



**Ansell**

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

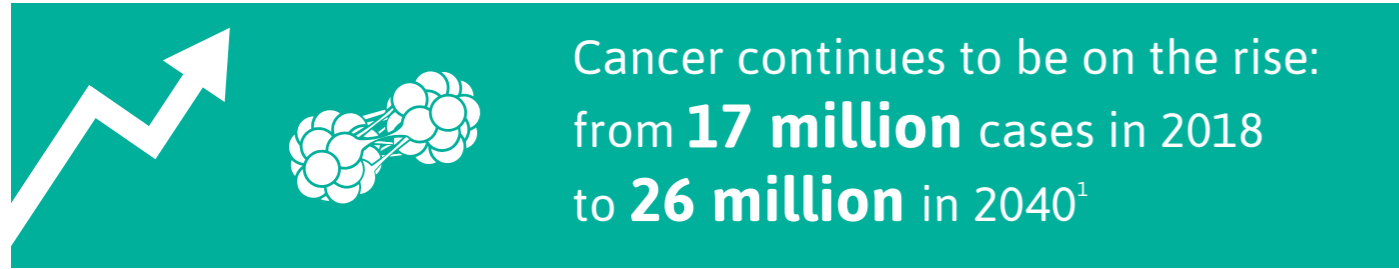
---

**ANSELL CYTOSTATIC  
PERMEATION PROGRAM  
(ACPP)**

[ansell.com](https://www.ansell.com)

# 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.



Figures exclude non-melanomatous skin cancers.

Ansell gloves are tested to EN 16523-1 and ASTM D6978 standards<sup>2</sup>, 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.

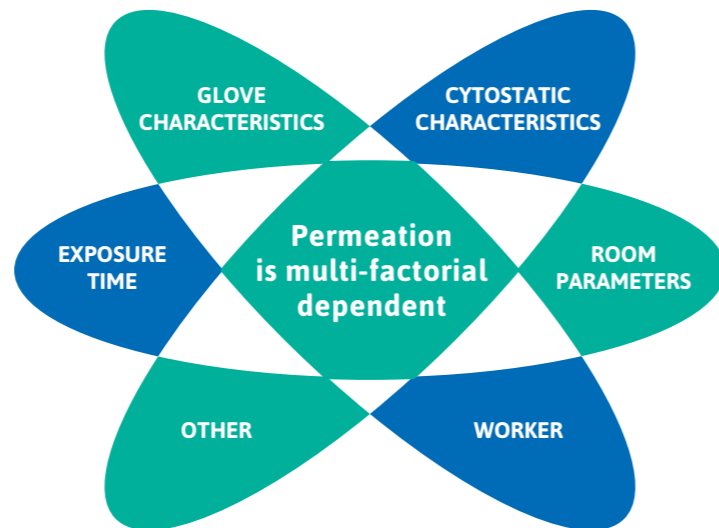


## Working conditions are dynamic, so why not test to in-use conditions?

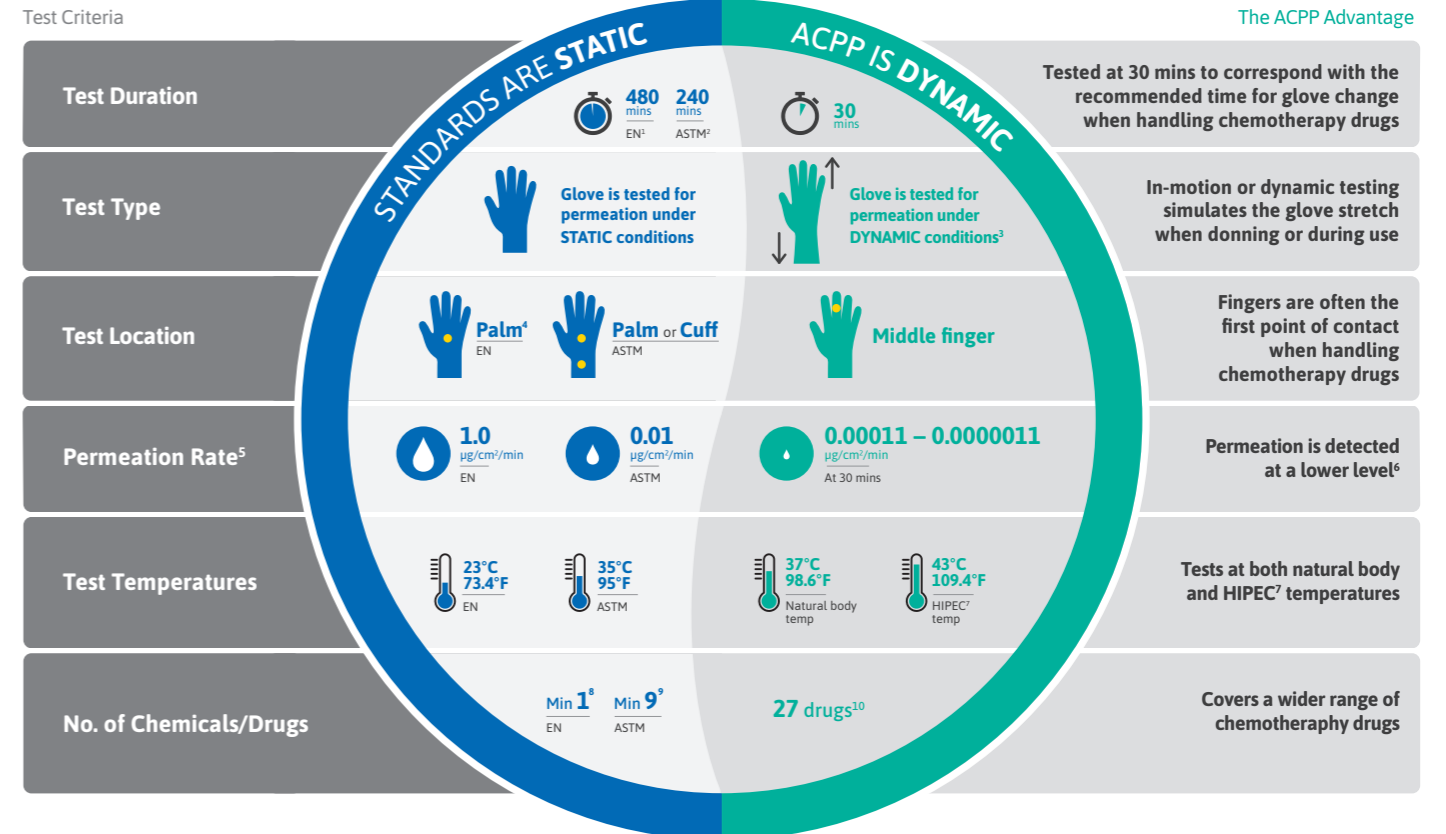
While ASTM and EN standards determine glove permeation under static test conditions, ACPP mimics the everyday use in your workplace through controlled dynamic conditions.

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.<sup>3, 4, 5, 6</sup>

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.



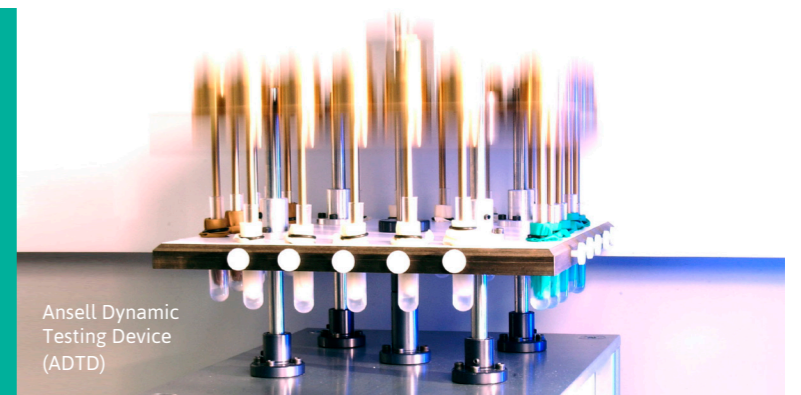
## ACPP mimics in-use conditions, and together with Standards, ensures the right glove for safer handling of hazardous drugs



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 (cm<sup>2</sup>) 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<sup>7</sup> 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.<sup>3</sup>

# MAXIMIZE YOUR CONFIDENCE BY MINIMIZING YOUR EXPOSURE

There is no safe level of exposure to chemotherapy drugs.<sup>8,9</sup>

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<sup>2</sup>/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<sup>2</sup>/min. This ability for earlier detection is made possible by the highly sensitive analytical devices used.<sup>10</sup>

**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 <sup>2</sup> /min	ACPP After 5 & 30 mins exposure @lowest limit of detection for Carmustine*
GAMMEX® Non-Latex PI	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.<sup>11</sup>

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**.<sup>12, 13, 14</sup>



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.<sup>16</sup>

## 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.**<sup>17</sup>

# 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.

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

		SURGICAL						LIFE SCIENCES				EXAMINATION							
		GAMMEX® Non-Latex PI	GAMMEX® PI Hybrid	GAMMEX® Non-Latex	GAMMEX® Non-Latex Sensitive	GAMMEX® Latex	ENCORE® Latex Acclaim	DermaShield™ 73-711	TouchNTuff® DermaShield™ 73-701	TouchNTuff® 73-500	TouchNTuff® 83-500	MICRO-TOUCH® Blue Nitrile	MICRO-TOUCH® NITRA-TEX™	MICRO-TOUCH® Nitrile Accelerator Free	MICRO-TOUCH® Nitrile	MICROFLEX® 93-853	MICROFLEX® 93-850	MICROFLEX® LifeStar EC 93-868	MICROFLEX® MidKnight™ XTRA 93-862
CHEMOTHERAPY DRUG (Concentration)		DETECTION OF PERMEATION*																	
Tested at 37°C	Bleomycin/Blenoxane (3.0 mg/ml)	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Busulfan (6.0 mg/ml)	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Carboplatin/Paraplatin (10.0 mg/ml)	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Carmustine (3.3 mg/ml)	Red	Green	Green	Green	Red	Red	Green	Green	Green	Red	Green	Green	Green	Green	Green	Green	Green	Green
	Cyclophosphamide (20.0 mg/ml)	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Cytarabine (50.0 mg/ml)	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Dacarbazine (10.0 mg/ml)	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Daunorubicin (5.0 mg/ml)	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Docetaxel (20.0 mg/ml)	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Red	Red	Red	Red	Red	Red	Red	Red
	Epirubicin/Ellence (2.0 mg/ml)	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Etoposide (20.0 mg/ml)	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Red	Red	Red	Green	Red	Red	Green	Red
	Fludarabine (25.0 mg/ml)	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Fluorouracil (50.0 mg/ml)	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Gemcitabine (40.0 mg/ml)	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Idarubicin (1.0 mg/ml)	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Ifosfamide (40.0 mg/ml)	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Irinotecan (20.0 mg/ml)	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Melphalan (5.0 mg/ml)	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Methotrexate (100.0 mg/ml)	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Mitoxantrone (2.0 mg/ml)	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
Paclitaxel (6.0 mg/ml)	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	
ThioTEPA (10.0 mg/ml)	Green	Green	Green	Green	Red	Red	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	
Vincristine Sulfate (1.0 mg/ml)	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	
Tested at 43°C	Cisplatin (1.0 mg/ml)	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Doxorubicin Hydrochloride (2.0 mg/ml)	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Mitomycin C (0.4 mg/ml)	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green
	Oxaliplatin (5.0 mg/ml)	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green	Green

## 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.

\*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). ACPP detection limits: Carboplatin, Cisplatin & Oxaliplatin - 0.001x10<sup>-3</sup>µg/cm²/min; Cyclophosphamide, Cytarabine, Dacarbazine, Fludarabine, Fluorouracil, Gemcitabine, Ifosfamide, Irinotecan, Melphalan, Paclitaxel & Mitomycin C - 0.002x10<sup>-3</sup>µg/cm²/min; Daunorubicin, Epirubicin, Idarubicin, Vincristine Sulphate & Doxorubicin Hydrochloride - 0.004x10<sup>-3</sup>µg/cm²/min; Methotrexate - 0.005x10<sup>-3</sup>µg/cm²/min; Busulfan, Docetaxel, Etoposide, Mitoxantrone & ThioTEPA - 0.011x10<sup>-3</sup>µg/cm²/min; Bleomycin/Blenoxane & Carmustine - 0.112x10<sup>-3</sup>µg/cm²/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.



For safer handling of chemotherapy drugs,  
let ACPP also be your guide.

➤ For more information, visit [www.ansell.com](http://www.ansell.com) or contact your Ansell representative.

**North America**

US Tel: 800 952 9916  
CA Tel: 844 494 7854

Email: [insidesalesus@ansell.com](mailto:insidesalesus@ansell.com)

**Central & South America**

Tel: +52(442) 296 20 50  
Email: [cslac@ansell.com](mailto:cslac@ansell.com)

**Brazil**

Tel: +55-11-3356-3100  
Email: [luvas.medicas@ansell.com](mailto:luvas.medicas@ansell.com)

**Europe, Middle East & Africa**

Tel: +32 (0) 2 528 74 00  
Email: [info@ansell.eu](mailto:info@ansell.eu)

**Asia Pacific**

Tel: +603 8310 6688  
Email: [apac.medical@ansell.com](mailto:apac.medical@ansell.com)

**China**

Tel: +86(21) 3827 5005  
Email: [infochina@ansell.com](mailto:infochina@ansell.com)

**Australia & New Zealand**

Tel: +61 3 9270 7270  
Email: [protection@ap.ansell.com](mailto:protection@ap.ansell.com)

**India**

Tel: +91 22 38124500  
Email: [info.india@ansell.com](mailto:info.india@ansell.com)

**References:** **1.** Wilson BE, Jacob S, Yap ML, Ferlay J, Bray F, Barton MB. Estimates of global chemotherapy demands and corresponding physician workforce requirements for 2018 and 2040: a population-based study. *Lancet Oncol.* 2019;20(7):769–780. **2.** ASTM is the American Society of Testing & Materials; and EN is the European Norm. **3.** Nalin M, Hug G, Boeckmans E, Machon C, Favier B and Guitton J. Permeation measurement of 27 chemotherapy drugs after simulated dynamic testing on 15 surgical and examination gloves: A knowledge update. *Journal of Oncology Pharmacy Practice.* 2020;0(0):1-14. **4.** Landeck L, Gonzalez E, Koch OM. Handling chemotherapy drugs-Do medical gloves really protect?. *Int J Cancer.* 2015;137(8):1800-1805. doi:10.1002/ijc.29058. **5.** Phalen RN, Le T, Wong WK. Changes in chemical permeation of disposable latex, nitrile, and vinyl gloves exposed to simulated movement. *J Occup Environ Hyg.* 2014;11(11):716-721. doi:10.1080/15459624.2014.908259. **6.** Dillon J and Schroeder L. Permeability and material characteristics of vulcanized latex film during and following cyclic fatigue in a saline environment. *Journal of Applied Polymer Science.* 1997;64(3):553-566. **7.** At the time of publishing, Ansell is the only glove manufacturer with its own dynamic testing device called the Ansell Dynamic Testing Device (ADTD). **8.** Sessink PJ, Bos RP. Drugs hazardous to healthcare workers. Evaluation of methods for monitoring occupational exposure to chemotherapeutic drugs. *Drug Saf.* 1999;20:347–59. **9.** Oriyama T, Yamamoto T, Yanagihara Y, et al. Evaluation of the permeation of antineoplastic agents through medical gloves of varying materials and thickness and with varying surface treatments. *J Pharm Health Care Sci.* 2017;3(13). **10.** ACPP uses Inductively coupled plasma-mass spectrometry (HPLC-DAD) and liquid chromatography-mass spectrometry (LC-MS/MS). **11.** Cancer Medicine 4th Edition, Encyclopedia of Cancer, Cancerologie Clinique Thérapeutique du Cancer, Compendium 20th Edition. **12.** Ivanova K, Avota M. Antineoplastic Drugs: Occupational Exposure and Side Effects. *Proceedings of the Latvian Academy Of Sciences.* 2016;70(5):325–329. doi:10.1515/prolas-2016-0049. **13.** Hon C, Teschke, K Demers, P. Venners, S. Antineoplastic drug contamination on the hands of employees working throughout the hospital medication system. *Ann Occup Hyg.* 2014;58(6): 761-770. **14.** Tracy Wyant, DNP, RN-BC, AOCN®, CHPN®, CPPS. <https://voice.ons.org/newsand-views/what-is-ons-stance-on-handling-chemotherapy-while-pregnant-breastfeeding-or-trying>. Accessed 17 Sept 2020. **15.** Bertrand Favier Thesis, Hospital Pharmacist, Centre Régional Léon-Bérard, Lyon – France. **16.** Hall A, Demers P, Astrakianakis G, Ge C, and Peters C. Estimating National-Level Exposure to Antineoplastic Agents in the Workplace: CAREX Canada Findings and Future Research Needs. *Annals of Work Exposures and Health.* 2017;61(6):656-658. **17.** <https://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare>. Accessed 17 Sept. 2020.

Ansell,® and™ are trademarks owned by Ansell Limited or one of its affiliates. © 2021 Ansell Limited. All Rights Reserved.

[ansell.com](http://ansell.com)

