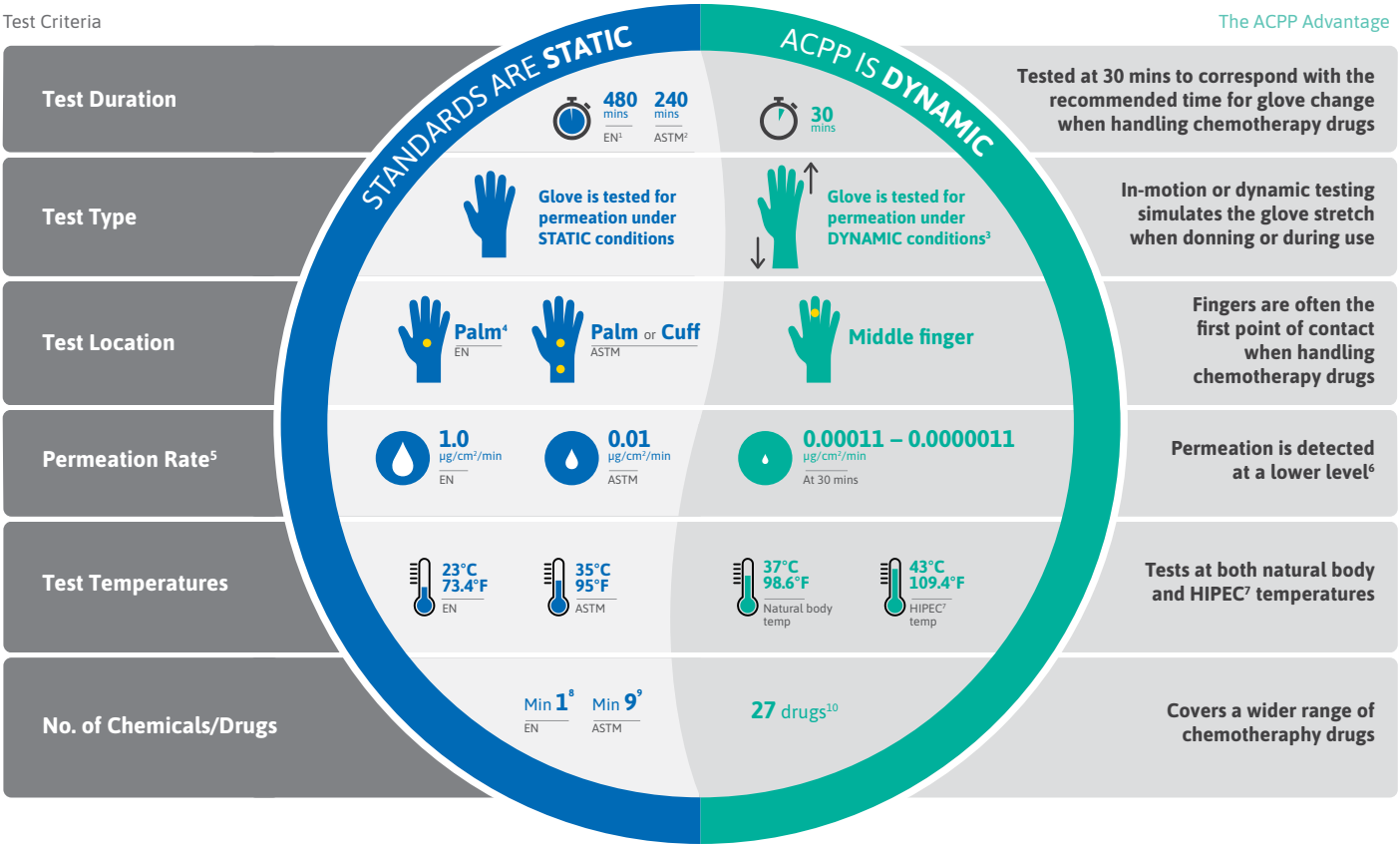
While ASTM and EN standards determine glove permeation under static test conditions, ACPP mimics the everyday use in your workplace through controlled dynamic conditions.

Current standards testing does not consider working conditions that may influence the permeation of your glove's protective barrier. This includes the concentration and exposure time of the chemotherapy drug being handled, glove properties such as thickness; the stretching and flexing motion of the task, as well as both body and workplace temperatures.[3, 4, 5, 6]



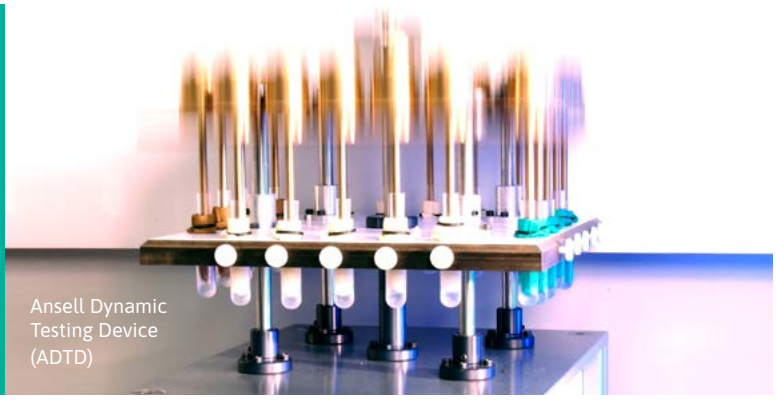
It is important you consider how static (standards) vs dynamic (ACPP) testing differs to gain a comprehensive view of how the permeability of a glove to a chemotherapy drug is affected under the different conditions.

ACPP mimics *in-use* conditions, and together with Standards, ensures the right glove for safer handling of hazardous drugs



1. *EN stated in this graphic refers to EN 16523-1.* ***2.*** *ASTM stated in this graphic refers to ASTM D6978.* ***3.*** *ACPP uses the ADTD unique to this program.* ***4.*** *For 400+ mm length gloves, both palm and cuff must be tested.* ***5.*** *Detection limit is based on the permeation rate expressed as the amount (in µg) of chemical per surface area (cm²) of the test specimen per minute (min).* ***6.*** *ACPP uses highly sensitive analytical methods, Liquid Chromatography - Mass Spectrometry (LS-MS) and Inductively Coupled Plasma - Mass Spectrometry (ICP-MS), to enable permeation to be detected at a very low level.* ***7.*** *HIPEC = Hyperthermic intraperitoneal chemotherapy: a highly concentrated, heated chemotherapy treatment.* ***8.*** *It is not mandatory to test using a chemotherapy drug for EN 16523-1.* ***9.*** *All 9 drugs tested for ASTM D6978 are chemotherapy drugs.* ***10.*** *All 27 drugs tested for ACPP are chemotherapy drugs.*

> *"Standards are static. Reality is dynamic."*
>
> *Professor Jérôme Guitton*



Ansell Dynamic Testing Device (ADTD)

Ansell is the only glove manufacturer[7] with its own dynamic permeation testing method and device, exclusively designed by the Université Catholique de Louvain, Brussels, Belgium.

Professor Jérôme Guitton, Head of the Pharma-Toxicology Department, Hospices Civils de Lyon, led the dynamic permeation testing of 15 Ansell surgical and examination gloves covering 27 chemotherapy drugs at high concentration levels based on general practice; and, using ACPP test criteria and the Ansell Dynamic Testing Device. Results are published in the Journal of Oncology Pharmacy Practice, August 2020.[3]

MAXIMIZE YOUR CONFIDENCE BY MINIMIZING YOUR EXPOSURE

There is no safe level of exposure to chemotherapy drugs.[8, 9]

Some chemotherapy drugs are more toxic than others. The earlier the permeation of a hazardous drug is detected, the safer your risk assessment becomes.

Minimizing the risks of exposure starts with using the available data that best guides you by presenting the earliest possible point of permeation detection.

EN and ASTM detection limits, based on the permeation rate of 1.0 and 0.01µg/cm^2/min respectively, are the defined thresholds applicable to all drugs tested to these standards.

ACPP however, detects for permeation of each drug at its lowest limit of detection which, depending on the chemotherapy drug, varies from 0.00011 to 0.000001µg/cm^2/min. This ability for earlier detection is made possible by the highly sensitive analytical devices used.[10]

Permeation detection is reported differently for Standards testing and ACPP. *ASTM D6978, for example, reports the time when breakthrough of the threshold limit is reached before the maximum 240 min exposure. ACPP, on the other hand, reports if permeation has been detected, or not, based on the test drug's lowest limit of detection after 30 mins exposure.*

Example of how permeation for Carmustine is reported

Product	Permeation Detection	
	ASTM D6978 Breakthrough time @0.01 µg/cm^2/min	**ACPP** After 5 & 30 mins exposure @lowest limit of detection for Carmustine*
TouchNTuff® 83-500	10.2 mins	Detected at 5 mins
MICRO-TOUCH® Nitrile E.P.	71.3 mins	Detected at 30 mins

**For ACPP, both Carmustine and ThioTEPA are also tested after 5 and 10 mins of exposure to reflect clinical practice usage guidance*

CHOOSING THE RIGHT GLOVE: WHAT YOU NEED TO KNOW

It may take only one carcinogenic molecule to induce cancer.[11]

Unwanted side effects occur not only in cancer patients undergoing treatment but pose risks for healthcare workers who handle chemotherapy drugs.

Reported effects range from **headaches**, **irritation** of **eyes/skin**, **hair loss** and **dizziness** to adverse outcomes including **genetic damage** leading to **infertility**, **cancer** and **miscarriages.** [12, 13, 14]

Whether you are reconstituting or administering chemotherapy treatments or involved in clean-up and disposal, the right, chemotherapy-tested gloves must be in place because the primary route of occupational exposure is your skin, directly or indirectly.

The largest group exposed is often pharmacy staff involved in drug preparation due to the frequency of use, and the quantities and concentration used.[16]

SAFE HANDLING CONSIDERATIONS

Safe handling recommendations across the globe are guided by industry and work safe agencies such as the Oncology Nursing Society (ONS), the National Institute for Occupational Safety & Health (NIOSH), Worksafe Australia, the European Agency for Safety and Health (EU, OSHA), the Japan Society for Clinical Oncology, and others.

Fundamentally, best practice guidelines are similar but you should always check the specific guidance from local agencies governing your healthcare setting.

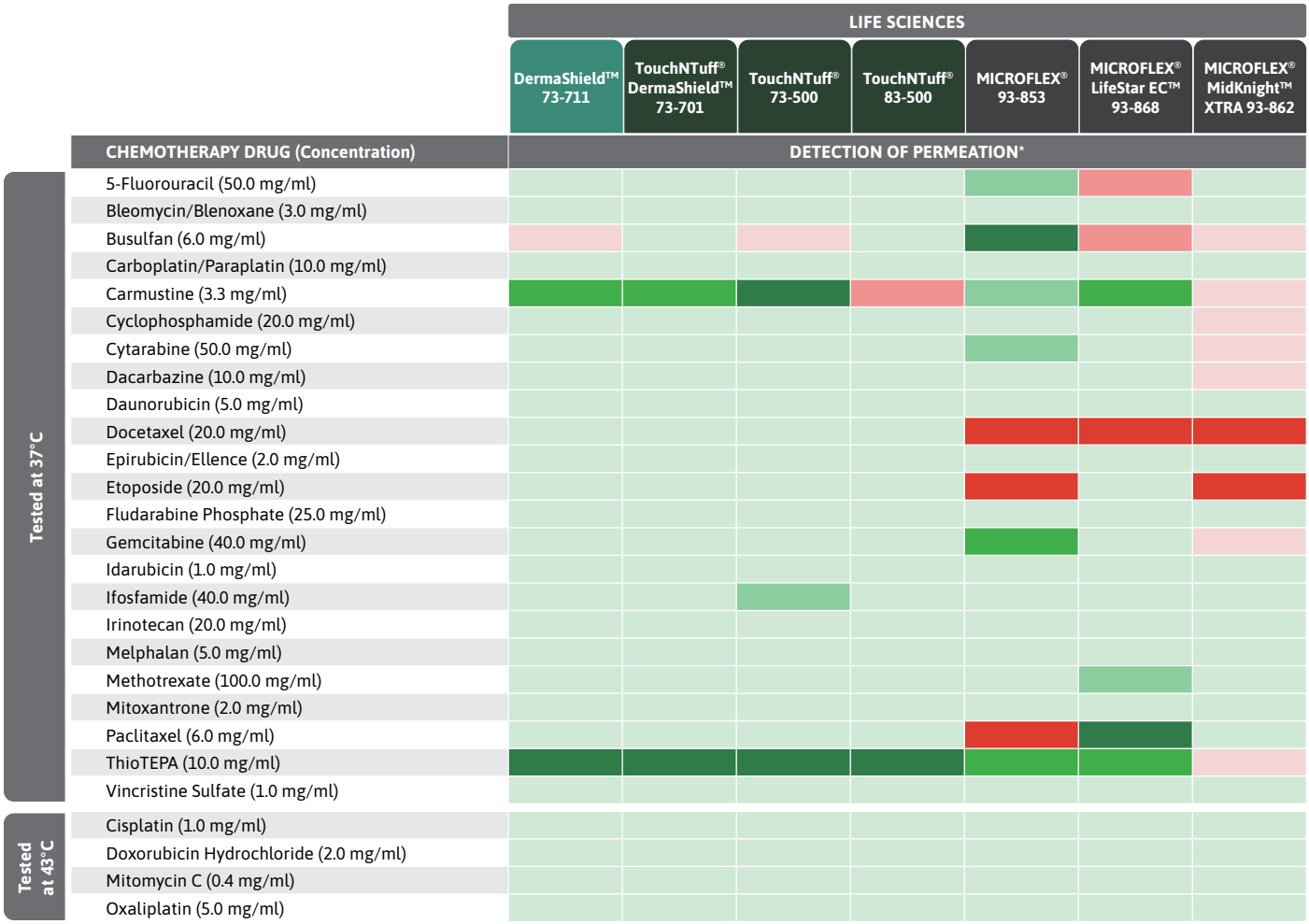
- Gloves **must be chemotherapy-tested** and pass the industry standards as required by regulators. Consider dynamic testing permeation data if available.
- Always inspect for physical defects before use. Do NOT use gloves with **pinholes** or **weak spots**.
- Chemotherapy-tested gloves should be changed **every 30 minutes** unless otherwise recommended by the manufacturer's documentation.
- When used for sterile compounding, the outer chemotherapy-tested gloves must be **sterile.**
- Use two pairs of chemotherapy-tested gloves for double the protection. **Double gloving with a colored under glove** allows for easy breach detection.
- Chemotherapy-tested gloves must be **powder-free** because powder can contaminate the work area and can absorb and retain Hazardous Drugs.

In the US, such guidelines are now mandated. The United States Pharmacopeia Convention (USP) released USP <800>, Hazardous Drugs-Handling in Healthcare Settings, to effectively make long-standing recommendations by agencies such as NIOSH, enforceable.[17]

ACPP RESULTS AT A GLANCE

ACPP provides a dynamic, *in-use* perspective of permeation detection to help you select the right Ansell glove for the work you do.

ACPP goes beyond ASTM and EN standards testing. Results should not be directly compared as test conditions and analytical methods are different.



HOW TO READ THE ACPP RESULTS

No permeation detected at 30 mins	Permeation detected at 30 mins
No permeation detected at 15 mins USE WITH CAUTION	Permeation detected at 5 mins NOT RECOMMENDED
No permeation detected at 10 mins USE WITH CAUTION	Breakage NOT RECOMMENDED
No permeation detected at 5 mins USE WITH CAUTION	

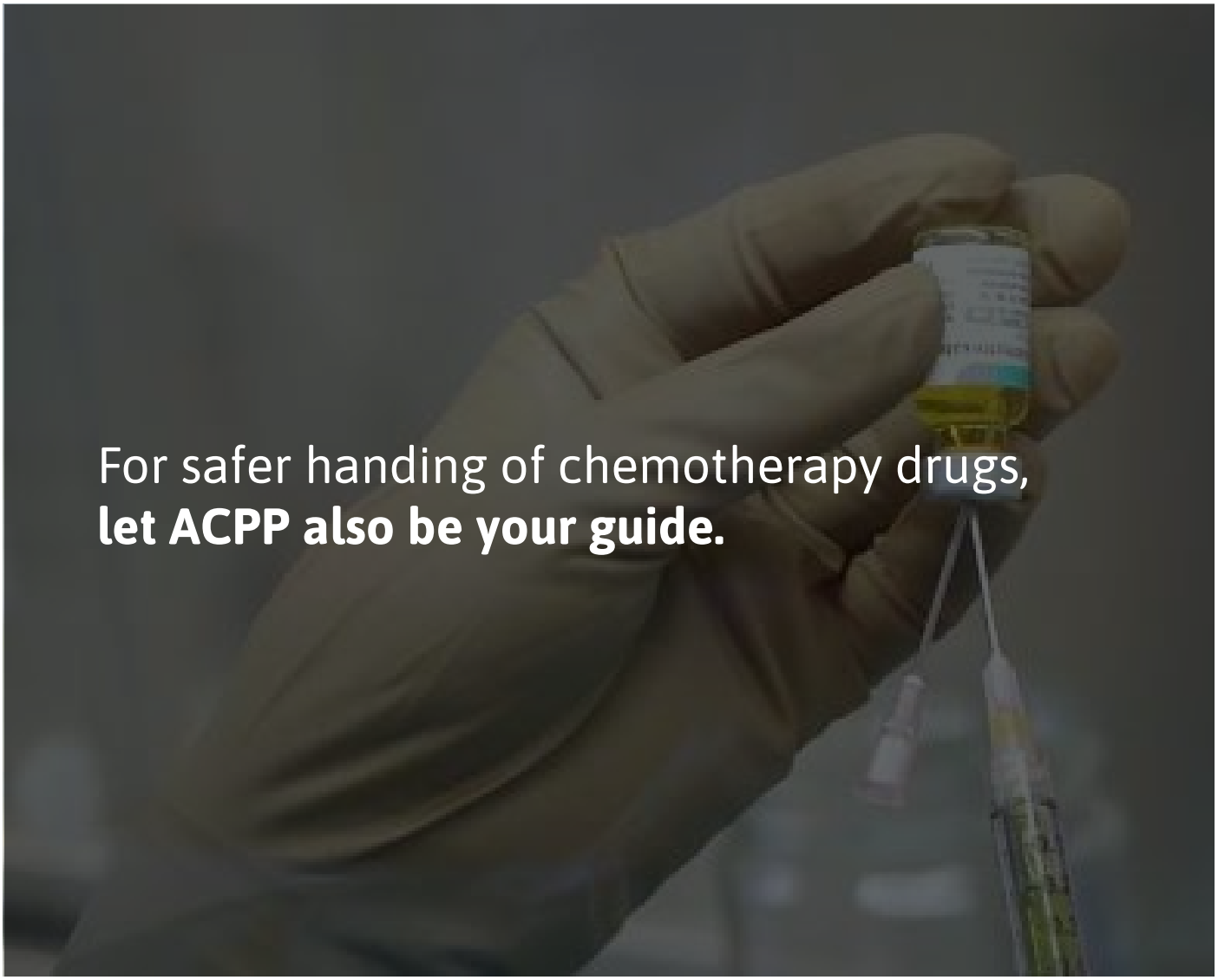
With the exception of examination gloves, where permeation was detected at 30 mins, retesting was conducted after 15 mins of exposure except for Carmustine and ThioTEPA, which were tested after 5 and 10 mins, in keeping with the recommended time for handling these drugs.

These results are **ONLY** and **SOLELY** valid for the gloves and molecules tested. Any extrapolation to other materials or brands would be erroneous.

**Detection limit is based on the permeation rate expressed as the amount (in µg) of chemical per surface area (cm^2) of the test specimen per minute (min). ACPP detection limits: Carboplatin, Cisplatin & Oxaliplatin - 0.001x10^{-3}µg/cm^2/min; Cyclophosphamide, Cytarabine, Dacarbazine, Fludarabine, Fluorouracil, Gemcitabine, Ifosfamide, Irinotecan, Melphalan, Paclitaxel & Mitomycin C - 0.002x10^{-3}µg/cm^2/min; Daunorubicin, Epirubicin, Idarubicin, Vincristine Sulphate & Doxorubicin Hydrochloride - 0.004x10^{-3}µg/cm^2/min; Methotrexate - 0.005x10^{-3}µg/cm^2/min; Busulfan, Docetaxel, Etoposide, Mitoxantrone & ThioTEPA - 0.011x10^{-3}µg/cm^2/min; Bleomycin/Blenoxane & Carmustine - 0.112x10^{-3}µg/cm^2/min.*

DISCLAIMER: Permeation detection results were determined in the laboratory simulating *in-use* conditions that may not always reflect the actual usage conditions of your specific environment. Variation in the environment or a mix of chemotherapy drugs used may impact the detection of permeation. Users should test the suitability of the glove selected against their specific chemotherapy drugs and environment. Results have been derived from tests conducted on behalf of Ansell, led by *Professor Jérôme Guitton, Head of the Pharma-Toxicology Department, Hospices Civils de Lyon.*

CAUTION: Safe use of gloves containing natural rubber latex by latex sensitized individuals has not been established. Products containing natural rubber latex may cause allergic reactions.



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