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
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
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
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
### Differences between the standards

<table>
<thead>
<tr>
<th>Difference</th>
<th>EN 374-3:2003</th>
<th>ASTM D 6978-05</th>
<th>Consequence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thickness of the test specimens</td>
<td>Sample has to be taken from the palm of the glove.</td>
<td>Sample has to be taken from either the palm or the cuff, whichever is the thinner.</td>
<td>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.</td>
</tr>
<tr>
<td>Test temperature</td>
<td>Test to be conducted at a temperature of 23º ± 1ºC.</td>
<td>Test to be conducted at a temperature of 35º ± 2ºC.</td>
<td>The ASTM standard specifies a test temperature that is 2ºC below body core temperature. This means that the gloves are tested at a temperature similar to that of a human hand.</td>
</tr>
<tr>
<td>Test chemicals</td>
<td>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.</td>
<td>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.</td>
<td>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.</td>
</tr>
<tr>
<td>Permeation limit</td>
<td>Breakthrough of the test chemical is deemed to have occurred when the permeation rate has reached 1µg cm⁻²/min⁻¹.</td>
<td>Breakthrough of the test chemical is deemed to have occurred when the permeation rate has reached 0.01µg cm⁻²/min⁻¹.</td>
<td>The ASTM test limit is set at 1/100th of the EN 374 limit. This requirement is far more stringent and reflects the potential hazard presented by chemotherapy drugs.*</td>
</tr>
<tr>
<td>Test time</td>
<td>The test time is defined (by EN 374-1) as 480 minutes.</td>
<td>The test time is defined as 240 minutes.</td>
<td>The shorter test time required by ASTM is a relative weakness of the standard.*</td>
</tr>
</tbody>
</table>

*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/cm²/min⁻¹ is reached.
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

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

<table>
<thead>
<tr>
<th>Product Name:</th>
<th>BioClean T-Zero Synthetic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Code:</td>
<td>BPZS</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Specified limit</strong></td>
<td><strong>ASTM D 6978-05</strong></td>
</tr>
<tr>
<td>Cisplatinum (Optional)</td>
<td>ND</td>
</tr>
<tr>
<td>Carmustine</td>
<td>50.3</td>
</tr>
<tr>
<td>Cyclophosphamide</td>
<td>ND</td>
</tr>
<tr>
<td>Doxorubicin Hydrochloride</td>
<td>ND</td>
</tr>
<tr>
<td>Fluorouracil</td>
<td>ND</td>
</tr>
<tr>
<td>Methotrexate (Optional)</td>
<td>ND</td>
</tr>
<tr>
<td>Etoposide</td>
<td>ND</td>
</tr>
<tr>
<td>Paclitaxel</td>
<td>ND</td>
</tr>
<tr>
<td>Thio Tepa</td>
<td>107.7</td>
</tr>
</tbody>
</table>

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
   Part three: Determination of resistance to permeation by chemicals
   ND = Permeation not detected during the 480 minute test period.
**BioClean P-Zero Chemical Permeation Performance against Biocide**

<table>
<thead>
<tr>
<th>Product Name:</th>
<th>BioClean P-Zero™ Synthetic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Code:</td>
<td>BPZS</td>
</tr>
<tr>
<td>EN 374-3:2003 ¹</td>
<td></td>
</tr>
<tr>
<td>Specified limit</td>
<td>1.0 µg/cm²/Min</td>
</tr>
<tr>
<td>Klercide BioCide*</td>
<td>Not Detected after 480 Minutes</td>
</tr>
</tbody>
</table>

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 P-Zero Permeation Against Carmustine

Permeation Rate

- 0.01 μ/cm²/min \( \text{ASTM D 6978-05} \)
- 0.10 μ/cm²/min \( \text{ASTM F 739-a} \)

Time Mins

- 50.3 Mins
- 87 Mins
- At 1.0 μ/cm²/min ND after 480 Mins
BioClean P-Zero Permeation Against Thio Tepa

**Permeation Rate**
- 0.01 µ/cm²/min (ASTM D 6978-05)
- 0.10 µ/cm²/min (ASTM F 739-a)

**Time Mins**
- 107.7 Mins
- 115 Mins
- At 1.0 µ/cm²/min ND after 480 Mins

(Time and permeation rates are indicated on the graph. The graph shows the permeation rate of BioClean P-Zero against Thio Tepa over time, with specific notes on time and permeation rates according to the standards mentioned.)
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

**Applications**
- Cleanroom
- Ideal for Isolator Cuffs
- Chemotherapy drug preparation
- Sterile environments
- Great dexterity
### Cytotoxic Permeation Performance

**Product Name:** BioClean Ultimate™ Synthetic

**Product Code:** BUPS

<table>
<thead>
<tr>
<th>Specified limit</th>
<th>ASTM D 6978-05&lt;sup&gt;1&lt;/sup&gt;</th>
<th>ASTM F 739-a&lt;sup&gt;2&lt;/sup&gt;</th>
<th>EN 374-3:2003&lt;sup&gt;3&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.01 µg/cm²/Min</td>
<td>2</td>
<td>38</td>
<td>ND</td>
</tr>
<tr>
<td>0.1 µg/cm²/Min</td>
<td>38</td>
<td>55.6</td>
<td>ND</td>
</tr>
<tr>
<td>1.00 µg/cm²/Min</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
</tr>
</tbody>
</table>

**Cisplatinum (Optional)**
- Specified limit: ND
- ASTM D 6978-05: ND
- ASTM F 739-a: ND
- EN 374-3:2003: ND

**Carmustine**
- Specified limit: 2
- ASTM D 6978-05: ND
- ASTM F 739-a: 38
- EN 374-3:2003: ND

**Cyclophosphamide**
- Specified limit: ND
- ASTM D 6978-05: ND
- ASTM F 739-a: ND
- EN 374-3:2003: ND

**Doxorubicin Hydrochloride**
- Specified limit: ND
- ASTM D 6978-05: ND
- ASTM F 739-a: ND
- EN 374-3:2003: ND

**Fluorouracil**
- Specified limit: ND
- ASTM D 6978-05: ND
- ASTM F 739-a: ND
- EN 374-3:2003: ND

**Methotrexate (Optional)**
- Specified limit: ND
- ASTM D 6978-05: ND
- ASTM F 739-a: ND
- EN 374-3:2003: ND

**Etoposide**
- Specified limit: ND
- ASTM D 6978-05: ND
- ASTM F 739-a: ND
- EN 374-3:2003: ND

**Paclitaxel**
- Specified limit: ND
- ASTM D 6978-05: ND
- ASTM F 739-a: ND
- EN 374-3:2003: ND

**Thio Tepa**
- Specified limit: 47.7
- ASTM D 6978-05: ND
- ASTM F 739-a: 55.6
- EN 374-3:2003: ND

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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 Ultimate Permeation Against Carmustine

- Permeation Rate:
  - 0.01 µ/cm²/min (ASTM D 6978-05)
  - 0.10 µ/cm²/min (ASTM F 739-a)

- Time:
  - 2 Mins
  - 38 Mins

- At 1.0 µ/cm²/min ND after 480 Mins

(ASM D 6978-05) (ASTM F 739-a)
BioClean Ultimate Permeation Against Thio Tepa

At 1.0 µ/cm²/min ND after 480 Mins

- Permeation Rate

Time Mins

0.01 µ/cm²/min
0.10 µ/cm²/min

47.7 Mins
55.6 Mins

(ASTM D 6978-05 ASTM F 739-a)
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 / Biotec
- Ideal as an under glove
- Ideal for delicate work
- Chemotherapy drug preparation

BioClean Emerald ™
**Product Name:** BioClean Emerald™ Nitrile

**Product Code:** BENS

<table>
<thead>
<tr>
<th></th>
<th><strong>ASTM 6978-05</strong> 1</th>
<th><strong>ASTM F 739</strong> 2</th>
<th><strong>EN 374</strong> 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specified limit</td>
<td>0.01 µg/cm²/Min</td>
<td>0.1 µg/cm²/Min</td>
<td>1.00 µg/cm²/Min</td>
</tr>
<tr>
<td>Cisplatinum (Optional)</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
</tr>
<tr>
<td>Carmustine</td>
<td>12.4</td>
<td>39.2</td>
<td>ND</td>
</tr>
<tr>
<td>Cyclophosphamide</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
</tr>
<tr>
<td>Doxorubicin Hydrochloride</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
</tr>
<tr>
<td>Fluorouracil</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
</tr>
<tr>
<td>Methotrexate (Optional)</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
</tr>
<tr>
<td>Etoposide</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
</tr>
<tr>
<td>Paclitaxel</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
</tr>
<tr>
<td>Thio Tepa</td>
<td>30.5</td>
<td>35.2</td>
<td>ND</td>
</tr>
</tbody>
</table>

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 Emerald Permeation Against Carmustine

- Permeation Rate: 0.01 µ/cm²/min (ASTM D 6978-05)
- Permeation Rate: 0.10 µ/cm²/min (ASTM F 739-a)

- Time Mins: 12.4 Mins
- Time Mins: 39.2 Mins
- Time Mins: At 1.0 µ/cm²/min ND after 480 Mins
BioClean Emerald Permeation Against Thio Tepa

At 1.0 µ/cm²/min ND after 480 Mins

Permeation Rate

0.01 µ/cm²/min

0.10 µ/cm²/min

30.5 Mins

35.2 Mins

(ASTM D 6978-05) (ASTM F 739-a)
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
# Double Gloving System
## Permeation Against Carmustine

<table>
<thead>
<tr>
<th>Product Name:</th>
<th>BioClean Ultimate™ &amp; BioClean™ Emerald Double Gloving</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product Code:</td>
<td>BUPS &amp; BENS</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>ASTM D 6978-05¹</th>
<th>ASTM F 739-a²</th>
<th>EN 374-3:2003³</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specified limit</td>
<td>0.01 µg/cm²/Min</td>
<td>0.1 µg/cm²/Min</td>
<td>1.00 µg/cm²/Min</td>
</tr>
<tr>
<td>Cisplatinum (Optional)</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
</tr>
<tr>
<td>Carmustine*</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
</tr>
<tr>
<td>Cyclophosphamide</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
</tr>
<tr>
<td>Doxorubicin Hydrochloride</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
</tr>
<tr>
<td>Fluorouracil</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
</tr>
<tr>
<td>Methotrexate (Optional)</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
</tr>
<tr>
<td>Etoposide</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
</tr>
<tr>
<td>Paclitaxel</td>
<td>ND</td>
<td>ND</td>
<td>ND</td>
</tr>
<tr>
<td>Thio Tepa</td>
<td>Currently Under Testing</td>
<td>Currently Under Testing</td>
<td>Currently Under Testing</td>
</tr>
</tbody>
</table>

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 Emerald & Ultimate (Double Gloving System) Permeation Against Carmustine

Permeation Rate - ND

At 0.01/0.10/1.0 µ/cm²/min ND after 240 Mins
<table>
<thead>
<tr>
<th></th>
<th>BioClean Ultimate</th>
<th>BioClean Emerald</th>
<th>BioClean P-Zero</th>
<th>Berner***</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specified Limit***</td>
<td>1.00 µ/cm²/Min</td>
<td>1.00 µ/cm²/Min</td>
<td>1.00 µ/cm²/Min</td>
<td>1.00 µ/cm²/Min</td>
</tr>
<tr>
<td>Cisplatinum (Optional)</td>
<td>&gt;480Min (Class 6)</td>
<td>&gt;480Min (Class 6)</td>
<td>&gt;480Min (Class 6)</td>
<td>&gt;480Min (Class 6)</td>
</tr>
<tr>
<td>Carmustine</td>
<td>&gt;480Min (Class 6)</td>
<td>&gt;480Min (Class 6)</td>
<td>&gt;480Min (Class 6)</td>
<td>&gt;60 Min (Class 3)</td>
</tr>
<tr>
<td>Cyclophosphamide</td>
<td>&gt;480Min (Class 6)</td>
<td>&gt;480Min (Class 6)</td>
<td>&gt;480Min (Class 6)</td>
<td>&gt;120 Min (Class 4)</td>
</tr>
<tr>
<td>Doxorubicin Hydrochloride</td>
<td>&gt;480Min (Class 6)</td>
<td>&gt;480Min (Class 6)</td>
<td>&gt;480Min (Class 6)</td>
<td>&gt;180 Min (Class 4)</td>
</tr>
<tr>
<td>Fluorouracil</td>
<td>&gt;480Min (Class 6)</td>
<td>&gt;480Min (Class 6)</td>
<td>&gt;480Min (Class 6)</td>
<td>&gt;180 Min (Class 4)</td>
</tr>
<tr>
<td>Methotrexate (Optional)</td>
<td>&gt;480Min (Class 6)</td>
<td>&gt;480Min (Class 6)</td>
<td>&gt;480Min (Class 6)</td>
<td>&gt;180 Min (Class 4)</td>
</tr>
<tr>
<td>Etoposide</td>
<td>&gt;480Min (Class 6)</td>
<td>&gt;480Min (Class 6)</td>
<td>&gt;480Min (Class 6)</td>
<td>Did Not Test</td>
</tr>
<tr>
<td>Paclitaxel</td>
<td>&gt;480Min (Class 6)</td>
<td>&gt;480Min (Class 6)</td>
<td>&gt;480Min (Class 6)</td>
<td>Did Not Test</td>
</tr>
<tr>
<td>Thio Tepa</td>
<td>&gt;480Min (Class 6)</td>
<td>&gt;480Min (Class 6)</td>
<td>&gt;480Min (Class 6)</td>
<td>Did Not Test</td>
</tr>
</tbody>
</table>

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.

** 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
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.
Omega Neotech

Features
• 240mm Textured
• Ambidextrous
• 100% Latex free
• Superior formulation

Applications
• Pharmaceutical / Biotec
• Chemotherapy drug preparation
• Excellent chemical protection

Code: ONB
Omega Neotech XP

Features
• 300mm Textured
• Ambidextrous
• 100% Latex free
• Superior formulation

Applications
• Pharmaceutical / Biotec
• Chemotherapy drug preparation
• Excellent chemical protection

Code: ONBXP
Thank You For Your Kind Attention. Any Questions?