



BioCleanTM

BioCleanTM



Company Overview

- Established: 1996
- Specialists: Cleanroom & Medical Consumables
Cleanroom Garments
- Markets: Europe
North America
Asia
- Directors:
 - Group Managing Derek Watts
 - Business Development Harry Kirk
 - Global Sales Richard Bryant
 - Regional (Asia Pacific) David Hughes
 - Regional (North America) Stan White

BioClean™



Contents

1. Introduction and overview
2. ASTM D 6978-05 – Standard practice for assessment of resistance of medical gloves to permeation by chemotherapy drugs
3. ASTM F 739 – 99 a - Standard test method for resistance of protective clothing materials to permeation by liquids or gases under conditions of continuous contact
4. EN 374-3:2003- Protective gloves against chemicals and micro organisms
Part three: determination of resistance to permeation by chemicals
5. BioClean Emerald & BioClean Ultimate double gloving system

BioClean[™]



Contents

6. Chemotherapy gloves for cytotoxic drug handling
Bioclean Ultimate™
Bioclean P-Zero™
Bioclean Emerald™
Test results and interpretation
7. Glove usage outside the pharmacy
Omega Neotech™
Omega Neotech XP™
8. Questions

Nitritex Malaysia Sdn Bhd

1,600 ft² cleanroom facility

47,300 ft² Total built-up facility

De-ionized water plant 18 mega ohm

Six production lines (washer/dryers)

Fully equipped in-house laboratory

Certified by NEBB (USA)

Contract processing services

ISO Class 4
Cleanroom



BioClean™

Differences between US & European standards

ASTM D-6978-05

- Test Temperature = 35°C (+/- 2°C)
- Permeation level measured at 0.01 µg/cm²/Min
- Specifically designed for cytotoxic drugs
- Test samples must meet EN 455 parts 1 & 2 medical gloves standard before submission
- Must use thinnest part of glove for testing

EN 374-3: 2003

- Test temperature = 23°C (= +/- 1°C)
- Permeation level measured at 1.0 µg/cm²/Min
- Designed for resistance to chemicals
- No requirement to submit samples for testing to EN455 parts 1 & 2
- Can use any part of glove for testing

BioClean™

Differences between the standards

Difference	EN 374-3:2003	ASTM D 6978-05	Consequence
Thickness of the test specimens	Sample has to be taken from the palm of the glove.	Sample has to be taken from either the palm or the cuff, whichever is the thinner.	The ASTM requirement ensures that the area of greatest risk is assessed. The cuff is usually the thinnest part of any glove, so gloves tested under EN 374 are not challenged as rigorously.
Test temperature	Test to be conducted at a temperature of 23° ± 1°C.	Test to be conducted at a temperature of 35° ± 2°C.	The ASTM standard specifies a test temperature that is 2°C below body core temperature. This means that the gloves are tested at a temperature similar to that of a human hand.
Test chemicals	A minimum of three chemicals must be used for the test. The chemicals are selected from a pre-defined list of 12. None of the predefined chemicals is a chemotherapy drug.	A minimum of nine chemotherapy drugs must be used for the test. Seven of them are predefined by the standard; the other two must be selected from a predefined list.	The EN 374 list of chemicals will not give a representation of how the gloves will perform when challenged by chemotherapy drugs. Users purchasing these gloves for chemo use should be advised to have them tested for suitability.
Permeation limit	Breakthrough of the test chemical is deemed to have occurred when the permeation rate has reached 1µg cm ⁻² /min ⁻¹ .	Breakthrough of the test chemical is deemed to have occurred when the permeation rate has reached 0.01µg cm ⁻² /min ⁻¹ .	The ASTM test limit is set at 1/100 th of the EN 374 limit. This requirement is far more stringent and reflects the potential hazard presented by chemotherapy drugs.*
Test time	The test time is defined (by EN 374-1) as 480 minutes.	The test time is defined as 240 minutes.	The shorter test time required by ASTM is a relative weakness of the standard.*

* Testing commissioned by Nitritex to ASTM D 6978 is routinely modified to extend the test time to 480 minutes and monitoring is continued beyond the 0.01µg cm⁻²/min⁻¹ limit to find the time at which the EN 374 limit of 1µg/cm⁻²/min⁻¹ is reached.

BioClean™

ASTM D 6978-05* Summary

Select 3 Gloves for Testing against each drug

Measure the glove thickness at palm and cuff

Take test samples from the thinnest part of the glove
(identify the outer surface)

Minimum number of test drugs is 9 for each glove (27
gloves in total)

7 mandatory drugs plus 2 others (list provided)

Samples must be tested per ASTM F739-a (outer surface
in contact with each drug for 4 hours)

Each test piece is examined for deterioration at the end of

testing

BioClean™

*Test Method used is ASTM F 739-a but the new standard imposes requirements for test sample selection and final report content

Code: BPZS

Chemo Gloves For Cytotoxic Drug Preparation & Handling

Features

- Proprietary Co-Polymer
- 300mm Textured
- Hand Specific / Sterile
- Excellent chemical Protection
- ISO Class 4, EU GMP Class A
- Double Bagged
- Latex-free to avoid type 1 allergies



Applications

- Cleanroom
- Chemotherapy drug preparation
- Sterile environments

BioClean™



Cytotoxic Permeation Performance

Product Name:	BioClean P-Zero [™] Synthetic		
Product Code:	BPZS		
	ASTM D 6978-05¹	ASTM F 739-a²	EN 374-3:2003³
Specified limit	0.01 µg/cm²/Min	0.1 µg/cm²/Min	1.00 µg/cm²/Min
Cisplatinum (Optional)	ND	ND	ND
Carmustine	50.3	87	ND
Cyclophosphamide	ND	ND	ND
Doxorubicin Hydrochloride	ND	ND	ND
Fluorouracil	ND	ND	ND
Methotrexate (Optional)	ND	ND	ND
Etoposide	ND	ND	ND
Paclitaxel	ND	ND	ND
Thio Tapa	107.7	115	ND

¹ ASTM D 6978-05 – Standard practice for assessment of resistance of medical gloves to permeation by chemotherapy drugs

² ASTM F 739 – 99a – Standard test method for resistance of protective clothing materials to permeation by liquids or gases under conditions of continuous contact

³ EN 374-3:2003 – Protective gloves against chemicals and micro organisms.

Part three: Determination of resistance to permeation by chemicals

ND = Permeation not detected during the 480 minute test period.

BioClean[™]

BioClean P-Zero Chemical Permeation Performance against Biocide

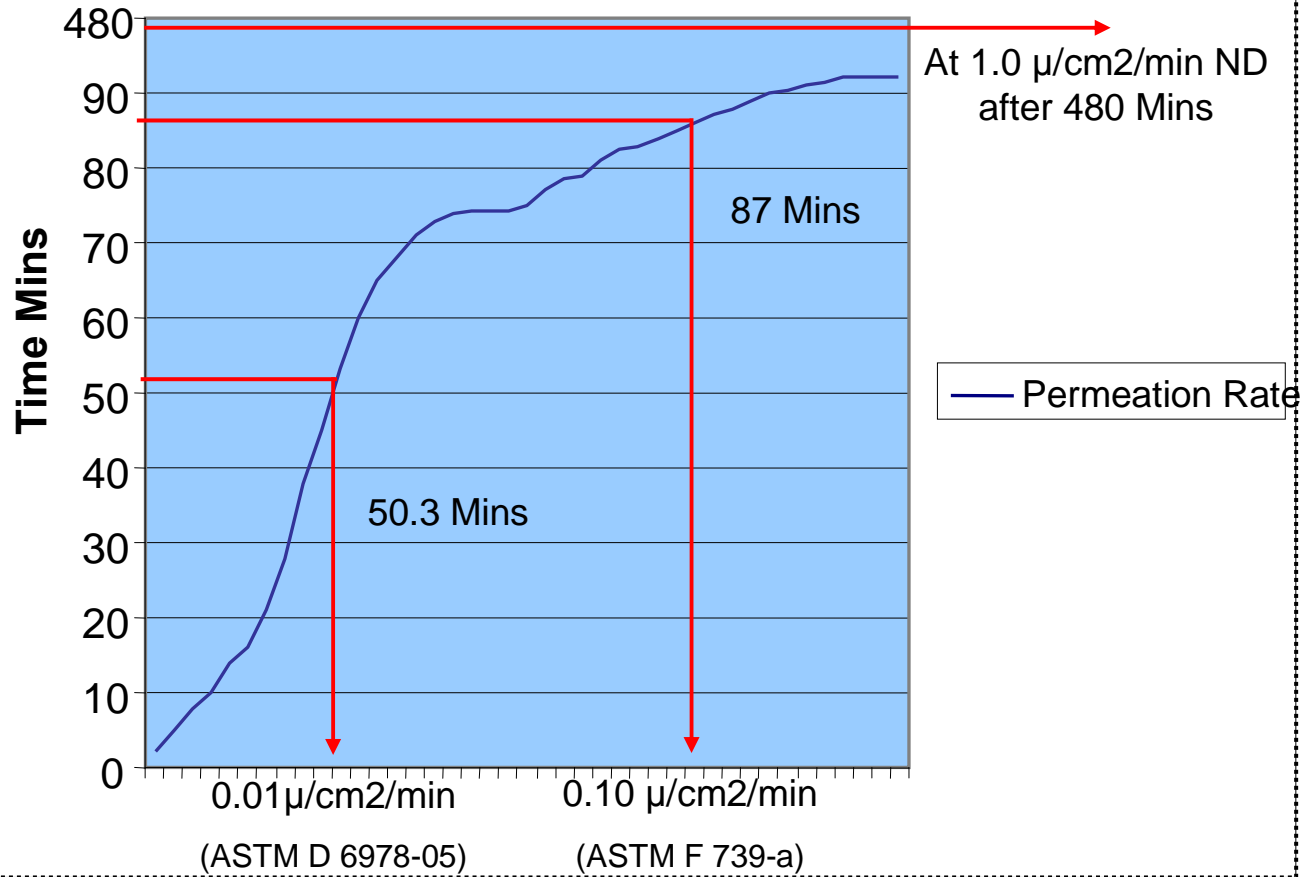
Product Name:	BioClean P-Zero™ Synthetic
Product Code:	BPZS
	EN 374-3:2003 ¹
Specified limit	1.0 µg/cm²/Min
Klercide BioCide*	Not Detected after 480 Minutes

¹ EN 374-3:2003 – Protective gloves against chemicals and micro organisms.
Part three: Determination of resistance to permeation by chemicals

* Market Leading Biocidal sterilisation agent

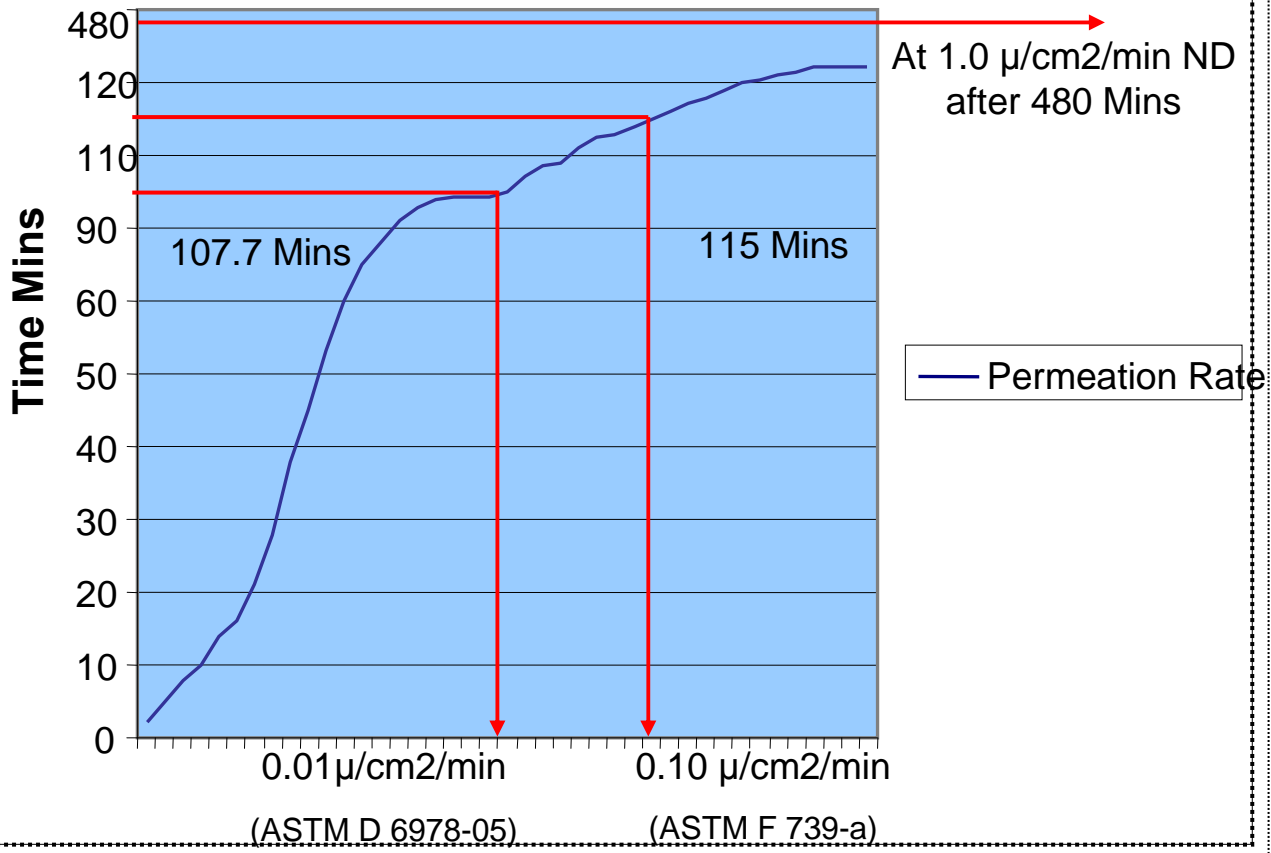
BioClean™

BioClean P-Zero Permeation Against Carmustine



BioClean™

BioClean P-Zero Permeation Against Thio Tapa



Code: BUPS

Chemo Gloves For Cytotoxic Drug Preparation & Handling

Features

- Proprietary Co-Polymer
- 300mm Textured
- Ideal for double gloving
- Sterile / Hand Specific
- Excellent chemical Protection
- ISO Class 4, EU GMP Class A
- Latex-free to avoid Type 1 allergies



BioClean Ultimate[™]

Applications

- Cleanroom
- Ideal for Isolator Cuffs
- Chemotherapy drug preparation
- Sterile environments
- Great dexterity

BioClean[™]



Cytotoxic Permeation

Product Name:	BioClean Ultimate™ Synthetic		
Product Code:	BUPS		
	ASTM D 6978-05¹	ASTM F 739-a²	EN 374-3:2003³
Specified limit	0.01 µg/cm²/Min	0.1 µg/cm²/Min	1.00 µg/cm²/Min
Cisplatinum (Optional)	ND	ND	ND
Carmustine	2	38	ND
Cyclophosphamide	ND	ND	ND
Doxorubicin Hydrochloride	ND	ND	ND
Fluorouracil	ND	ND	ND
Methotrexate (Optional)	ND	ND	ND
Etoposide	ND	ND	ND
Paclitaxel	ND	ND	ND
Thio Tepa	47.7	55.6	ND

¹ **ASTM D 6978-05** – Standard practice for assessment of resistance of medical gloves to permeation by chemotherapy drugs

² **ASTM F 739 – 99a** – Standard test method for resistance of protective clothing materials to permeation by liquids or gases under conditions of continuous contact

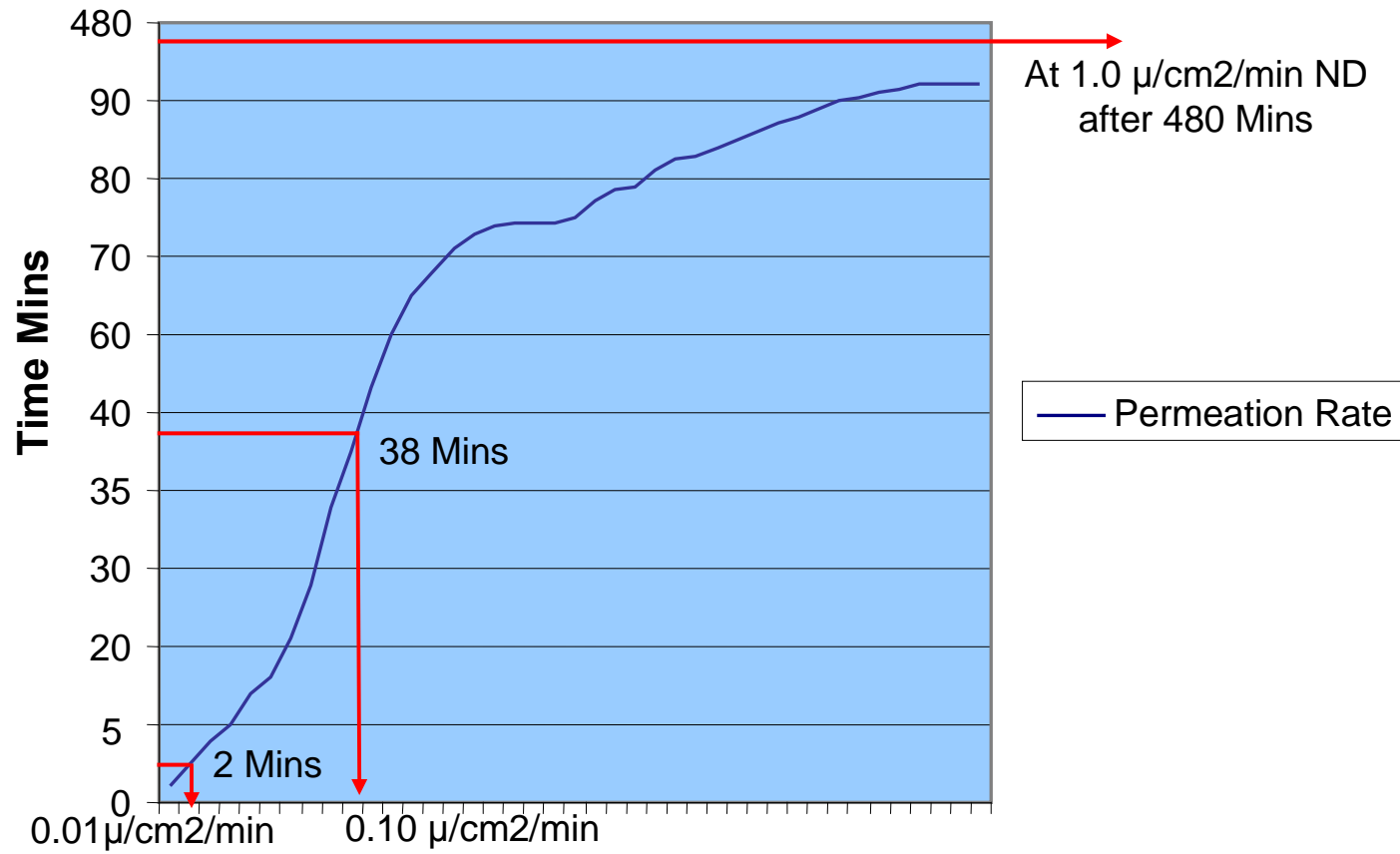
³ **EN 374-3:2003** – Protective gloves against chemicals and micro organisms.

Part three: Determination of resistance to permeation by chemicals

ND = Permeation not detected during the 480 minute test period.

BioClean™

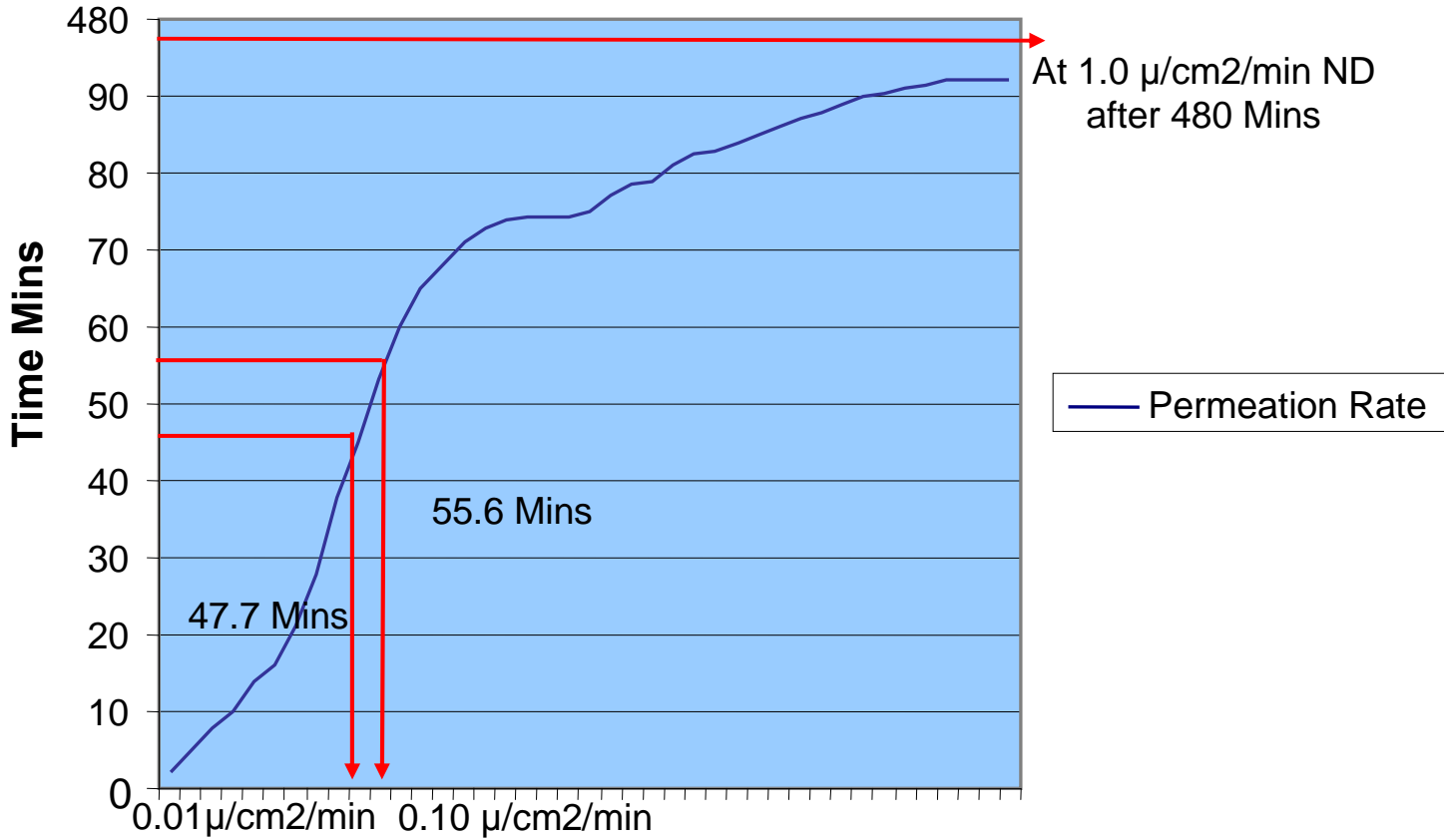
BioClean Ultimate Permeation Against Carmustine



(ASTM D 6978-05) (ASTM F 739-a)

BioClean[™]

BioClean Ultimate Permeation Against Thio Tapa



(ASTM D 6978-05) ASTM F 739-a

Code: BENS

Chemo Gloves for Cytotoxic Drug Preparation & Handling

Features

- Nitrile
- 300mm Textured
- Ideal for double gloving
- Hand Specific / Sterile
- Ultra sensitive
- ISO Class 4, EU GMP Class A
- Latex and accelerator free to avoid Type 1 & Type 4 allergies



Applications

- Cleanroom
- Pharmaceutical / Biotech
- Ideal as an under glove
- Ideal for delicate work
- Chemotherapy drug preparation

BioClean™



Cytotoxic Permeation Performance

Product Name:	BioClean Emerald™ Nitrile		
Product Code:	BENS		
	ASTM 6978-05 ¹	ASTM F 739 ²	EN 374 ³
Specified limit	0.01 µg/cm²/Min	0.1 µg/cm²/Min	1.00 µg/cm²/Min
Cisplatinum (Optional)	ND	ND	ND
Carmustine	12.4	39.2	ND
Cyclophosphamide	ND	ND	ND
Doxorubicin Hydrochloride	ND	ND	ND
Fluorouracil	ND	ND	ND
Methotrexate (Optional)	ND	ND	ND
Etoposide	ND	ND	ND
Paclitaxel	ND	ND	ND
Thio Tepa	30.5	35.2	ND

¹ **ASTM D 6978-05** – Standard practice for assessment of resistance of medical gloves to permeation by chemotherapy drugs

² **ASTM F 739 – 99a** – Standard test method for resistance of protective clothing materials to permeation by liquids or gases under conditions of continuous contact

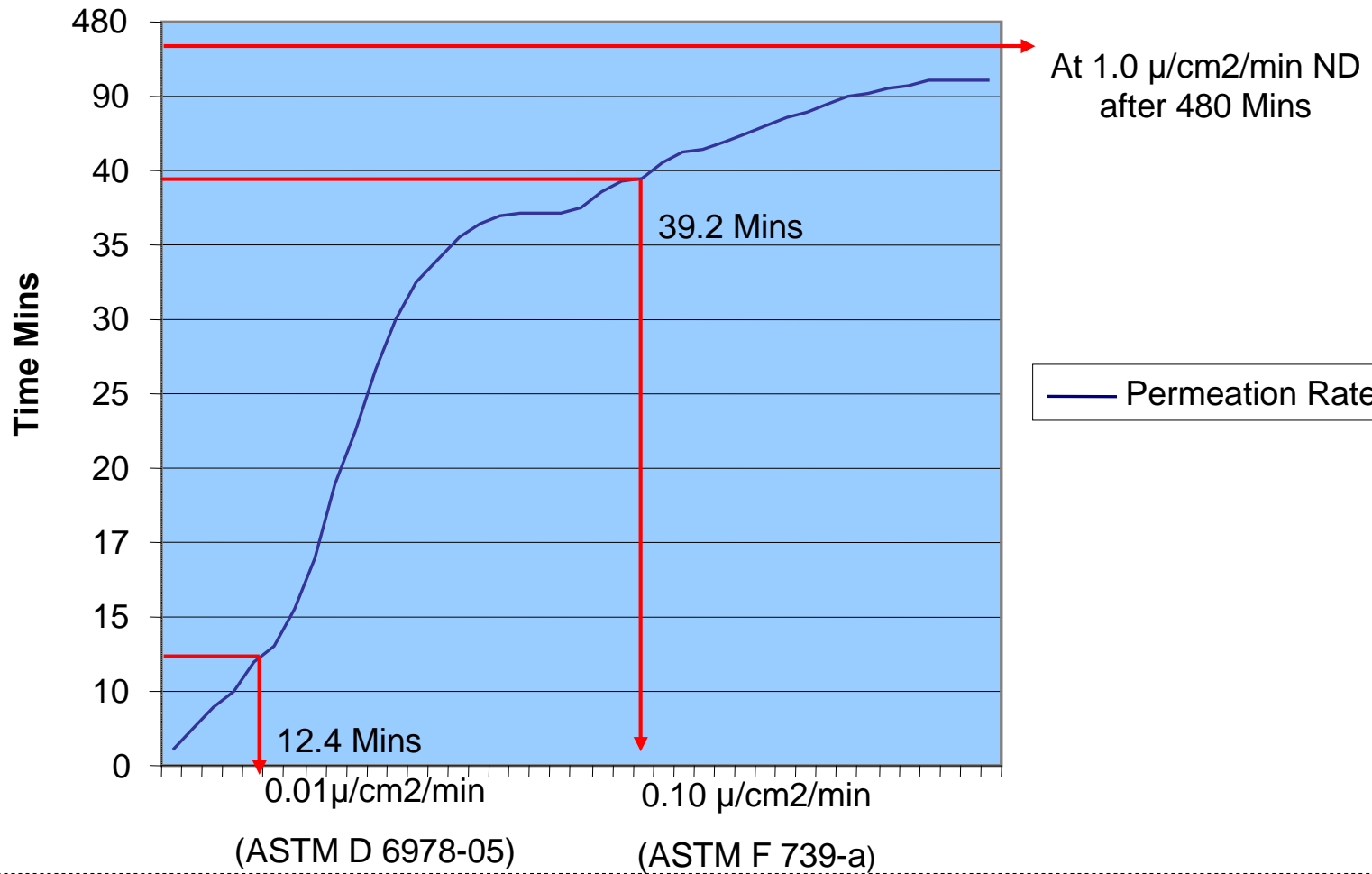
³ **EN 374-3:2003** – Protective gloves against chemicals and micro organisms.

Part three: Determination of resistance to permeation by chemicals

ND = Permeation not detected during the 480 minute test period.

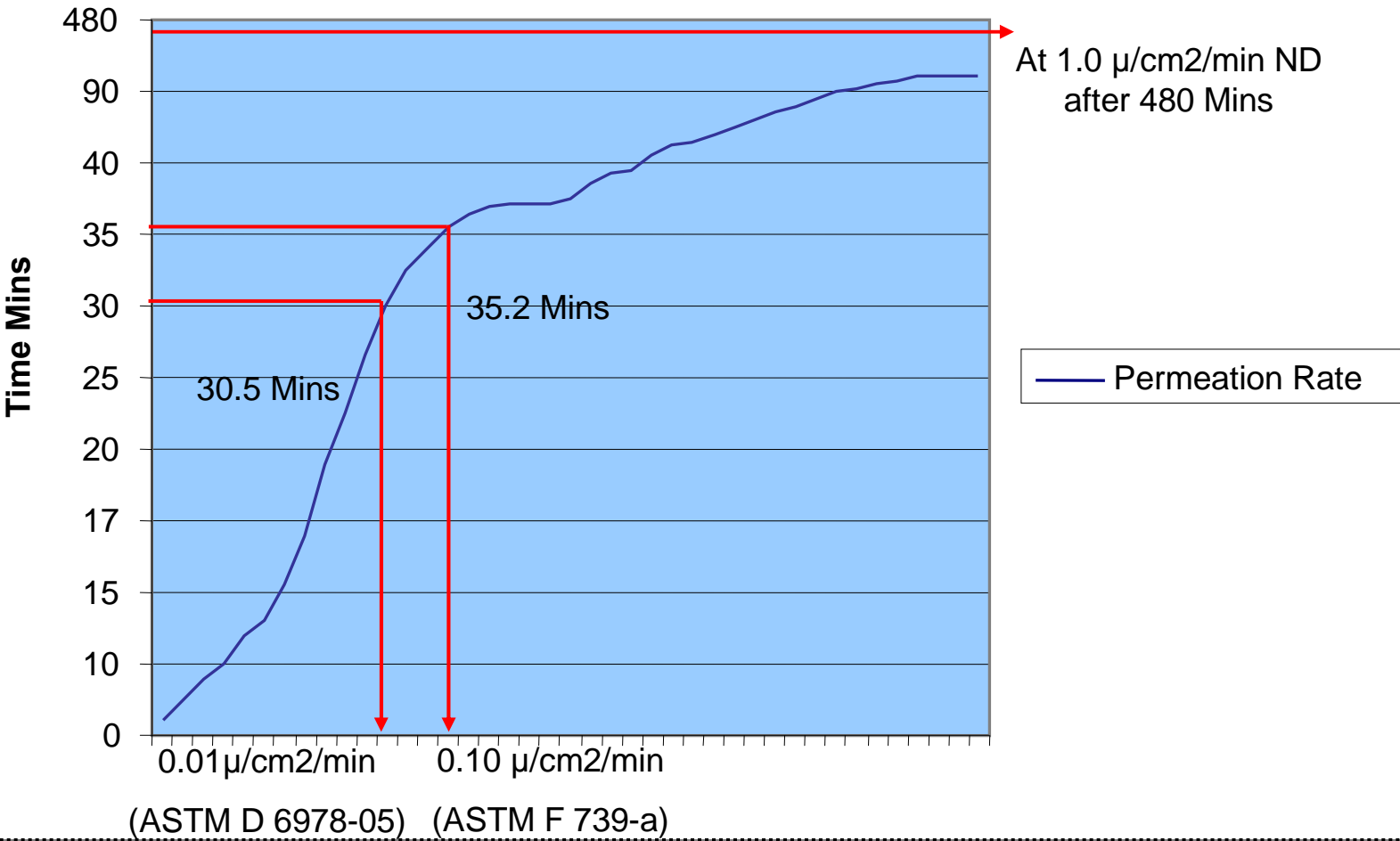
BioClean™

BioClean Emerald Permeation Against Carmustine



BioClean[™]

BioClean Emerald Permeation Against Thio Tapa





Double Gloving System. BioClean Ultimate™ & BioClean Emerald™

- **BioClean Emerald - inner glove**
 - 100% Accelerator free & Latex Free
 - Easy double donning facilitated by smooth outer surface
 - Distinctive green colour
- **BioClean Ultimate - outer glove**
 - Provides excellent tactility and sensitivity
 - Performs well against chemotherapy drugs
 - 100% Latex free

BioClean™

Double Gloving System Permeation Against Carmustine

Product Name:	BioClean Ultimate™ & BioClean™ Emerald Double Gloving		
Product Code:	BUPS & BENS		
	ASTM D 6978-05¹	ASTM F 739-a²	EN 374-3:2003³
Specified limit	0.01 µg/cm²/Min	0.1 µg/cm²/Min	1.00 µg/cm²/Min
Cisplatinum (Optional)	ND	ND	ND
Carmustine*	ND	ND	ND
Cyclophosphamide	ND	ND	ND
Doxorubicin Hydrochloride	ND	ND	ND
Fluorouracil	ND	ND	ND
Methotrexate (Optional)	ND	ND	ND
Etoposide	ND	ND	ND
Paclitaxel	ND	ND	ND
Thio Tapa	Currently Under Testing	Currently Under Testing	Currently Under Testing

¹ **ASTM D 6978-05** – Standard practice for assessment of resistance of medical gloves to permeation by chemotherapy drugs

² **ASTM F 739 – 99a** – Standard test method for resistance of protective clothing materials to permeation by liquids or gases under conditions of continuous contact

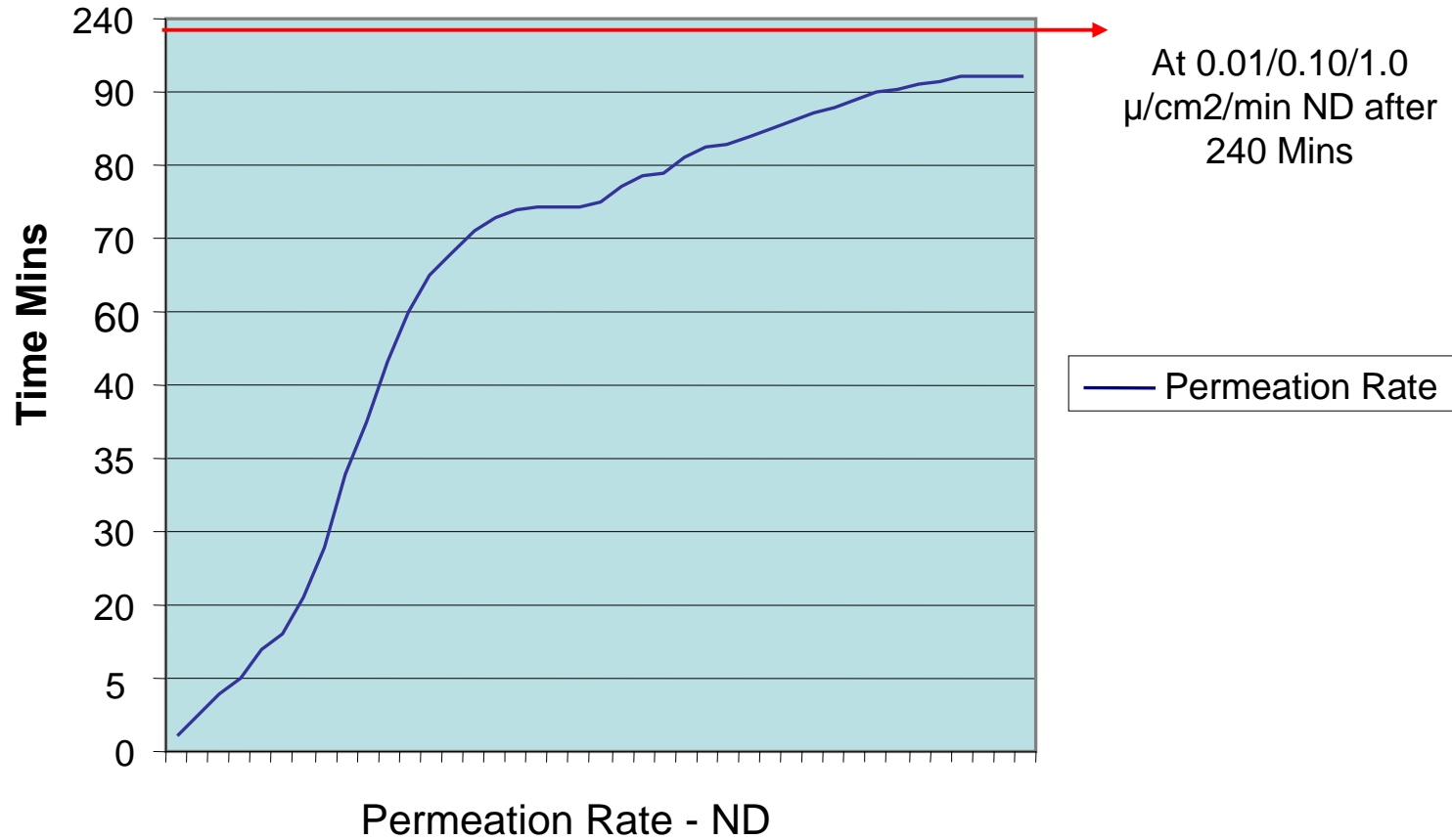
³ **EN 374-3:2003** – Protective gloves against chemicals and micro organisms.

Part three: Determination of resistance to permeation by chemicals

ND = Permeation not detected during the 480 minute test period.

BioClean™

BioClean Emerald & Ultimate (Double Gloving System) Permeation Against Carmustine



Berners Cytotoxic Permeation Performance Comparison

	BioClean Ultimate	BioClean Emerald	BioClean P-Zero	Berner****
	EN 374-3:2003*	EN 374-3:2003*	EN 374-3:2003*	EN 374-3:2003*
Specified Limit***	1.00 µ/cm ² /Min	1.00 µ/cm ² /Min	1.00 µ/cm ² /Min	1.00 µ/cm ² /Min
Cisplatinum (Optional)	>480Min (Class 6)	>480Min (Class 6)	>480Min (Class 6)	> 180 Min (Class 4)
Carmustine	>480Min (Class 6)	>480Min (Class 6)	>480Min (Class 6)	> 60 Min (Class 3)
Cyclophosphamide	>480Min (Class 6)	>480Min (Class 6)	>480Min (Class 6)	> 120 Min (Class 4)
Doxorubicin Hydrochloride	>480Min (Class 6)	>480Min (Class 6)	>480Min (Class 6)	> 180 Min (Class 4)
Fluorouracil	>480Min (Class 6)	>480Min (Class 6)	>480Min (Class 6)	> 180 Min (Class 4)
Methotrexate (Optional)	>480Min (Class 6)	>480Min (Class 6)	>480Min (Class 6)	> 180 Min (Class 4)
Etoposide	>480Min (Class 6)	>480Min (Class 6)	>480Min (Class 6)	Did Not Test
Paclitaxel	>480Min (Class 6)	>480Min (Class 6)	>480Min (Class 6)	Did Not Test
Thio Tepa	>480Min (Class 6)	>480Min (Class 6)	>480Min (Class 6)	Did Not Test

Table shows the time in minutes, after exposure to the chemical, at which the permeation rate reaches 1.00 µg/cm²/Min

Nitritex have tested gloves using ASTM6978-05** which has identical methodology to EN374-3:2003 with the following exceptions:

1. ASTM D 6978-05 is developed specifically for the testing of Chemotherapy drugs. EN374-3:2003 is not.
2. ASTM D 6978-05 Tests at 35 degrees Celsius (± 1) against 23 degrees Celsius (± 1) for EN374-3:2003 giving more realistic in use permeation rate
3. ASTM D 6978-05 Tests chemicals on thinnest part of glove. EN374-3:2003 tests the palm.

* EN374-3:2003. Definition: Protective gloves against chemicals and micro organisms. Determination of resistance to permeation by chemicals.

** ASTM D 6978-05. Definition: Standard practice for assessment of resistance of medical gloves to permeation by chemotherapy drugs

*** Nitritex have also conducted testing at 0.1µg/cm²/Min and 0.01 µg/cm²/Min. results can be furnished on request

**** Source: Berner. www.berner-international.de. Document: 08th September 2006

BioCleanTM



Glove Use Outside The Pharmacy

Contact with cytotoxic drugs also occurs outside the pharmacy.

Primarily:

A) when being transported to point of use.

B) at point of use.

In both instances there is no requirement for sterile gloves, but there remains a requirement for protection against exposure to cytotoxic drugs.

For safe handling and administration of cytotoxic drugs outside the pharmacy we can recommend 2 latex-free gloves.

These gloves are either:

Omega NeoTech™ 240mm length ambidextrous Polychloroprene glove

Or

Omega NeoTech XP™ 300mm length ambidextrous Polychloroprene glove.

BioClean™

Code: ONB

Omega Neotech

Features

- 240mm Textured
- Ambidextrous
- 100% Latex free
- Superior formulation



Applications

- Pharmaceutical / Biotec
- Chemotherapy drug preparation
- Excellent chemical protection



BioClean™

Code: ONBXP

Omega Neotech XP

Features

- 300mm Textured
- Ambidextrous
- 100% Latex free
- Superior formulation



Applications

- Pharmaceutical / Biotec
- Chemotherapy drug preparation
- Excellent chemical protection

BioClean™



**Thank You For Your
Kind Attention.
Any Questions?**

BioClean[™]