SOUTH QUALITY

PROFICIENCY TESTING PROVIDER

REPORT No 11269

Date of issue: *July 25, 2025*

Status: FINAL REPORT

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EN 455-1

MEDICAL GLOVES FOR SINGLE USE

- FREEDOM FROM HOLES -

Program: SQ-5050

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TABLE OF CONTENTS

1. FOREWORD

This report summarizes the results of the **SQ-5050** proficiency testing program on the determination of freedom from holes on medical gloves for single use. This program is conducted in a bilateral format, following the A.3.3 classification of the ISO 17043 standard ("Split-sample testing schemes").

South Quality conducted the testing program in June 2025 with the aim of assessing the laboratory's ability to competently perform the designated tests.

2. ORGANIZATION

Program Coordinator:	Lic. Esther Casas
Assistant Technician:	Berenice Ferrel
Statistic:	Lic. Manuel Tozaki
Supervision:	Eng. Emiliano Medina

3. OBJECTIVE

The objective of this proficiency testing program is to determine the number of non-conforming gloves (%), using the following standard:

Standard
EN 455-1: 2020 + A1: 2022

To verify this, samples of medical gloves for single use have been selected.

Participants in this program have not been previously informed about the expected values or value ranges of the samples they receive.

4. PARTICIPANT

Company:	**NHS Wales Shared Service Partnership**
Laboratory:	**Surgical Materials Testing laboratory**
Country:	United Kingdom
Client ID:	E512
Contact person:	Dr. Pamela Ashman Technical Manager pamela.ashman@wales.nhs.uk

5. HOMOGENEITY

Several batches were prepared identically by the staff at South Quality.

Subsequently, a homogeneity study was conducted with an ISO 17025 accredited laboratory.

The control process followed ISO Guide 35: 2017, clause 7.4.1.2. Stratified random sampling was employed, and samples were chosen using random number generation software.

The results of this test are presented below:

Size of each batch: **500 pairs** Tested samples from each batch: **120 pairs**

DETERMINATION	HOMOGENEITY OF RESULTS IN THE ANALYZED SAMPLES		
	BATCH: LPP3416	BATCH: LPP3417	BATCH: LPP3418
WATER LEAKAGE	YES	NO	NO

Samples for this program are taken from the selected batch identified as LPP3416.

For the indicated batch, the values determined in the homogeneity study are utilized as the assigned values.

The analysis of the test data indicated that the selected samples exhibited sufficient homogeneity for the program. Therefore, the results of participants identified as outliers cannot be attributed to sample variability.

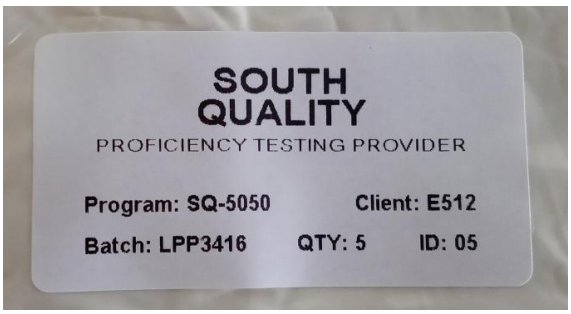
6. SAMPLE INFORMATION

The following samples were sent for testing:

Batch:	LPP3416
Sample ID:	05
Characteristics:	Synthetic latex medical gloves Size: Small 25 pairs

7. IMAGES

SAMPLES



8. ASSIGNED VALUES

BATCH	NUMBER OF NON-CONFORMING GLOVES (%)
LPP3416	28

9. PARTICIPANT RESULTS (SEE APPENDIX B)

CODE	NUMBER OF NON-CONFORMING GLOVES (%)
LPP3416-05	28

10. STATISTICS

The results must be treated as qualitative.

For qualitative results, the comparison will be made directly against the assigned values, so any difference will be evaluated as **Unsatisfactory**.

11. EVALUATION OF PERFORMANCE

PARAMETER	BATCH: LPP3416		PERFORMANCE RESULT
	PARTICIPANT RESULT	ASSIGNED VALUE	
NUMBER OF NON-CONFORMING GLOVES (%)	28	28	SATISFACTORY

12. CONCLUSIONS

The overall performance on this **SQ-5050** program from the participant laboratory **NHS WALES SHARED SERVICE PARTNERSHIP - SURGICAL MATERIALS TESTING LABORATORY**, is **SUFFICIENT** based on expected results.

The criteria used for the evaluation of the overall performance is the following:

- **SUFFICIENT** performance: No unsatisfactory results were obtained.
- **INSUFFICIENT** performance: An unsatisfactory result was obtained.

APPENDIX A

INSTRUCTIVE

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INSTRUCTIVE

PROGRAM:	Medical gloves for single use - Freedom from holes -
CODE:	SQ-5050
VERSION:	-
STANDARD:	EN 455-1
COORDINATOR:	Lic. Esther Casas (ecasas@ptsouthquality.com)

DSQ-012 - REV 03 - SQ-5050 1 de 3

1 - General

This document is a guide for managing the results of the **SQ-5050** program.

2 - Standard

EN 455-1: 2020 + A1: 2022

3 - Tests involved

TEST
Water leakage - Number of non-conforming gloves (%)

4 - Samples

CODE	SAMPLE	QUANTITY
LPP3416-05	Synthetic latex medical gloves - Size: Small	25 pairs

5 - Notes

a) Being a bilateral program there is no deadline to accomplish sending results.
b) Participants must test all the samples.
c) Participants must submit the results in the usual report used by their laboratory.
d) The samples must be kept until the end of the program, which closes with the submission of the final report.
e) To review the results, sending images of the tests will be appreciated. Images can be attached to the end of this document or inserted into your regular report.

PHOTOGRAPHS

APPENDIX B

PARTICIPANT RESULTS

(Results form)

SURGICAL MATERIAL TESTING LABORATORY

TEST REPORT

PT South Quality Test Scheme Report - EN 455 1-2

Report No: 25/7219/1

Report Date: Monday 2nd June, 2025

Authors:
Heath Davies

Revision Information:
Template Version: ef0d2c3
Revision: 1.3
Revision date: Monday 2nd June, 2025
Revision Author: louise

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PT South Quality Test Scheme Report - EN 455 1-2
Report No: 25/7219/1

Heath Davies

Monday 2nd June, 2025

1 Name & Address of Client/Requesting Authority

Esther Casas
Test Scheme Coordinator
PT South Quality SAS
Pareja 3981
Villa Devoto
Ciudad Autónoma de Buenos Aires
Argentina

Email: ecasas@ptsouthquality.com

2 Introduction

This document presents the results of Examination Gloves tested to BS EN 455 Parts 1[1] and 2[2].

3 Test Products/Samples for this project

Table 1: Samples

Manufacturer	Product Name	Description	Catalogue Number	Batch/Lot Number	Quantity	Date received	SMTL Sample ID
Not Stated	Examination Gloves	Size small	SQ-5050	LPP3416	50	26/02/2025	79485
Not Stated	Examination Gloves	Size large	SQ-5022	LPP3077	30	26/02/2025	79486

Note:

The test results in this report relate only to the test sample(s) analysed.

The Manufacturer, Product Name, Description, Catalogue & Batch Numbers were provided by the client.

3.1 Departures/Abnormalities of Sample Condition

BS EN 455-2:2024 specifies that gloves should be tested in accordance with section 5.3 (challenged aged force at break) when within 12 months of manufacture. No date of manufacture information was provided with the gloves, however the client requested Section 5.3 testing be undertaken.

No manufacturing material was stated on the packaging. However, additional information provided by the scheme supplier stated that the examination gloves were manufactured from synthetic latex.

4 Date of Testing

14th March to 9th April 2025

5 Location of Testing

Dimensions TM-343[3] testing was performed at SMTL IP5 Newport premises.

All other testing was performed at SMTL POWH Bridgend premises.

6 Testing Details

6.1 Perforations - TM-22[4]

The number and location of glove perforations in a designated sample size were noted in accordance with *BS EN 455-1:2020 +A1 2022 Medical gloves for single use. Requirements and testing for freedom from holes* using the SMTL test method TM-22.

Gloves were sampled in accordance with *ISO 2859-1:1999* using a single or multiple sampling plan, the sample size code letter was selected according to the batch size at general inspection level I. Acceptance/rejection numbers were set according to an acceptance quality level (AQL) of 1.5% for examination gloves or 0.65% for surgical gloves.

Gloves were selected at random and attached to a filling tube of appropriate dimensions to fit the glove. Each glove was positioned so that the cuff overlapped the tube by a maximum of 40mm and then secured to obtain a watertight seal.

The gloves were then filled with 1000 ±50ml of water and examined for evidence of leaks. Gloves were allowed to hang for 2-3 minutes, then again examined for evidence of leaks. The position and number of any leaks were recorded. Any leaks identified within 40mm of the cuff were recorded for information purposes but not used in assessing compliance.

6.2 Force at break - TM-342[5]

The force at break of the gloves was measured in accordance with *BS EN 455-2:2024 Medical gloves for single use. Requirements and testing for physical properties* using SMTL test method TM-342.

The strength of the gloves was determined during shelf life and following ageing (7 days at 70 ± 2°C). Dumb-bell test pieces were cut from 13 individual (or from seven pairs) gloves from the same lot, following a conditioning period of at least 16 hours. Using a tensometer with a cross-head speed of 500mm/min the force at break in newtons (N) was recorded.

The single wall thickness of each dumb-bell and the double wall thickness of the middle finger tip of each glove was measured using a thickness gauge and a correction factor applied if applicable.

The median of the 13 samples (with correction factor applied if necessary) was calculated.

6.3 Dimensions - TM-343[3]

The length and width of the gloves was measured in accordance with *BS EN 455-2:2024 Medical gloves for single use. Requirements and testing for physical properties* using SMTL test method TM-343.

Length

The glove length was measured by freely suspending the glove by the middle finger on a vertical graduated rule with a rounded tip. Folds and wrinkles were removed without stretching the gloves and the minimum length to the nearest mm recorded.

This was repeated so that a total of 13 gloves were measured and the median length was calculated.

Width

The width of the glove was measured using a calibrated rule to the nearest mm, when the glove was placed onto a flat surface.

This was repeated so that a total of 13 gloves were measured and the median width was calculated.

6.4 Standards relevant to the test method

- BS EN 455 Part 1: 2020 +A1 2022 Medical gloves for single use - Part 1: Requirements and testing for freedom from holes[1]
- BS EN 455 Part 2: 2024 Medical gloves for single use - Part 2: Requirement and testing for physical properties[2]

6.5 Testing conditions

6.5.1 Perforations - TM-22[4]

- Gloves were filled with water at a temperature of 15-35°C.

6.5.2 Force at break - TM-342[5]

- Testing and conditioning was performed at 23 ±2°C, and at a relative humidity of 50 ±10%.
- Challenge testing (ageing) of gloves was performed at 70±2°C.

6.5.3 Dimensions - TM-343[3]

- No specific testing conditions required.

6.6 Deviations/exclusions from, and additions to standard methods

6.6.1 Perforations - TM-22[4]

- None.

6.6.2 Force at break - TM-342[5]

- None.

6.6.3 Dimensions - TM-343[3]

- None.

6.7 Uncertainty of Measurement

Uncertainty of measurement (UoM) has been taken into account with regards to probability when interpreting the test results compliance with limits. The UoM budget for the test method is presented in Appendix A, and can be used to assess compliance of individual test results taking into account the UoM.

6.8 Sampling Details

All samples were selected and supplied by the scheme provider.

The batch size of the gloves supplied was not stated by the client. In accordance with BS EN 455 Part 1, a batch size between 35,001 to 150,000 was chosen, and therefore 50 gloves per stage were tested for perforations using General Inspection Level I at an AQL of 1.5%. With reference to Table 3, the sample size was tested up to the fifth sampling stage or until compliance or non compliance was determined.

6.9 Sample Preparation

Samples were prepared according to the relevant test method used.

7 Results

7.1 Perforation Testing - TM-22[4]

The results of perforation testing are presented in Table 2. Compliance has been determined with reference to Table 3.

Table 2: Glove Perforations - Examination Gloves, SQ-5050, SID 79485

Stage No	Cumulative No Tested	Cumulative No Failed	Compliance
First	50	7	Does not comply
Second	100	-	NA
Third	150	-	NA
Fourth	200	-	NA
Fifth	250	-	NA

Note:

Perforations were detected in the finger crotch and palm (1 glove), finger (5 gloves), and thumb crotch (1 glove).

Table 3: Limits

Stage	Cumulative No Tested	Accept	Reject
1	50	0	4
2	100	1	6
3	150	3	8
4	200	5	9
5	250	9	10

7.2 Force at Break - TM-342[5]

The results of testing are presented in Table 4. Compliance has been determined with reference to Table 5.

Table 4: Force at Break (FAB) - Examination Gloves, SQ-5022, SID 79486

Sample	FAB (N) Unchallenged	FAB (N) Challenged
1	5.1	4.6
2	5.2	4.3
3	4.8	5.0
4	5.2	5.4
5	5.0	4.7
6	5.8	4.1
7	5.2	4.9
8	4.5	4.9
9	6.1	3.6
10	5.6	4.8
11	5.6	4.4
12	4.7	5.2
13	5.0	4.9
Median Result	**5.2 Does not comply**	**4.8 Does not comply**

BS EN 455-2:2024 specifies that medical gloves should be tested in accordance with section 5.3 (challenged aged force at break) when within 12 months of manufacture. However, no date of manufacture information was supplied with the gloves.

Table 5: FAB Limits for synthetic latex gloves

	Limit (N)
Force at break during shelf life (Unchallenged)	≥ 6.0
Force at break after challenge testing (Within 12 months of manufacture)	≥ 6.0

7.3 Dimensions - TM-343[3]

The results of dimension testing are presented in Table 6. Compliance has been determined with reference to Table 7.

Table 6: Dimensions - Examination Gloves, SQ-5022, SID 79486

Sample	Length (mm)	Width (mm)
1	239	106
2	238	106
3	238	104
4	239	104
5	242	106
6	240	105
7	240	106
8	244	106
9	237	105
10	238	105
11	241	106
12	243	106
13	243	105
Median Result	**240 Complies**	**106 Complies**

Table 7: Dimension Limits for size large gloves

Size	Length (mm)	Width (mm)
Large	≥ 240	110 ±10

8 Authorisation

Approved and signed electronically. Please see last page of this document.

Dr. Gavin Hughes, Director, SMTL.

9 Appendix A - Uncertainty of Measurement

9.1 Glove Force at Break (FAB) - Examination Gloves

UoM for TM-342 Force at Break (FAB) of Medical Glove testing is 1.8%. The reported uncertainty is an expanded uncertainty using a coverage factor of k=2, which provides a level of confidence of approximately 95%. The limit for FAB is ≥ 6N (Newtons).

A shared risk model using the binary rule (as per ILAC G8) is used for the decision rules. The table below documents the decision rules for selected values of x (FAB in N), and details the:

- Pc% - Probability of conformity;
- PFA% - Probability of false acceptance if accepted;
- PFR% - Probability of false rejection if rejected;

Table 8: Decision Rule Table - Examination Gloves FAB (N)

x (N)	Decision.Rule	Pc%	PFR%	PFA%
5.5	Reject	0.0	0.0	
5.6	Reject	0.0	0.0	
5.7	Reject	0.0	0.0	
5.8	Reject	0.0	0.0	
5.9	Reject	3.0	3.0	
6.0	Accept	50.0		50.0
6.1	Accept	96.6		3.4
6.2	Accept	100.0		0.0
6.3	Accept	100.0		0.0
6.4	Accept	100.0		0.0

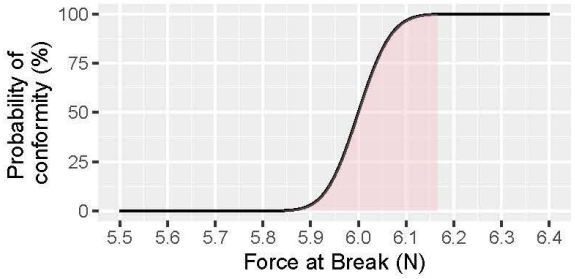

Figure 1: Probability of conformity for Examination Gloves FAB - shaded area denotes Pc <100 & > 0

9.2 Examination Glove Length

The Uncertainty of Measurement (UoM) for TM-343 Dimensions of Medical Glove testing is 1mm for length measurements. The reported uncertainty is an expanded uncertainty using a coverage factor of k=2, which provides a level of confidence of approximately 95%. The limit for length is ≥ 240mm.

A shared risk model using the binary rule (as per ILAC G8) is used for the decision rules. The table below documents the decision rules for selected values of x (length of glove), and details the:

- Pc% - Probability of conformity;
- PFA% - Probability of false acceptance if accepted;
- PFR% - Probability of false rejection if rejected;

Table 9: Decision Rule Table - Examination Glove Length

x (mm)	Decision.Rule	Pc%	PFR%	PFA%
236.0	Reject	0.0	0.0	
236.5	Reject	0.0	0.0	
237.0	Reject	0.0	0.0	
237.5	Reject	0.0	0.0	
238.0	Reject	0.0	0.0	
238.5	Reject	0.1	0.1	
239.0	Reject	2.3	2.3	
239.5	Reject	15.9	15.9	
240.0	Accept	50.0		50.0
240.5	Accept	84.1		15.9
241.0	Accept	97.7		2.3
241.5	Accept	99.9		0.1
242.0	Accept	100.0		0.0
242.5	Accept	100.0		0.0
243.0	Accept	100.0		0.0
243.5	Accept	100.0		0.0
244.0	Accept	100.0		0.0

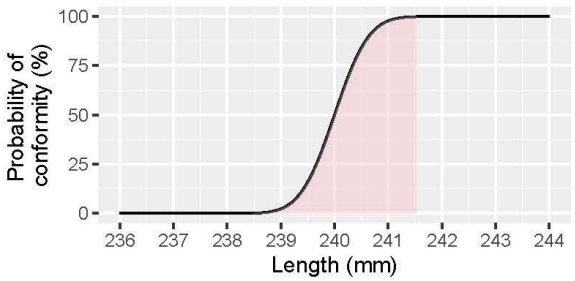

Figure 2: Probability of conformity for Examination Glove Length - shaded area denotes Pc <100 & > 0

9.3 Examination Glove Width - Large

The Uncertainty of Measurement (UoM) for TM-343 Dimensions of Medical Glove testing is 1mm for width measurements. The reported uncertainty is an expanded uncertainty using a coverage factor of k=2, which provides a level of confidence of approximately 95%. The limit for width is 100mm - 120mm.

A shared risk model using the binary rule (as per ILAC G8) is used for the decision rules. The table below documents the decision rules for selected values of x (width of glove), and details the:

- Pc% - Probability of conformity;
- PFA% - Probability of false acceptance if accepted;
- PFR% - Probability of false rejection if rejected;

Table 10: Decision Rule Table - Glove Width - Large

x (mm)	Decision.Rule	Pc%	PFR%	PFA%
97	Reject	0.0	0.0	
98	Reject	0.0	0.0	
99	Reject	2.3	2.3	
100	Accept	50.0		50.0
101	Accept	97.7		2.3
102	Accept	100.0		0.0
105	Accept	100.0		0.0
110	Accept	100.0		0.0
115	Accept	100.0		0.0
117	Accept	100.0		0.0
118	Accept	100.0		0.0
119	Accept	97.7		2.3
120	Accept	50.0		50.0
121	Reject	2.3	2.3	
122	Reject	0.0	0.0	
123	Reject	0.0	0.0	

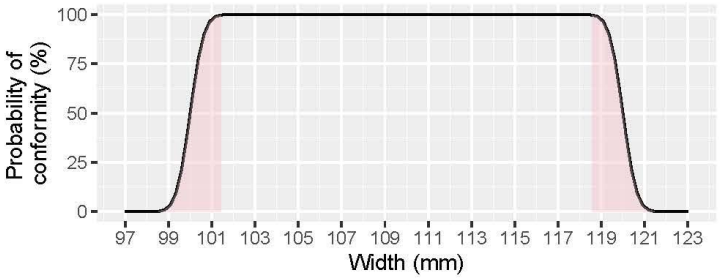

Figure 3: Probability of conformity for Large Examination Glove Width - shaded area denotes Pc <100 & > 0

References

[1] *Medical gloves for single use - Part 1: Requirements and testing for freedom from holes.*„ (BS EN 455-1:2020 +A1 2022).

[2] *Medical gloves for single use - Part 2: Requirement and testing for physical properties.*„ (BS EN 455-2:2024).

[3] SMTL. *Determination of dimensions of medical gloves to BS EN 455 Part 2.* [TM-343].

[4] SMTL. *Detection of perforations in medical gloves to BS EN 455 Part 1.* [TM-22].

[5] SMTL. *Force at break testing of medical gloves to BS EN 455 Part 2.* [TM-342].

Digitally signed by Gavin Hughes
Date: 2025.06.10 09:43:51 BST

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