

## ***Barrier Integrity of Punctured Gloves: NR Superior to Vinyl and Nitrile<sup>†</sup>***

H. HASMA<sup>\*#</sup>, A.B. OTHMAN<sup>\*</sup> AND M.S. FAUZI<sup>\*</sup>

*Barrier integrity of NR, vinyl and nitrile examination gloves was determined by assessing the amount of virus (ΦX174) suspension penetrating through the fingers punctured with acupuncture and syringe needles of 0.22 mm to 0.45 mm diameter. The water leak test showed a 100% failure in vinyl and nitrile gloves when punctured with 0.3 mm and 0.4 mm needles, respectively. NR gloves, however, showed markedly less failure even when punctured with needles up to 0.45 mm diameter. Failure in water leak test indicated a virus penetration of >2 μL. Puncture with 26G syringe needle showed > 2500 μL of virus suspension penetrating through vinyl and nitrile gloves compared to < 25 μL with NR gloves. The low leak from punctured NR gloves was observed to be associated with their low modulus and high tear strength resistance compared to those of vinyl and nitrile gloves. Scanning electron micrograph showed apparently closed tear slit in NR gloves compared to the opened tear in vinyl and nitrile gloves.*

**Key words:** NR; gloves; barrier integrity; water leak test; failure; tear strength; modulus; SEM; virus leak; needle puncture

Latex gloves are widely used for barrier protection against the transmission of infectious microorganisms, principally against human immunodeficiency virus (HIV), hepatitis B virus (HBV) and hepatitis C virus (HCV), which are the three recognised blood borne pathogens most commonly involved in occupational transmission<sup>1</sup>. The importance of barrier performance has, however, been overshadowed by the emergence of latex protein allergy issue in recent years<sup>2,3</sup>. The fear instilled by the latter has led to adverse campaigns against NR gloves, which indirectly

promote the synthetic counterparts. The question is how effective are these gloves compared to NR gloves in protecting individuals against the viral infection?

Intact NR gloves have long been shown to be impermeable to HIV<sup>4</sup> and herpes simplex virus<sup>5</sup>. When used to simulate procedures in clinical settings, they are found to be markedly more effective than vinyl gloves<sup>6</sup> in protection against virus penetration although their performance seemed to be comparable to nitrile gloves<sup>7</sup>. On puncture with 0.3 mm

<sup>†</sup>Partly adopted from the paper presented at the Latex 2001 First International Liquid Elastomers Conference, 4–5 December 2001, Munich, Germany (Organised by RAPRA Technology Ltd, UK)

<sup>\*</sup>Rubber Research Institute of Malaysia, Malaysian Rubber Board, P.O. Box 10150, 50908 Kuala Lumpur, Malaysia

<sup>#</sup>Corresponding author (e-mail: hasma@lgn.gov.my)

acupuncture needle some NR gloves are found not to even leak water nor virus<sup>8</sup> However, this could not be said for vinyl or nitrile as no established study has been done to assess their barrier performance on puncture, although needle puncture is known to be one of the major causes of glove perforations in surgery and obstetrics The fact that examination gloves are also used in clinical procedures exposed to sharp objects such as syringe needles, the following study was undertaken to evaluate the barrier effectiveness of needle punctured gloves of vinyl, nitrile and NR against the penetration of  $\Phi$ X174 virus The modulus and tear strength of the gloves were also determined to assess their influence on the degree of puncture while scanning electron microscopy was used to photograph the tear

## MATERIALS AND METHODS

### Virus Penetration Test

**Gloves** Examination gloves from 3 brands of vinyl, 4 brands of nitrile and 4 brands of NR (powder and powder-free) were used throughout the study The profile of the gloves is shown in Table 1 The gloves tested were drawn from a single box for each brand

**Challenge virus** The bacteriophage  $\Phi$ X174 was chosen as a surrogate<sup>9</sup> for human pathogenic virus as it is a small virus of 27 nm diameter, non-pathogenic to humans, stable at different temperatures and pH levels and least adsorbing<sup>10</sup> The virus culture and bioassay utilising *Escherichia coli* C as the host were as previously reported<sup>11</sup> For the experiments, the virus was suspended in a solution of 0.1% Tween-80<sup>®</sup> (v/v) in sterile deionised water

**Penetration of virus  $\Phi$ X174 through punctured glove fingers** The test involved

puncturing the glove fingers, checking the visible water leak and determining the amount of virus penetrated through the punctured fingers (Figure 1)

A circle of diameter 1 cm was marked 2 cm from the tip of the finger The glove finger was held horizontally (without stretching) and punctured through both sides at the centre of the circle with acupuncture or syringe needle The acupuncture needles (made in Suzhou, China) were of different diameters ranging from 0.22 mm to 0.35 mm while the syringe needles (from Terumo Belgium) were the 27G and 26G needles of diameters 0.4 mm and 0.45 mm, respectively The fingers were punctured on the same day as the test

The water leak and virus penetration tests were performed sequentially on each glove The open end of the glove was fastened to a sterilised glass cylinder (6 cm outside diameter) and clamped to a retort stand A 500 mL suspension of virus  $\Phi$ X174-containing about  $1 \times 10^6$  plaque-forming units (pfu)/mL in 0.1% Tween-80<sup>®</sup> was then carefully poured into the glove Defective gloves with visible leak outside the circled fingers were discarded The gloves with no apparent defects were checked for any visible leak near the marked spot after 2 min The extent of the water leak was noted as 0, no visible leak, 1+ small bead of water, 2+, and large bead to trickle of water

The virus penetration test was then performed 2 min after water leak test by dipping the punctured fingers into 50 mL sterile plastic centrifuge tubes containing 35 mL of 0.1% Tween-80<sup>®</sup> collection fluid for 1 h Aliquot of the collection fluid was then assayed for virus  $\Phi$ X174 infectivity The virus penetration test determined the amount of virus originally present in the glove penetrated through the punctured finger into the collection

TABLE 1. PROFILE OF GLOVES USED IN THE STUDY

Gloves	Size	Estimated age of the gloves (years)	Glove finger texture	Forefinger thickness (mm)	Powder content (mg/glove)
V -1	Medium	3	Smooth	0.15	9
V -2	Small	3	Smooth	0.19	82
V -3	Medium	ND	Smooth	0.14	<1
N -1	Medium	0.5	Smooth	0.16	<1
N -2	Small	2	Smooth	0.13	4
N -3	Medium	1	Textured	0.18	<1
N -4	Medium	ND	Textured	0.16	<1
NR-1	Medium	1	Smooth	0.18	3
NR-2	Medium	1	Smooth	0.17	9
NR-3	Medium	1	Textured	0.22	3
NR-4	Small	2	Smooth	0.16	<1

Note: V= vinyl; N= nitrile and NR= natural rubber gloves

ND: Not determined

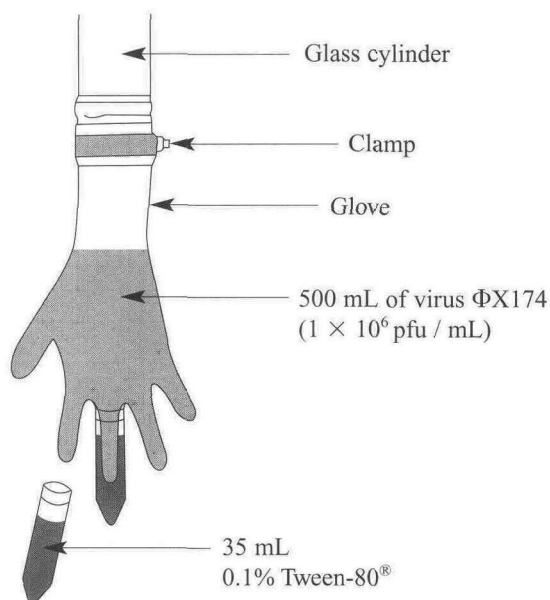


Figure 1. Water leak and virus penetration tests.

tube The limit of detection using this method was an equivalent virus suspension penetration of about 0.02  $\mu\text{L}$  (or 18 pfu) Virus assay was performed for a virus suspension leak of < 2.5 mL, above which the amount was measured volumetrically

### Physical Properties

The modulus at 300% extension and the tear strength from trouser tear were determined according to standard test methods of ISO 37 and ISO 34, respectively

### Scanning Electron Microscope

The tear sections were cut from the gloves and mounted on specimen stubs using double-sided tape, sputter-coated with gold and examined under a scanning electron microscope (JEOL JSM-5300)

and NR gloves were punctured with needles of diameters varying from 0.22 mm to 0.45 mm. The amount of virus leak with the extent of water leak was determined

The amount of virus suspension penetrating the punctured fingers of vinyl, nitrile and NR gloves, which showed no visible water leak (level 0) varied from <0.02  $\mu\text{L}$  to 2  $\mu\text{L}$  with the average amount ranging from 0.2  $\mu\text{L}$  to 0.5  $\mu\text{L}$  (Table 2). The amount from punctured fingers that leaked water at the lowest detectable level (level 1+) was higher, ranging from 1  $\mu\text{L}$  to 9  $\mu\text{L}$  and with an average of 2.4  $\mu\text{L}$  to 3.9  $\mu\text{L}$  (Table 2). As 60 to 90% of these fingers leaked > 2  $\mu\text{L}$  and the fact that the maximum virus leak undetected by the water leak test was 2  $\mu\text{L}$  it could be deduced that the maximum virus suspension penetrating through punctured fingers, which passed the current 500 mL water leak test was 2  $\mu\text{L}$ . Furthermore the amount of virus penetration at the two levels of water leak was independent of the glove materials

Similar amount of  $\Phi\text{X174}$  virus suspension was observed by Kotilainen *et al.*<sup>8</sup> to penetrate through punctured NR glove fingers, which passed the one litre water leak test. This indicated that there was not much difference in conformation or hydrostatic pressure in the glove fingers between 500 mL or 1000 mL of water

## RESULTS AND DISCUSSION

### Virus Penetration through Punctured Gloves

*Correlation of the amount of virus penetration with the extent of water leak* The middle and forefingers of different brands of vinyl, nitrile

TABLE 2. AMOUNT OF VIRUS SUSPENSION PENETRATED THROUGH TWO LEVELS OF WATER LEAKS IN PUNCTURED FINGERS OF VINYL, NITRILE AND NR GLOVES

Gloves	Amount of penetrated virus suspension ( $\mu\text{L}$ ) <sup>a</sup>	
	Water leak (0) level	Water leak (1+) level
Vinyl	0.5 (0.1–1.0)	2.4 (1–8)
Nitrile	0.2 (<0.02–1.0)	3.4 (1–9)
NR	0.5 (<0.02–2.0)	3.9 (1–7)

<sup>a</sup> Mean value presented, with the minimum to maximum value in parentheses

*Failure rate of punctured gloves to 500 mL water leak test.* Failure of gloves to the 500 mL water leak test was determined by the presence of water beads at the vicinity of punctured holes after 2 min of filling the gloves with 500 mL of virus suspension or by asserting the amount of virus suspension collected after 1 h to be  $>2 \mu\text{L}$ . For this evaluation, the thumb, index and middle fingers of vinyl, nitrile and NR gloves were punctured at random with needles of different diameters. Assessment on percentage failure was based on the number of failed fingers over the total fingers tested.

Results in *Table 3* show that vinyl and nitrile gloves were vulnerable to needle puncture. Vinyl gloves showed 78% failure with acupuncture needle of diameter as small as 0.22 mm and 100% failure with all needles of greater or equal to 0.3 mm diameter. Nitrile gloves showed 53% failure when punctured with acupuncture needle of 0.22 mm diameter and 100% failure with all needles of greater or equal to 0.4 mm diameters. NR gloves on the other hand exhibited a higher tolerance to puncture with acupuncture needles. None failed with 0.22 mm nor with 0.25 mm acupuncture needles and  $<20\%$  failed with bigger acupuncture needles of 0.3 mm to 0.35 mm. With the smallest syringe needles of 27G (0.4 mm) and 26G (0.45 mm) about 50% to 70% of NR gloves failed the test whereas vinyl and nitrile gloves registered a 100% failure. Failure with this 500 mL virus suspension test indicated a virus leak of  $>2 \mu\text{L}$ .

*Virus leak through 26G syringe needle puncture.* The forefingers of thirteen gloves from each brand of vinyl, nitrile and NR gloves were punctured with 26G needle and the amount of virus leak determined.

Puncture with the 26G needle, which is one of the smallest syringe needles commonly

used in healthcare sector, resulted in a serious leak of more than 2.5 mL in 3 brands of vinyl and 4 brands of nitrile gloves (*Table 4*). The amount of virus leak from these gloves averaged from 3 mL to 22 mL. The 4 brands of NR gloves, on the other hand, leaked less averaging from 0.013 mL to 0.023 mL. This could not be largely attributed to the differences in the size, age, finger thickness, texture or powder content of the gloves as they were carefully chosen so as to minimise the differences in these properties (*Table 1*). In fact one brand of vinyl gloves (V-2) with the highest powder content and thick fingers leaked more virus than NR gloves (NR-3) with low powder content and equally thick fingers. The presence of powder could have blocked the puncture defects to some extent and thus minimised the level of virus leak, as reported<sup>12</sup>. The vast difference in the amount of virus penetration between the NR and synthetic gloves could stem from the different formulations used to manufacture the gloves. NR gloves thus stood above vinyl and nitrile gloves in allowing very low level (about  $10^2$  lower) of virus suspension penetrating through the punctured holes or tears.

It is appropriate to consider the implications on the HIV and HBV infection with the different levels of virus penetration through punctured vinyl, nitrile and NR gloves. For HBV, which has very high titers in blood and has high infectivity, the volume of exposure to fluid may be less important than the number of exposures to any amount of fluid, no matter how small<sup>13</sup>. HIV, the AIDS virus, has low infectivity and has much lower titer in blood than HBV<sup>13</sup>. Thus exposure to a relatively large volume of blood is required for its transmission. With the high volume of virus leak through punctured vinyl and nitrile gloves compared to punctured NR gloves, it could be expected that the risk of infection to HIV with

TABLE 3. PERCENTAGE FAILURES OF GLOVE FINGERS PUNCTURED WITH NEEDLES OF DIFFERENT DIAMETERS TO THE 500 ML WATER LEAK TEST

Gloves	% Failures at different needle diameters					
	0.22 mm	0.25 mm	0.3 mm	0.35 mm	0.4 mm	0.45 mm
Vinyl	78	89	100	100	100	100
Nitrile	53	78	80	92	100	100
NR	0	0	14	18	47	67

TABLE 4. TEAR STRENGTH, MODULUS AND AMOUNT OF VIRUS SUSPENSION THROUGH VINYL, NITRILE AND NR GLOVES PUNCTURED WITH 26G SYRINGE NEEDLE

Gloves	Virus leak (mL)	Tear resistance (N/mm)	Modulus M300 (MPa)
V -1	18	6	9.4
V -2	10	4	7.4
V -3	3	5	11.5
N -1	22	5	2.9
N -2	8	4	2.8
N -3	10	5	4.7
N -4	11	5	4.6
NR-1	0.014	24	1.4
NR-2	0.023	22	1.4
NR-3	0.021	20	2.2
NR-4	0.013	22	2.3

these two gloves would be markedly higher than with NR gloves.

2.8 MPa to 4.6 MPa for nitrile and 7.4 MPa to 11.5 MPa for vinyl gloves.

### Physical Properties of Gloves

Needle puncture is reported to produce a tear in the latex membrane<sup>14</sup>. This prompted an evaluation of the tear strength resistance and the elastic modulus of NR, vinyl and nitrile gloves (Table 4). Characteristic of NR, the NR gloves showed high tear strength of 20 N/mm to 24 N/mm, about five times higher than that of vinyl and nitrile gloves. The two synthetic gloves recorded tear strength resistance in the range of 4 N/mm to 6 N/mm. The NR gloves also exhibited a low modulus of 1.4 MPa to 2.3 MPa compared to the higher modulus values of

The low elastic modulus of NR glove enabled it to stretch partially over the needle rather than tear. This together with the high tear strength resistance could have resulted in a shorter tear or crack propagation in the punctured NR gloves. Lytle *et al.*<sup>14</sup> showed that the needle puncture of NR latex membrane produces a tear length of 35% to 77% of the diameter of the needle. Thus a puncture with 0.22 mm needle, the smallest acupuncture needle used in the study, could presumably result in a tear of 77  $\mu$ m to 170  $\mu$ m long. This is bigger than the 40  $\mu$ m diameter of the smallest finger hole in NR gloves detectable by water leak test. With the expansion under hydrostatic pressure during the virus penetration

test the tear would be expected to allow virus penetration. The fact that there was no water or virus leak in a number of NR gloves at this puncture size and bigger implied that the tear slits were essentially closed. Microscopic study by Lytle *et al.*<sup>14</sup> reveals no incidence of open holes with small puncture (0.12 mm needle) tears of latex condoms under relax condition, not under the pressure of the virus penetration test. The recent scanning electron micrograph of the glove membrane, which had been subjected to the pressure of virus penetration test, recorded a similar observation. The micrograph (Figure 2) of the tear from NR glove punctured with syringe needle taken after the 1 h virus penetration test showed no open tear but tear slit which was apparently closed. The absence of open slit in puncture tear of NR glove could be due to the ability of NR glove to reseal, a characteristic of NR gloves that has been well appreciated with

regards to the good barrier performance of the gloves on puncture<sup>15</sup>. This resealing effect and the high tear strength of NR gloves could explain the exceptionally low level of virus penetration through punctured NR gloves compared to the synthetic alternatives.

The low tear strength and the inability of vinyl and nitrile gloves to reseal, on the other hand, could be the factors inducing opened tears in their punctured gloves as observed in the scanning electron micrographs (Figures 3 and 4). Presumably, it is due to the opened tear that the level of virus penetration through the two punctured gloves was prominently higher than through the NR gloves. In fact it has been postulated that a change in the extent to which the narrow tear slit is stretched open will be much more important for virus penetration than a proportional change in the length of tear<sup>14</sup>.

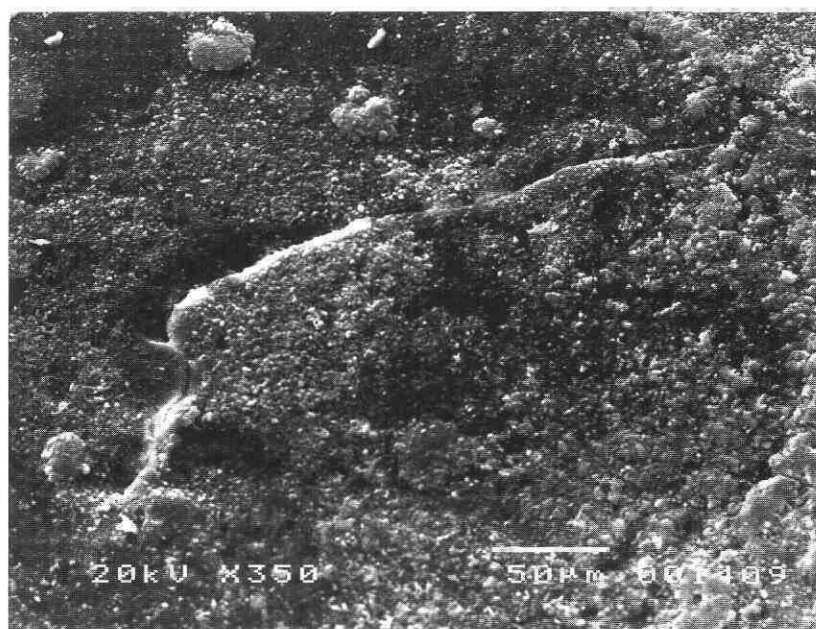
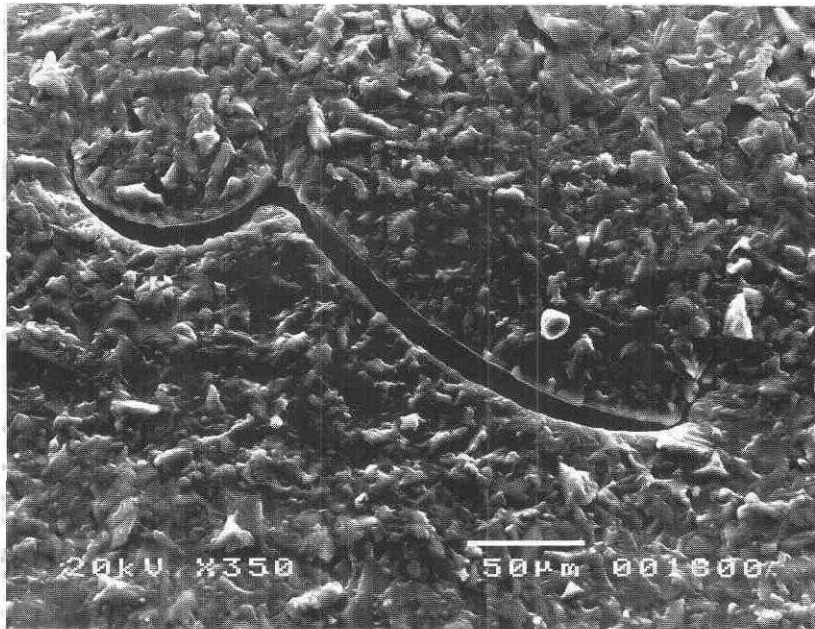
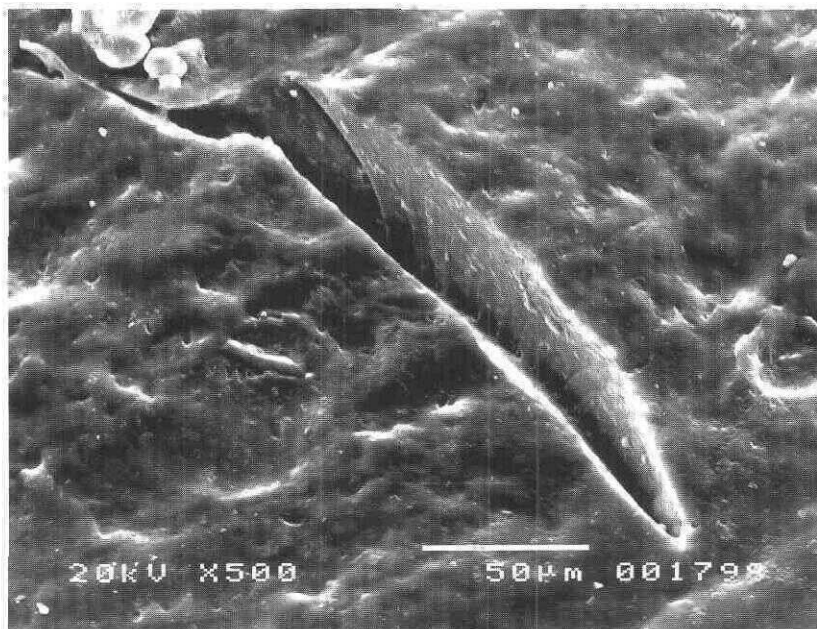


Figure 2: Scanning electron micrograph of the tear from punctured NR glove.



*Figure 3: Scanning electron micrograph of the tear from punctured vinyl glove.*



*Figure 4: Scanning electron micrograph of the tear from punctured nitrile glove.*



## CONCLUSION

The water leak test revealed the better performance of NR gloves compared to the synthetic gloves. NR gloves registered zero failure when punctured with 0.22 mm to 0.25 mm acupuncture needles. With 27G and 26G syringe needles, NR gloves showed a failure rate of 50% to 70%. Vinyl and nitrile gloves, however, showed a 100% failure with even smaller needles of 0.3 mm and 0.4 mm diameter, respectively. Failure in the water leak test indicated a virus penetration of > 2 µL.

Puncture with one of the smallest syringe needle of 26G (0.45 mm) showed serious leaks in vinyl and nitrile gloves. Both gloves leaked > 2500 µL of the virus suspension whereas NR glove leaked < 25 µL. Hence the risk of infection with punctured vinyl and nitrile gloves will be markedly higher than with punctured NR gloves.

The low virus leak from punctured NR gloves was observed to be associated with their apparently closed tear slits and good elastic property; low modulus values and high tear strength.

## ACKNOWLEDGEMENTS

The authors would like to thank the Ministry of Science, Technology and Environment for funding the study under the IRPA (Intensification of Research Priority Areas) grant. Special thanks to Dr Lai Pin Fah, Dr Azemi Samsuri and Dr Shahnaz Murad for all the help given. The skilled technical assistance of Mohd Yusof Rais and Abdul Karim and the co-operation of some Malaysian glove manufacturers and Grahame Jones of Vectra Pty Ltd are greatly appreciated.

*Date of receipt: September 2003*  
*Date of acceptance: November 2003*

## REFERENCES

1. BELTRAMI, E.M., WILLIAMS, I.T., SHAPIRO, C.R. AND CHAMBERLAND, M.E. (2000) Risk and Management of Blood-borne Infections in Health Care Workers. *Clinical Microbiology Reviews*, **13**, 385–407
2. NUTTER, A.F. (1979) Contact Urticaria to Rubber. *Br. J. Dermatol.*, **101**, 597.
3. TURJANMAA, K. (1987) Incidence of Immediate Allergy to Latex Gloves in Hospital Personnel. *Contact Dermatitis*, **17**, 270.
4. DALGLEISH, A.G. AND MALKOVSKY, M. (1988) Surgical Gloves as a Mechanical Barrier against Human Immunodeficiency Viruses. *Br. J. Surg.*, **75**, 171–172.
5. ZBITNEW, A., GREER, K., HEISE-QUALTIERE, J. AND CONLY, J. (1989) Vinyl versus Latex Gloves as Barriers to Transmission of Viruses in Health Care Setting. *J. of Acquired Immune Deficiency Syndromes*, **2**, 201–204
6. KORNIWICZ, D.M., KIRWIN, M., CRESCI, K. AND LARSON, E. (1993) Leakage of Latex and Vinyl Exam Gloves in High and Low Risk Clinical Settings. *Am Ind Hyg Assoc. J.*, **54**, 22–25.
7. REGO, A. AND ROLEY, L. (1999) In-use Barrier Integrity of Gloves: Latex and Nitrile Superior to Vinyl. *AJIC.*, **27**, 405–410.
8. KOTILAINEN, H.R., CYR, W.H., TRUSCOTT, W., GANTZ, N.M., ROUTSON, L.B. AND LYTLE, C.D. (1992) Ability of 1000 mL Water Leak Test for Medical Gloves to Detect Gloves with Potential for Virus Penetration, *Performance of Protective Clothing* (McBriarty and Henry, N.W. eds.) pp. 38–48. Fourth

Volume, *ASTM STP 1133* Philadelphia *Am Soc Tests and Materials*

- 9 LYTLE, C D, TRUSCOTT, W, BUDACZ, A P, NENEGAS, L, ROUTSON, L B AND CYR, WH (1991) Important Factors for Testing Barrier Materials with Surrogate Viruses *Appl Environ Microbiol* **57**, 2549–2554
- 10 LYTLE, C D AND ROUTSON, L B (1995) Minimized Virus Binding for Tests of Barrier Materials *Appl Environ Microbiol* , **61**, 643–649
- 11 LYTLE, C D, BUDACZ, A P, KEVILLE, E, MILLER, S A AND PRODOUZ, K N (1991) Differential Inactivation of Surrogate Viruses with Merocyanine 540 *Photochem Photobiol* , **54**, 489–493
- 12 MEHTA, R I, LYTLE, C D AND ROUTSON, L B (1998) The Cause of Cessation of Viral Passage through Artificially-induced Holes in Latex Condoms *J Rubb Res* , **1**, 1–13
- 13 CAREY, R F AND LYTLE C D (1997) Should Medical Gloves be Subjected to More Strenuous Quality Assurance Testing? *Rubber Asia*, **11**, 69–70
- 14 LYTLE, C D, ROUTSON, L B, THOMAS, D P, REGNAULT, W F AND CYR, WH (1996) Two Parameters Limiting the Sensitivity of Laboratory Tests of Condoms as Viral Barriers *J Testing and Evaluation*. **24**, 279–28
- 15 KORNIEWICZ, D M (1997) Intelligently Selecting Gloves *Surgical Service Management*, **3**, 13–15