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Lack of Latex Porosity: A Review of Virus Barrier Tests

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Evidence regarding whether latex films as found in condoms and medical gloves are effective barriers to virus passage is reviewed, together with new data from additional tests The primary focus was to determine whether latex films are porous as opposed to having occasional defects The published and new evidence from studies using viruses are consistent only with the presence of occasional defects, and are not consistent with porosity sufficient to allow virus passage However, quality control of manufactured products based on acceptable quality levels using standardised tests does not guarantee that every sample is perfect The risk of a specific product is related to the defect rate, the use situation, and the disease of interest, in particular the quantity of virus-carrying fluid needed to constitute an 'infectious dose ' The possibility of latex film hydration leading to porosity to virus passage was also found to be unlikely and not supported by data

The importance of latex films as barriers to disease transmission continues to motivate the development of adequate testing of its barrier integrity There are standardised quality assurance (QA) tests for the two primary products, condoms and medical (examination and surgical) gloves, which use a visually-detectable water leak as the test endpoint for barrier integrity[1,2] Since these QA tests are only capable of detecting at best holes of 3 μm diameter for condoms[3] or 25 μm for gloves[4,5] and since human viruses are very much smaller (0 03 μm – 0 30 μm)[5,6] than these QA test-detectable holes, additional tests have been developed to evaluate their barrier effectiveness to virus passage[7–19] Some of the tests have used viruses as challenge probes[7–14,16,18], others have used fluorescent microspheres[15,19], and even others microscopy[20] The studies that utilised viral probes have indicated that latex films are effective barriers However, three studies, using other probes or techniques, call into question the barrier effectiveness of latex condoms or gloves[19–21] These disparate results have motivated further tests with viruses The purpose of this review is to present the key published information for comparison purposes, to present the results of additional testing, and to summarise the current state of knowledge

As a starting point for discussion, it is important to define and distinguish between porosity sufficient to allow virus permeation through a membrane and occasional defects that allow virus penetration through the membrane Porosity is a property of the

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material in general and allows passage (permeation) of fluids and particles through interstitial spaces between the solid components of the membrane or film It is expected to be at least roughly similar from one sample to another of a specific product, that is, all samples of a given formulation would demonstrate the same level of porosity Porosity can be envisioned as arising from a high density of very small holes Defects, on the other hand, would occur occasionally and would consist of holes likely varying greatly in size and shape, depending on their cause(s) These occasional defective samples with holes would allow varying levels of virus passage (penetration) from one sample to another With adequate QA controls, defects should be infrequent, such that most samples would not allow virus passage Inadequate QA controls may allow enough defects to occur that they can be considered a property of the material in general, *i e , de facto* porosity In this case, test results would frequently, or even usually, demonstrate apparent porosity Inhomogeneity in the membrane, of course, might conceivably result in porous and/or otherwise defective areas interspersed with non-porous, non-defective areas

Condoms

The first level of evidence for the barrier effectiveness of latex condoms was clinical they demonstrate efficacy for preventing disease and pregnancy[22] Lack of proper use is considered the primary reason for failure[22 24] Laboratory tests of latex membranes as virus barriers were conducted first on condoms[7 8] The initial studies indicated barrier effectiveness, but were typically done with low numbers of samples and with low or undefined levels of test sensitivity (*i e* , the level of virus penetration that could just be detected in that particular test protocol)[7–12] The U S FDA laboratories developed tests that provided careful control over several important test parameters, allowing extrapolation of results to expected actual-use conditions[15 16 18 21 25] The virus test, in which the entire condom surface is challenged by a virus (ΦX174, 0 027 μm diameter) suspension under pressure (1 15 p s i) for 30 min (conditions more stringent than those expected in actual use), could detect holes as small as 2 μm in diameter[18] The results indicated that few latex condoms allowed virus penetration[26] A summarised form of this study is presented in *Table 1* Important among the results were (i) a low frequency of failure (2 6%[26]) and (ii) a wide range of virus penetration (~10^6-fold[26]) Overall, these tests indicated a lack of porosity and infrequent defects, based on the low number of samples that allowed any level of detectable virus passage Corroborating evidence comes from tests of condom integrity with small dye molecules[27–29], *e g* , bromophenol blue (0 0005 μm) did not pass through 21 latex condoms in 150 min[27]

One more aspect of these data should be mentioned the number of condoms that allowed virus passage in this laboratory test was higher than would be expected from the Acceptable Quality Level (AQL, 0 4%) because the virus test can detect smaller holes than can the AQL water leak test[25] An important issue here is that the amount of virus penetration that can occur through the holes that are undetectable by the water leak test is lower by one or more orders of magnitude from that through the water-leak detectable holes, for condoms and gloves[25 30] For risk-assessment purposes, the importance

of virus passage depends on the 'infectious dose' which is specific for individual virus types (see below) The overall conclusion is that while a low proportion (<0 2%) of condoms may allow passage of an infectious dose in semen of a low titer, low-infectivity virus (*e g*, HIV, the AIDS virus), a larger proportion (~1 3%) may allow passage of an infectious dose of a high titer, high-infectivity virus[25]

ASTM Test Method F1671[31] (Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System) is used to determine whether materials used in medical barrier clothing, such as surgical gowns or drapes, are effective barriers to virus passage The method determines whether the small virus may pass through a 25 cm^2 test material specimen under conditions that include 2 p s i pressure for 60 s This test method can detect a single 1 µm hole in condom latex films with laser-drilled holes[32], no virus passage was found in control samples with no intentional defects (*Table 1*)

These virus passage methods can detect smaller holes, but only if there are many of them For example, results with the *F1671* test[32] indicate that the Poiseuille model of fluid flow through a cylindrical hole (fluid flow rate is proportional to the radius of the hole to the fourth power)[33], althouth derived for much larger holes, still holds for holes as small as 2 µm diameter It is expected that it would hold for even smaller holes, although there is at present no way to produce cylindrical holes of diameter less than 2 micron to test the model If the Poiseuille model is valid for virus-size holes, the r^4 relationship indicates that for 0 10 µm holes (diameter of HIV) to be minimally detectable there would have to be at least 10^4 such holes in the test sample

Gloves

Tests of virus (ΦX174) penetration or permeation through latex gloves have yielded similar outcomes to those of latex condoms with a difference in the frequencies of holes (5 8% of tested fingers, see *Table 1*)[34], probably a result of a higher AQL[1] Thus, there is evidence of occasional defects, but not porosity

Recently, a more stringent test was developed for samples taken from the palms or backs of latex gloves[35] In this case, samples were stretched to 9 times their original area and then tested for virus (ΦX174) passage under low pressure The three-phase test[35] [(i) water leak visible on paper towel, (ii) virus passage onto agar plate for location of small leak, and (iii) virus passage into collection buffer for quantitation of leak] could determine where any virus passage occurred and how much It could detect virus passage through laser-drilled 2 µm holes in unstretched latex, and since stretching the material would stretch a hole (9× or more) and produce a much thinner film, it is expected that even smaller holes should be detectable No virus passage was found in any glove sample, nor in specially-formulated latex films (having different sources of high-ammoniated latex concentrate, different levels of non-rubber constituents, different modulus, either post-vulcanisation or prevulcanisation, or different leaching processes and, in addition, some being artifically aged at 70°C)(see *Table 1*) Thus, permeation through quite thin, stretched samples with this very sensitive test was not

TABLE 1. RESULTS OF VIRUS PENETRATION TESTS OF LATEX PRODUCTS AT DIFFERENT PRESSURES AND DURATIONS

Test protocol	Latex product	# Samples tested	# Samples failed	Test parameters Pressure (p.s.i)	Duration (min)	Detection limit (mL)	Ref
Whole condom							
	Condom	60	3	1.15	30	$<1 \times 10^{-4}$	16
	Condom	470	12	1 15	30	$<2 \times 10^{-6}$	26
Glove fingers							
		588	34	0 43–0 54	60	$<2 \times 10^{-5}$	34
9× Stretched samples*							
	Films from special formulations						
		20	0	0.03	15	$<5 \times 10^{-6}$	35
	Glove	6	0	0 03	15	$<5 \times 10^{-6}$	35
Modified *ASTM F1671*							
	Condom	3	0	2.0	1	$<2 \times 10^{-8}$	32
	Glove	12	0	2.0	1	$<4 \times 10^{-8}$	N
	Glove	58	4	2 0	1	$<2 \times 10^{-8}$	N**
	Condom	5	0	2 0	5	$<4 \times 10^{-8}$	N
	Glove	6	0	5 0	120	$<3 \times 10^{-8}$	N
	Condom 4× stretch*	1	0	5.0	120	$<5 \times 10^{-8}$	N
	Glove 4× stretch*	1	0	5.0	120	$<4 \times 10^{-8}$	N

N: New data, not previously published

*Samples were stretched in area the designated amount, yielding a thinner test sample whose pores or holes, if any, should also be larger by the designated amount.

**One-third of the samples had been artificially aged for 7 days at 70°C, one-third for 14 days

found. This is interpreted to mean that there are few, if any, pores or holes through unstretched latex films large enough to allow virus passage in a reasonable time

A single example of porosity to virus (ΦX174) passage through latex gloves has been found in our laboratory over the past decade. A defective lot of unusually low modulus gloves was found to fail the water leak test in an unusual manner. it 'wept' in a broad area that was greatly stretched, apparently allowing water passage through many holes or pores in that area. When the glove was 'challenged' with virus-containing buffer, virus was found in the 'weepage' at a titer nearly as high as in the challenge suspension inside the glove All eleven gloves challenged were found to allow

passage of the small virus, but not a large virus (herpes simplex virus, 130 nm diameter) No other example of latex porosity to viruses has been found in any other latex products tested in this laboratory

Contradictory Evidence

A few studies have been reported concluding that latex membranes in unused manufactured products (condoms or gloves) may be porous to virus passage Arnold *et al* reported in a brief note in *Nature*[20] that in freeze-fractured sections of latex gloves 'tortuous channels (5 μm) penetrated the entire thickness of the glove' It was implied that such a defect was common and that it was an inherent property of the material before freeze-fracturing We are not aware of any corroborating reports

Two studies utilising fluorescent microspheres have suggested either a high defect occurrence rate or porosity in latex films The polystyrene microspheres were 0 10 μm – 0 11 μm in diameter (size of HIV) and used fluorescent dyes (rhodamine or fluorescein) as the indicator Carey *et al*[21] concluded that enough fluorescent (rhodamine) signal was detected above background signal to indicate that 29 of 89 latex condoms allowed passage of the microspheres The parameters of their test protocol (pressure, duration, use of restrainer to limit expansion under pressure, *etc* [15]) were used to design the virus-based tests used by Lytle *et al* [16 18] No further studies have been published using this method incorporating fluorescent microspheres and trans-membrane pressure

Recently, another report (Roland *et al*, of the U S Naval Research Laboratory[19]) suggested even higher defect rates or porosity, also in condom latex samples The test sample was placed over a diffusion cell containing a suspension of fluorescent (fluorescein-labelled) microspheres in distilled water The loaded cell was then inverted and placed in more water to collect any microspheres that passed through the latex sample The smaller 0 10 μm microspheres passed through one sample much faster (many within an hour, more over 24 h) than 1 0 μm microspheres passed through a different sample, qualitatively consistent with diffusion through either a single large hole or many smaller holes With only two samples reported on for each microsphere size, it is not known how common this phenomenon is A single attempt in our laboratory (with the assistance of Dr M J Schroeder, NRL) to repeat this with a small virus (ΦX174) and 0 10 μm microspheres showed no passage at 1, 2, or 24 h for either particle

This leaves the question of whether the experiments using microspheres led to false positive results regarding particle passage or whether those using viruses, particularly those with ΦX174, led to false negative results One theoretical possibility was that the virus particles adsorbed to the latex (thereby leading to negative results in the presence of holes) but the microspheres did not Experimental data, however, yield the opposite results the microspheres do adsorb to latex[36], but ΦX174 adsorbs little, if any[37] Another possibility is that the fluorescent dye comes loose from the microspheres (perhaps as a result of chemical interactions among the supporting buffer, the microspheres and the latex film) and permeates through pores too small to allow virus or microsphere passage Attempts to detect free fluorescein dye after microsphere contact with latex (passage through a long channel lined with latex) have been unsuccessful[36] Thus,

properties of the microspheres do not explain the discrepancy in the penetration results with viruses and microspheres A third possibility is that the exposure of the latex to the buffer results in elution of chemicals from the latex into the buffer that yields a misleading fluorescence[15,36] that has been incorrectly attributed to microspheres having passed through the latex barrier

Newer Tests

Higher pressure, longer duration While the methods developed for condoms, gloves and stretched pieces of latex can detect single, small holes, use of higher pressure and/or longer duration should be even more convincing The apparatus for the *ASTM F1671* test[31] can be used at pressures of 1 p s i – 5 p s i for any length of time Many samples of latex gloves have now been tested at 2 p s i for 1 min and some, including a 4×-stretched sample, at 5 p s i for 2 h, with 4 of 77 samples showing only minimal evidence of virus passage (*Table 1*) Samples of condom latex have also been tested (*Table 1*) with similar results If the Poiseuille relationship holds as expected, the tests at 5 p s i for 2 h should be able to detect a single hole of 0 24 μm diameter [or 33 holes of 0 10 μm (HIV size), or 1066 holes of 0 042 μm (hepatitis B virus size)]

Long diffusion times Diffusion through condoms has now been tested over extended periods of time These experiments consisted of placing 8 mL of a high-titer suspension of ΦX174 in buffer with a surfactant (0 1% *Tween 80*) to minimise any low level adsorption that might be possible at such long exposures and submerging most of the condom in 50 mL of similar buffer with surfactant to collect any virus that passes through the condom 60%–70% of the condom surface was tested The results are shown in *Table 2* No evidence of diffusion was found, even after 16 days!

Hydration and Porosity

Hydration has been thought to affect latex porosity in two opposing ways In the past some investigators have supposed that hydration results in swelling of the latex structure, thereby causing holes to shrink in size Mehta and Lytle[38] found that over one hour no such shrinkage was discernable by light microscopy for holes in the 11 μm – 32 μm diameter range The change of diameter was less than 3%, indicating neither a measurable decrease or increase Other data with condoms suggest that even smaller holes do not close in several minutes (*e g*, virus passage rate through a 2 6 μm hole did not change over 7 min)[38] However, we know of no evidence regarding whether holes less than 1 μm still might change dimensions

The possibility that hydration can lead to virus passage has been proposed to account for the passage of viruses (ΦX174) through gloves[39,40] This amounts to an argument for permeation of viruses virus-carrying fluid hydrates the latex through interstitial pores, carrying the virus through the latex membrane For pores large enough to allow virus passage, such hydration would take place quickly (<1 min) One can deduce this from considering capillary flow (*i e*, surface tension-based wetting) that would provide the hydration in those pores The relationship between capillary flow and pore radius[41] is given by

$$dl/dt = r\gamma \cos\theta/4\eta l \qquad 1$$

TABLE 2 TESTS OF DIFFUSION OF ΦX174 THROUGH LATEX CONDOMS

# Tested	# Failed*	Length of test (day)
34	0	1
28	0	2
25	0	3
21	0	7
14	0	15
4	0	16

*Test sensitivity capable of detecting virus passage equivalent to passage of $>5 \times 10^{7}$ mL challenge suspension

where r is the pore radius, η is the fluid viscosity, γ is the surface tension at the fluid/latex interface, l is the distance travelled, and θ is the contact angle between the fluid and latex (related to surface tension) For pores just large enough to allow passage of very small viruses (*e g* , 0 026 μm, so $r = 0\ 013\ \mu m = 1\ 3 \times 10^{-6}$ cm) through a typical thickness of latex film (ℓ = 80 μm = 0 008 cm) with buffered physiological saline [η = 0 01 dyne sec/cm^2, γ = 72 9 dyne/cm, and typical θ = 85° (range 81°–89°)(ref)][3 42], the speed of the advancing fluid, dl/dt, is calculated to be 0 026 cm/sec (range 0 005–0 46) or 260 μm/sec And a pore just large enough to allow passage of HIV would yield an advancing-fluid speed of 1000 μm/sec Thus, pores large enough to allow virus passage would fill quickly and deliver viruses across the latex film in less than a second if the pores were straight and in less than a minute if the pores followed tortuous paths The amount of virus passage would, of course, depend on the number of such pores and the concentration of virus Since virus passage is not normally detected (even over weeks[1]), one must deduce that there are few, if any, pores that could allow virus passage

CONCLUSION

Recent virus passage results from more stringent tests are consistent with earlier, published results, confirming that condom and glove latex films are not normally porous and do not normally have many holes Regarding the few studies that have produced data contradicting this conclusion, it could be that the test samples were unusually defective, perhaps a result of inappropriate storage conditions, or that some confounding factor was not accounted for

This does not mean that the manufactured products are perfect Some manufacturing defects occur because the finite AQL's allow a certain level of imperfection These are thought to be reasonably controlled with appropriately chosen AQL's for water leak-detectable holes[1 2]

There may still be holes large enough to allow virus permeation that would not be detectable by any of the mentioned tests However, the Poiseuille relationship (fluid flow proportional to r^4) tells us that the amount of

passage would be exceedingly small That is, virus penetration through detectable defects is much more important, with tears during use being first in importance and then manufacturing defects (detectable by the water leak tests) The risk of virus passage is greatest through holes that are water leak-detectable (holes and tears created during use probably fall primarily in this category)[25 30], then those detectable only with a virus passage test, and finally those not detected by any presently-available test The difference of risk between these categories is orders of magnitude for viruses of low titer and low infectivity (see below)[25] The difference is less for viruses of high titer and high infectivity

The AQL tests and the virus passage tests were static and did not include motion of the test film It is possible that some additional holes could be detected with motion or that more virus would penetrate holes that allow some virus passage when still However, it is thought that any additional virus passage would not significantly change the primary conclusions reached in this review

What amount of virus passage (by permeation and/or penetration) is of concern? That is, what constitutes an 'infectious dose?' That depends on the titer (concentration) and infectivity of the virus in question and on the route of exposure For example. HIV (the AIDS virus) has low infectivity (probability of disease from one virus particle) and has low titer in semen[43 44], so exposure through a latex condom to a relatively large volume (probably more than 0 1 mL) of semen is required for disease transmission during sexual intercourse On the other hand, hepatitis B virus has high infectivity and high titer[45], so that an infectious exposure could be much less (perhaps 0 000 001 mL – 0 000 01 mL) An infectious dose from disease-carrying blood passed through gloves brings an additional consideration usually the skin of the individual wearing the glove is intact Intact skin is an excellent barrier to virus passage Non-intact skin (whether through abrasion, cuts, needle sticks, *etc*) is not and may permit passage into the body While the same overall considerations are valid regarding level of virus titer and infectivity, the levels of virus titer are normally much higher in blood than in semen[43–45] Thus the risk of disease transmission through different types and sizes of defects in latex products depends greatly on the virus of concern and the route of exposure

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REFERENCES

1 Department of Health and Human Services, Food and Drug Administration (1990) Medical Devices Patient Examination and Surgeons' Gloves, Adulteration, Final Rule *Federal Register*, **55**, 12 December 1990

2 PIERDOMINICI, V J B, JR DOUCETTE J M, BOIVIN, W S, AND NEUNABER, L M (1995) Water Leak Testing of Male Latex Condoms *Laboratory Information Bulletin*, **3970**

3 HERMAN, B A, CAREY, R F AND RINALDI J E (1993) Sensitivity of Water Leak Tests for Latex Condoms *J Test Eval*, **21**, 124–128

4 CAREY, R, HERMAN, W, HERMAN, B, KROP, B, AND CASAMENTO, J (1989) A Laboratory Evaluation of Standard Leakage Tests for Surgical and Examination Gloves *J Clin Eng*, **14**, 133–143

5 LYTLE, C D CYR W H, CAREY, R F, SHOMBERT D G, HERMAN, B A, DILLON,

J G, SCHROEDER, L W, BUSHAR, H F, AND KOTILAINEN, H J R (1994) Standard Quality Control Testing and Virus Penetration, *Protective Gloves for Occupational Use (Mellstrom, G A., Wahlberg, J E and Maibach, H.I eds)*, 109–127 Boca Raton CRC Press

6 LYTLE, C D, TONDREAU, S C, TRUSCOTT, W, BUDACZ, A P, KUESTER, R K, VENEGAS, L, SCHMUKLER, R E, AND CYR, W H (1992) Filtration Sizes of Human Immunodeficiency Virus Type 1 and Surrogate Viruses used to Test Barrier Materials *Appl Environ Microbiol*, **58**, 747–749

7 CONANT, M A, SPICER, D W, AND SMITH, C D (1984) Herpes Simplex Virus Transmission Condom Studies *Sex Trans Dis*, **11**, 94–95

8 KATZNELSON, S, DREW, W L, AND MINTZ, L (1984) Efficacy of the Condom as a Barrier to the Transmission of Cytomegalovirus *J Infect Dis*, **150**, 155–157

9 MINUK, G Y, BOHME, C E, AND BOWEN, T J (1986) Condoms and Hepatitis B Virus Infection *Ann Intern Med*, **103L**, 694–699

10 MINUK, G Y, BOHME, C E, AND BOWEN, T J (1987) Efficacy of Commercial Condoms in the Prevention of Hepatitis B Virus Infection *Gastroenterology*, **93**, 710–714

11 VAN DE PERRE, P, JACOBS, D, AND SPRECHER-GOLDBERGER, S (1987) The Latex Condom, an Efficient Barrier against Sexual Transmission of AIDS-related Viruses *AIDS*, **1**, 49–52

12 RIETMEIJER, C A M, KREBS, J W, FEORINO, P M, AND JUDSON, F N (1988) Condoms as Physical and Chemical Barriers against Human Immunodeficiency Virus *JAMA*, **259**, 1851–1853

13 LYTLE, C D, CARNEY, P G, VOHRA, S, CYR, W H, AND BOCKSTAHLER, L E (1990) Virus Leakage through Natural Membrane Condoms *Sex Trans Dis*, **17**, 58–62

14 KORNIEWICZ, D M, LAUGHON, B E, CYR, W H, LYTLE, C D, AND LARSON, E (1990) Leakage of Virus through used Vinyl and Latex Examination Gloves *J Clin Microbiol*, **28**, 787–788

15 RETTA, S M, HERMAN, W A, RINALDI J E, CAREY, R F, HERMAN, B A, AND ATHEY, T W (1991) Test Method for Evaluating the Permeability of Intact Prophylactics to Viral-size Microspheres under Simulated Physiologic Conditions *Sex Trans Dis*, **18**, 111–118

16 LYTLE, C D, ROUTSON, L B, AND CYR, W H (1992) A Simple Method to Test Condoms for Penetration by Viruses *Appl Environ Microbiol*, **58**, 3180–3182

17 CAREY, R (1994) A Different Air Deflation Quality Assurance Test for Surgical Gloves *J Test Eval*, **22**, 442–448

18 LYTLE, C D, ROUTSON, L B, DUFF, J E FLEHARTY, B, AND CYR, W H (1997) A Sensitive Method for Evaluating Condoms as Virus Barriers *J AOAC Intl*, **80**, 319–324

19 ROLAND, C M, CHOI, I S, AND SCHROEDER, M J (1998) Intrinsic Defect Effects on NR Permeability *Rubb Plast News*, January 12, 14–15

20 ARNOLD, S G, WHITMAN, J E, FOX, C H, AND COTTLER-FOX, M H (1988) Latex Gloves not Enough to Exclude Viruses *Nature*, **335**, 19

21 CAREY, R F , HERMAN, W.A., RETTA, R.S., RINALDI, J E.. HERMAN, B A , AND ATHEY, T.W. (1992) Effectiveness of Latex Condoms as a Barrier to Human Immunodeficiency Virus-sized Particles under Conditions of Simulated Use. *Sex Trans. Dis* , **19**, 230–234

22. GORDON, R (1989) A Critical Review of the Physics and Statistics of Condoms and their Role in Individual *versus* Societal Survival of the AIDS Epidemic. *J. Sex Marital Therapy*, **15**, 5–30

23. TRUSSEL, J., WARNER, D L , AND HATCHER, R. (1992) Condom Performance during Vaginal Intercourse: Comparison of Trojan-Enz and Tactylon Condoms *Contraception*, **45**, 11–15.

24 STEINER, M , PIEDRAHITA, C , JOANIS, C., GLOVER, L , AND SPRUYT, A. (1994) Condom Breakage and Slippage Rates among Study Participants in Eight Countries *Intern. Family Plan. Perspec.*, **20**, 55–58

25. CAREY, R.F., LYTLE, C D , AND CYR, W H. (1999) Implications of Laboratory Tests of Condom Integrity *Sex Trans. Dis.*, (in press)

26 LYTLE, C.D , ROUTSON, L B , SEABORN, G.B., DIXON, L.G., AND CYR, W.H. (1997) An *in vitro* Evaluation of Condoms as Barriers to a Small Virus *Sex Trans. Dis.*, **24**, 161–164

27. RETTA, S.M., AND SAGRIPANTI, J.L. (1988) A Permeability Study of Latex and Natural Membrane Condoms *Proceedings of the 14th Annual Northeast Bioengineering Conference, Durham, NH, March 10–11*, 104–106.

28. JAY, G.D., DRUMMOND, E , AND LANE, B. (1992) Altered Surface Character of Stretched Condom Latex *Contraception*, **45**, 105–110

29 GUTTMAN, C M (1987) Flow of Molecules through Condoms *National Bureau of Standards*, Report *NBSIR 88–3721*, Gaithersburg, MD.

30. CAREY, R F , AND LYTLE, C.D. (1997) Should Medical Gloves be Subjected to more Strenuous Quality Assurance Testing? *Rubber Asia*, **11**, 69–70.

31. AMERICAN SOCIETY FOR TESTING AND MATERIALS (1995) Test Method for Resistance of Materials used in Protective Clothing to Penetration by Blood-borne Pathogens using Phi-X174 Bacteriophage Penetration as a Test System. *ASTM F1671–95*. Philadelphia American Society for Testing and Materials

32. BAKER, K.H., AND LYTLE, C D. (1999) Ability of a Viral Penetration Test (*ASTM F1671–95*) to Detect Small Holes. *J. Test. Eval.*, (in press).

33. WHITE, F.M. (1974) *Viscous Fluid Flow*, McGraw-Hill, p. 121.

34. 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 Potential for Virus Penetration, *Performance of Protective Clothing: Fourth Volume, ASTM STP 1133 (McBriarty, J.P. and Henry, N.W. eds.)*, American Society for Testing and Materials.

35 HASMA, H., AND LYTLE, C D (1998) Impermeability of Differently Formulated NR Latex Films and Gloves to ΦX174. *J. Rubb. Res.*, **1(4)**, 209–221.

36. KAPLAN, D., LYTLE, C D , ROUTSON, L.B., AND MYERS, M.R (1999) Issues

Associated with Using Fluorescent Microspheres to Evaluate Barrier Integrity. *J. Rubb. Res.* (submitted).

37 MYERS, M.R., LYTLE, C D. AND ROUTSON, L B (1999) A Mathematical Model for Simulating Virus Transport through Synthetic Barriers *Bull. Math Biophys.*, **61**, 111–138

38. MEHTA, R I., LYTLE, C.D , THOMAS, D P , AND MYERS, M R. (1998) The Cause of Cessation of Viral Passage through Artificially-induced Holes in Latex Condoms *J. Rubb. Res.*, **1(1)**, 1–13

39 MILLER, I M , COLLIER, C S , AND GRIFFITH, N.M (1972) Permeability of Surgical Rubber Gloves. *Am. J. Surg.*, **124**, 57.

40. THOMPSON, R., KORNIEWICZ, D., BENNETT, J , CACIOLI, P., KELLY, K , MURALI. P S., KURUP, V , AND FINK, J (1996) The Relationship between Latex Allergies, Hydration and Compromised Barriers in Surgical Gloves *American Academy of Allergy, Asthma and Immunology, March 15–20, New Orleans, L.A.*

41 WASHBURN, E W (1921) The Dynamics of Capillary Flow *Phys. Rev.*, **17**, 273–283

42 DAVIS, G B , AND SCHROEDER, L W (1990) Influence of Contact Angles on the Leakage of Latex Condoms *J. Test. Eval.*, **18**, 352–358

43 LEVY, J A (1994) *HIV and the Pathogenesis of AIDS* American Society of Microbiology, pp 12–16

44 HOLMBERG, S D., HORSBURGH, C R , JR , WARD, J W., AND JAFFE H.W (1989) Biologic Factors in the Sexual Transmission of Human Immunodeficiency Virus *J. Infect. Dis* , **160**, 116–125

45. JENISON, S A , LEMON, S M., BAKER, L N . AND NEWBOLD, J E (1987) Quantitative Analysis of Hepatitis B Virus DNA in Saliva and Semen of Chronically Infected Homosexual Men *J Infect Dis* . **156**, 299–307