



Comfort Rubber Gloves Industries Sdn.Bhd.
Ms. Nur Amira Mohd Yusoff
Lot 821 & 2209, Jalang Matang
34750 MATANG, TAIPING, PERAK
Maleisië



Your notice of
06-06-2017

Your reference

Date
23-08-2017

Analysis Report 17.03303.03

Required tests :
ISO 16604 (2004)

**Resistance to penetration by blood-borne pathogens – Test
method using Phi-X174 bacteriophage**

Identification number	Information given by the client	Date of receipt
T1712259	Nitrile Powder Free Examination Gloves - Product Type OCF40NBBL - Lot N° 70504M1510	06-06-2017

Hilde Rubben

Order responsible

This report may be reproduced, as long as it is presented in its entire form, without written permission of Centexbel.
The results of the analysis cover the received samples. Centexbel is not responsible for the representativeness of the samples.
In assessing compliance with the specifications, we did not take into account the uncertainty on the test results.



Reference: T1712259 - Nitrile Powder Free Examination Gloves - Product Type
OCF40NBBL - Lot N° 70504M1510

Resistance to penetration by blood-borne pathogens – Test method using Phi-X174 bacteriophage

Date of ending the test	21-06-2017
Standard used	ISO 16604 (2004)
Product standard	ISO 374-5 (2016)
Type of sample	Nitrile gloves
Dimension of the test specimens	7.5cm x 7.5cm
Number of test specimens	3
Sampling	1 test specimen per glove in the palm of hand
Paraffin-sealed edges	No
Test specimens conditioning	21 ± 5°C and 60 ± 10%RH The sample is not tested in conditioned area but directly after conditioning.
Sterilization	None
Pre treatment performed	None
Side in contact with the bacteriophage suspension	Outer side
Test procedure used	Procedure B (0 kPa 5 min + 14kPa 1 min + 0kPa 4 min - With screen)
Retaining screen specifications	Metal square mesh screen (open area >50%), limiting the deflection of the sample to ≤ 5.0 mm
Surface tension of the bacteriophage suspension	0.042 ± 0.002 N/m
Used bacteriophage	<i>Bacteriophage Phi-X 174</i> (ATCC13706-B1)
Host bacteria	<i>Escherichia coli</i> (ATCC 13706)
Compatibility ratio	2.6
Deviation from the standard	The measure of the thickness and the mass have not been done on the tested specimens.



Results

Test pressure 14 kPa

Test validity

Controls	Number of PFU/ml of assay fluid	Pass/Fail results
Negative control (polyester film)	< 1 (No penetration)	Pass
Positive control (microporous PE film)	Penetration	Fail

Environmental plate results 0 PFU on each settle plate

Bacteriophage concentration

Starting bacteriophage challenge titer (PFU/ml) 5.1 10⁸
Ending bacteriophage challenge titer (PFU/ml) 4.9 10⁸

Sample results

Test specimen	Number of PFU/ml of assay fluid	Pass/Fail results
#1	< 1 (No penetration)	Pass
#2	< 1 (No penetration)	Pass
#3	< 1 (No penetration)	Pass

Pass = no penetration of bacteriophages through the specimen
Fail = penetration of bacteriophages through the specimen