

**INTERLABORATORY PROFICIENCY
TRIAL OF CONDOM TESTING
LABORATORIES, 2011**

NOVEMBER, 2011

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1 Introduction

This report describes the results of the 17th annual ENERSOL Interlaboratory Proficiency Trial of condom testing laboratories.

The trial was conducted between mid-July and October, 2011. Sixty-five (65) laboratories enrolled in the trial. Eight (8) laboratories requested one or more sets of additional samples for some of the tests.

In this report these extra samples are referred to as separate laboratories. There were up to seventy-four (74) sets of samples in tests this year.

The first such proficiency trial for condoms was conducted in 1995, on behalf of the World Health Organization, and from then on it has been done annually. This trial is funded by contributions from the participating laboratories.

In order to facilitate comparisons between proficiency trials in different years, laboratory code numbers are the same as they were in previous years for continuing participants.

The aims of this proficiency trial were:

1. to identify those laboratories disagreeing in a statistical sense or in a practical sense, from the majority, so that their results can be the subject of further consideration;
2. to give laboratories feedback on their performance relative to the consensus results;
3. to give laboratories sufficient data to enable them to identify and correct techniques and calibrations;
4. in the longer term, to maintain international confidence in the results from all the laboratories;
5. to be used by accredited laboratories as a tool for the compliance with ISO 17025;
6. to have an estimate of the precision components of the various measurements as defined in ISO 5725.

Most of the tests performed on condoms are inherently destructive, and are performed on a sample from the population submitted. The products are inherently variable to some extent, so perfect agreement amongst sub-samples cannot be expected. It is often difficult to separate variations in measurement from variations in the product itself. Further, for many of the tests, there is no "right" answer available beforehand, against which results may be compared. In these cases, the statistical techniques establish a consensus value from all results, ignoring extreme results (so different in value or range from the others that it is improbable that they are correct).

In the case of freedom from holes and package seal tests, a known number of defective items were included in each sub-sample. In those cases, there is a very high probability that the "right" answer for the number of defectives is the number added, although some variation is possible. For these tests, the results obtained are compared with the number of defectives added.

While the techniques used here may identify laboratories which do not agree with the consensus result, all inferences are based on probability and statistics. Where a laboratory is identified as being an outlier or straggler, that means that its results are improbable, not that they are definitely wrong (definitions in Section 9).

Generally, the analysis of results can be used to suggest possible causes for deviations from consensus results, and these need to be analysed by an expert examining the equipment, the test methods and the results of this trial.

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This report gives graphs and tables that show the results of all the laboratories, test by test. In addition, each laboratory has been given a summary showing its own performance, compared with consensus values.

At the Enersol Pty Ltd laboratory, the tests were conducted by staff that had nothing to do with the preparation of samples, where that preparation could have given a prior knowledge of the results.

Enersol Pty Ltd staff involved in running and analyzing the trial included:

John Gerofi - Managing Director, Lisa Henretty - Business Manager, Grace Iskander - Laboratory Manager, Manhong Huang - Technical Officer, Kely Silveira - Administrative Assistant

2 Participating laboratories

The participating laboratories in 2011 were:

Ansell-Suretex Ltd, Surat Thani, THAILAND

British Standards Institution - BSI Product Services, Hemel Hempstead, UK

Church & Dwight Co Inc, Colonial Heights VA, USA

CPR Produktions-und Vertriebs GmbH, Sarstedt, GERMANY

Cupid Rubbers India Ltd, Nashik, INDIA

ENERSOL Pty Ltd, Annandale NSW, AUSTRALIA

ENERSOL Sdn Bhd, Penang, MALAYSIA

ESR, Porirua, NEW ZEALAND

Family Health International (FHI), Bangkok, THAILAND

Family Health International (FHI), Durham NC, USA

Food and Drug Administration, Taiwan, Taipei City, TAIWAN

Government Laboratory, Kowloon, HONG KONG

Guangzhou GuangXiang Enterprises Group Co., Ltd, Guangzhou, CHINA

Guilin Latex Factory, Guilin, CHINA

Hankook Latex Gongup Group Co Ltd, Kangwon-Do, KOREA

HLL LifeCare Limited, Belgaum, INDIA

HLL LifeCare Limited, Cochin, INDIA

HLL LifeCare Limited, Thiruvananthapuram, INDIA

Hong Kong Standards Testing Centre (HKSTC), Taipo, HONG KONG

Indus Medicare Ltd, Hyderabad, INDIA

Innolates Limited, Songkhla, THAILAND

Innolates Sdn Bhd, Port Klang, MALAYSIA

Instituto Nacional de Tecnologia (INT), Rio de Janeiro, BRAZIL

Instituto Nacional de Tecnologia Industrial INTI – Caucho, Buenos Aires, ARGENTINA

J.K. Ansell Ltd, Aurangabad, INDIA

Karex Industries Sdn Bhd, Johor, MALAYSIA

Kenya Bureau of Standards, Nairobi, KENYA

Kiskot Trading, Markopoulo, GREECE

L.A. Falcão Bauer C.T.C.Q Ltda, São Paulo, BRAZIL

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Laboratoire National de Métrologie et d'Essais, Trappes, FRANCE
Laboratorio de Insumos para la Salud y Productos Varios - Instituto Nacional de Vigilancia de Medicamentos y Alimentos INVIMA, Bogotá, COLOMBIA
Lanacome, Yaoundé, CAMEROON
Medical-Latex (DUA) Sdn Bhd, Senai, MALAYSIA
Medicines Control Authority of Zimbabwe (MCAZ), Harare, ZIMBABWE
Testing Laboratory Medpack LTD, UKRAINE
Mercator Healthcare Ltd, Mumbai, INDIA
National Drug Authority, Kampala, UGANDA
National Drug Quality Control Laboratory, Gaborone, BOTSWANA
National Quality Control Laboratory of Drug and Food, NQCLDF, Jakarta, INDONESIA
National Rubber and Latex Products Quality Supervision and Inspection Center, Yunnan, CHINA
TGA Biomaterials and Engineering, Canberra, ACT, AUSTRALIA
Pleasure Latex Products Sdn Bhd, Sembilang, MALAYSIA
Polar Pharma Ltd, West Bengal, INDIA
Proteccion SICO, S.A. de C.V., MEXICO
Qingdao Double Butterfly Group Co Ltd, Qingdao, CHINA
Qingdao London Durex International Co Ltd, Qingdao, CHINA
Research Center for Biomaterials S.A. (EKEVYL), Athens, GREECE
RFSU AB, Ramsjö, SWEDEN
Society for Family Health, Lagos, NIGERIA
South African Bureau of Standards (SABS), Pretoria, SOUTH AFRICA
SSL Manufacturing (Thailand) Ltd, Chachoengsao, THAILAND
SSL Manufacturing Thailand Ltd, Technical Innovation Centre, Chachoengsao, THAILAND
SSN Medical Products Sdn Bhd, Selangor, MALAYSIA
Suretex Prophylactics (India) Ltd, Bangalore, INDIA
Tanzania Bureau of Standards, Dar Es Salaam, TANZANIA
Thai Nippon Rubber Industries Co. Ltd, Sriracha, THAILAND
Tianjin Human-Care Latex Corporation Laboratory, Tianjin, CHINA
TTK-LIG Limited Research and Development, Chennai, INDIA
TTK-LIG Limited, Pudhucherry, INDIA
TTK-LIG Ltd, Virudhunagar, INDIA
TÜV SÜD PSB Pte Ltd, SINGAPORE
Unidus (Zhangjiagang) Rubber Products China, Zhangjiagang City, CHINA
Unidus Corporation, Seoul, KOREA
Valendor (Mauritius) Ltd, Coromandel, MAURITIUS
Zhanjiang Fitone Medicine Co.,Ltd, Zhanjiang Guangdong, CHINA

3 Test methods covered

The test methods on which the proficiency trial was conducted were:

- Total lubricant (dressing materials)
- Length
- Width
- Thickness
- Inflation - bursting volume and pressure (unaged)
- Tensile Properties - Force at break
- Tensile Properties - Elongation at break
- Freedom from Holes, Visual, Conductivity and ASTM (Hang & Squeeze) methods
- Package seal integrity

The test methods used in this trial were in accordance with ISO 4074:2002 and introduced to the 2010 trial the ASTM method for Freedom from Holes testing.

The determination of thickness was done by either one of the two recognised methods - the micrometer gauge or the mass method.

Laboratories were allowed to use alternative methods, provided they documented these methods.

4 Instructions to participants

Samples were shipped with an instruction letter that directed participants to the Enersol website to download the Instruction Booklet and data spreadsheet. The Instruction Booklet was as brief as possible and participants were instructed to follow the methods in the appropriate standards.

Participants were requested to return results by E-mail. Participants were also instructed to send the samples with failures found during the Freedom from Holes tests and the cut tensile samples to Enersol by courier or post.

5 Sample selection

For most tests, two different samples were selected. They were chosen to give a range of different results.

For all samples except those "seeded" with flaws (i.e. Freedom From Holes and Package Seal Integrity), the entire sample was divided at random into the sub-samples sent to each laboratory.

For samples P 1 and P 2 the deliberately damaged packs and the intact packs were assembled into the sub-samples which were sent to participants. Similarly for H 1 to H 9 the deliberately damaged condoms and the intact condoms were assembled into the sub-samples which were sent out to participants.

Brief details about the samples follow.

5.1 Total Lubricant

Two samples, L 1 and L 2, with different lubricant doses, were distributed to participants of this test.

Participants were asked to perform the test in accordance with ISO 4074:2002, where the lubricant quantity measured is that on the condom and in the pack.

5.2 Dimensions (Length, Width, Thickness)

For the dimensions tests of length, width and thickness, two samples, identified as DIM 1 and DIM 2 were distributed to participants of these tests. The length, width and thickness of samples were selected to be slightly different. Each participating laboratory received 10 condom samples in each bag.

5.3 Inflation - Bursting Volume and Pressure

For bursting volume and pressure, two samples, identified as IN 1 and IN 2 were distributed. In this trial, samples IN 1 were nominally 49 mm in width and IN 2 samples were nominally 56 mm in width. Each participating laboratory received 104 condoms in each bag, of which 4 condoms were spares.

5.4 Tensile Properties

Four sets of samples were distributed as TBL 1, TBL 2, TCE 3 and TTE 4.

Three sets of tensile data are available:

- Samples cut and tested by the participating laboratories (TBL 1 and TBL 2)
- Samples cut by Enersol and tested by the participating laboratories (TCE 3)
- Samples cut by the participating laboratory and tested by Enersol (TTE 4)

Samples TBL 2, TCE 3 and TTE 4 were identical condoms. Each participating laboratory was supplied with 10 condom samples in each bag or 10 cut pieces where required.

5.5 Freedom from Holes

All samples were non-lubricated condoms and were distributed rolled and unfoiled (naked).

Holes were deliberately made in a proportion of the condoms at Enersol, and a known number of condoms with holes were introduced into each sub-sample. The holes were located in one of five distinct regions on the condom and the number of condoms with holes in each region per sub-sample was also known. The location of the introduced holes is described in Table 1, Table 2 and Table 3.

Before distribution of the samples, a random sample of the condoms with holes was tested using the three test methods at Enersol, and detectable holes were found in all condoms tested.

Each participating laboratory received 100 condoms in each bag. The number and position of holes in the condoms was selected, known and distributed into each bag by Enersol's Business Manager and Laboratory Manager only.

Table 1: Holes introduced into sub-samples – Visual Method

Region of holes	Location from open end (mm)	Needle diameter (mm)	No. holes made		
			H 1	H 2	H 3
A	40	0.33	1	0	0
B	70	0.22	1	0	0
C	100	0.22	1	1	0
D	140	0.22	0	0	1
E	Tip	0.33	0	0	1
Total	5 locations	2 needle sizes	3 holes	1 hole	2 holes

Table 2: Holes introduced into sub-samples – Conductivity Method

Region of holes	Location from open end (mm)	Needle diameter (mm)	No. holes made		
			H 4	H 5	H 6
A	40	0.90	1	0	0
B	70	0.90	0	1	1
C	100	0.55	0	1	0
D	140	0.55	0	0	1
E	Tip	1.10	0	0	1
Total	5 locations	3 needle sizes	1 hole	2 holes	3 holes

Table 3: Holes introduced into sub-samples – ASTM (Hang & Squeeze) Method

Region of holes	Location from open end (mm)	Needle diameter (mm)	No. holes made		
			H 7	H 8	H 9
A	40	0.33	1	0	0
B	70	0.22	1	0	0
C	100	0.22	0	1	0
D	140	0.22	0	1	0
E	Tip	0.33	0	1	1
Total	5 locations	2 needle sizes	2 holes	3 holes	1 hole

5.6 Package Seal Integrity

Two sets of samples identified as P 1 and P 2 were distributed to laboratories participating in this test. Each bag contained 20 condom samples in foil packs. Holes were deliberately made in a proportion of the condom packages, and a known number of the damaged packages were introduced into each sample.

Table 4 shows the total number of damaged packs and their identifying numbers.

Table 4: Damaged packs introduced into sub-samples – Package Seal Integrity

Sample	Total number of damaged packs	Identifying numbers of the damaged packs
P 1	3	3, 17, 20
P 2	6	1, 5, 8, 12, 14, 19

6 Packaging and dispatch of samples

Each participant's samples were packed in labeled snap-locked plastic bags. Each label identified the trial name, test ID, test name, test description, the number of samples in the bag and the bag ID number. The bags were shipped in a strong cardboard box, which was sent by courier or airmail. Samples were sent by mid June and laboratories were requested to confirm receipt of their samples by fax or by email.

Laboratories were asked to complete the tests and return results by August 23rd. Due to a portion of participants requesting an extension; the return date was extended to September 14th.

An instruction letter was supplied in each parcel that directed participants to the Enersol website to download the Instruction Booklet and Data Spreadsheet.

7 Receipt of results

In general, communications with the laboratories were effective, and most laboratories returned their results in a reasonable time. The first results were received from laboratories 35 and 100 on August 2nd.

Results from around 90% of the laboratories arrived by the extended deadline. The remaining participants sent their results by first week of October, and the last tensile cut samples were received in the 3rd week of October.

It is important that laboratories adhere to the deadline in order to facilitate the release of this report as soon as possible. The late submission from one laboratory causes delayed feedback to all.

8 Presentation of results in this report

Each test involved the generation of a large number of results. The purpose of statistical analysis is to reduce these results to comprehensible summaries and to infer conclusions.

Section 9 presents the main definitions to help in the understanding of this report.

Section 10 highlights the overall mean results, indicates the extreme results and provides comments and discussion of the results. It includes tables showing the consensus results, repeatability and reproducibility, after removing the extreme results.

For the inflation test, there is additional information in the form of scale factors for each laboratory, giving a numerical comparison with consensus values for the mean and standard deviation.

For the Freedom from Holes tests, there are tables for the Visual, Conductivity and ASTM (Hang & Squeeze) tests, showing how many holes each laboratory found in each location, enabling comparison with the number of holes made by Enersol. A similar table is present for the Package Seal Integrity test.

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Section 11 provides a discussion of the extreme results.

Section 12 provides the overall conclusions.

Appendix A provides graphical presentations and tables with the results for each test and laboratory in a number of ways, including:

- Histograms of laboratories' mean results
- Histograms of laboratories' standard deviations
- Summary statistics and extreme results

Histograms (frequency distributions) of the laboratories' mean results are presented for each of the samples. The mean results, by test and sample, of each laboratory relative to the others can be seen on the graphs. Each laboratory's result is shown by its code number. From these histograms, one can in most cases examine the consistency of performance of each laboratory. The resolution of these histograms is limited, so the class intervals are not ideal in all cases.

Histograms of the standard deviations of the laboratories' results are also presented. These give a comparison of the repeatability of each laboratory's results on each test. Within each test, the same scale is used wherever possible.

The summary statistics, by test and sample, are presented in tables with the traditional statistical parameters, before and after removing the extreme results. The laboratories which had extreme results are identified by their code number. The repeatability and the reproducibility with their uncertainties, after removal of extreme results, are also presented.

The Quantile-Quantile plots for the inflation test for each laboratory are in the individual results, making it easier for the participant to see their performance.

8.1 Individual laboratory results

The code number for each laboratory is printed on the cover of the individual laboratory results and appears in the covering letter.

Each individual laboratory receives a report designed to provide, at a glance, information about how each it performed for all tests. The results for extra samples (extra sets) are presented together with the individual laboratory results that requested them, with a different code number.

The individual laboratory results are presented in three tables and a set of Quantile-Quantile plots.

Table 1 compares your laboratory's **mean results** with consensus means calculated from the analysis of all results. This summary shows, using + and - signs, whether the laboratory's result was above or below the consensus mean, or expected value, and the magnitude of deviation. The magnitude of deviation is expressed in number of standard deviations, of each laboratory, from the consensus mean and it is shown in 4 columns (<1; 1-2; 2-3; >3).

Table 2 compares your laboratory's **standard deviations** with a "pooled" standard deviation, calculated from the analysis of all results. This summary is present in a similar format to the previous summary. Asterisks are used to show the ratio of the laboratory standard deviation and the pooled standard deviation.

Table 3 shows the results for **Freedom from Holes** and **Package Seal Integrity** reported by your laboratory compared with the holes and damaged packs introduced by Enersol.

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On the first two summaries, in general, the higher value for the totals on column (<1), the better the performance of the laboratory. Laboratories should investigate reasons for tests results in columns (2-3; >3).

Quantile-Quantile plots. Each laboratory's ordered results are plotted against the corresponding ordered results of the reference distribution. Estimates of missing results are included where required. On these plots, the reference distribution is plotted on the horizontal axis, and the laboratory's results on the vertical. The ideal result in this plot would be all points lying on a line of slope 1. These plots have been used because of the significant skewness of the distributions.

For all results presented (tables, histograms, summary statistics and quantile-quantile plots) some extreme individual values may be omitted in the interests of keeping a common scale on which most results are well represented.

9 Definitions

The following definitions are intended to help the understanding to this report.

Accuracy - the closeness of agreement between a test result and the "true" value.

Coefficient of variation (Coef Var'n) – the ratio of the standard deviation to the mean (may be expressed as a percentage)

Consensus mean - the mean of the reported mean results calculated after excluding all extreme results (ie stragglers and outliers).

Extreme result - a result within a set of results that appears to have been derived from a different statistical distribution from the majority of the remaining results. It can be a straggler or an outlier.

Outlier - see repeatability outlier or reproducibility outlier.

Pooled STD DEV - a "consensus" standard deviation for a particular test result, taken over all participating laboratories, after excluding all extreme results. In principle it is calculated by taking square root of the sum of the squares of the individual standard deviations, and dividing by the number of laboratories.

Precision - the closeness of agreement of results obtained under stipulated conditions.

Random error - the deviation of a result from the "true" result, due to random causes.

Repeatability - the closeness of agreement between two test results, conducted twice by one laboratory. There are two ways of estimating repeatability. One is based on replicates of the same sample, and comparison of the dispersion of the results. The second is based on single values or sample means of two samples with different properties. In the latter case, the repeatability is based on the agreement of the difference between the two values with a consensus figure.

Repeatability conditions - conditions where mutually independent test results are obtained with the same method on identical test material in the same laboratory by the same operator using the same equipment within short intervals of time.

Repeatability extreme result - an extreme result whose underlying distribution appears to have larger random error variability – either a straggler or an outlier.

Repeatability straggler- a repeatability extreme result significant at the 5% level but not significant at the 1% level.

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Repeatability outlier - a repeatability extreme result significant at the 1% level.

Repeatability value (r) - the value below which the absolute difference between two single test results obtained under repeatability conditions may be expected to lie with a probability of 95%.

Reproducibility - the closeness of agreement between two test results, conducted by different laboratories. It is assessed by analysing the distribution of mean values obtained by the participants for each test.

Reproducibility conditions - conditions where test results are obtained with the same test method on identical test material in different laboratories with different operators using different equipment.

Reproducibility value (R) - the value below which the absolute difference between two single value test results obtained under reproducibility conditions may be expected to lie with a probability of 95%.

Reproducibility extreme result - an extreme result whose underlying distribution appears to have a mean not from the population of means for the majority of the remaining results – either a straggler or an outlier.

Reproducibility straggler - a reproducibility extreme result significant at the 5% level but not one significant at the 1% level.

Reproducibility outlier - a reproducibility extreme result significant at the 1% level.

Sample - for the purposes of this trial, a set of condoms for a particular test, taken from a production lot of condoms, and mixed in preparation for division amongst participating laboratories.

Standard deviation – a measure of the dispersion of a distribution

Standard deviation of means (SD) - the standard deviation of the distribution of laboratory mean values (with or without extreme results).

Standard error (Std Error) - the standard deviation of a distribution of values divided by the square root of the number of values in the data set. This value is also the standard deviation of the distribution of means.

Straggler - an extreme result significant at the 5% level but not one significant at the 1% level.

Sub-sample – a selection of condoms from one sample (above) sent to a particular laboratory. For watertightness, each sub-sample had a known number of condoms with artificially made holes included.

Uncertainty - the deviation from the "true" value for which 99 in every 100 estimates, independently estimated, are not expected to exceed. (Note that in many other situations, 95 out of 100 is used instead of 99 out of 100).

10 Summary and discussion of results

Sixty-five (65) laboratories participated in the trial; of these, eight (8) laboratories requested extra samples in various tests. Each set of extra samples is counted as a separate laboratory for the purpose of this report; therefore the total number of laboratories was seventy-seven (77). Not all laboratories participated in all tests.

10.1 Total Lubricant

Fifty-five (55) laboratories participated in Total Lubricant test.

The results for this test are shown in Table 5. This table shows the precision components (repeatability and reproducibility) after removing any extreme results. Histograms of mean and standard deviation and summary statistics are shown in Appendix A.

This year four laboratories appeared to have recorded the lubricant quantity in grams, while the standard required the results in mg. The laboratories who reported in grams were 5, 71, 101 and 107. Of these laboratories three also reported the results in grams last year. The standard requests results in mg and in order to analyse all results Enersol converted these labs results to mg. It is hoped that next year these laboratories will record the results in mg or note on their forms that the result is being presented in a different unit. Space for test details is available on the spreadsheet for such observations.

Statistically, many laboratories showed up as repeatability outliers, especially in sample L 2.

For sample L 1: Laboratories 5, 26 and 122

For sample L 2: Laboratories 34, 43, 55, 61, 63, 107, 118, 144, 230 and 630.

Table 5: Results for Total Lubricant (mg)

Sample	No of laboratories in estimate	Mean (mg)	Repeatability (mg)	Reproducibility (mg)
L 1	52	454.9	86.2	104.2
L 2	45	506.3	29.9	60.3

10.2 Dimensions

The definition of a test result on each measurement is as shown below:

- Length: single measurement on a condom (to nearest mm)
- Width: single measurement on a condom (to nearest 0.5 mm)
- Thickness: average of three measurements taken on one condom

Histograms of mean and standard deviation and summary statistics, are shown in Appendix A.

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10.2.1 Length

Sixty-six (66) laboratories participated in this test.

For both samples: Laboratory 35 was a repeatability outlier and reproducibility outlier for DIM 1 and a reproducibility straggler for DIM 2.

Laboratory 100 was a reproducibility outlier for both samples, and reported the lowest mean, almost less than half the consensus mean.

For sample DIM 1: Laboratories 54 and 141 were repeatability outliers

There were no other extreme results for DIM 2.

It should be noted that laboratory 35 reported the highest mean for both samples while laboratory 100 reported the lowest mean for both samples. This appears to be a repeat of the results reported in the last two years for lab 35.

These two laboratories should investigate why this is so, as there are many reasons to get these kinds of readings such as:

- Incomplete unrolling of the condom
- Stretching un-powdered condoms
- Not looking for the shortest point around the circumference
- Measuring from the top of the reservoir
- Incorrect mandrel size

Accordingly, laboratories need to ensure that the condoms are fully unrolled, and hanging freely (if necessary by powdering the samples). Also the operator should position his/her eyes at the same level as the bead (open end). The correct sized mandrel should be used for the measurement.

Length results are summarized in Table 6. This table shows the precision components (repeatability and reproducibility), after removing any extreme results.

Table 6: Results for Length (mm)

Sample	No of laboratories in estimate	Mean (mm)	Repeatability (mm)	Reproducibility (mm)
DIM 1	62	188.2	3.7	5.7
DIM 2	64	186.3	4.3	5.9

10.2.2 Width

Sixty-six (66) laboratories participated in the width measurement. DIM 1 was nominally 49 mm in width and DIM 2 was nominally 56 mm in width.

For both samples: Laboratory 133 was a repeatability outlier for DIM 1 and DIM 2.
Laboratory 132 was a repeatability outlier for DIM 1 and reproducibility outlier for DIM 2.

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For sample DIM 1: Laboratories 15, 29, 34 and 35 were repeatability outliers. Laboratory 17 was a repeatability straggler, while laboratories 34 and 108 were reproducibility outliers.

For sample DIM 2: Laboratories 64, 100 and 123 were repeatability outliers, while laboratory 15 was a repeatability straggler. Laboratories 5, 36 and 141 were reproducibility outliers.

Laboratories 34 and 108 reported a higher mean than the consensus for DIM 1. It should be noted that Lab 34 did report one enormous result that would contribute to this, where Lab 108 reported consistently higher results.

Laboratories 5, 36, and 141 reported lower mean than the consensus for DIM 2. Laboratory 132 also had a mean result slightly lower than the majority of labs

As in the previous four trials, many laboratories reported exactly the same reading for each condom within at least in one of the samples DIM 1 and/or DIM 2. These readings may be due to:

- Rounding to the nearest mm instead of 0.5mm as required in ISO4074
- The technician assuming that all the condoms will have the same width

For sample DIM 1 there were 9 laboratories that reported the same width for all 10 condoms. Similarly for DIM 2 there were 11 laboratories. This results in a zero standard deviation and that would push some laboratories with non zero standard deviation into being identified as a repeatability outlier. Several laboratories are apparently still measuring only to the nearest mm. This increases the inter-laboratory spread, although it may decrease the within-laboratory spread of results. Measurement to 0.5 mm should be possible with readily available rulers. This matter has been discussed in previous reports.

The test method for width involves laying the condom flat across a ruler. There are four obvious potential sources of error. They are:

1. Misreading the ruler scale. This can yield either low or high results.
2. Failing to remove all creases from the condoms, which tend to stick together due to the lubricant. If the laboratory fails to remove the creases, the result will be low.
3. Not hanging the condom perpendicular to the ruler. This will increase the measurement obtained, although a 5 degree misalignment will result in less than 0.5% error.
4. Measurement at the wrong point on the condom. Some brands taper slightly (but none in this trial).

Width results are summarized in Table 7. This table shows the precision components (repeatability and reproducibility), after removing any extreme results.

Table 7: Results for Width (mm)

Sample	No of laboratories in estimate	Mean (mm)	Repeatability (mm)	Reproducibility (mm)
DIM 1	58	49.2	0.6	1.1
DIM 2	55	56.8	0.7	1.1

10.2.3 Thickness

There were sixty-one (61) laboratories that participated in the thickness test. Of these, 24 used the ISO mass-based method and 37 used the micrometer method. One laboratory submitted results for DIM 1 using mass method and DIM 2 using the micrometer method. One laboratory (61), did not state which method they used, and therefore their results are not included in the data for the individual methods.

The choice of tests reflects an increase in the participation in the micrometer method, and a continuing swing away from the mass method, because it is so cumbersome to use on lubricated condoms.

As in previous years, the mean result on the micrometer method was systematically less than on the mass method. This year, the difference was about 0.0038 mm for DIM 1 and 0.0029 mm for DIM 2 samples. Compared with the reproducibility of the methods, this difference is not large, and the composite histogram is not bi-modal. The consensus mean for both methods is approximately halfway between the two individual values.

As in the last four years, the mass method had better reproducibility than the micrometer sample. The combined data shows a similar reproducibility to the micrometer method, of approximately 9 microns. The mass method alone has a reproducibility of approximately 6 microns.

Thickness results are summarised in Table 8. This table shows the precision components (repeatability and reproducibility), after removing any extreme results.

Table 8: Results for Thickness (mm)

Method	Sample	No of laboratories in estimate	Mean (mm)	Repeatability (mm)	Reproducibility (mm)
Combined methods	DIM 1	51	0.072	0.003	0.009
	DIM 2	52	0.075	0.004	0.008
Mass	DIM 1	23	0.074	0.003	0.006
	DIM 2	23	0.076	0.003	0.005
Micrometer	DIM 1	32	0.070	0.005	0.009
	DIM 2	31	0.073	0.005	0.007

10.2.3.1 Mass Method

For sample DIM 1: Laboratory 5 reported low values compared with other participants, it was a repeatability outlier and reproducibility straggler.

For sample DIM 2: There were no extreme results.

Laboratory 15 was the only participant to report in microns and Enersol converted the results to mm.

10.2.3.2 Micrometer Method

A number of laboratories had extreme results in both samples. Only two other laboratories had extreme results and these were in the DIM 2 sample only.

Laboratories 26 and 145 reported high results for both samples DIM 1 and DIM 2. Laboratory 26 may have reported the double-wall thickness rather than single-wall thickness as requested by the standard.

For both samples: Laboratories 26, 107, 108 and 145 were repeatability outliers
Laboratories 26 and 145 were reproducibility outliers

For sample DIM 2: Laboratory 29 and 71 were reproducibility stragglers

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In both samples DIM 1 and DIM 2 lab 71 reported the lowest mean and lab 89 also had a low mean in both samples. Laboratory 29 reported the highest mean in both samples after removal of extreme results. The laboratories reporting low or high results should check the samples while taking the measurements to ensure there is no cause to provide a low result such as stretching of the condom, or a high result such as not removing the powder or not laying the condom flat.

10.3 Inflation - Bursting Volume and Pressure

The inflation test is similar to the dimensions tests in that each test result is based on replicate measurements. For the inflation test, the number of replicates is much higher than that in the dimensions test, and the pass/fail criteria implicitly involve the shape of the distribution.

It is known from experience with inflation testing that the results are not necessarily normally distributed. Also, the pass-fail criterion involves the low end of the distribution curve. Therefore, the analysis of results for this test is different from the others. The large sample size enables comparison of distributions, and this is done by constructing a reference distribution.

It was constructed from the combined results by:

1. Ordering each laboratory's results in increasing order (n= 1 to 100)
2. Taking the median across laboratories of each ordered result (eg the median of the 20th from the lowest of the ordered values from each laboratory). This is then the 20th value from the bottom in the reference distribution
3. Where a laboratory does not return the full 100 values for a sample, synthesised values are included in its results, spread evenly across the distribution for the purposes of generating the reference distribution (these synthesised values are not part of the values reported as the laboratory's results)

Result summaries for the inflation test include:

1. **Table 9**, where mean results, repeatability and reproducibility based on means and sample pair results are presented;
2. **Table 10 and Table 11**, show the observations of laboratory in Volume Pressure;
3. **Table 12 and Table 13**, where scale factors, comparing the mean and standard deviation results of each laboratory with those of the reference distribution are presented. Ideally, all scale factors would be 1.00. Scale factors greater than 1.00 indicate a positive bias, those less than 1.00 indicate a negative one;
4. Histograms of mean values and laboratory standard deviations and a summary statistics with and without the extreme results for the mean volumes and pressures, determined using Dixon's and Cochran's tests. These are shown in **Appendix A**;
5. **Quantile-Quantile plots**. Each laboratory's ordered results are plotted against the corresponding ordered results of the reference distribution. Estimates of missing results are included where required. On these plots, the reference distribution is plotted on the horizontal axis, and the laboratory's results on the vertical. The ideal result in this plot would be all points lying on a line of slope 1. These plots have been used because of the significant skewness of the distributions; they are shown in the individual laboratory reports.

For most results presented (tables, histograms and Quantile-Quantile plots) the extreme individual values have been omitted in the interests of keeping a common scale on which most results are well represented.

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Due to limitations in the software currently used, Dixon's test as outlined in ISO 5725 can only be applied to the **mean** inflation results. Repeatability extreme results can only be determined with respect to differences between results for the different samples, because there is only one replicate of the mean. Laboratories whose results are not identified as extreme by Dixon's test may still have a problem, if the Quantile-Quantile plots show significant deviation from the ideal straight line.

On these plots, the reference distribution as described earlier is plotted on the horizontal axis, and the laboratory's results on the vertical. The ideal result in this plot would be all points lying on a line of slope 1. A point above the line indicates that the laboratory's result is higher than the reference, while a point below the line indicates the opposite.

Where the results approximate a straight line of slope other than 1.00, that suggests a systematic error, such as calibration. Straight lines not passing through the origin indicate standard deviations different from that of the reference distribution.

Where the results deviate consistently from a straight line at one end of the distribution more than at the other, this suggests that there is a problem with either high or low readings, for example with condoms that slip as the pressure rises towards burst.

Laboratories should examine their own Quantile-Quantile plots and look for trends that are consistent across the two samples, IN 1 and IN 2.

10.3.1 Discussion of Inflation results

Seventy-four (74) laboratories participated in the inflation test.

There was a wide difference in the mean burst properties among the samples. The difference was about 10.7L and 0.54KPa for the volume and pressure respectively.

Mean results, repeatability and reproducibility based on the pair of the two sub samples results are summarised in Table 9. For the inflation test, the repeatability assessments are based on the differences between means (not on standard deviations of individual laboratories for individual sub-samples). Therefore, high standard deviations alone will not show up as extreme results in the statistical tests.

The data spreadsheets were supplied automatically calculating the mean and standard deviation of the numbers entered, so laboratories should have been able to check for implausible results. Also, in the case of inflation, laboratories with Enersol equipment have the option of submitting raw data files from their computers to eliminate transcription error, and Enersol and other providers of inflation testing equipment provide a means of copying the data into a spreadsheet. Transcription errors in inflation test results should therefore be avoidable in most cases.

Table 9: Results for Inflation Volume and Pressure

Test	Sample	No of laboratories in estimate	Mean	Repeatability	Reproducibility
Volume	IN 1	74	29.5	3.0	5.2
	IN 2	74	40.2		
Pressure	IN 1	74	2.41	0.14	0.22
	IN 2	74	1.87		

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10.3.1.1 Volume

There were no extreme results for both samples IN 1 and IN 2.

Laboratory 108 had the highest mean in both samples, but shared the highest mean in IN 2 with laboratory 144. Laboratory 26 had the lowest mean on IN 2 and was close to the lowest on IN 1.

Based on the standard deviations, laboratory 71 was very high on both samples and appears off the charts in Appendix A. Also at the high end in the standard deviations for both samples are laboratories 243 and 89. While they don't have the highest standard deviations, they appear at the high end in both samples and laboratory 89 is significantly higher than most laboratories in IN 2.

Observations can be made, based on the scale factors for mean and for standard deviation (Table 12 and Table 13) and on the Quantile-Quantile plots, which are supplied to each laboratory individually. The main observations for the burst pressure are shown in Table 10.

Table 10: Inflation Volume – observations

Lab. No.	Inflation (Volume) observations
26	Low mean for both samples, high standard deviation for IN 1
528	Many low values
29	Low mean for IN1
34	High standard deviation for IN 1
35	Low mean for IN1
42	Low mean and high standard deviation for IN 1
243	Slightly low mean and high standard deviation on both samples
54	Low mean for IN 1
55	High standard deviation for both samples
56	High standard deviation on IN 1
64	Low mean for IN 1
69	High mean for IN 2
71	Very high standard deviation for both samples
72	Low mean for IN 1
81	Low mean for IN 2 and IN 1 slightly low
87	High mean for IN 1
89	High mean for IN 1
90	High standard deviation for IN 1
98	High standard deviation for IN 1
100	High standard deviation for IN 2
110	Low mean for IN 2
201	High standard deviation for IN 1
108	High mean and high standard deviation for both samples.
127	High mean for IN 1
227	High mean and standard deviation for IN 1
137	Low mean for IN 1 and a high standard deviation for IN 2
144	High mean for IN 2 and high standard deviation for both samples

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10.3.1.2 Pressure

There were no extreme results for both samples IN 1 and IN 2. Laboratory 118 has the highest mean in both samples, but shares the highest mean in IN 1 with laboratories 35 and 77. Laboratory 243 has the low end pressure mean for both samples IN 1 and IN 2.

Observations can be made, based on the scale factors for mean and for standard deviation (Table 12 and Table 13) and on the Quantile-Quantile plots. The main observations for the burst pressure are shown in Table 11.

Table 11: Inflation Pressure – observations

Lab. No.	Inflation (Pressure) observations
528	High standard deviation for IN 1 and many low values
34	High standard deviation for IN 1
42	High standard deviation for IN 1
243	Slightly low mean and high standard deviation for both samples
55	High standard deviation for IN 1
71	High standard deviation for both samples, means slightly low
89	Low mean and high standard deviation for both samples
98	Low mean and high standard deviation for IN 1
100	High standard deviation for both samples
118	High mean for both samples
227	High standard deviation for IN 1
137	High standard deviation for IN 2
143	High standard deviation on IN 1

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Table 12: Results for Inflation test - scale factors for Mean

Lab	Volume		Pressure		Lab	Volume		Pressure	
	IN 1	IN 2	IN 1	IN 2		IN 1	IN 2	IN 1	IN 2
4	1.03	1.00	1.02	1.02	88	1.03	1.00	0.97	0.98
5	1.04	1.03	1.03	1.02	89	1.11	1.05	0.94	0.91
15	1.05	0.99	0.99	0.96	90	0.95	1.03	1.02	0.99
17	1.00	1.00	1.01	1.01	92	0.96	1.04	1.05	1.06
20	1.00	0.98	0.99	1.00	98	1.02	1.06	0.91	0.94
26	0.85	0.87	1.03	1.04	100	0.95	0.97	0.99	0.97
28	1.00	0.98	1.02	1.01	101	1.03	1.07	1.01	1.00
228	1.00	0.99	1.02	1.01	201	1.06	1.07	0.99	0.98
328	0.99	0.97	1.02	1.02	105	0.99	0.99	0.97	0.97
428	1.04	1.04	1.00	0.99	106	0.97	0.97	0.99	0.97
528	0.98	0.97	1.00	0.99	107	0.96	1.03	1.01	1.03
29	0.89	1.00	1.02	0.99	108	1.18	1.11	1.01	1.00
32	1.02	1.02	1.05	1.06	110	0.93	0.91	0.99	0.99
34	1.02	1.00	0.95	1.00	115	0.97	0.96	1.01	1.00
35	0.90	0.97	1.07	1.04	118	0.95	0.93	1.09	1.12
36	1.07	1.03	0.99	1.03	122	1.02	1.03	0.96	0.96
37	0.99	0.99	1.03	1.02	123	1.00	1.02	0.98	1.00
38	0.97	0.99	1.04	1.06	125	1.07	1.01	0.97	0.94
39	1.05	0.99	0.97	0.97	126	1.01	1.02	1.01	1.02
42	0.92	0.95	0.97	0.99	127	1.12	1.05	0.98	0.96
43	0.99	1.00	1.00	1.03	227	1.08	1.05	0.96	0.96
243	0.93	0.93	0.92	0.93	128	1.01	1.00	1.00	0.98
54	0.86	0.97	1.00	1.00	130	0.99	0.98	0.99	0.98
55	0.98	1.00	0.96	0.96	230	1.02	1.03	1.00	1.01
56	1.02	1.00	0.99	1.02	330	1.05	1.02	0.99	0.99
61	0.98	0.95	0.99	1.00	430	1.02	1.00	1.00	0.98
63	0.98	1.00	1.02	1.03	530	1.01	1.03	0.99	1.00
64	0.91	0.97	1.02	0.99	630	1.02	0.99	1.01	1.00
66	0.97	0.95	1.01	0.99	132	1.07	1.04	0.97	1.01
69	1.07	1.08	1.01	0.99	133	0.94	0.99	0.99	1.00
71	0.97	1.07	0.92	0.94	134	1.00	1.00	1.00	0.99
72	0.89	0.97	1.00	1.01	137	0.83	0.96	1.04	1.00
75	1.03	1.06	0.98	0.97	139	1.00	1.01	1.01	1.02
77	0.94	0.97	1.05	1.06	141	0.95	1.00	1.02	1.01
81	0.93	0.88	0.98	0.98	143	1.01	1.06	1.02	1.05
87	1.10	1.03	0.95	0.93	144	1.04	1.12	1.01	0.99
287	1.04	0.99	1.01	1.00	145	1.05	0.98	1.01	1.00
ref	1.00	1.00	1.00	1.00	ref	1.00	1.00	1.00	1.00

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Table 13: Results for inflation test - scale factors for Standard Deviation

Lab	Volume		Pressure		Lab	Volume		Pressure	
	IN 1	IN 2	IN 1	IN 2		IN 1	IN 2	IN 1	IN 2
4	0.84	1.11	0.89	1.14	88	1.14	0.93	1.15	0.90
5	0.87	1.00	0.79	0.99	89	2.15	2.01	1.76	1.70
15	1.07	1.18	1.11	1.23	90	1.67	0.83	1.20	0.84
17	0.89	1.03	0.85	1.08	92	1.00	0.70	0.97	0.70
20	0.77	0.79	0.83	0.80	98	2.12	1.46	2.02	1.32
26	1.69	0.76	0.93	0.85	100	1.29	1.50	1.49	1.57
28	0.94	1.16	1.04	1.22	101	0.92	1.16	0.82	0.92
228	0.97	1.28	1.05	1.30	201	1.97	1.11	1.17	0.98
328	0.91	0.99	0.91	0.97	105	1.11	1.17	0.95	1.33
428	0.89	1.02	0.96	1.00	106	0.73	0.89	0.80	1.09
528	1.38	1.42	1.57	1.48	107	0.95	0.91	1.00	0.92
29	0.93	1.22	1.00	1.16	108	1.48	1.50	1.29	1.26
32	0.88	0.96	0.93	0.97	110	0.99	1.00	1.19	1.15
34	1.60	1.29	1.72	1.32	115	0.86	0.90	0.87	0.85
35	1.07	0.84	1.21	0.85	118	1.04	1.05	1.35	1.35
36	1.18	1.09	1.13	1.19	122	1.17	1.04	1.21	1.07
37	0.80	0.84	0.81	0.89	123	0.92	1.00	1.32	0.95
38	0.93	0.82	0.92	0.81	125	0.96	1.16	0.97	1.29
39	0.86	0.83	0.83	0.84	126	1.11	1.27	1.01	1.21
42	1.60	1.18	1.86	1.23	127	0.99	1.21	0.96	1.20
43	1.36	0.94	1.39	0.96	227	1.79	1.19	1.72	1.09
243	2.31	1.69	2.17	1.53	128	0.86	1.07	1.18	1.11
54	0.96	1.05	1.02	1.11	130	0.79	0.97	0.87	1.05
55	1.60	1.46	1.72	1.43	230	0.85	0.91	0.92	0.90
56	1.45	1.02	1.44	0.99	330	0.95	0.87	0.96	0.84
61	0.99	0.81	0.93	0.96	430	0.92	1.14	1.03	1.02
63	0.78	0.96	0.84	1.04	530	0.70	0.85	0.71	0.86
64	1.07	0.97	1.11	1.00	630	0.78	0.90	0.80	0.94
66	0.99	0.91	0.91	1.01	132	0.64	0.98	0.47	0.48
69	1.03	1.13	0.97	1.04	133	0.79	0.88	0.97	0.87
71	3.84	2.47	2.51	1.68	134	0.76	0.97	0.92	1.04
72	1.04	0.85	1.25	0.93	137	1.15	1.65	0.93	1.87
75	0.79	1.19	0.75	1.12	139	1.07	0.89	1.39	0.86
77	0.89	0.90	1.01	0.97	141	0.95	0.94	0.94	1.00
81	0.83	0.93	1.00	1.09	143	1.09	0.81	1.49	1.16
87	1.47	1.23	1.03	0.95	144	1.85	1.73	1.41	1.21
287	0.94	0.84	1.02	0.89	145	0.95	1.04	0.79	1.04
ref	1.00	1.00	1.00	1.00	ref	1.00	1.00	1.00	1.00

10.4 Tensile Properties

Commonly used standards have used three tensile properties:

- Force at Break
- Elongation at Break
- Tensile Strength

The force and elongation are independent quantities, but the tensile strength is calculated by dividing the force at break by the cross-sectional area of the sample. This latter quantity involves the thickness, which must be measured separately.

Tensile strength is no longer required in the ISO standard, and has been omitted from the trial. The tensile test has lost favour in condom standards. One reason for this was the difficulty in cutting a good sample and the effect of sample defects on the result. While ISO 4074 still uses the tensile force as a requirement for extra strong condoms, most manufacturers have stopped using the claim.

10.4.1 Force at Break

Thirty-three (33) laboratories performed Force at Break. Table 14 describes the results for these tensile properties.

There were no extreme results for TBL 1, TBL 2 and TTE 4.

Laboratory 141 reported low values for TBL1, TCE 3 and TTE 4, and it was a reproducibility outlier in TCE 3.

For sample TCE 3 Laboratory 15 was a repeatability outlier. Laboratories 53 and 72 were reproducibility outliers and reported some of the highest means for all of the three samples tested in the labs (TBL1, TBL2 and TCE3).

Laboratory 141 was also a reproducibility outlier on TCE 3.

TCE 3 samples were cut by Enersol and tested by the laboratories. TTE 4 samples were cut by the labs and returned to Enersol for testing.

Table 14: Results for Tensile Properties – Force at Break

Test	Sample	No of laboratories in estimate	Mean	Repeatability	Reproducibility
Force at break (N)	TBL 1	33	80.9	30.6	44.5
	TBL 2	33	77.9	28.6	38.1
	TCE 3	29	77.8	24.7	25.2
	TTE 4	31	76.4	34.4	42.3

10.4.2 Elongation at Break

Thirty-two (32) laboratories performed Elongation at Break. Table 15 describes the results for the Elongation and Break tensile properties.

Laboratory 53 was a repeatability outlier for TBL 1, TBL 2 and TCE 3. This laboratory was also a reproducibility straggler for TCE 3 and reported the highest mean values.

Laboratory 141 was a reproducibility outlier for TBL 1, TBL 2 and TCE 3. This laboratory reported very low values for TBL 1, TBL 2 and TCE 3. This laboratory needs to check their machine and their calculation of the elongation.

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Laboratory 15 was a repeatability outlier for TCE 3.

Laboratories 66 and 89 had consistently low results across TBL 1, TBL 2 and TCE 3. they should also check their elongation measurement techniques.

For sample TTE 4 there were no extreme results.

Table 15: Results for Tensile Properties – Elongation at Break

Test	Sample	No of laboratories in estimate	Mean	Repeatability	Reproducibility
Elongation at break (%)	TBL 1	30	743	71	140
	TBL 2	30	769	66	127
	TCE 3	29	777	55	122
	TTE 4	30	720	82	102

10.4.3 Tensile cut pieces

Sample TTE 4 involved laboratories cutting samples and sending the cut pieces to Enersol for testing. For this reason it was possible for Enersol to examine the appearance of samples before doing the test.

This year most of the laboratories participating in this test returned tensile pieces with a good cut, which is the same as last year.

It appears from comparing the results submitted by laboratories against the results achieved by Enersol that some laboratories have well cut samples but they have a problem either with the testing technique, handling the test samples or with machine calibration. Some laboratories in this trial either recorded low or high values for the force but the samples tested by Enersol show the results for their cut samples were close to the consensus mean.

10.5 Freedom from Holes

The analysis of this test differs from most other tests in that the results of the latter are the mean of a series of measurements of a continuous variable, while this one is a test of attributes yielding a single integer as the result - the number of holes found.

Condoms are known not to be entirely hole-free. In order to make the results reasonably reproducible, Enersol chose condoms with very few holes, and then artificially introduced a known number of holes in known locations into each sub-sample. Laboratories were assessed on the number of holes they found in the regions where Enersol introduced them. In this way the probability of a naturally-occurring hole being in the regions chosen for the introduced holes is very low.

While it is probable that the number of holes in each of the sub-samples sent out is as intended by the organisers, it is still possible that the number is different. Reasons for this include:

- Human error: either the wrong number of condoms with holes introduced, or holes improperly made
- Holes in a sub-sample which were caused during manufacture
- Some degree of re-sealing due to continuing vulcanisation in the product.

The assembly of samples and the successful creation of holes was checked as carefully as practicable. Samples tested soon after the creation of holes indicated that they were all detectable. It was not possible to pre-test all the condoms without artificially introduced holes that were actually distributed

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to the participants. However, sub-samples tested before the distribution of samples confirmed the low incidence of holes.

It is improbable that any one laboratory would have received more than one condom with a hole originating from the factory in any one sub-sample.

Therefore, it is highly probable that the number of holes in the regions chosen by Enersol in each sub-sample was the number introduced. Laboratories finding fewer holes than those introduced have most probably missed holes which were actually there.

In view of the above, the techniques of analysis are different from those used for the previous tests. In this case, the results obtained are compared with the number of holes introduced by the organisers, and not with consensus values.

10.5.1 Discussion of Freedom from Holes results

Laboratories were able to perform any or all of the following Freedom from Holes tests:

- Visual Method
- Conductivity Method
- ASTM (Hang & Squeeze) Method

Samples H 1, H 2 and H 3 were for the Visual testing method and samples H 4, H 5 and H 6 were for the Conductivity testing method. Samples H 7, H 8 and H 9 were for the ASTM (Hang and Squeeze) method.

The following summaries of results for the three test methods are presented:

- The tables on the following pages present the details for the Visual, Conductivity and ASTM (Hang & Squeeze) methods
- The tables show the holes found in the regions where the holes were introduced and the total holes found, by laboratory
- Histograms of total holes found in the Enersol regions for the Visual method, Conductivity method and the hang & squeeze method are on the following pages
- Histograms of total holes found in each sub-sample and of holes found in the regions where they were introduced (Appendix A)

10.5.2 Visual Method

Fifty-nine (59) laboratories performed the Visual method.

Laboratory 28 requested 4 extra sets, laboratory 130 requested 5 extra sets and laboratory 142 requested 2 extra sets. These are included in the total of the 59 laboratories.

Overall, 97.9% of the introduced holes were found.

Out of the 59 participating laboratories, 54 found all of the 6 holes introduced; 3 found all but one hole; 2 found all but 2 holes.

Over the 3 samples, all holes introduced in region B were detected. 98.3% of introduced holes in region C were detected. In regions A, D and E, the detection rate was approximately 96.6% on each location. The sizes of the holes varied from one location to the other, with the largest needle being used to make the holes in region E.

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Table 16: Visual Method – Sample H 1 results

Lab	Region			Extras	Total in Enersol regions	Total found	Lab	Region			Extras	Total in Enersol regions	Total found
	A	B	C					A	B	C			
4	1	1	1	0	3	3	87	1	1	1	0	3	3
5	1	1	1	0	3	3	88	1	1	1	1	3	4
15	1	1	1	1	3	4	90	1	1	1	0	3	3
17	1	1	1	1	3	4	98	1	1	1	0	3	3
20	1	1	1	0	3	3	101	1	1	1	0	3	3
26	1	1	1	1	3	4	105	1	1	1	0	3	3
28	1	1	1	0	3	3	106	1	1	1	0	3	3
228	1	1	1	0	3	3	110	1	1	1	1	3	4
328	1	1	1	0	3	3	115	1	1	1	0	3	3
428	1	1	1	0	3	3	118	1	1	1	0	3	3
528	1	1	1	0	3	3	123	1	1	1	0	3	3
29	1	1	1	0	3	3	125	1	1	1	0	3	3
32	1	1	1	0	3	3	126	1	1	1	0	3	3
34	1	1	1	0	3	3	128	1	1	1	0	3	3
35	1	1	1	1	3	4	130	1	1	1	0	3	3
36	1	1	1	0	3	3	230	1	1	1	0	3	3
37	1	1	1	1	3	4	330	1	1	1	0	3	3
38	0	1	1	0	2	2	430	1	1	1	0	3	3
39	1	1	1	0	3	3	530	1	1	1	0	3	3
43	1	1	1	0	3	3	630	1	1	1	0	3	3
53	1	1	1	0	3	3	132	1	1	1	0	3	3
55	1	1	1	0	3	3	134	1	1	1	0	3	3
61	1	1	1	0	3	3	141	1	1	1	0	3	3
63	1	1	1	4	3	7	142	1	1	1	0	3	3
66	1	1	1	0	3	3	242	1	1	1	0	3	3
69	1	1	1	0	3	3	342	1	1	1	0	3	3
72	1	1	1	0	3	3	143	1	1	1	0	3	3
75	1	1	1	0	3	3	144	0	1	1	0	2	2
77	1	1	1	0	3	3	145	1	1	1	0	3	3
81	1	1	1	0	3	3							
made	1	1	1	0	3		made	1	1	1	0	3	

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Table 17: Visual Method – Sample H 2 results

Lab	Region	Extras	Total in Enersol regions	Total found	Lab	Region	Extras	Total in Enersol regions	Total found
	C					C			
4	1	0	1	1	87	1	0	1	1
5	1	0	1	1	88	1	0	1	1
15	1	3	1	4	90	1	0	1	1
17	1	0	1	1	98	1	0	1	1
20	1	0	1	1	101	1	0	1	1
26	1	0	1	1	105	1	0	1	1
28	1	0	1	1	106	1	0	1	1
228	1	0	1	1	110	1	0	1	1
328	1	0	1	1	115	1	0	1	1
428	1	0	1	1	118	1	0	1	1
528	1	0	1	1	123	1	1	1	2
29	1	0	1	1	125	1	0	1	1
32	1	0	1	1	126	1	1	1	2
34	1	0	1	1	128	1	0	1	1
35	1	1	1	2	130	1	0	1	1
36	1	0	1	1	230	1	0	1	1
37	1	0	1	1	330	1	0	1	1
38	1	0	1	1	430	1	0	1	1
39	1	0	1	1	530	1	0	1	1
43	1	0	1	1	630	1	0	1	1
53	1	1	1	2	132	1	0	1	1
55	0	1	0	1	134	1	0	1	1
61	1	4	1	5	141	1	0	1	1
63	1	0	1	1	142	1	0	1	1
66	1	0	1	1	242	1	0	1	1
69	1	0	1	1	342	1	0	1	1
72	1	0	1	1	143	1	0	1	1
75	1	1	1	2	144	1	0	1	1
77	1	0	1	1	145	1	0	1	1
81	1	0	1	1					
made	1	0	1		made	1	0	1	

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Table 18: Visual Method – Sample H 3 results

Lab	Region		Extras	Total in Enersol regions	Total found	Lab	Region		Extras	Total in Enersol regions	Total found
	D	E					D	E			
4	1	1	0	2	2	87	1	1	0	2	2
5	1	1	0	2	2	88	1	1	0	2	2
15	1	1	0	2	2	90	1	1	1	2	3
17	1	1	0	2	2	98	1	1	0	2	2
20	1	1	0	2	2	101	1	1	0	2	2
26	1	1	0	2	2	105	1	1	0	2	2
28	1	1	1	2	3	106	1	1	0	2	2
228	1	1	0	2	2	110	1	1	0	2	2
328	1	1	2	2	4	115	1	1	0	2	2
428	1	1	1	2	3	118	1	1	0	2	2
528	1	1	0	2	2	123	1	1	0	2	2
29	1	1	1	2	3	125	1	1	0	2	2
32	1	1	0	2	2	126	1	1	0	2	2
34	1	1	0	2	2	128	1	1	0	2	2
35	1	1	0	2	2	130	1	1	0	2	2
36	1	1	0	2	2	230	1	1	0	2	2
37	1	1	0	2	2	330	1	1	0	2	2
38	1	1	1	2	3	430	1	1	0	2	2
39	1	1	0	2	2	530	1	1	0	2	2
43	1	1	1	2	3	630	1	1	0	2	2
53	1	1	0	2	2	132	1	1	0	2	2
55	0	1	1	1	2	134	1	1	0	2	2
61	1	0	2	1	3	141	1	1	0	2	2
63	1	1	0	2	2	142	1	1	0	2	2
66	1	1	0	2	2	242	1	1	0	2	2
69	1	1	0	2	2	342	1	1	0	2	2
72	1	1	0	2	2	143	1	1	1	2	3
75	1	1	0	2	2	144	1	1	0	2	2
77	1	1	0	2	2	145	0	0	0	0	0
81	1	1	0	2	2						
made	1	1	0	2		made	1	1	0	2	

10.5.3 Conductivity Method

Fifty-one (51) laboratories participated in the conductivity method.

Laboratory 130 requested 5 extra sets, these are included in the total of the 51 laboratories.

Overall, 99% of the introduced holes were found. Out of the 51 participants, 49 laboratories found all the holes introduced and 2 laboratories found all but one hole. Holes in regions A, C and D were all found, regions B and E had a 98% detection rate.

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Table 19: Conductivity Method – Sample H 4 results

Lab	Region	Extras	Total in Enersol regions	Total found	Lab	Region	Extras	Total in Enersol regions	Total found
	A					A			
15	1	0	1	1	105	1	0	1	1
17	1	0	1	1	106	1	0	1	1
20	1	0	1	1	107	1	0	1	1
26	1	0	1	1	108	1	0	1	1
32	1	0	1	1	110	1	1	1	2
34	1	0	1	1	115	1	0	1	1
38	1	0	1	1	118	1	0	1	1
39	1	0	1	1	122	1	0	1	1
42	1	0	1	1	125	1	0	1	1
43	1	0	1	1	126	1	0	1	1
54	1	0	1	1	127	1	0	1	1
55	1	0	1	1	227	1	0	1	1
56	1	0	1	1	130	1	0	1	1
61	1	0	1	1	230	1	1	1	2
64	1	0	1	1	330	1	0	1	1
66	1	0	1	1	430	1	0	1	1
69	1	0	1	1	530	1	0	1	1
71	1	0	1	1	630	1	0	1	1
72	1	0	1	1	132	1	0	1	1
75	1	0	1	1	134	1	0	1	1
81	1	0	1	1	142	1	0	1	1
87	1	1	1	2	242	1	0	1	1
88	1	1	1	2	342	1	0	1	1
89	1	1	1	2	143	1	0	1	1
92	1	0	1	1	145	1	0	1	1
101	1	0	1	1					
made	1	0	1		made	1	0	1	

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Table 20: Conductivity Method – Sample H 5 results

Lab	Region		Extras	Total in Enersol regions	Total found	Lab	Region		Extras	Total in Enersol regions	Total found
	B	C					B	C			
15	1	1	0	2	2	101	1	1	0	2	2
17	1	1	0	2	2	105	1	1	0	2	2
20	1	1	0	2	2	106	1	1	0	2	2
26	1	1	0	2	2	107	1	1	0	2	2
32	1	1	0	2	2	108	1	1	0	2	2
34	1	1	0	2	2	110	1	1	0	2	2
38	1	1	0	2	2	115	1	1	0	2	2
39	1	1	0	2	2	118	1	1	2	2	4
42	1	1	0	2	2	122	1	1	0	2	2
43	1	1	0	2	2	125	1	1	0	2	2
54	1	1	0	2	2	126	1	1	0	2	2
55	1	1	0	2	2	127	1	1	0	2	2
56	1	1	0	2	2	227	1	1	0	2	2
61	1	1	1	2	3	130	1	1	0	2	2
64	1	1	0	2	2	230	1	1	0	2	2
66	1	1	0	2	2	330	1	1	0	2	2
69	1	1	0	2	2	430	1	1	0	2	2
71	1	1	0	2	2	530	1	1	0	2	2
72	1	1	0	2	2	630	1	1	0	2	2
75	1	1	0	2	2	134	1	1	0	2	2
81	1	1	0	2	2	142	1	1	0	2	2
87	1	1	0	2	2	242	1	1	0	2	2
88	1	1	0	2	2	342	1	1	0	2	2
89	1	1	0	2	2	143	1	1	0	2	2
92	1	1	0	2	2	145	1	1	0	2	2
made	1	1	0	2		made	1	1	0	2	

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Table 21: Conductivity Method – Sample H 6 results

Lab	Region			Extras	Total in Enersol regions	Total found	Lab	Region			Extras	Total in Enersol regions	Total found
	B	D	E					B	D	E			
15	1	1	1	0	3	3	101	1	1	1	0	3	3
17	1	1	1	0	3	3	105	1	1	1	0	3	3
20	1	1	1	0	3	3	106	1	1	1	0	3	3
26	1	1	1	0	3	3	107	1	1	1	0	3	3
32	1	1	1	0	3	3	108	1	1	1	0	3	3
34	1	1	1	0	3	3	110	1	1	1	0	3	3
38	1	1	1	0	3	3	115	1	1	1	0	3	3
39	1	1	1	0	3	3	118	1	1	1	2	3	5
42	1	1	1	0	3	3	122	1	1	1	0	3	3
43	1	1	1	0	3	3	125	1	1	1	0	3	3
54	1	1	1	0	3	3	126	1	1	1	0	3	3
55	1	1	1	0	3	3	127	1	1	1	0	3	3
56	1	1	1	0	3	3	227	1	1	1	0	3	3
61	1	1	1	0	3	3	130	1	1	1	0	3	3
64	1	1	1	0	3	3	230	1	1	1	1	3	4
66	1	1	1	0	3	3	330	1	1	1	0	3	3
69	1	1	1	0	3	3	430	1	1	1	0	3	3
71	1	1	1	0	3	3	530	1	1	1	0	3	3
72	1	1	1	0	3	3	630	1	1	1	0	3	3
75	1	1	1	0	3	3	134	1	1	1	0	3	3
81	1	1	1	0	3	3	142	1	1	1	0	3	3
87	1	1	1	0	3	3	242	1	1	1	0	3	3
88	1	1	1	0	3	3	342	1	1	0	0	2	2
89	1	1	1	0	3	3	143	1	1	1	0	3	3
92	0	1	1	0	2	2	145	1	1	1	0	3	3
made	1	1	1	0	3	3	made	1	1	1	0	3	3

10.5.4 ASTM (Hang & Squeeze) Method

Thirty-five (35) laboratories participated in the ASTM (Hang and Squeeze) test.

Laboratory 130 requested 4 extra sets, these are included in the total of the 35 laboratories.

Overall an average of 97.6% of the introduced holes were found.

Out of the 35 participants, 29 laboratories found all of the holes introduced and 6 laboratories found all but one hole.

All holes in regions B and E were found. Region A had a 91% detection rate, region C had a 97% detection rate and region D had a 94% detection rate.

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Table 22: ASTM (Hang & Squeeze) Method – Sample H 7 results

Lab	Region		Extras	Total in Enersol regions	Total found	Lab	Region		Extras	Total in Enersol regions	Total found
	A	B					A	B			
5	1	1	0	2	2	97	1	1	0	2	2
15	1	1	0	2	2	101	1	1	0	2	2
28	1	1	1	2	3	105	1	1	0	2	2
32	1	1	0	2	2	106	1	1	0	2	2
34	1	1	0	2	2	110	1	1	1	2	3
37	1	1	0	2	2	115	1	1	0	2	2
43	1	1	0	2	2	118	1	1	0	2	2
53	1	1	1	2	3	123	1	1	0	2	2
55	1	1	0	2	2	125	1	1	0	2	2
61	1	1	0	2	2	128	1	1	0	2	2
63	1	1	0	2	2	130	1	1	0	2	2
66	1	1	1	2	3	230	1	1	0	2	2
69	1	1	0	2	2	330	1	1	0	2	2
72	1	1	0	2	2	430	1	1	0	2	2
75	0	1	1	1	2	630	1	1	0	2	2
87	1	1	0	2	2	141	0	1	0	1	1
88	1	1	1	2	3	144	1	1	0	2	2
90	0	1	1	1	2						
made	1	1	0	2		made	1	1	0	2	

Table 23: ASTM (Hang & Squeeze) Method – Sample H 8 results

Lab	Region			Extras	Total in Enersol regions	Total found	Lab	Region			Extras	Total in Enersol regions	Total found
	C	D	E					C	D	E			
5	1	1	1	0	3	3	97	1	0	1	1	2	3
15	0	1	1	1	2	3	101	1	1	1	0	3	3
28	1	1	1	0	3	3	105	1	1	1	0	3	3
32	1	1	1	0	3	3	106	1	1	1	0	3	3
34	1	0	1	0	2	2	110	1	1	1	0	3	3
37	1	1	1	0	3	3	115	1	1	1	0	3	3
43	1	1	1	0	3	3	118	1	1	1	0	3	3
53	1	1	1	1	3	4	123	1	1	1	0	3	3
55	1	1	1	0	3	3	125	1	1	1	0	3	3
61	1	1	1	2	3	5	128	1	1	1	0	3	3
63	1	1	1	0	3	3	130	1	1	1	0	3	3
66	1	1	1	1	3	4	230	1	1	1	0	3	3
69	1	1	1	1	3	4	330	1	1	1	0	3	3
72	1	1	1	0	3	3	430	1	1	1	0	3	3
75	1	1	1	0	3	3	630	1	1	1	0	3	3
87	1	1	1	0	3	3	141	1	1	1	0	3	3
88	1	1	1	0	3	3	144	1	1	1	0	3	3
90	1	1	1	0	3	3							
made	1	1	1	0	3		made	1	1	1	0	3	

Table 24: ASTM (Hang & Squeeze) Method – Sample H 9 results

Lab	Region	Extras	Total in Enersol regions	Total found	Lab	Region	Extras	Total in Enersol regions	Total found
	E					E			
5	1	0	1	1	97	1	0	1	1
15	1	0	1	1	101	1	1	1	2
28	1	1	1	2	105	1	0	1	1
32	1	0	1	1	106	1	0	1	1
34	1	0	1	1	110	1	0	1	1
37	1	0	1	1	115	1	0	1	1
43	1	0	1	1	118	1	1	1	2
53	1	2	1	3	123	1	0	1	1
55	1	0	1	1	125	1	2	1	3
61	1	0	1	1	128	1	0	1	1
63	1	0	1	1	130	1	0	1	1
66	1	1	1	2	230	1	1	1	2
69	1	0	1	1	330	1	0	1	1
72	1	0	1	1	430	1	0	1	1
75	1	0	1	1	630	1	0	1	1
87	1	0	1	1	141	1	0	1	1
88	1	0	1	1	144	1	0	1	1
90	1	0	1	1					
made	1	0	1		made	1	0	1	

10.5.5 Comparison of the Visual, Conductivity and ASTM (Hang & Squeeze) Method results

Laboratories were more likely to get additional holes in the Visual method than the other methods and the extras found are more than three times that of the Conductivity method. This is likely to be due to the fact that all condoms must be rolled in the visual method, and that there is more opportunity to observe the condoms during the test, but it is also clear that some laboratories can be over-zealous in the rolling operation.

Overall, more of the holes introduced by Enersol were found in the conductivity method than the other methods. This is different to the results in 2010 where the ASTM Method was more successful in finding the holes Enersol made.

Laboratories found an average of 97.9% of the introduced holes in the Visual method, 99.0% using Conductivity and 97.6% using ASTM (Hang & Squeeze).

10.6 Package Seal Integrity

This test yields results similar in principle to those of the Freedom from Holes test. The test result is the number of leaking packs found. Therefore, the individual laboratory results are compared with the number of deliberately damaged packs. The packs were numbered and it was possible to identify from the laboratories’ reports whether they had found the deliberately introduced leaks (damaged packs) or other leaks. All packs were checked at Enersol before being sent to the participants.

Table 25 and Table 26 present the results of the package seal test for samples P 1 and P 2, respectively. The tables also show which of the deliberately damaged packs were found by each laboratory, and any extra leaking packs found.

Sixty (60) laboratories participated in this test. Laboratory 130 requested 4 extra sets; these are

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included in the total of the 60 laboratories.

For sample P 1: Laboratory 145 missed all 3 of the damaged packs

Laboratories 38, 64, 102 and 105 missed 1 of the damaged packs

For sample P 2: Laboratory 145 missed all 6 of the damaged packs

Laboratories 5 and 26 missed 1 of the damaged packs

There were 10 extra leaking packs found in P 1 samples and 11 in the P 2 samples.

In some of the cases, the missed packs could have been due to identification or transcription errors. For example, lab 145 reported 6 damaged packs in P 1 and 3 damaged packs in P 2 instead of 3 for P1 and 6 for P 2.

It is possible that laboratories 5, 102 and 105 reported the pack number incorrectly as 7 instead of 17 or as 2 instead of 12.

Overall, 540 leaking packs were distributed, and out of these, all but 15 were found therefore about 97% of the damaged packs were found.

Table 25: Package Seal Integrity – P 1

Lab	No. found	Packs damaged by Enersol and identified by labs			Extras	Lab	No. found	Packs damaged by Enersol and identified by labs			Extras
		3	17	20				3	17	20	
4	3	1	1	1	0	87	3	1	1	1	0
5	3	1	1	1	0	88	3	1	1	1	0
15	3	1	1	1	0	89	3	1	1	1	0
17	3	1	1	1	0	90	3	1	1	1	0
20	3	1	1	1	0	98	3	1	1	1	0
26	3	1	1	1	0	100	3	1	1	1	0
28	3	1	1	1	0	101	3	1	1	1	0
29	3	1	1	1	0	102	3	1	0	1	1
32	3	1	1	1	0	105	3	1	0	1	1
34	3	1	1	1	0	106	3	1	1	1	0
36	3	1	1	1	0	107	3	1	1	1	0
37	3	1	1	1	0	110	3	1	1	1	0
38	3	1	0	1	1	115	3	1	1	1	0
39	3	1	1	1	0	118	3	1	1	1	0
42	3	1	1	1	0	122	3	1	1	1	0
43	3	1	1	1	0	123	3	1	1	1	0
53	3	1	1	1	0	125	3	1	1	1	0
54	3	1	1	1	0	126	4	1	1	1	1
55	3	1	1	1	0	127	3	1	1	1	0
56	3	1	1	1	0	128	3	1	1	1	0
61	3	1	1	1	0	130	3	1	1	1	0
63	3	1	1	1	0	230	3	1	1	1	0
64	2	1	1	0	0	330	3	1	1	1	0
66	3	1	1	1	0	430	3	1	1	1	0
69	3	1	1	1	0	630	3	1	1	1	0
71	3	1	1	1	0	134	3	1	1	1	0
72	3	1	1	1	0	141	3	1	1	1	0
75	3	1	1	1	0	143	3	1	1	1	0
77	3	1	1	1	0	144	3	1	1	1	0
81	3	1	1	1	0	145	6	0	0	0	6
made	3	1	1	1	0	made	3	1	1	1	0

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Table 26: Package Seal Integrity – P 2

Lab	No. found	Packs damaged by Enersol and identified by labs						Extras	Lab	No. found	Packs damaged by Enersol and identified by labs						Extras
		1	5	8	12	14	19				1	5	8	12	14	19	
4	6	1	1	1	1	1	1	0	87	6	1	1	1	1	1	1	0
5	6	1	1	1	0	1	1	1	88	6	1	1	1	1	1	1	0
15	6	1	1	1	1	1	1	0	89	6	1	1	1	1	1	1	0
17	6	1	1	1	1	1	1	0	90	10	1	1	1	1	1	1	4
20	6	1	1	1	1	1	1	0	98	6	1	1	1	1	1	1	0
26	6	1	0	1	1	1	1	1	100	6	1	1	1	1	1	1	0
28	6	1	1	1	1	1	1	0	101	6	1	1	1	1	1	1	0
29	6	1	1	1	1	1	1	0	102	6	1	1	1	1	1	1	0
32	6	1	1	1	1	1	1	0	105	6	1	1	1	1	1	1	0
34	6	1	1	1	1	1	1	0	106	6	1	1	1	1	1	1	0
36	6	1	1	1	1	1	1	0	107	6	1	1	1	1	1	1	0
37	6	1	1	1	1	1	1	0	110	6	1	1	1	1	1	1	0
38	6	1	1	1	1	1	1	0	115	6	1	1	1	1	1	1	0
39	6	1	1	1	1	1	1	0	118	6	1	1	1	1	1	1	0
42	6	1	1	1	1	1	1	0	122	6	1	1	1	1	1	1	0
43	6	1	1	1	1	1	1	0	123	7	1	1	1	1	1	1	1
53	6	1	1	1	1	1	1	0	125	7	1	1	1	1	1	1	1
54	6	1	1	1	1	1	1	0	126	6	1	1	1	1	1	1	0
55	6	1	1	1	1	1	1	0	127	6	1	1	1	1	1	1	0
56	6	1	1	1	1	1	1	0	128	6	1	1	1	1	1	1	0
61	6	1	1	1	1	1	1	0	130	6	1	1	1	1	1	1	0
63	6	1	1	1	1	1	1	0	230	6	1	1	1	1	1	1	0
64	6	1	1	1	1	1	1	0	330	6	1	1	1	1	1	1	0
66	6	1	1	1	1	1	1	0	430	6	1	1	1	1	1	1	0
69	6	1	1	1	1	1	1	0	630	6	1	1	1	1	1	1	0
71	6	1	1	1	1	1	1	0	134	6	1	1	1	1	1	1	0
72	6	1	1	1	1	1	1	0	141	6	1	1	1	1	1	1	0
75	6	1	1	1	1	1	1	0	143	6	1	1	1	1	1	1	0
77	6	1	1	1	1	1	1	0	144	6	1	1	1	1	1	1	0
81	6	1	1	1	1	1	1	0	145	4	0	0	0	0	0	0	4
made	6	1	1	1	1	1	1	0	made	6	1	1	1	1	1	1	0

11 Extreme results

Table 27 shows the number of tests performed, the number of extreme results and the percentage of extreme results for each laboratory. The table is based on the outliers in Appendix A. Only those tests with a variable as an outcome are included in this table. Outliers on sample pairs in the inflation test have been counted as outliers on each individual sample.

In analysing this table, it should be borne in mind that an extreme result can occur by chance, and that if the laboratory does enough tests on inherently variable products, it is likely that one will occur. Different approaches to defining extreme results can lead to different totals. All extreme results should be investigated, but laboratories with many extreme results should investigate particularly thoroughly.

Those with a high number of extreme results and those with extreme results recurring from year to year need to take urgent action. Those laboratories with several extreme results should pay attention not only to the test methods concerned, but to their procedures, equipment and laboratory skills in general.

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The Freedom from Holes test and the Package Seal test are both attributes tests, and the definitions above cannot be used to identify extreme results. To assess their overall performance on these tests, laboratories can look at their individual results and consider the overall number of defects missed. The following charts display the total number of introduced holes found by laboratories in the Visual and Conductivity methods.

Chart 1: Visual Method – Total holes found in Enersol regions (H 1 + H 2 + H 3)

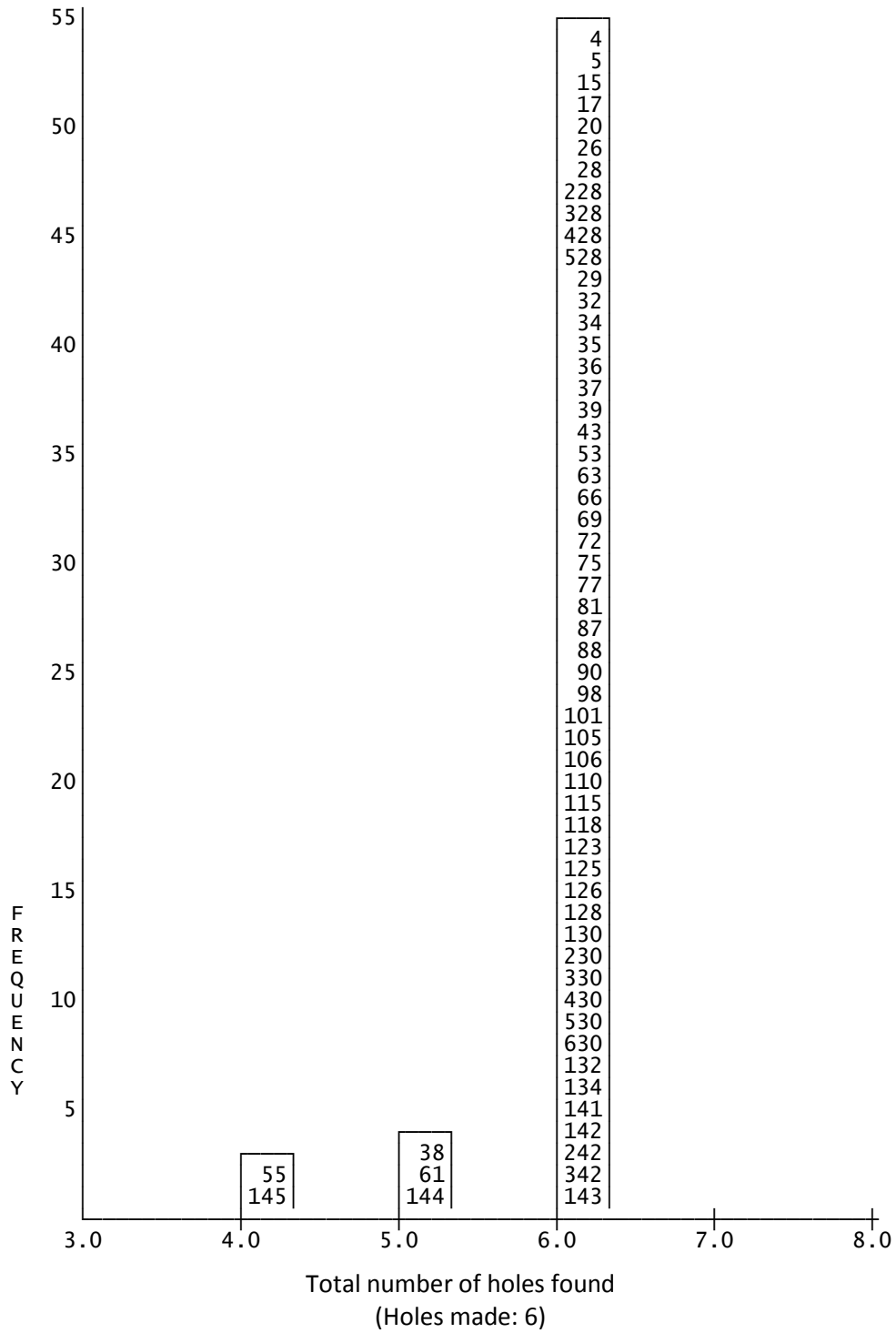
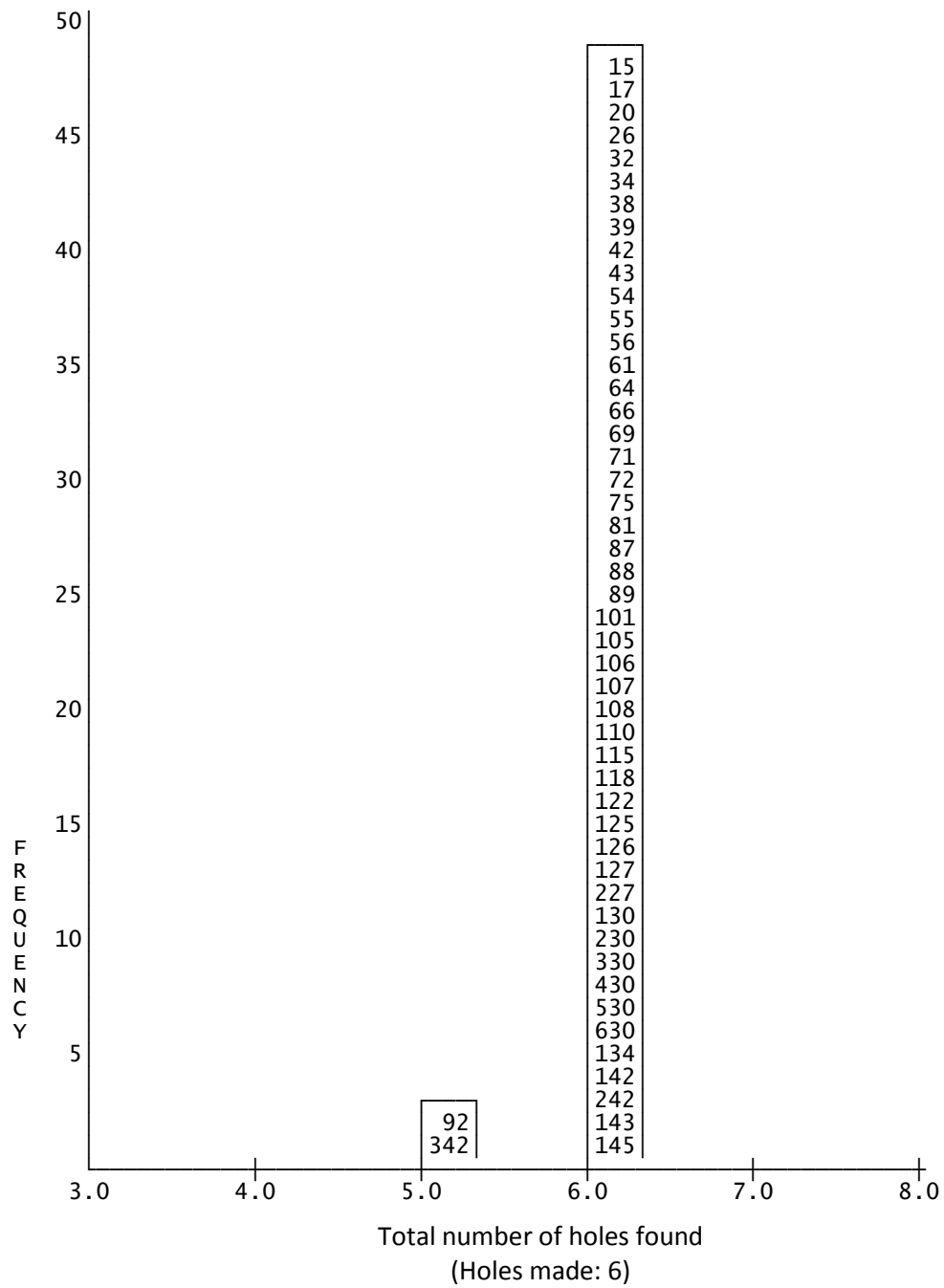
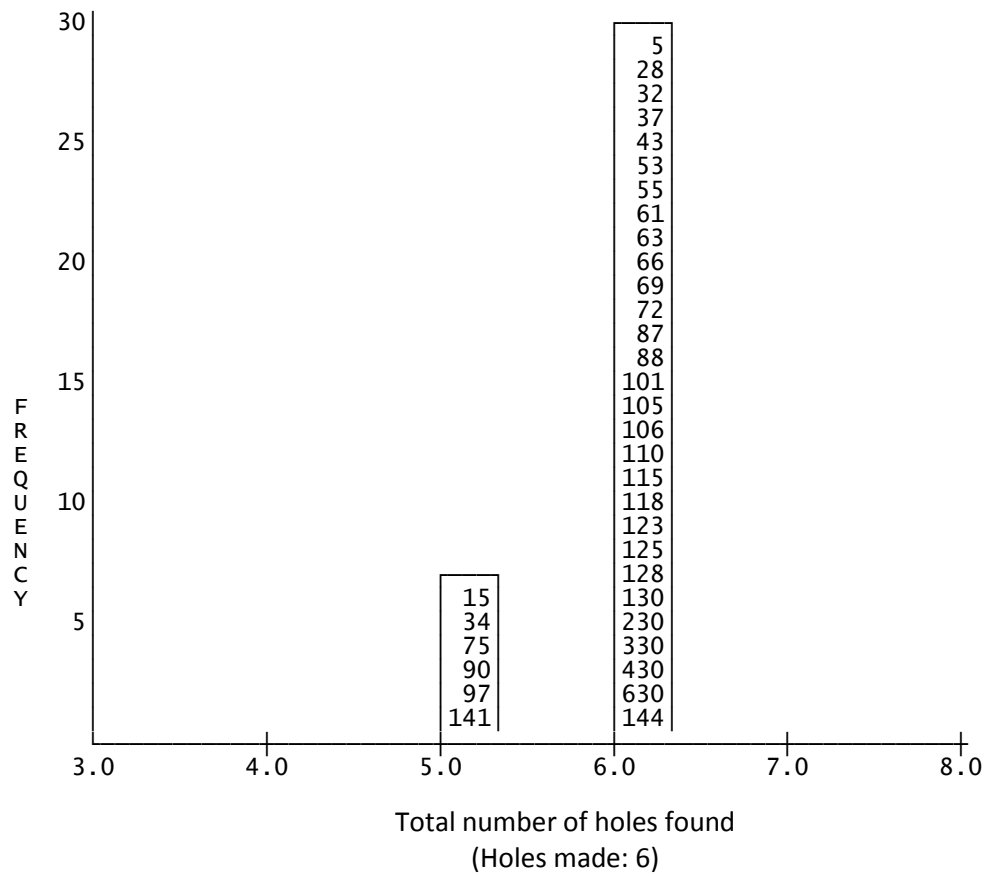


Chart 2: Conductivity Method – Total holes found in Enersol regions (H 4 + H 5 + H 6)



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Chart 3: ASTM (Hang & Squeeze) Method – Total holes found in Enersol regions (H 7 + H 8 + H 9)



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Table 27: Extreme results by laboratory

Lab	No. Tests	No. Extreme Results	Percentage (%) of Extreme Results	Lab	No. Tests	No. Extreme Results	Percentage (%) of Extreme Results
4	16	0	0	89	18	2	11
5	20	2	10	90	18	0	0
15	20	4	20	92	4	0	0
17	20	1	5	97	4	0	0
20	20	0	0	98	12	0	0
26	12	3	25	100	8	3	38
28	20	0	0	101	12	0	0
228	10	0	0	201	4	0	0
328	4	0	0	102	2	0	0
428	4	0	0	105	20	0	0
528	4	0	0	106	12	0	0
29	20	2	10	107	12	3	25
32	20	0	0	108	10	3	30
34	20	3	15	110	20	0	0
35	8	3	38	115	12	0	0
36	12	2	17	118	20	1	5
37	20	0	0	122	12	1	8
38	12	0	0	123	12	1	8
39	20	0	0	125	12	0	0
42	12	0	0	126	20	0	0
43	20	1	5	127	12	0	0
243	4	0	0	227	4	0	0
53	14	4	29	128	12	0	0
54	12	1	8	130	20	0	0
55	12	2	17	230	20	1	5
56	10	1	10	330	11	0	0
61	20	1	5	430	11	0	0
63	12	1	8	530	4	0	0
64	12	3	25	630	20	1	5
66	20	0	0	132	12	2	17
69	20	0	0	133	20	2	10
71	12	1	8	134	12	0	0
72	20	1	5	137	4	0	0
75	12	0	0	139	18	0	0
77	10	0	0	141	20	7	35
81	12	0	0	143	18	0	0
87	20	0	0	144	12	1	8
287	4	0	0	145	20	2	10
88	12	0	0				

It can be seen that the percentage of extreme results based on the criteria used, ranged from zero to 38%. Laboratories 35 and 100 both had more than 35% of their results show up as extreme. Laboratories 15, 26, 53, 64 and 107 had 20% to 35% of their results show up as extreme.

For the Freedom from Holes tests, it is difficult to use a statistical approach. Since the number of introduced holes is known. For the Visual method, laboratories 55 and 145 missed 2 holes out of the 6 made. In the other tests laboratories either found all holes or missed only one.

The package seal test is also an attributes test where laboratories look for a known number of leaking packs. Laboratory 145 missed all holes on both package seal tests. Six laboratories missed 1 hole over the two samples.

12 Conclusions

This trial has shown the level of agreement amongst laboratories on the tests usually conducted on condoms. It is clear that most laboratories understand the fundamentals of the testing procedures and reporting.

It should be noted that the criteria for defining extreme results used in this report are relatively liberal, and that some of the results that are not statistically extreme could still be the cause of important differences in practice.

While the range of results in some tests is relatively large, it must be remembered that this is due partly to the inherent variability of the product.

Generally, the repeatability and reproducibility figures are about the same as previous years, and these values seem to have stabilised.

This year, the number of the extra holes found by the Visual method equals the number for both Conductivity and ASTM test methods. The rate of hole detection was very high this year. It should be noted that the hole sizes for the conductivity test were deliberately made larger than the other tests, so the ISO 4074 test method would detect them.

In tensile testing, most of the laboratories sent good cut samples – as per last two years it is very impressive.

Enersol would like all participants in next year's trial to check their data before submitting. As Enersol does not change any of the data submitted by the participants, and it is a responsibility of the participants to provide the correct values for their results. In the package seal test one laboratory apparently swap the numbers of damaged packs for the two samples tested. Also in the thickness tests some of the participants appeared to report double-wall thickness.

It is notable that some other laboratories are outliers in a large proportion of the tests they participated in (see Table 27). Three laboratories were outliers in 35% or more of the tests they performed. This is either an extraordinary coincidence, or an indication that there are general problems with the operation of the laboratories concerned. Similarly, some laboratories found relatively few of the introduced holes.

In all these cases, the assistance of an outside expert, familiar with other condom testing laboratories, would be useful.

It is to be hoped that laboratories whose results are not close to the consensus will study their calibration, equipment, procedures and training to try to identify possible causes for the differences. Apparently, not all such laboratories traced and rectified the underlying problems after last year's trial, as there are a few laboratories who are outliers on the same tests year after year.

13 Contact ENERSOL

If you have any inquiries about this trial or to discuss your results, please contact Enersol using one of the methods below:

Phone: +61 2 9552 1707

Fax: +61 2 9552 1709

E-Mail: interlab-trials@enersol.com.au

APPENDIX A

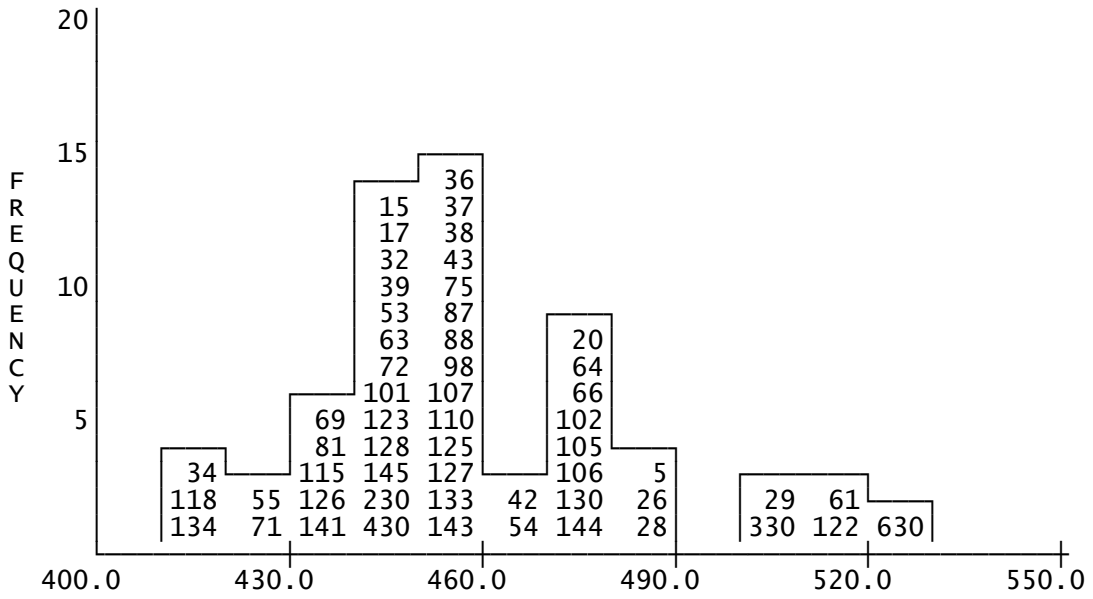
**HISTOGRAMS AND SUMMARY
STATISTICS BY TEST**

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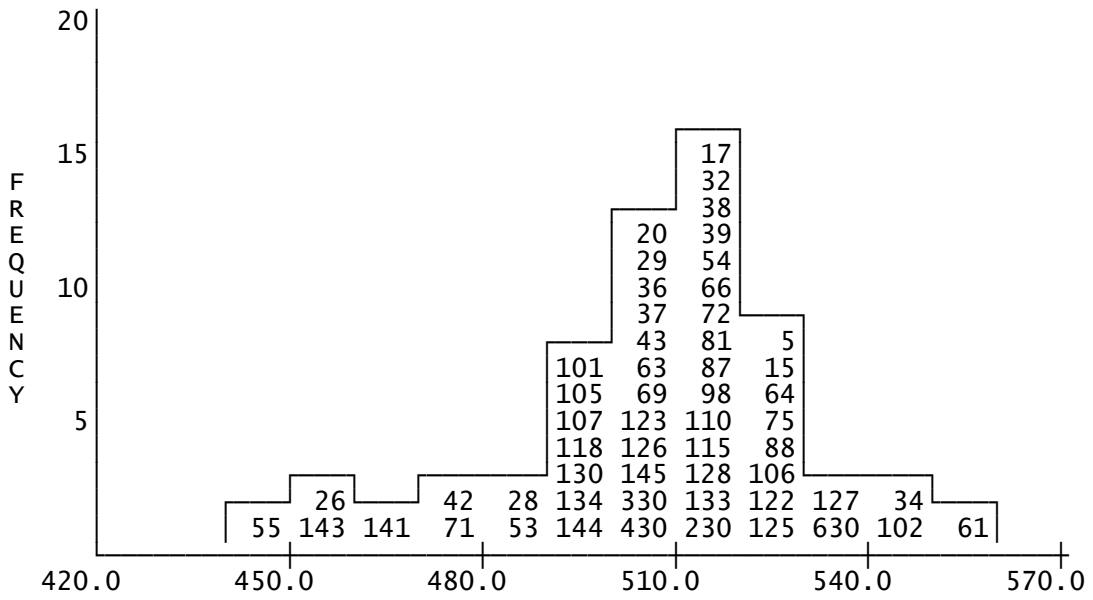
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Total Lubricant (mg) - Laboratory Means

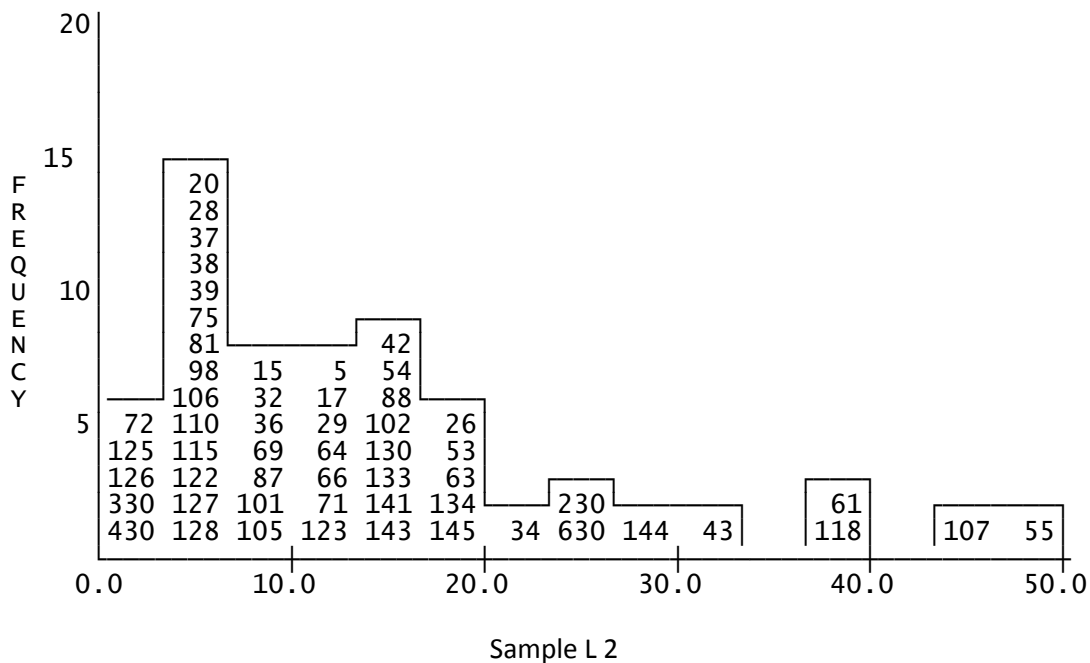
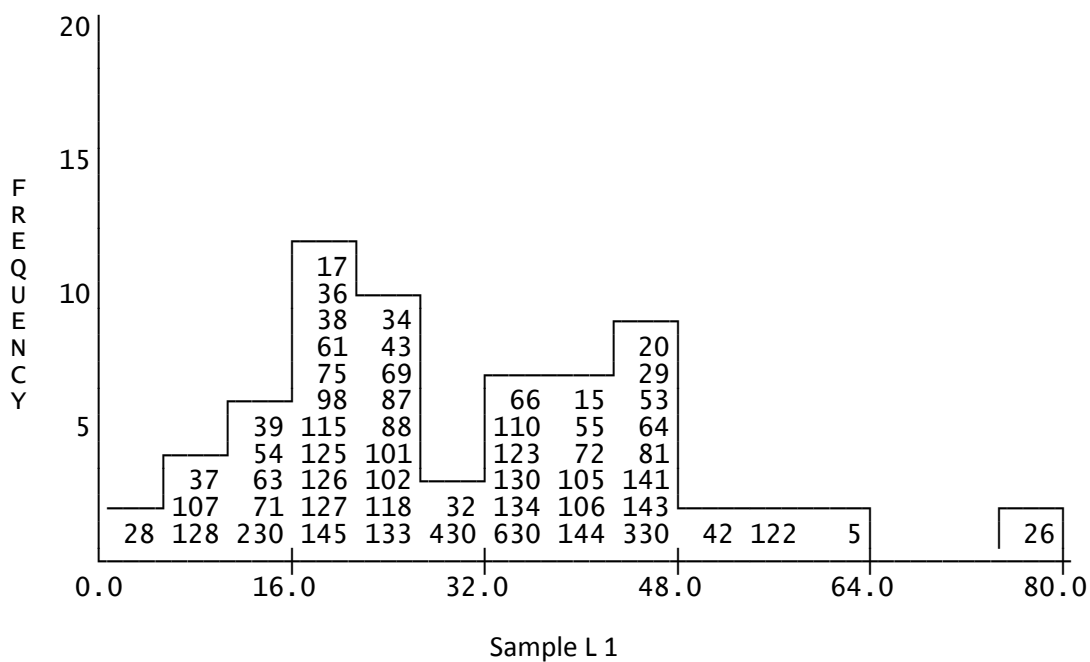


Sample L 1
(Mean: 454.9 / SD: 22.8)



Sample L 2
(Mean: 506.3 / SD: 18.8)

Total Lubricant (mg) - Laboratory Standard Deviations



ENERSOL Interlaboratory Proficiency Trial of Condom Testing Laboratories, 2011

SUMMARY STATISTICS for Total Lubricant (mg)

Sample L 1:

Statistical Parameters	Before Removing Extreme Results	After Removing Extreme Results
No. Labs	55	52
Mean	457.0	454.9
Std Dev'n	24.2	22.8
Std Error	3.3	3.2
Coef Var'n	5.3	5.0
Minimum	412.6	412.6
Maximum	520.0	520.0
Range	107.4	107.4

Extreme Results (Laboratory code no's)	
Repeatability Stragglers	None
Repeatability Outliers	5,26,122
Reproduc'ility Stragglers	None
Reproduc'ility Outliers	None

Sample L 2:

Statistical Parameters	Before Removing Extreme Results	After Removing Extreme Results
No. Labs	55	45
Mean	506.8	506.3
Std Dev'n	21.4	18.8
Std Error	2.9	2.8
Coef Var'n	4.2	3.7
Minimum	441.5	455.7
Maximum	555.0	545.0
Range	113.5	89.3

Extreme Results (Laboratory code no's)	
Repeatability Stragglers	None
Repeatability Outliers	34,43,55,61,63,107,118,144,230,630
Reproduc'ility Stragglers	None
Reproduc'ility Outliers	None

PRECISION ACHIEVED (after removal of extreme results)

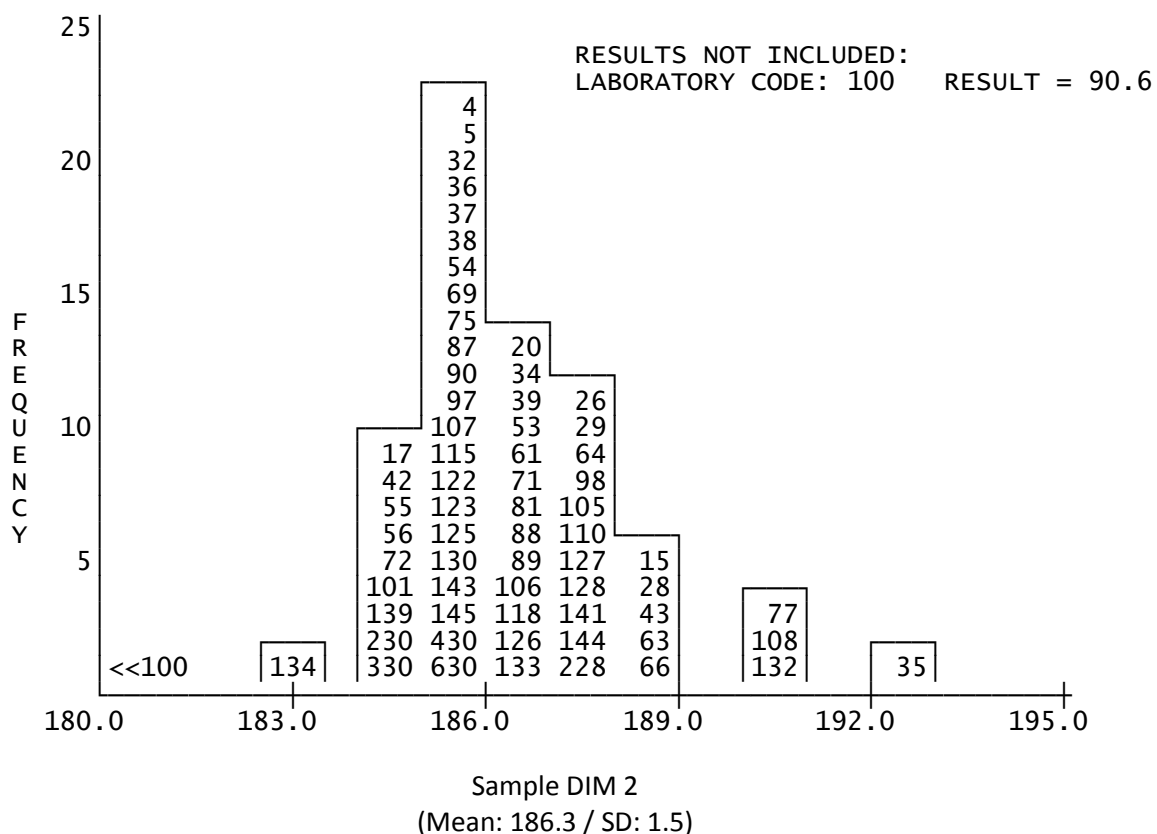
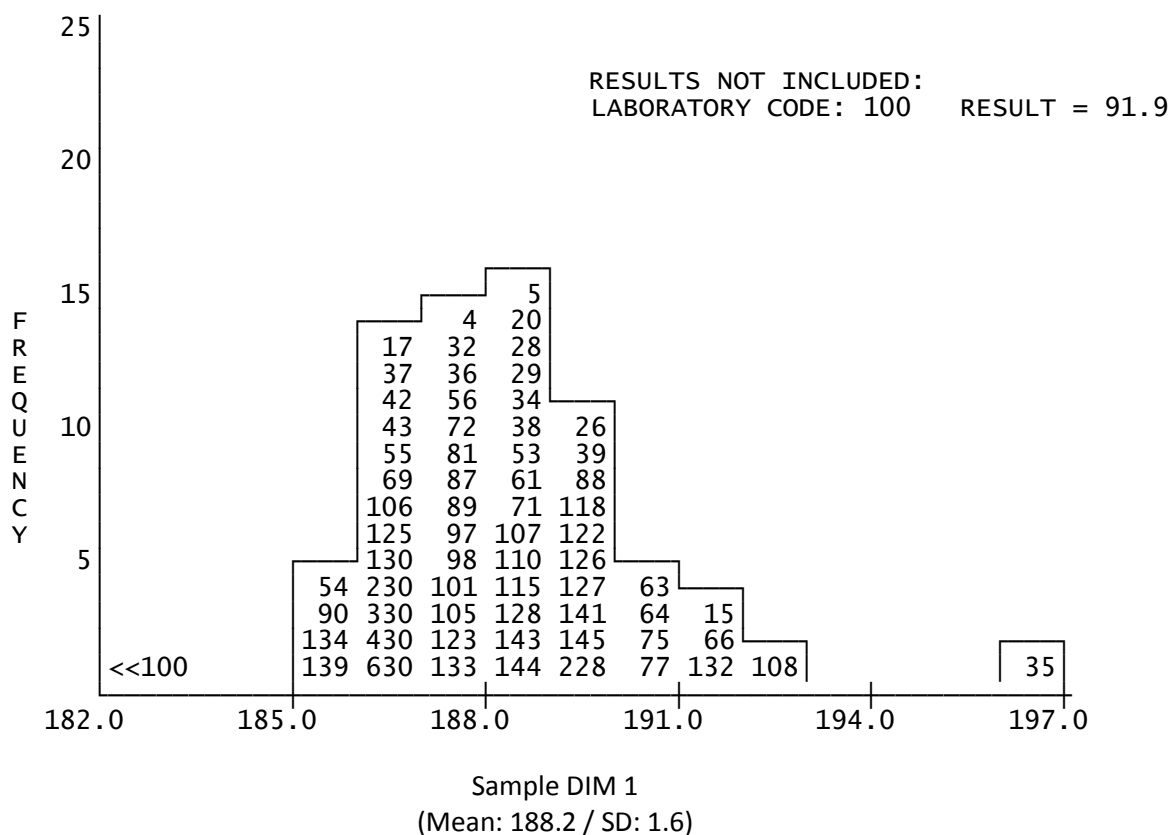
LUBRICANT (mg)

Sample : L 1
 Number of Laboratories : 52
 Consensus Mean : 454.9
 Repeatability Estimate : 86.2 ± 8.5
 Reproducibility Estimate : 104.2 ± 13.4

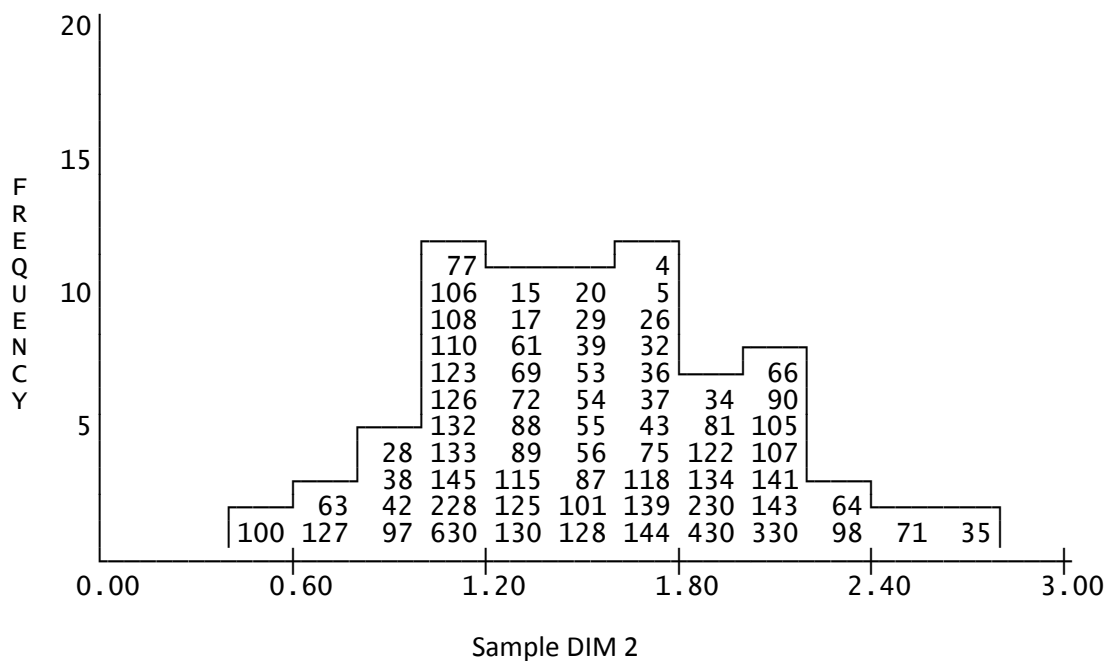
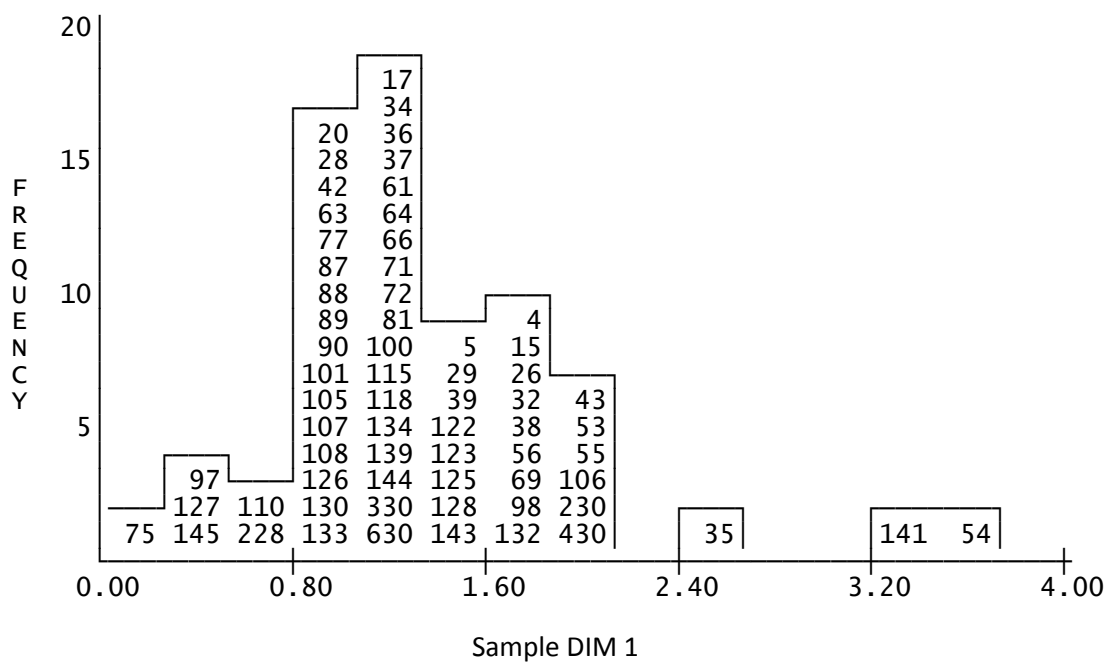
Sample : L 2
 Number of Laboratories : 45
 Consensus Mean : 506.3
 Repeatability Estimate : 29.9 ± 3.1
 Reproducibility Estimate : 60.3 ± 15.1

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Length (mm) – Laboratory Means



Length (mm) – Laboratory Standard Deviations



ENERSOL Interlaboratory Proficiency Trial of Condom Testing Laboratories, 2011

SUMMARY STATISTICS for Length (mm)

Sample DIM 1:

Statistical Parameters	Before Removing Extreme Results	After Removing Extreme Results
No. Labs	66	62
Mean	186.8	188.2
Std Dev'n	12.0	1.6
Std Error	1.5	0.2
Coef Var'n	6.4	0.8
Minimum	91.9	185.8
Maximum	197.0	192.7
Range	105.1	6.9

Extreme Results (Laboratory code no's)	
Repeatability Stragglers	None
Repeatability Outliers	35,54,141
Reproduc'ility Stragglers	None
Reproduc'ility Outliers	35,100

Sample DIM 2:

Statistical Parameters	Before Removing Extreme Results	After Removing Extreme Results
No. Labs	66	64
Mean	185.0	186.3
Std Dev'n	11.9	1.5
Std Error	1.5	0.2
Coef Var'n	6.4	0.8
Minimum	90.6	182.8
Maximum	192.0	190.6
Range	101.4	7.8

Extreme Results (Laboratory code no's)	
Repeatability Stragglers	None
Repeatability Outliers	None
Reproduc'ility Stragglers	35
Reproduc'ility Outliers	100

PRECISION ACHIEVED (after removal of extreme results)

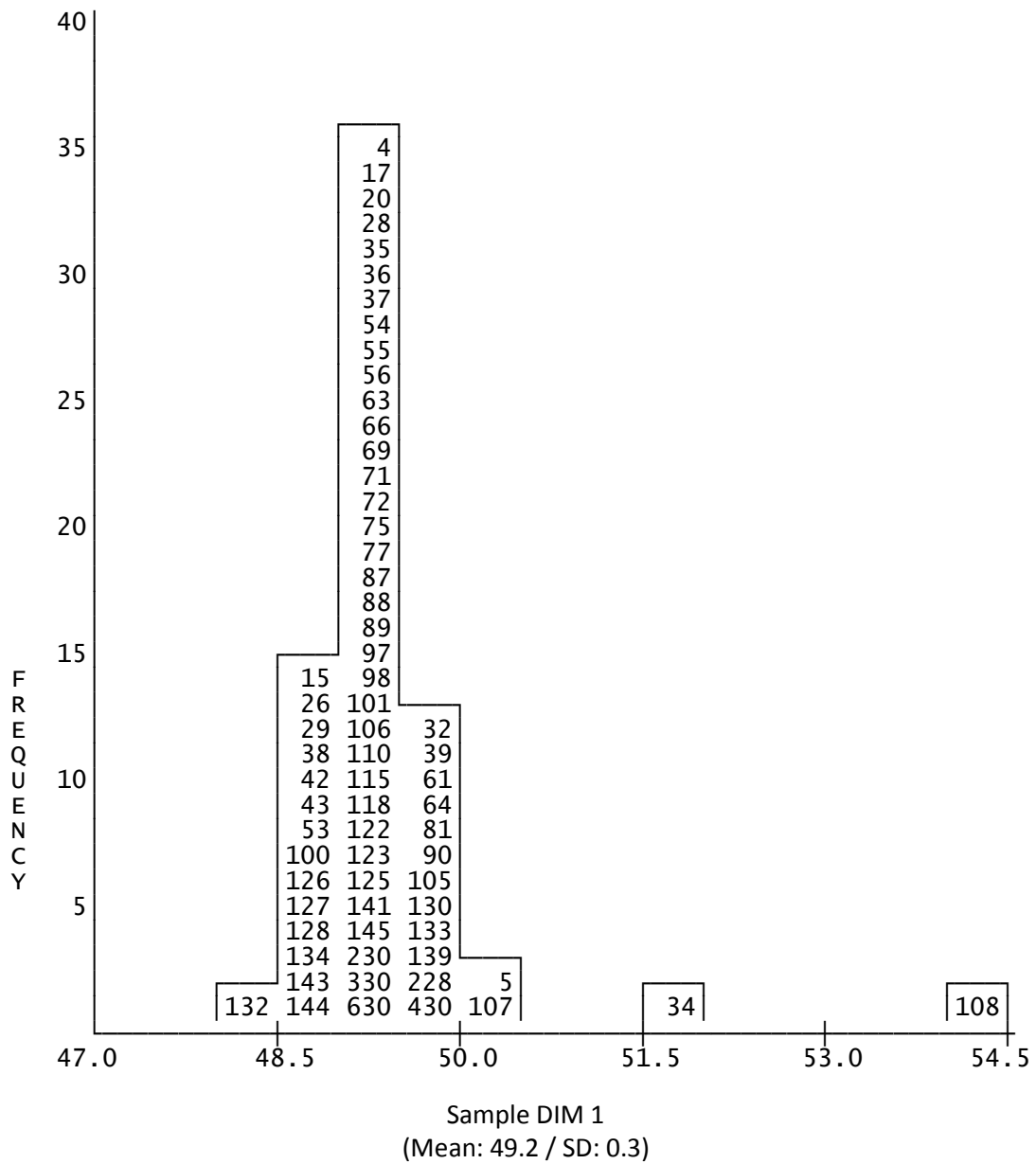
LENGTH (mm)

Sample : DIM 1
 Number of Laboratories : 62
 Consensus Mean : 188.2
 Repeatability Estimate : 3.7 ± 0.3
 Reproducibility Estimate : 5.7 ± 1.0

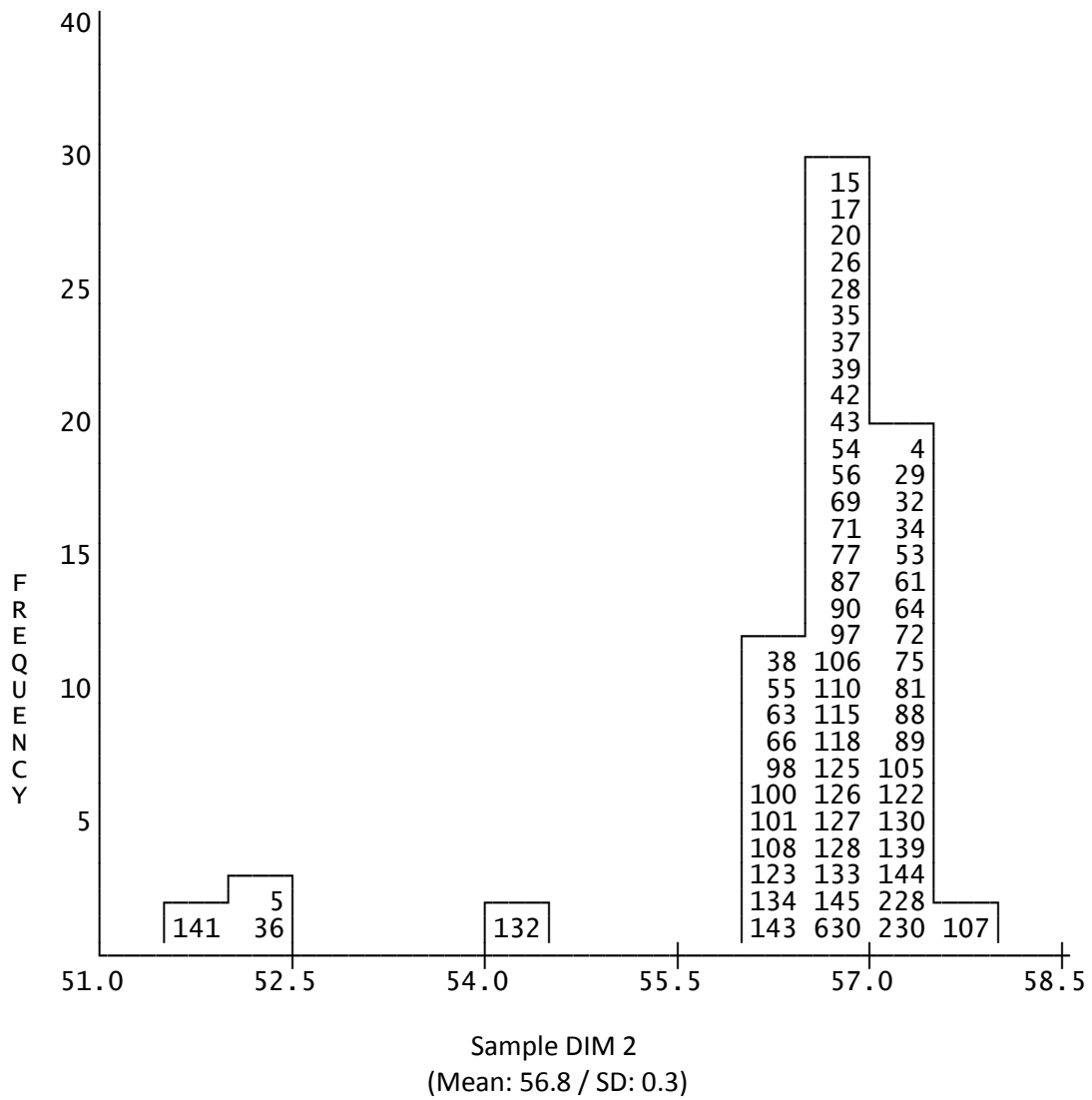
Sample : DIM 2
 Number of Laboratories : 64
 Consensus Mean : 186.3
 Repeatability Estimate : 4.3 ± 0.4
 Reproducibility Estimate : 5.9 ± 0.9

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Width (mm) - Laboratory Means

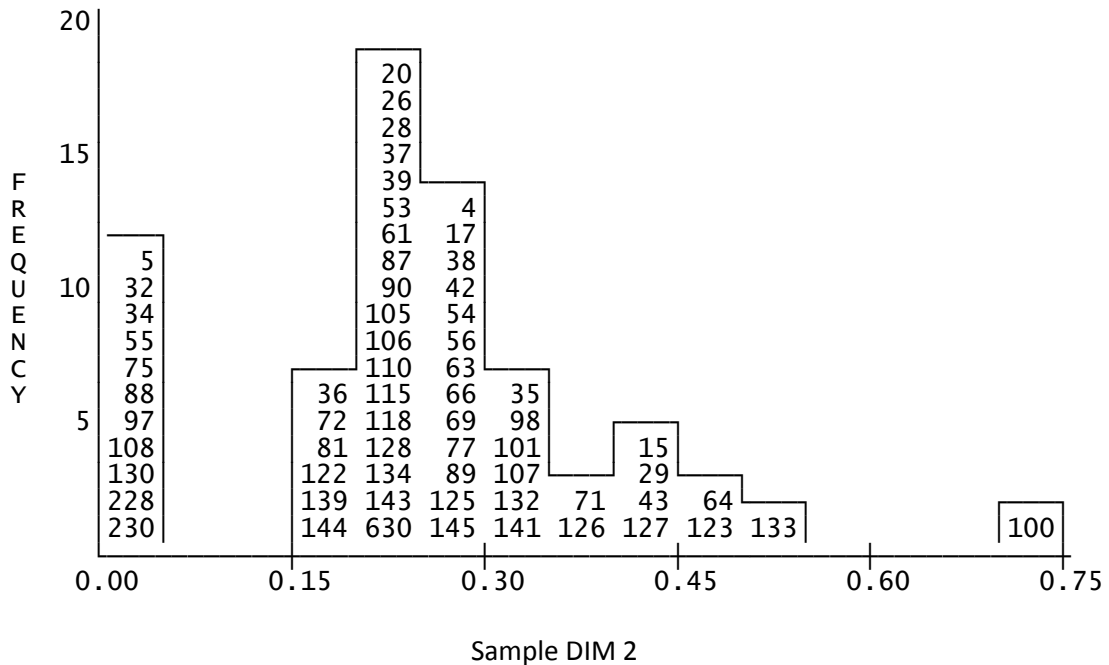
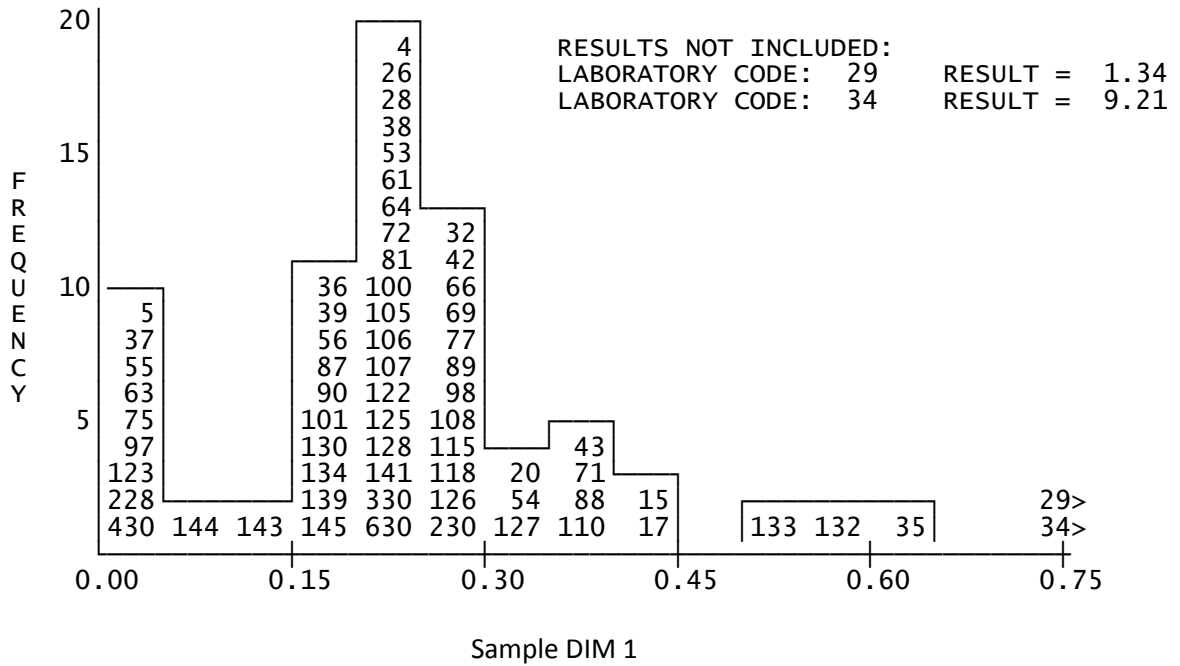


Width (mm) - Laboratory Means (continued)



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Width (mm) - Laboratory Standard Deviations



ENERSOL Interlaboratory Proficiency Trial of Condom Testing Laboratories, 2011

SUMMARY STATISTICS for Width (mm)

Sample DIM 1:

Statistical Parameters	Before Removing Extreme Results	After Removing Extreme Results
No. Labs	66	58
Mean	49.3	49.2
Std Dev'n	0.8	0.3
Std Error	0.1	0.0
Coef Var'n	1.6	0.6
Minimum	48.1	48.5
Maximum	54.3	50.1
Range	6.2	1.6

Extreme Results (Laboratory code no's)	
Repeatability Stragglers	17
Repeatability Outliers	15,29,34,35,132,133
Reproduc'ility Stragglers	None
Reproduc'ility Outliers	34,108

Sample DIM 2:

Statistical Parameters	Before Removing Extreme Results	After Removing Extreme Results
No. Labs	64	55
Mean	56.5	56.8
Std Dev'n	1.1	0.3
Std Error	0.1	0.0
Coef Var'n	2.0	0.6
Minimum	51.8	56.0
Maximum	57.5	57.5
Range	5.7	1.5

Extreme Results (Laboratory code no's)	
Repeatability Stragglers	15
Repeatability Outliers	64,100,123,133
Reproduc'ility Stragglers	None
Reproduc'ility Outliers	5,36,132,141

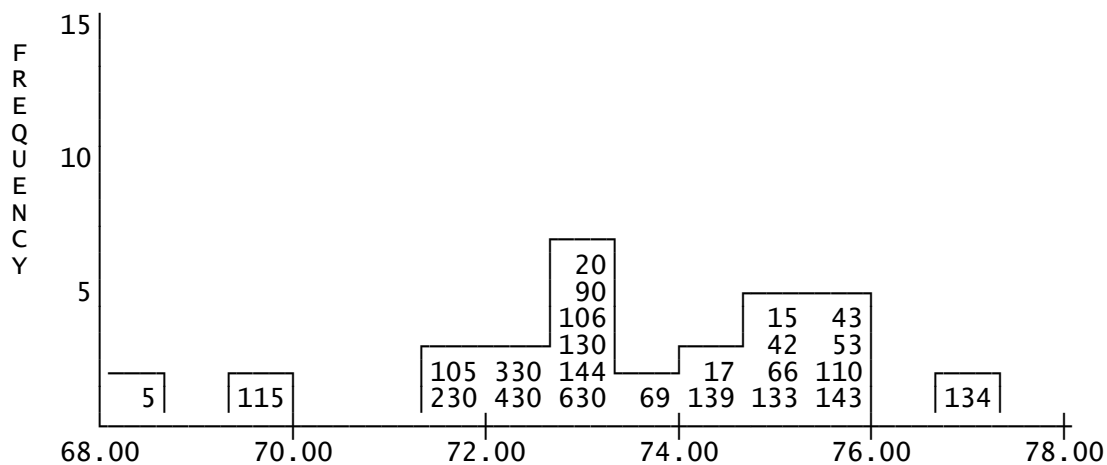
PRECISION ACHIEVED (after removal of extreme results)

WIDTH (mm)

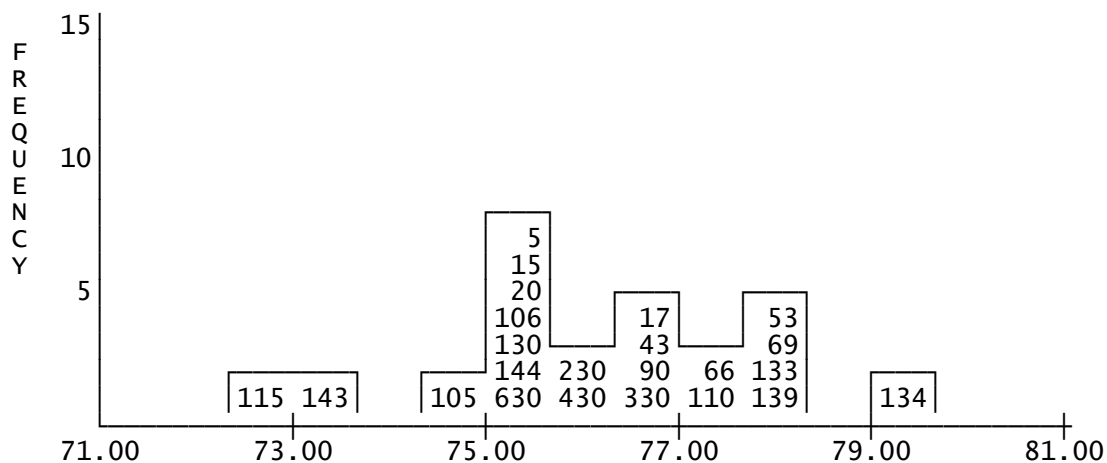
Sample : DIM 1
 Number of Laboratories : 58
 Consensus Mean : 49.2
 Repeatability Estimate : 0.6 ± 0.1
 Reproducibility Estimate : 1.1 ± 0.2

Sample : DIM 2
 Number of Laboratories : 55
 Consensus Mean : 56.8
 Repeatability Estimate : 0.7 ± 0.1
 Reproducibility Estimate : 1.1 ± 0.2

Thickness (microns) - Mass Method - Laboratory Means

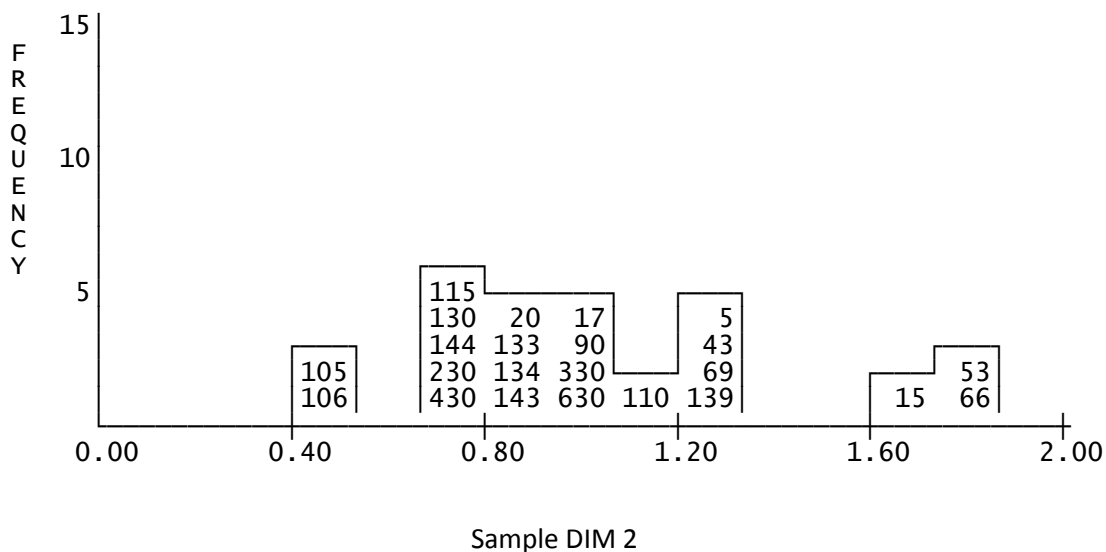
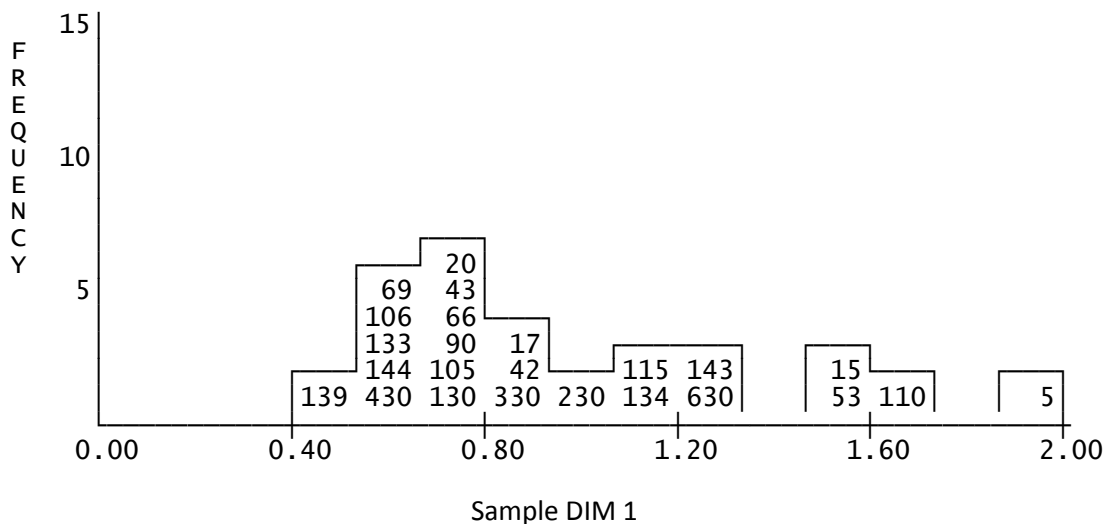


Sample DIM 1
(Mean: 73.8 / SD: 1.7)



Sample DIM 2
(Mean: 76.2 / SD: 1.5)

Thickness (microns) - Mass Method - Laboratory Standard Deviations



ENERSOL Interlaboratory Proficiency Trial of Condom Testing Laboratories, 2011

SUMMARY STATISTICS for Thickness (microns) - Mass Method

Sample DIM 1:

Statistical Parameters	Before Removing Extreme Results	After Removing Extreme Results
No. Labs	24	23
Mean	73.6	73.8
Std Dev'n	2.0	1.7
Std Error	0.4	0.4
Coef Var'n	2.8	2.4
Minimum	68.3	69.5
Maximum	77.2	77.2
Range	8.9	7.7

Extreme Results (Laboratory code no's)	
Repeatability Stragglers	None
Repeatability Outliers	5
Reproduc'ility Stragglers	5
Reproduc'ility Outliers	None

Sample DIM 2:

Statistical Parameters	Before Removing Extreme Results	After Removing Extreme Results
No. Labs	23	23
Mean	76.2	76.2
Std Dev'n	1.5	1.5
Std Error	0.3	0.3
Coef Var'n	2.0	2.0
Minimum	72.9	72.9
Maximum	79.0	79.0
Range	6.1	6.1

Extreme Results (Laboratory code no's)	
Repeatability Stragglers	None
Repeatability Outliers	None
Reproduc'ility Stragglers	None
Reproduc'ility Outliers	None

PRECISION ACHIEVED (after removal of extreme results)

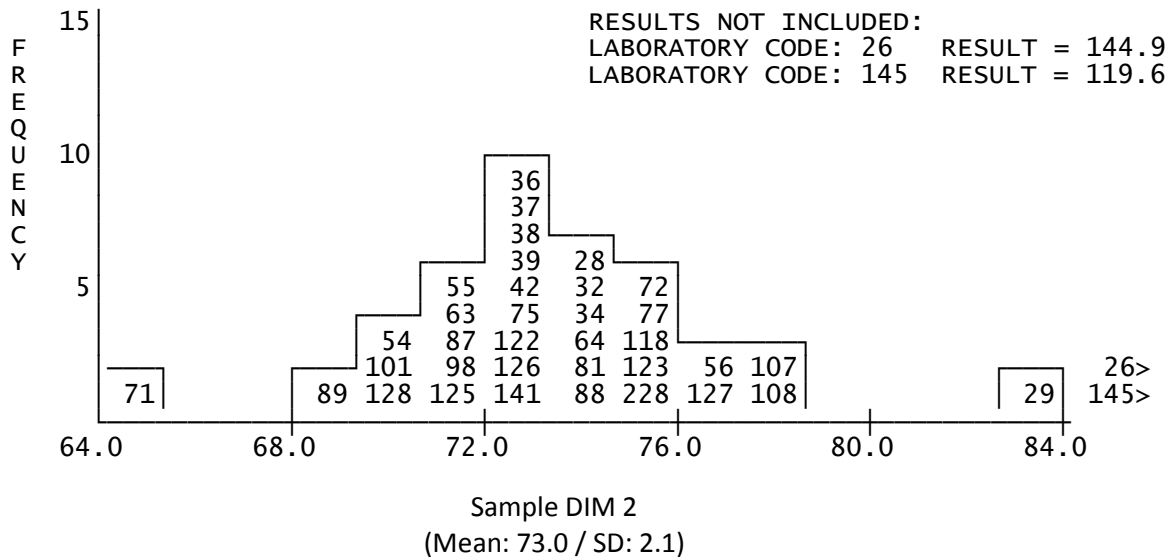
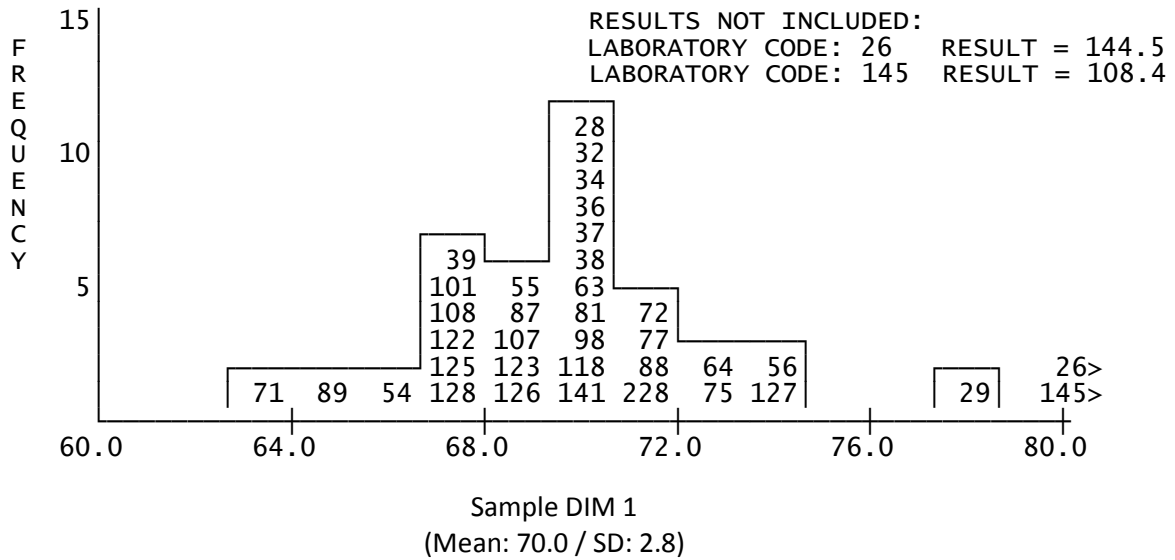
THICKNESS (microns) - Mass Method

Sample : DIM 1
 Number of Laboratories : 23
 Consensus Mean : 73.8
 Repeatability Estimate : 2.7 ± 0.4
 Reproducibility Estimate : 5.5 ± 2

Sample : DIM 2
 Number of Laboratories : 23
 Consensus Mean : 76.2
 Repeatability Estimate : 3.0 ± 0.4
 Reproducibility Estimate : 5.2 ± 1.6

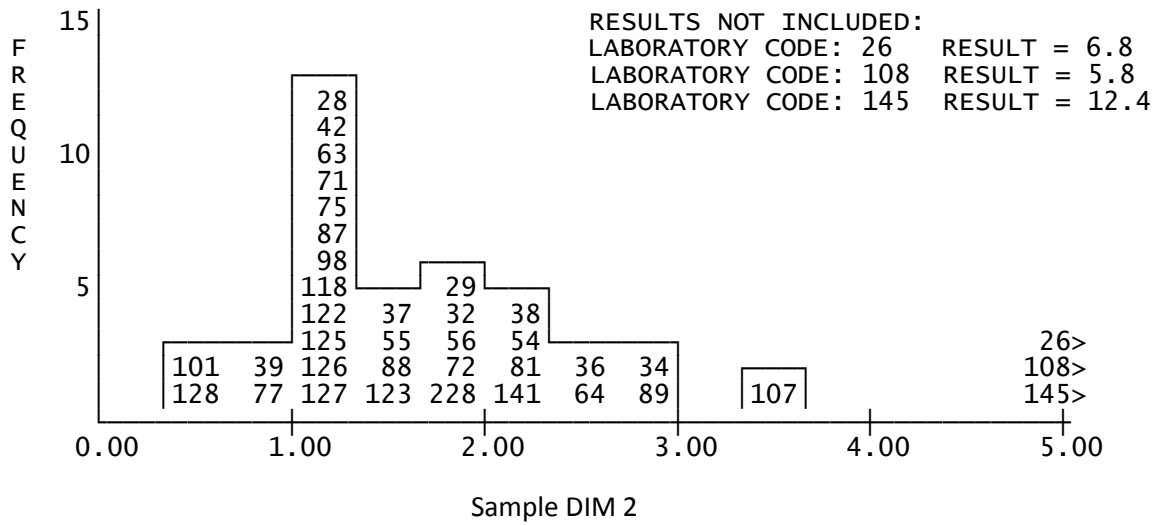
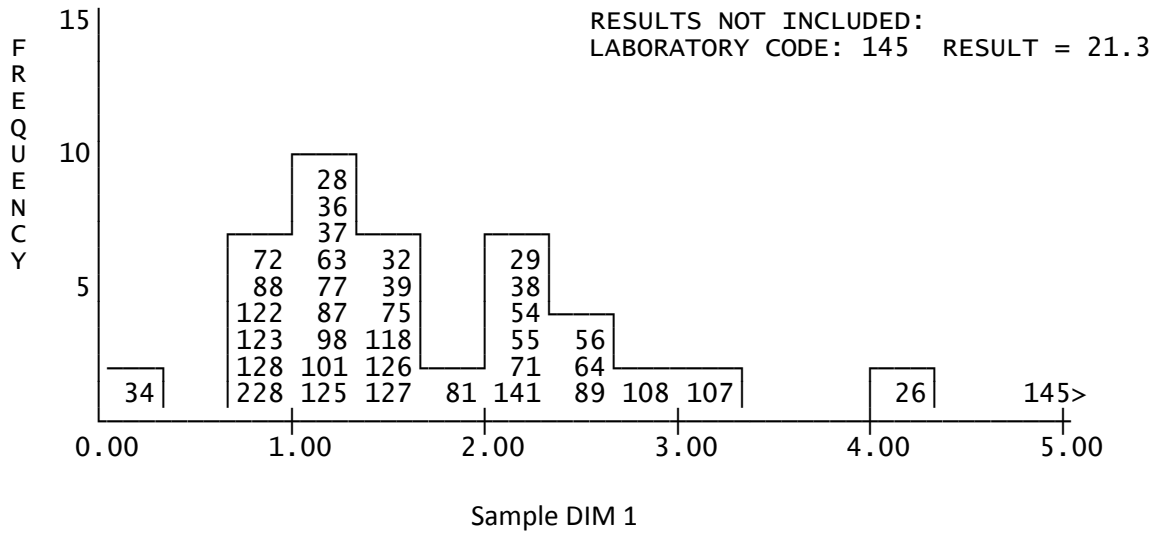
ENERSOL Interlaboratory Proficiency Trial of Condom Testing Laboratories, 2011

Thickness (microns) - Micrometer Gauge Method - Laboratory Means



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Thickness (microns) - Micrometer Gauge Method - Laboratory Standard Deviations



ENERSOL Interlaboratory Proficiency Trial of Condom Testing Laboratories, 2011

SUMMARY STATISTICS for Thickness (microns) - Micrometer Gauge Method

Sample DIM 1:

Statistical Parameters	Before Removing Extreme Results	After Removing Extreme Results
No. Labs	36	32
Mean	73.0	70
Std Dev'n	14.1	2.8
Std Error	2.4	0.5
Coef Var'n	19.3	4.0
Minimum	63.2	63.2
Maximum	144.5	78.4
Range	81.3	15.2

Extreme Results (Laboratory code no's)	
Repeatability Stragglers	None
Repeatability Outliers	26,107,108,145
Reproduc'lity Stragglers	None
Reproduc'lity Outliers	26,145

Sample DIM 2:

Statistical Parameters	Before Removing Extreme Results	After Removing Extreme Results
No. Labs	37	31
Mean	76.5	73
Std Dev'n	14.2	2.1
Std Error	2.3	0.4
Coef Var'n	18.5	2.8
Minimum	64.0	68.1
Maximum	144.9	76.5
Range	80.9	8.4

Extreme Results (Laboratory code no's)	
Repeatability Stragglers	None
Repeatability Outliers	26,107,108,145
Reproduc'lity Stragglers	29,71
Reproduc'lity Outliers	26,145

PRECISION ACHIEVED (after removal of extreme results)

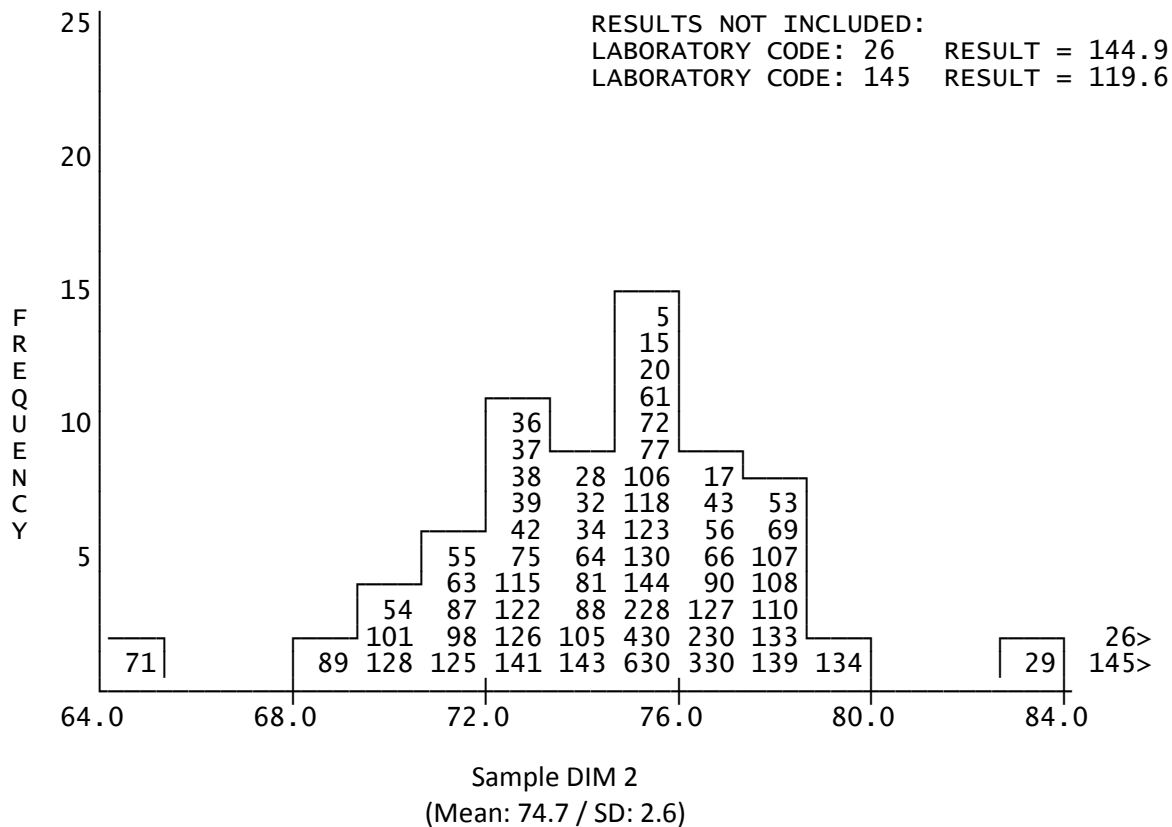
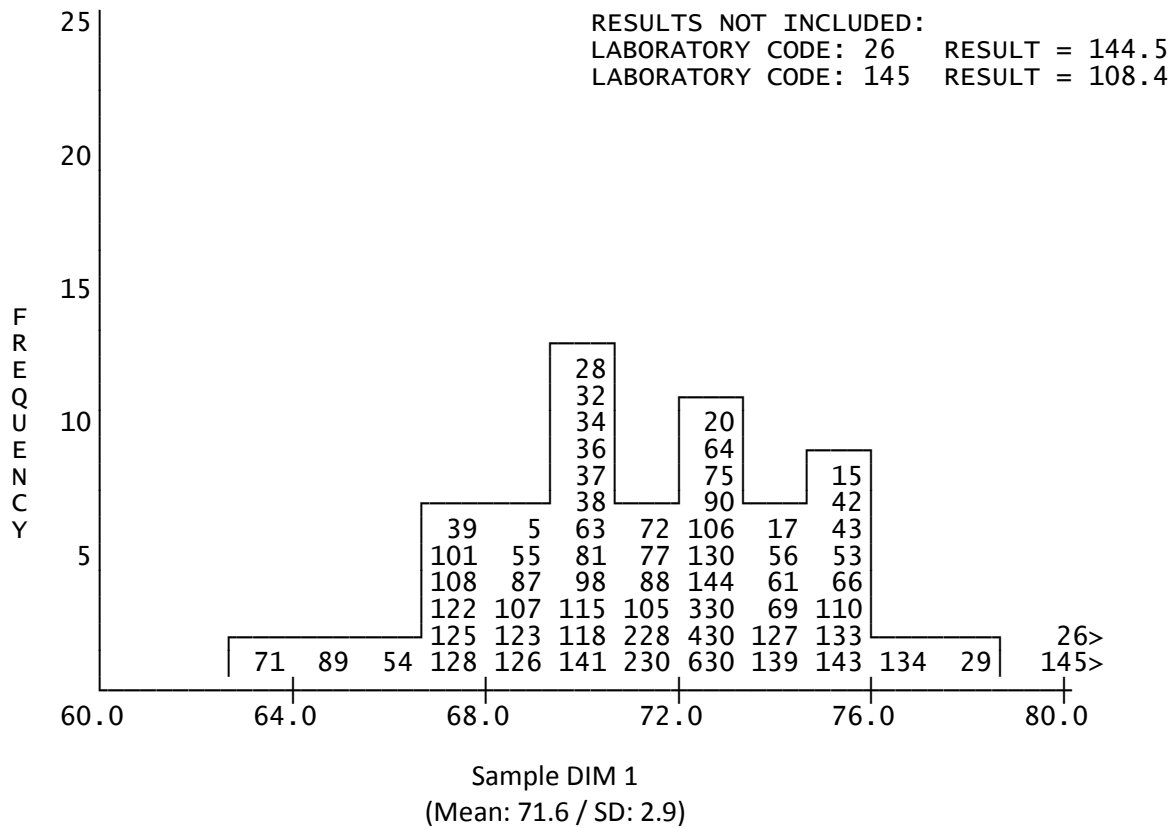
THICKNESS (microns) - Micrometer Gauge Method

Sample : DIM 1
 Number of Laboratories : 32
 Consensus Mean : 70
 Repeatability Estimate : 4.5 ± 0.6
 Reproducibility Estimate : 9.1 ± 2.7

Sample : DIM 2
 Number of Laboratories : 31
 Consensus Mean : 73
 Repeatability Estimate : 4.7 ± 0.6
 Reproducibility Estimate : 7.3 ± 1.8

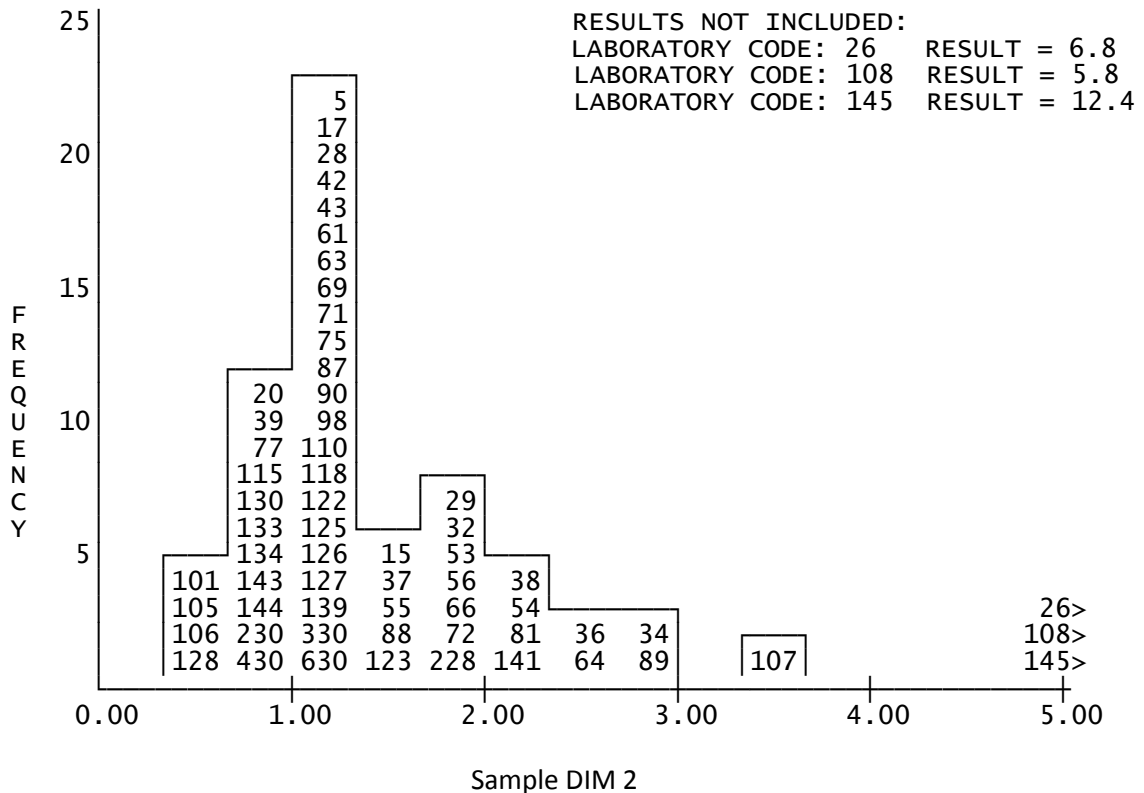
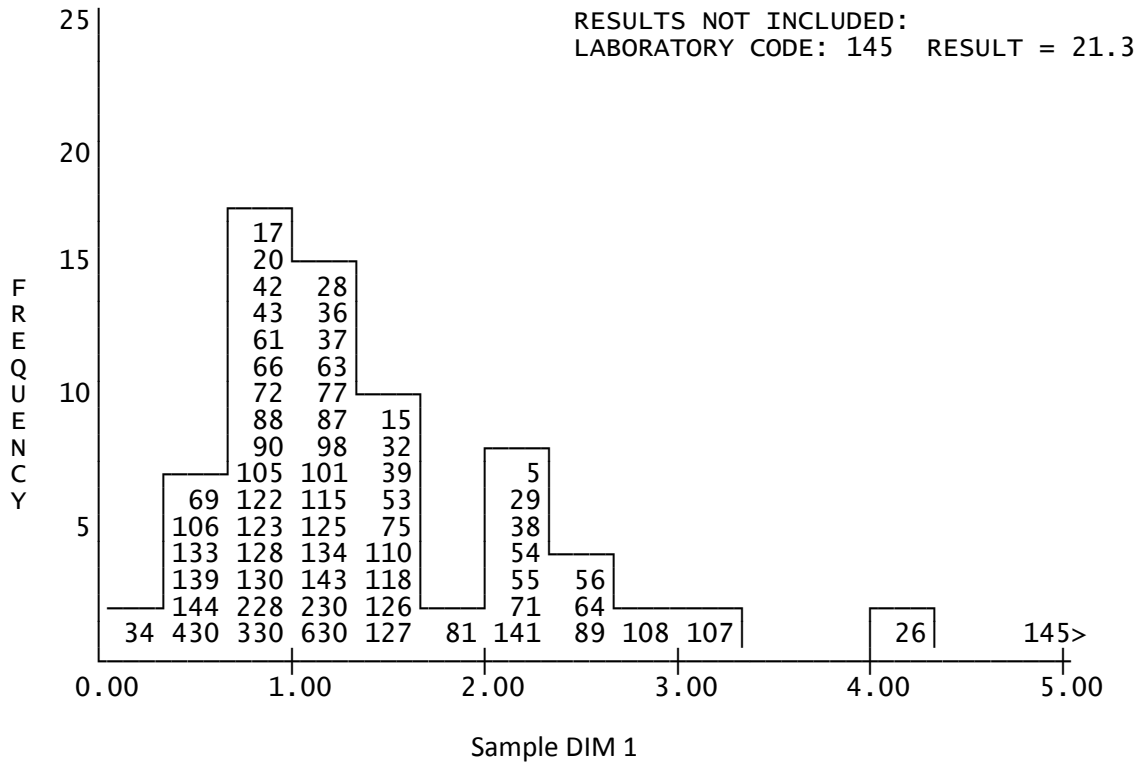
ENERSOL Interlaboratory Proficiency Trial of Condom Testing Laboratories, 2011

Thickness (microns) - Both Methods - Laboratory Means



ENERSOL Interlaboratory Proficiency Trial of Condom Testing Laboratories, 2011

Thickness (microns) - Both Methods - Laboratory Standard Deviations



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SUMMARY STATISTICS for Thickness (microns) - Both Methods

Sample DIM 1:

Statistical Parameters	Before Removing Extreme Results	After Removing Extreme Results
No. Labs	61	51
Mean	73.2	71.6
Std Dev'n	10.8	2.9
Std Error	1.4	0.4
Coef Var'n	14.8	4.0
Minimum	63.2	63.2
Maximum	144.5	77.2
Range	81.3	14.0

Extreme Results (Laboratory code no's)	
Repeatability Stragglers	None
Repeatability Outliers	26,29,55,56,64,89,107,108,141,145
Reproduc'ility Stragglers	None
Reproduc'ility Outliers	26,145

Sample DIM 2:

Statistical Parameters	Before Removing Extreme Results	After Removing Extreme Results
No. Labs	61	52
Mean	76.4	74.7
Std Error	11.0	2.6
Std Error	1.4	0.4
Coef Var'n	14.4	3.4
Minimum	64.0	69.6
Maximum	144.9	83.1
Range	80.9	13.5

Extreme Results (Laboratory code no's)	
Repeatability Stragglers	None
Repeatability Outliers	26,34,36,64,89,107,108,145
Reproduc'ility Stragglers	71
Reproduc'ility Outliers	26,145

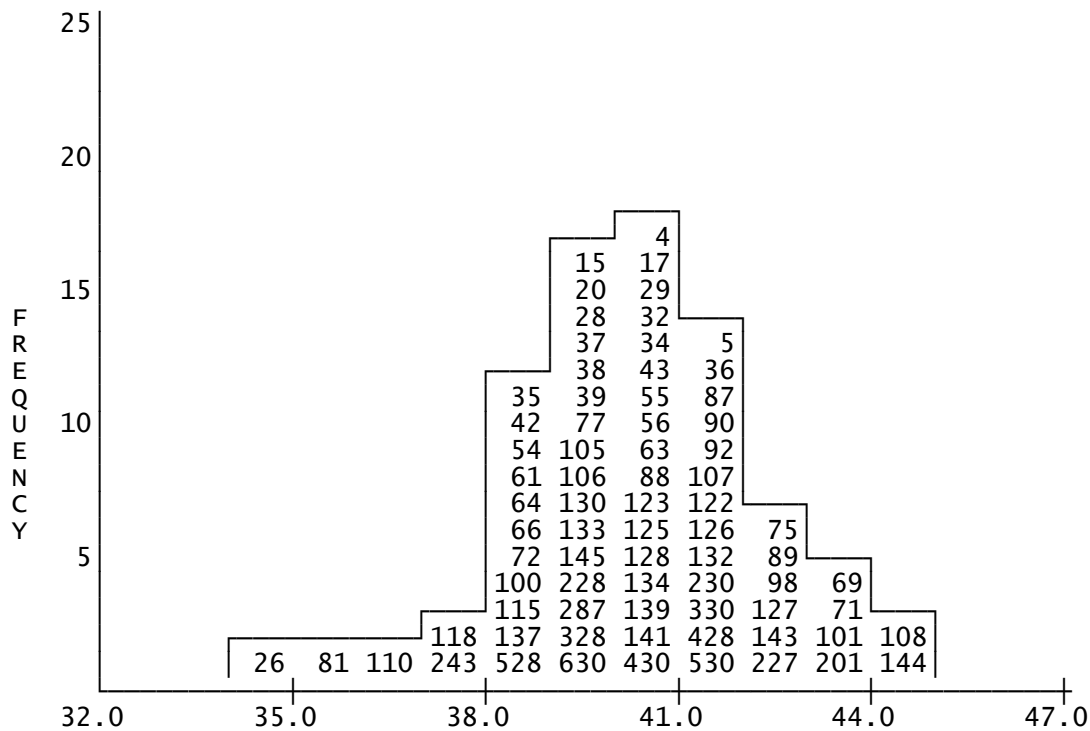
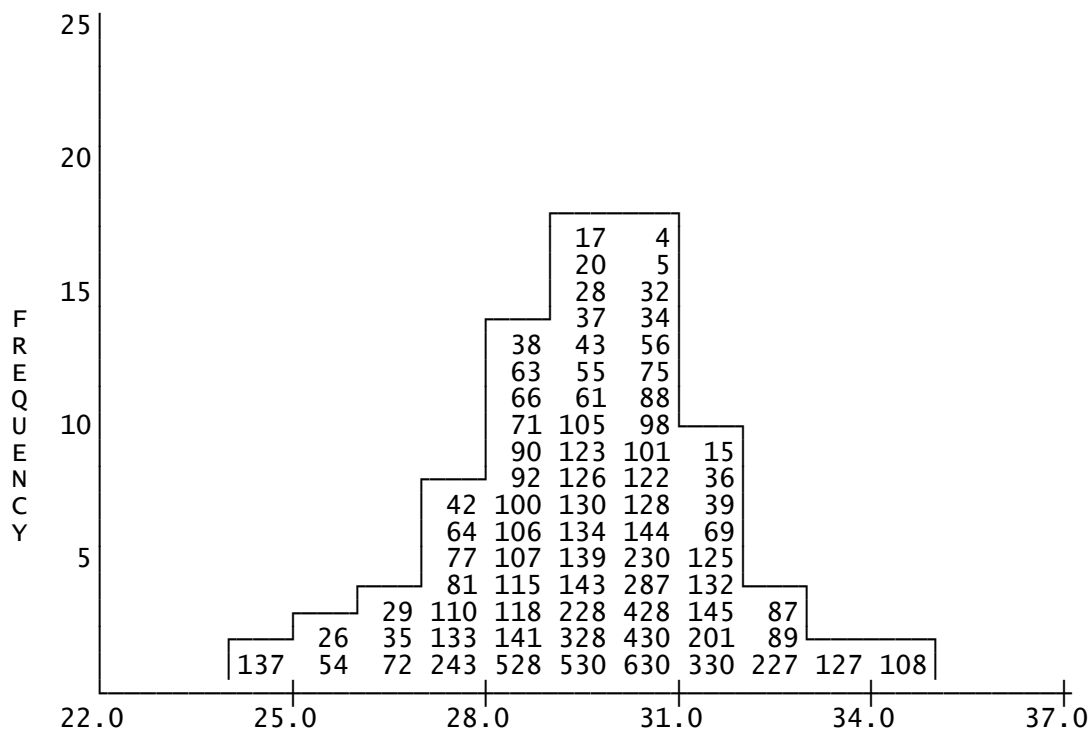
PRECISION ACHIEVED (after removal of extreme results)

THICKNESS (microns) - Both Methods

Sample : DIM 1
 Number of Laboratories : 51
 Consensus Mean : 71.6
 Repeatability Estimate : 3.3 ± 0.3
 Reproducibility Estimate : 8.8 ± 2.3

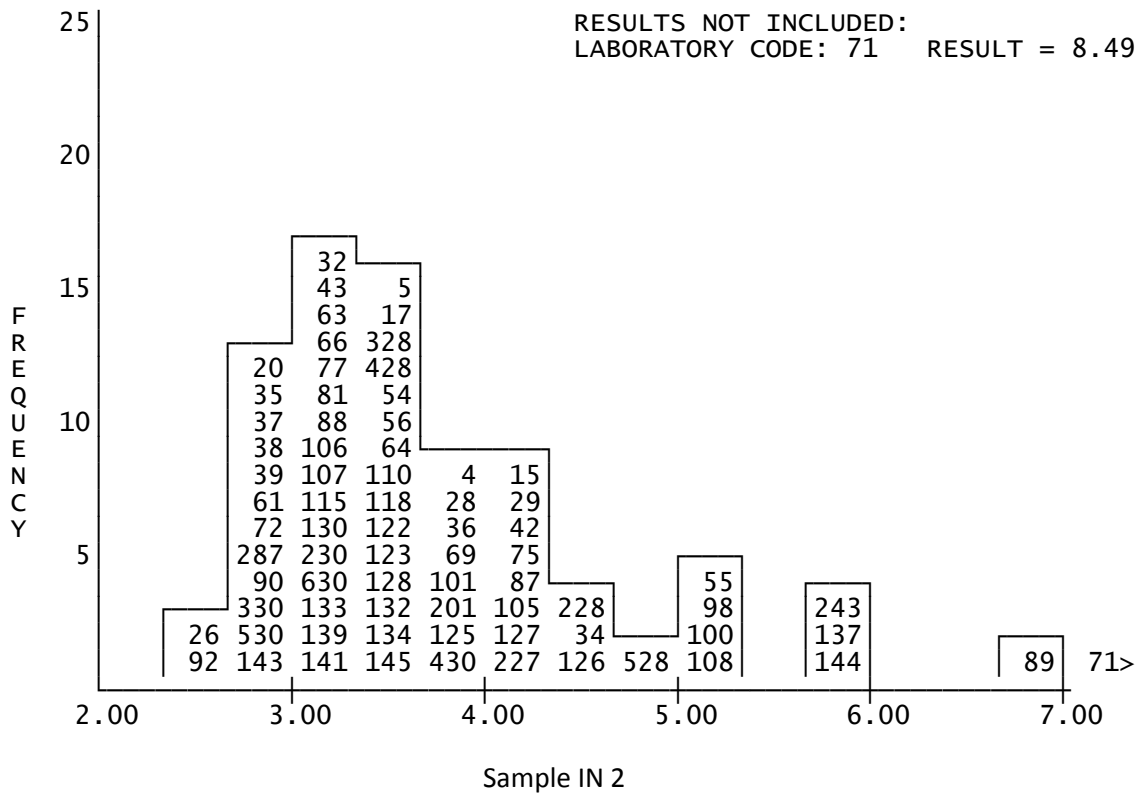
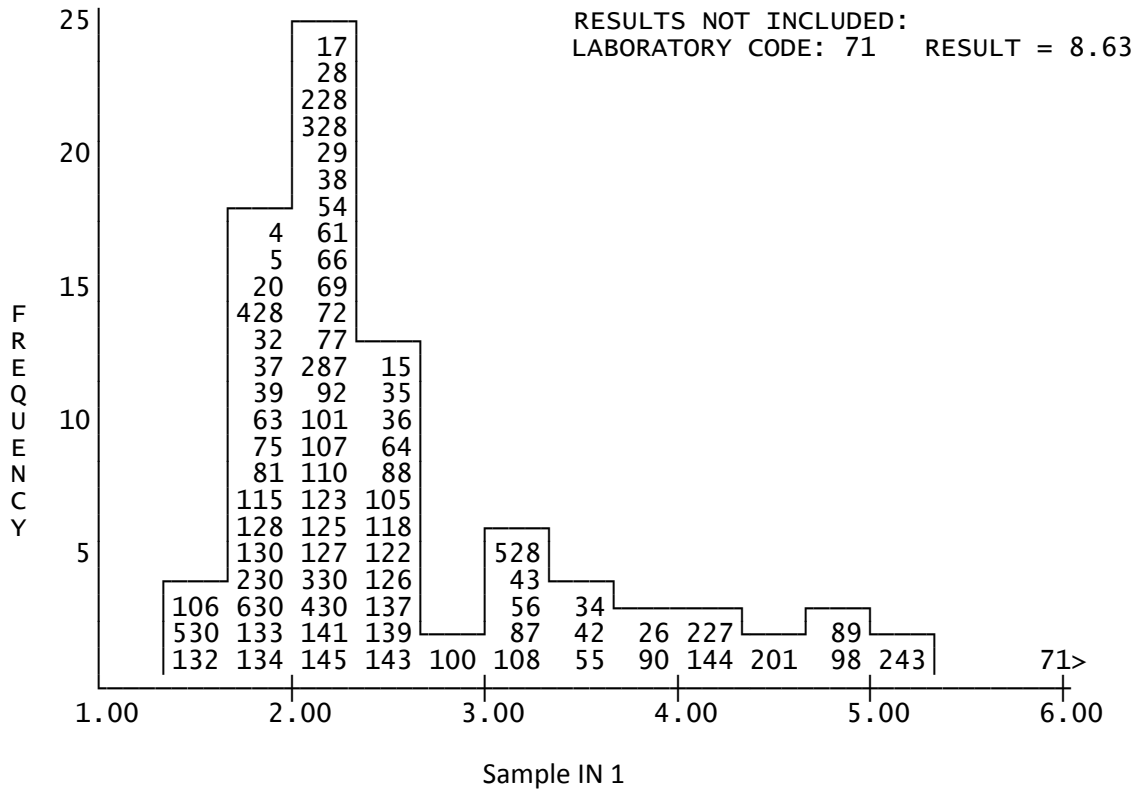
Sample : DIM 2
 Number of Laboratories : 52
 Consensus Mean : 74.7
 Repeatability Estimate : 3.7 ± 0.4
 Reproducibility Estimate : 8.1 ± 2.0

Inflation Volume (L) - Laboratory Means



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Burst Volume (L) – Laboratory Standard Deviations



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SUMMARY STATISTICS for Inflation Volume (L)

Sample IN 1

Statistical Parameters	Before Removing Extreme Results	After Removing Extreme Results
No. Labs	74	74
Mean	29.5	29.5
Std Dev'n	1.8	1.8
Std Error	0.2	0.2
Coeff Var'n	6.3	6.3
Minimum	25	25
Maximum	35	35
Range	10	10

Sample IN 2

Statistical Parameters	Before Removing Extreme Results	After Removing Extreme Results
No. Labs	74	74
Mean	40.2	40.2
Std Dev'n	1.8	1.8
Std Error	0.2	0.2
Coeff Var'n	4.5	4.5
Minimum	35	35
Maximum	45	45
Range	10	10

Repeatability Extreme Results:
 For sample pair None

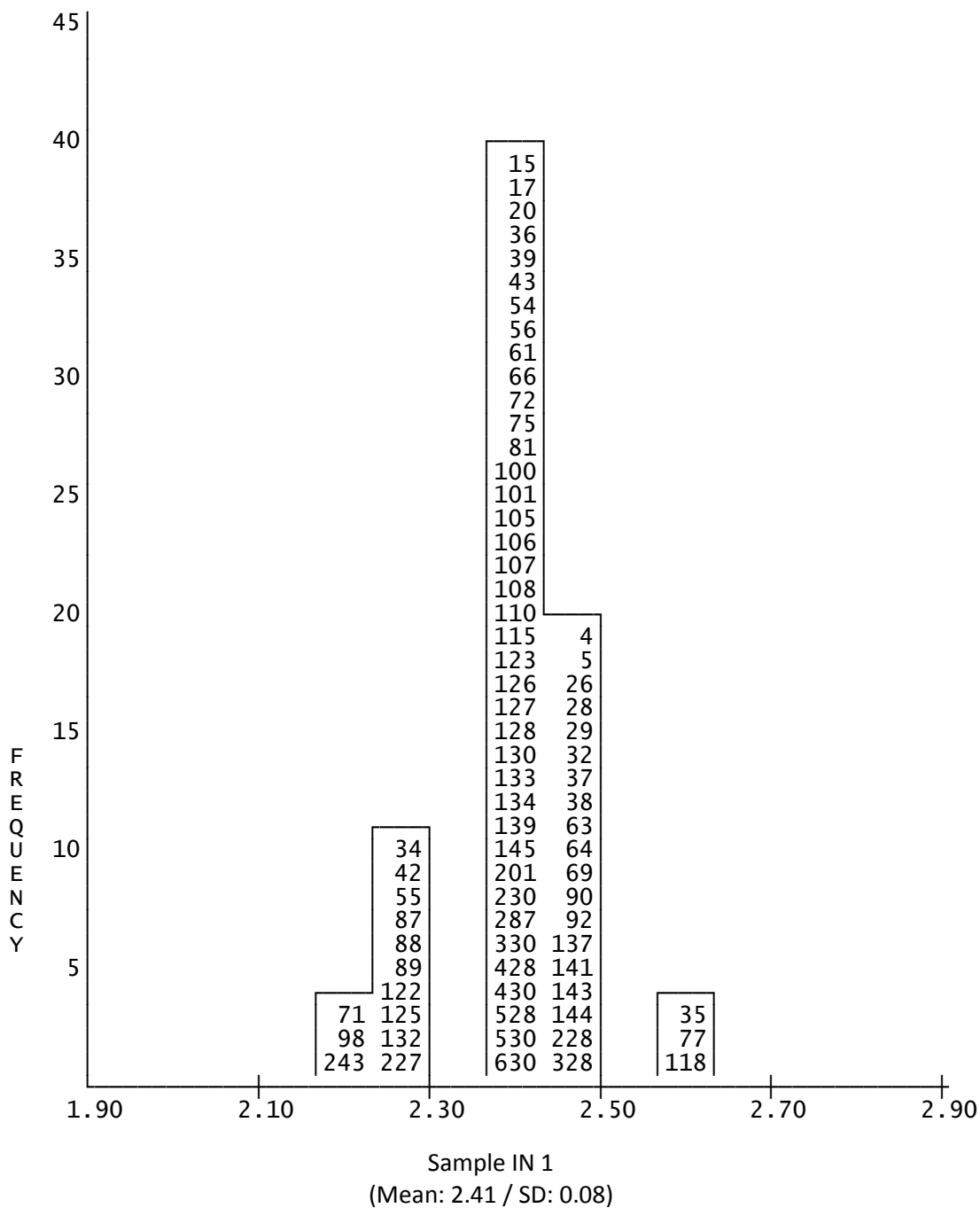
Reproducibility Extreme Results:
 Sample IN 1 None
 Sample IN 2 None

PRECISION ACHIEVED for Sample Pair (after removal of extreme results)

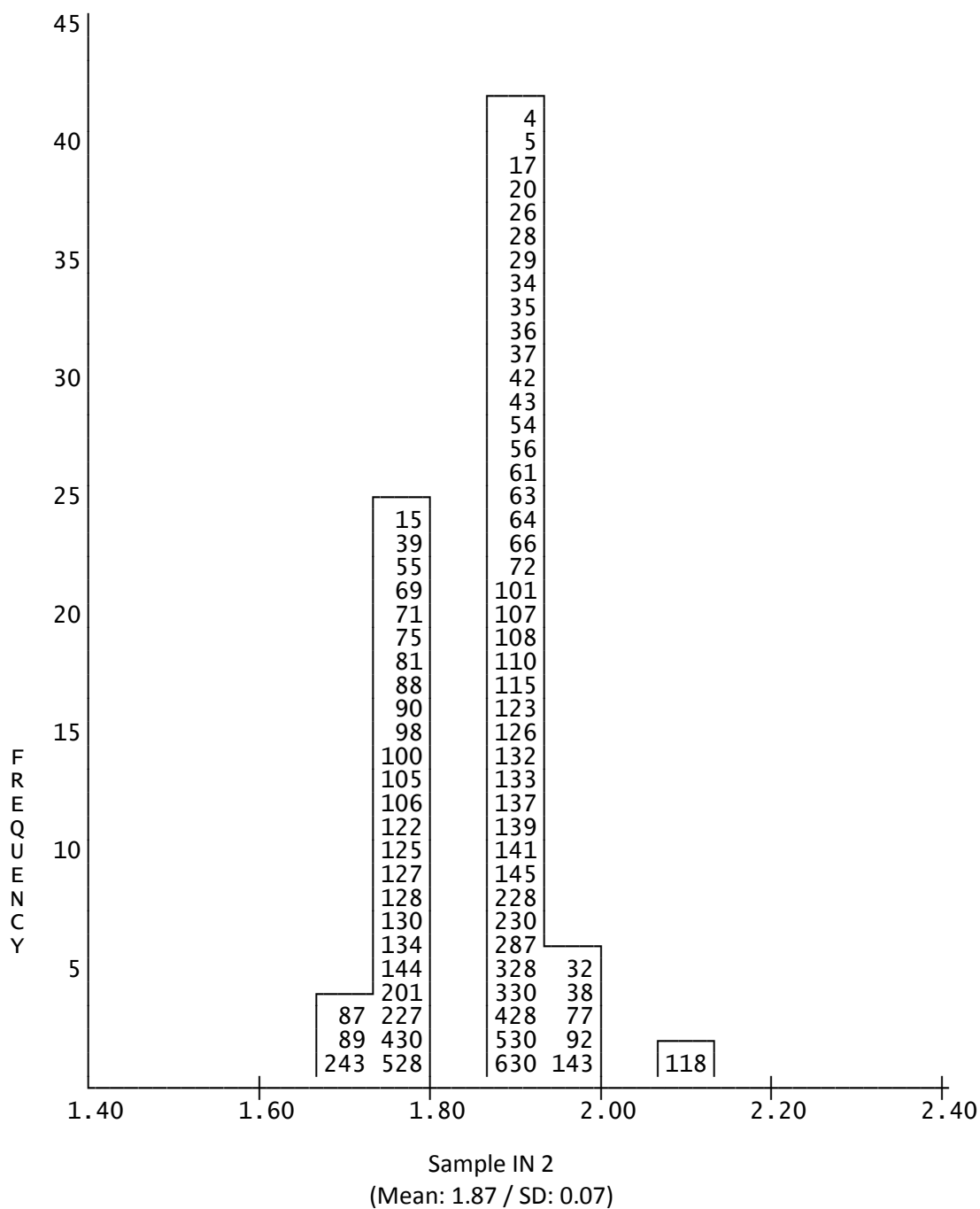
INFLATION VOLUME (L)

Number of Laboratories: 74
 Consensus Mean: IN 1 29.5
 IN 2 40.2
 Repeatability Estimate: 3 ± 0.7
 Reproducibility Estimate: 5.2 ± 1.1

Inflation Pressure (kPa) - Laboratory Means

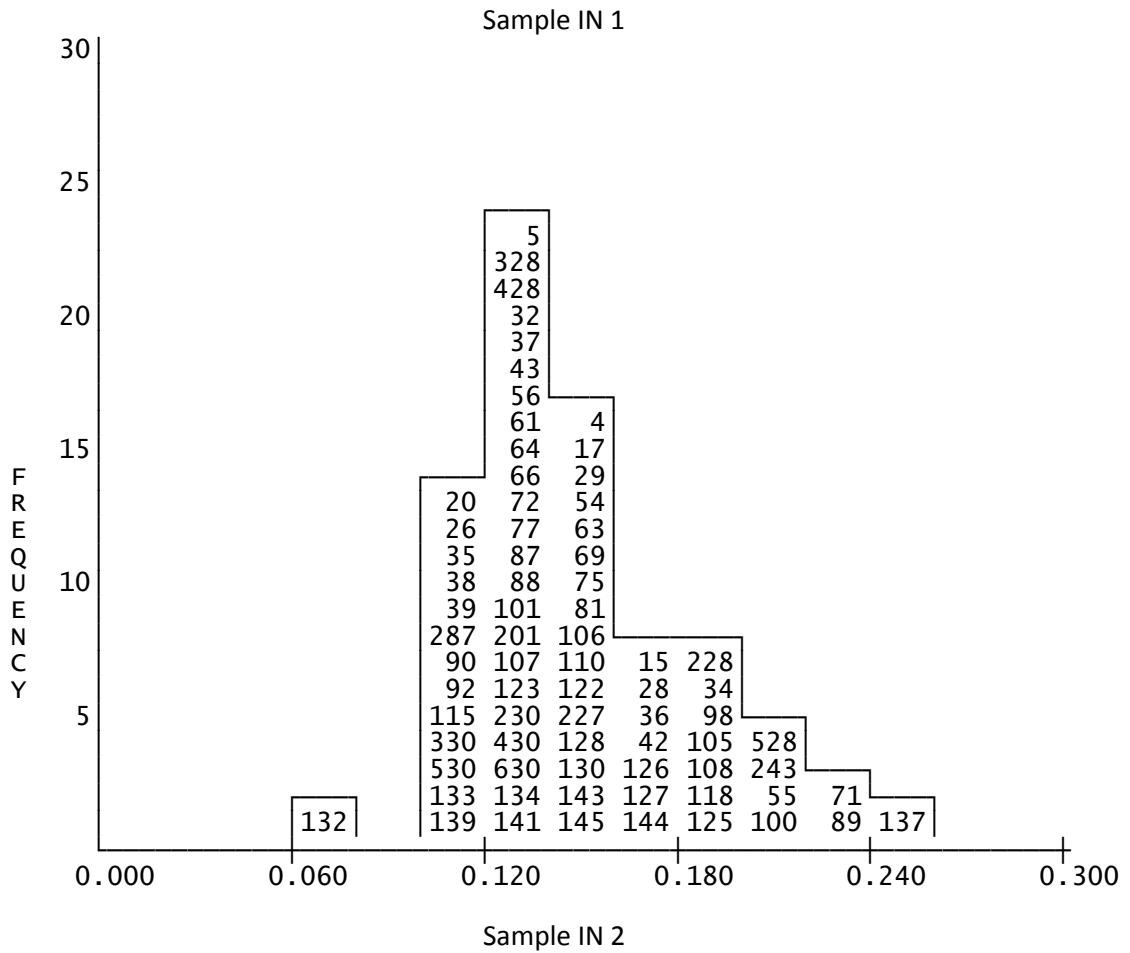
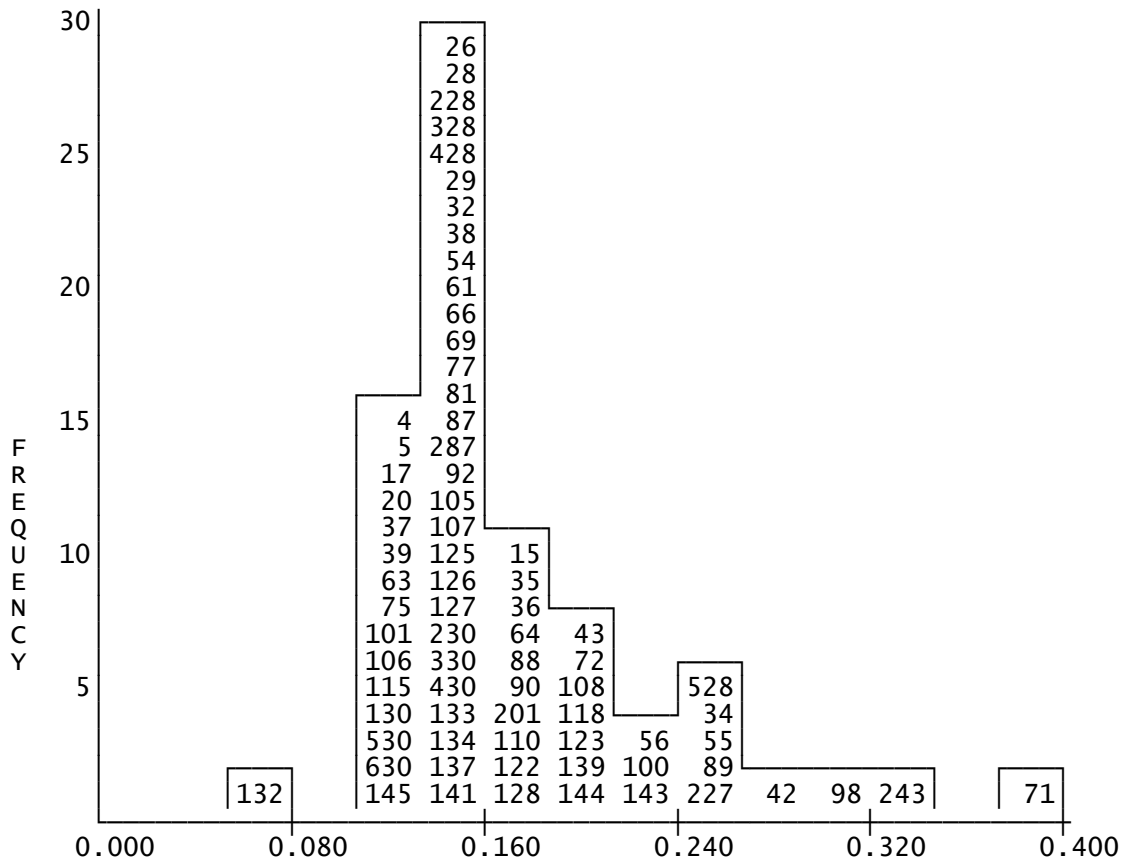


Inflation Pressure (kPa) - Laboratory Means (continued)



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Inflation Pressure (kPa) - Laboratory Standard Deviations



ENERSOL Interlaboratory Proficiency Trial of Condom Testing Laboratories, 2011

SUMMARY STATISTICS for Inflation Pressure (kPa)

Sample IN 1			Sample IN 2		
Statistical Parameters	Before Removing Extreme Results	After Removing Extreme Results	Statistical Parameters	Before Removing Extreme Results	After Removing Extreme Results
No. Labs	74	74	No. Labs	74	74
Mean	2.41	2.41	Mean	1.87	1.87
Std Dev'n	0.08	0.08	Std Dev'n	0.07	0.07
Std Error	0.01	0.01	Std Error	0.01	0.01
Coeff Var'n	3.50	3.50	Coeff Var'n	3.85	3.85
Minimum	2.2	2.2	Minimum	1.7	1.7
Maximum	2.6	2.6	Maximum	2.1	2.1
Range	0.4	0.4	Range	0.4	0.4

Repeatability Extreme Results:
 For sample pair None

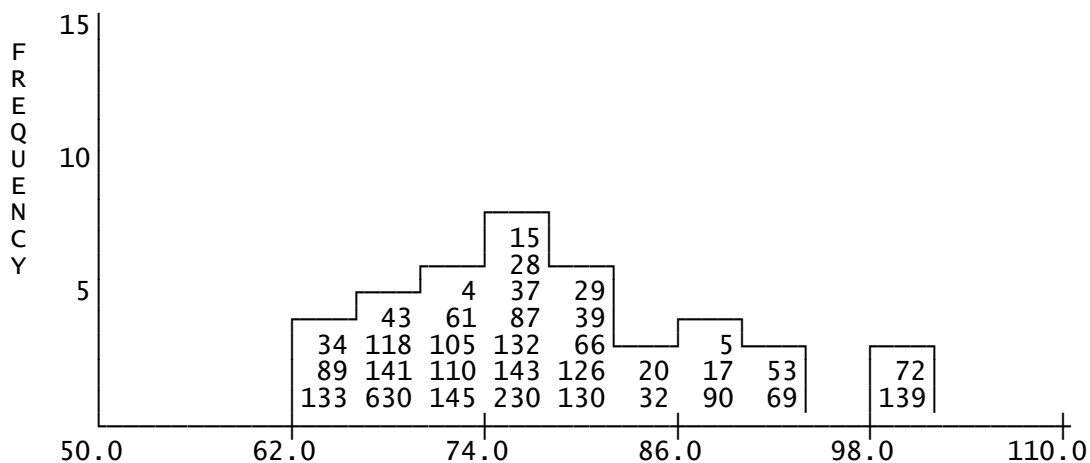
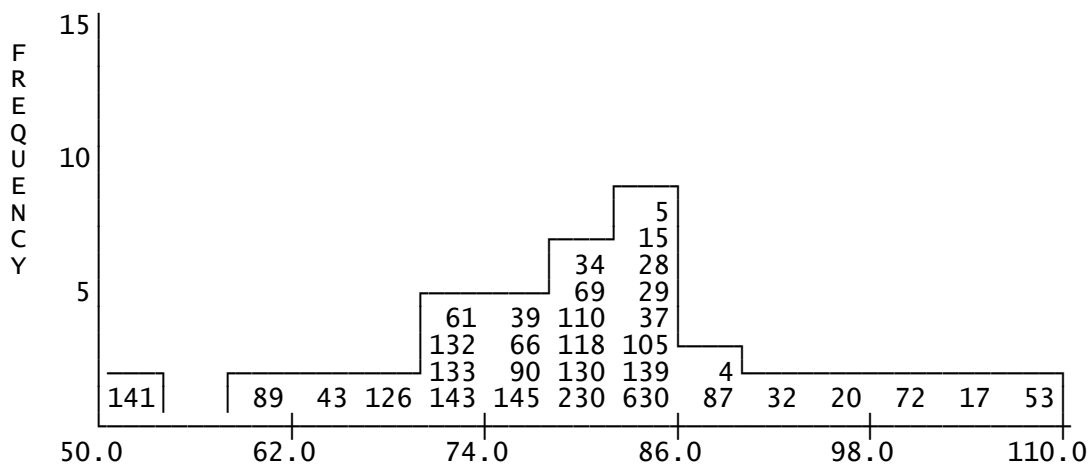
Reproducibility Extreme Results:
 Sample IN 1 None
 Sample IN 2 None

PRECISION ACHIEVED for Sample Pair (after removal of extreme results)

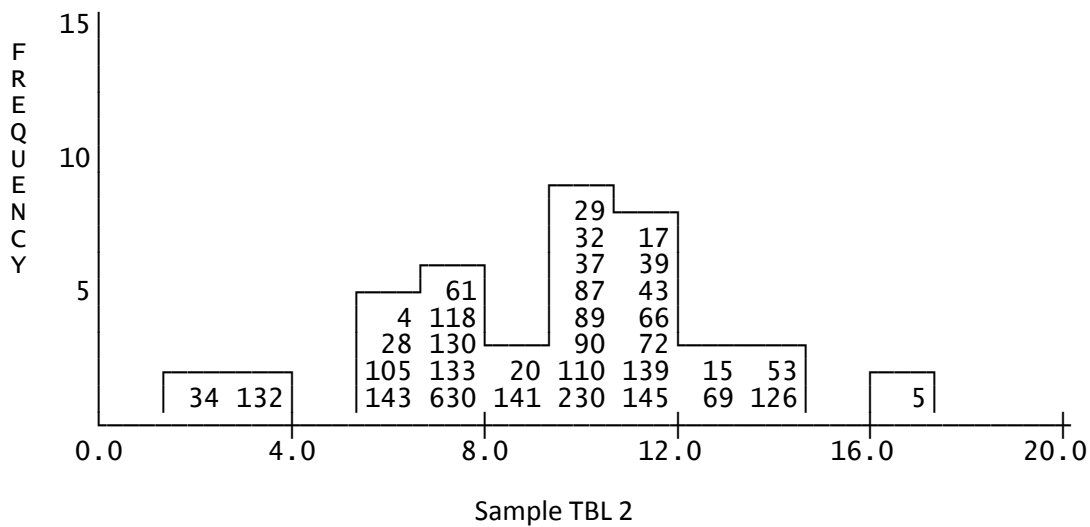
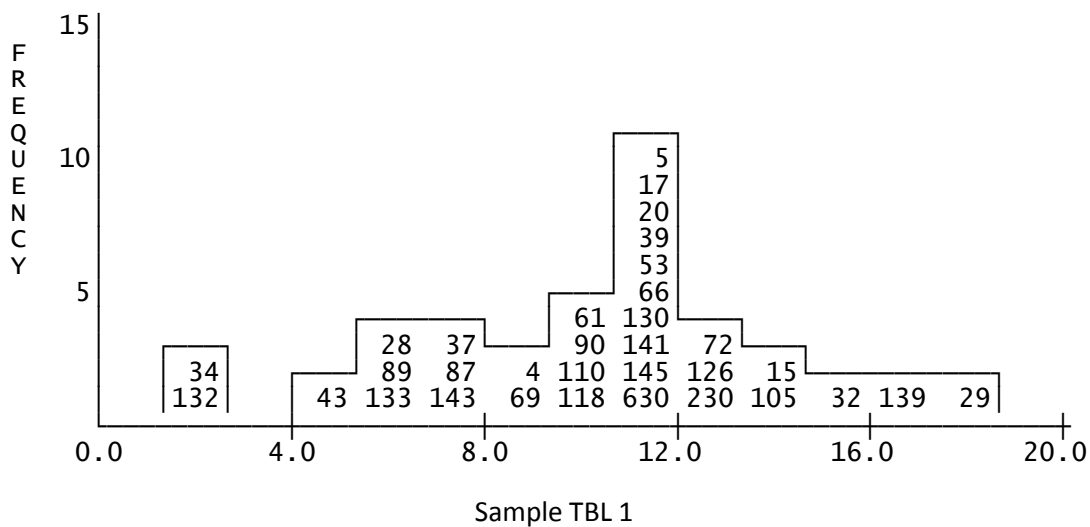
INFLATION PRESSURE (kPa)

Number of Laboratories: 74
 Consensus Mean: IN 1 2.41
 IN 2 1.87
 Repeatability Estimate: 0.14 ± 0.03
 Reproducibility Estimate: 0.22 ± 0.05

Force at Break (N) - Laboratory Means



Force at Break (N) - Laboratory Standard Deviations



SUMMARY STATISTICS for Force at Break (N)

Sample TBL 1:

Statistical Parameters	Before Removing Extreme Results	After Removing Extreme Results
No. Labs	33	33
Mean	80.9	80.9
Std Dev'n	11.9	11.9
Std Error	2.1	2.1
Coef Var'n	14.7	14.7
Minimum	51.6	51.6
Maximum	109.8	109.8
Range	58.2	58.2

Extreme Results (Laboratory code no's)	
Repeatability Stragglers	None
Repeatability Outliers	None
Reproduc'ility Stragglers	None
Reproduc'ility Outliers	None

Sample TBL 2:

Statistical Parameters	Before Removing Extreme Results	After Removing Extreme Results
No. Labs	33	33
Mean	77.9	77.9
Std Dev'n	9.5	9.5
Std Error	1.6	1.6
Coef Var'n	12.1	12.1
Minimum	62.7	62.7
Maximum	98.6	98.6
Range	35.9	35.9

Extreme Results (Laboratory code no's)	
Repeatability Stragglers	None
Repeatability Outliers	None
Reproduc'ility Stragglers	None
Reproduc'ility Outliers	None

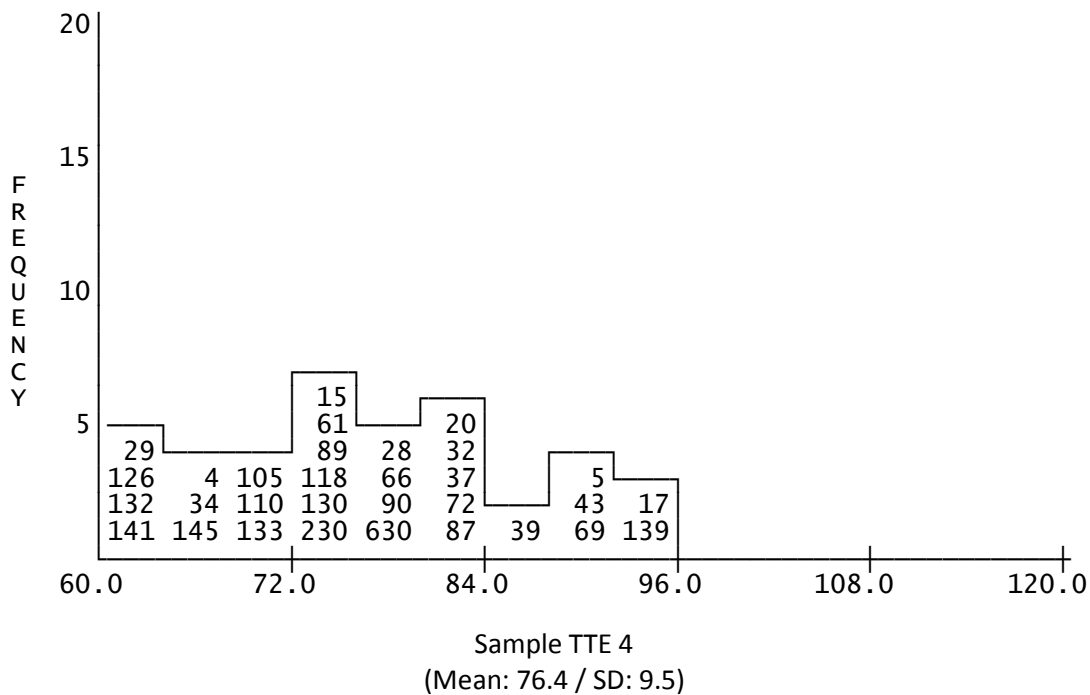
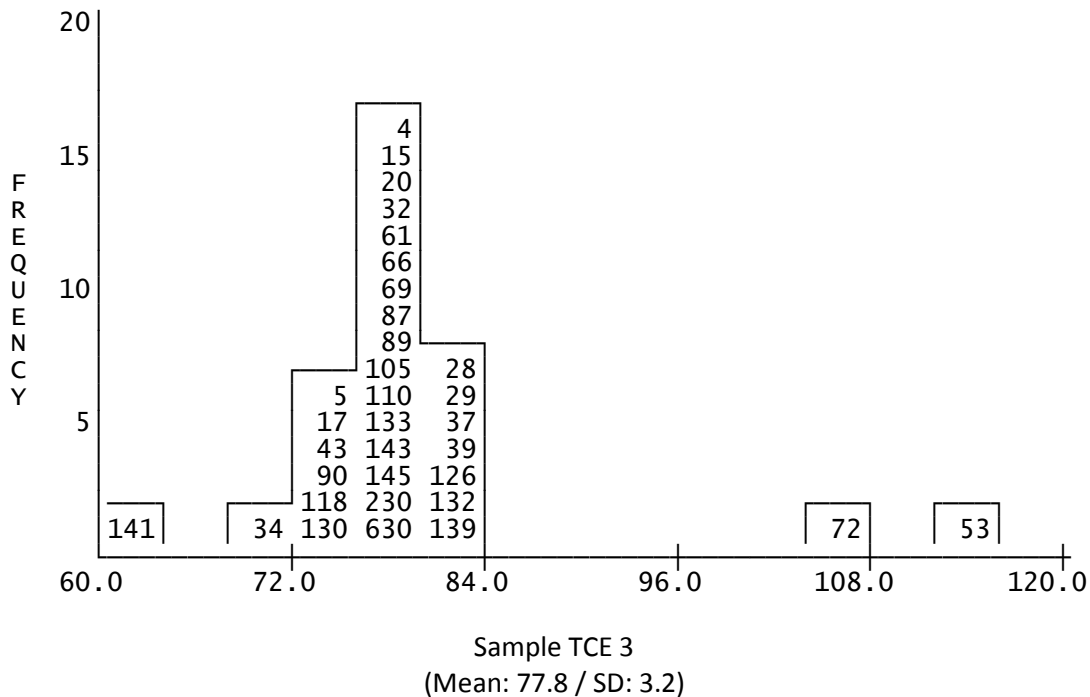
PRECISION ACHIEVED (after removal of extreme results)

FORCE (N)

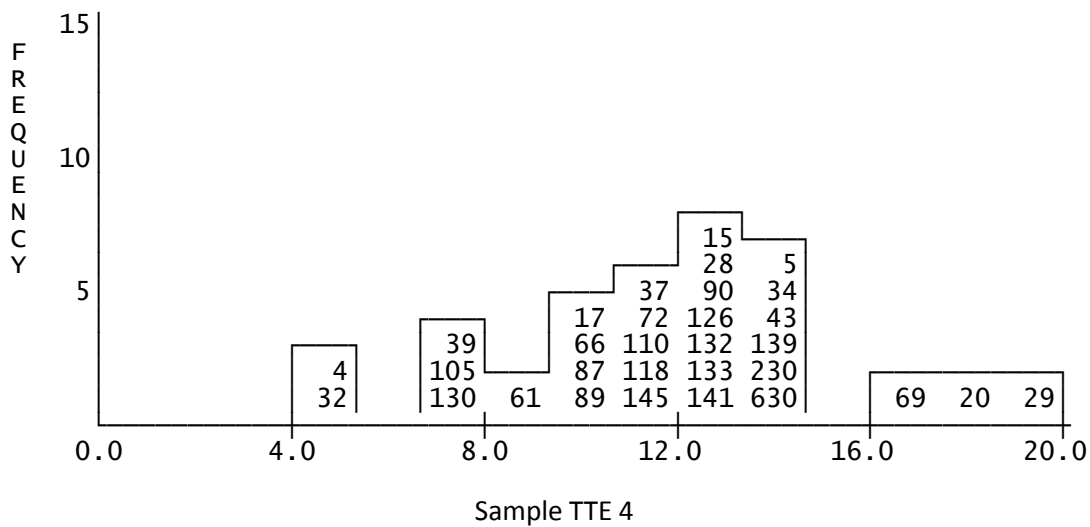
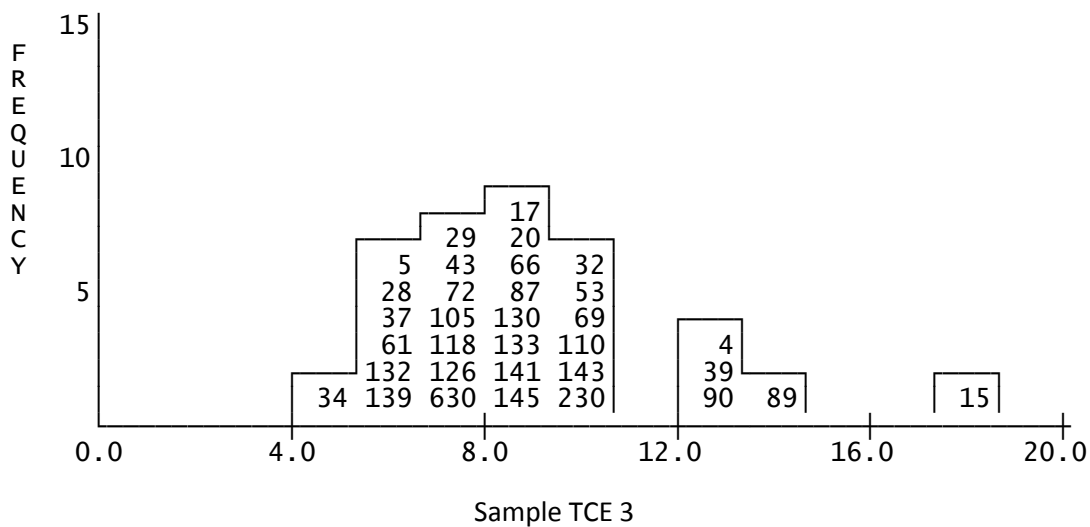
Sample : TBL 1
 Number of Laboratories : 33
 Consensus Mean : 80.9
 Repeatability Estimate : 30.6 ± 3.8
 Reproducibility Estimate : 44.5 ± 9.9

Sample : TBL 2
 Number of Laboratories : 33
 Consensus Mean : 77.9
 Repeatability Estimate : 28.6 ± 3.5
 Reproducibility Estimate : 38.1 ± 7.4

Force at Break (N) - Laboratory Means



Force at Break (N) - Laboratory Standard Deviations



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SUMMARY STATISTICS for Force at Break (N)

Sample TCE 3:

Statistical Parameters	Before Removing Extreme Results	After Removing Extreme Results
No. Labs	33	29
Mean	79.4	77.8
Std Dev'n	9.3	3.2
Std Error	1.6	0.6
Coef Var'n	11.7	4.1
Minimum	62.1	70.0
Maximum	115.2	82.8
Range	53.1	12.8

Extreme Results (Laboratory code no's)	
Repeatability Stragglers	None
Repeatability Outliers	15
Reproduc'ility Stragglers	None
Reproduc'ility Outliers	53,72,141

Sample TTE 4:

Statistical Parameters	Before Removing Extreme Results	After Removing Extreme Results
No. Labs	31	31
Mean	76.4	76.4
Std Dev'n	9.5	9.5
Std Error	1.7	1.7
Coef Var'n	12.5	12.5
Minimum	61.1	61.1
Maximum	94.5	94.5
Range	33.4	33.4

Extreme Results (Laboratory code no's)	
Repeatability Stragglers	None
Repeatability Outliers	None
Reproduc'ility Stragglers	None
Reproduc'ility Outliers	None

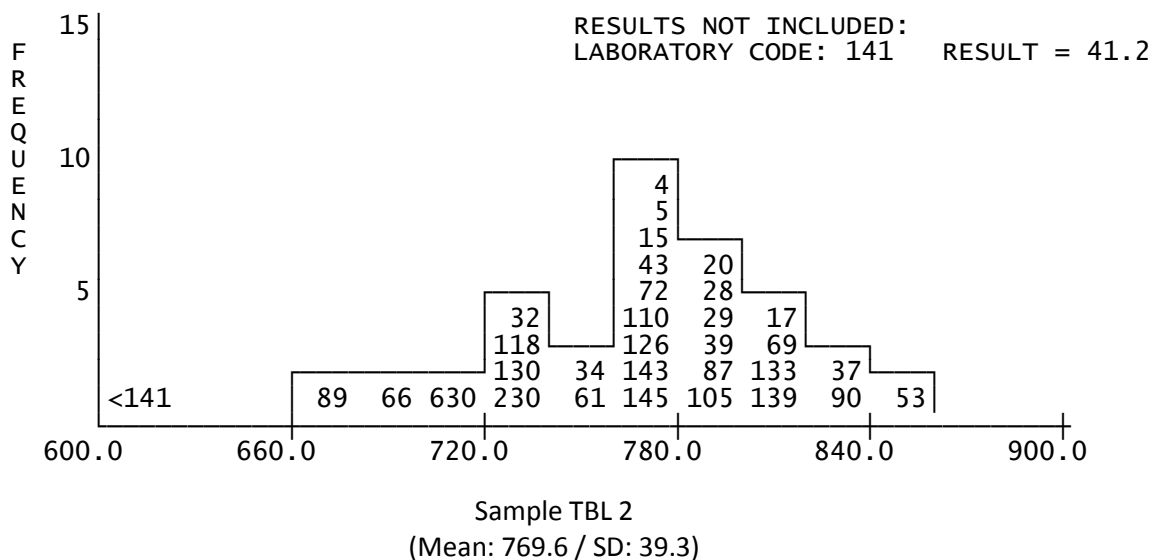
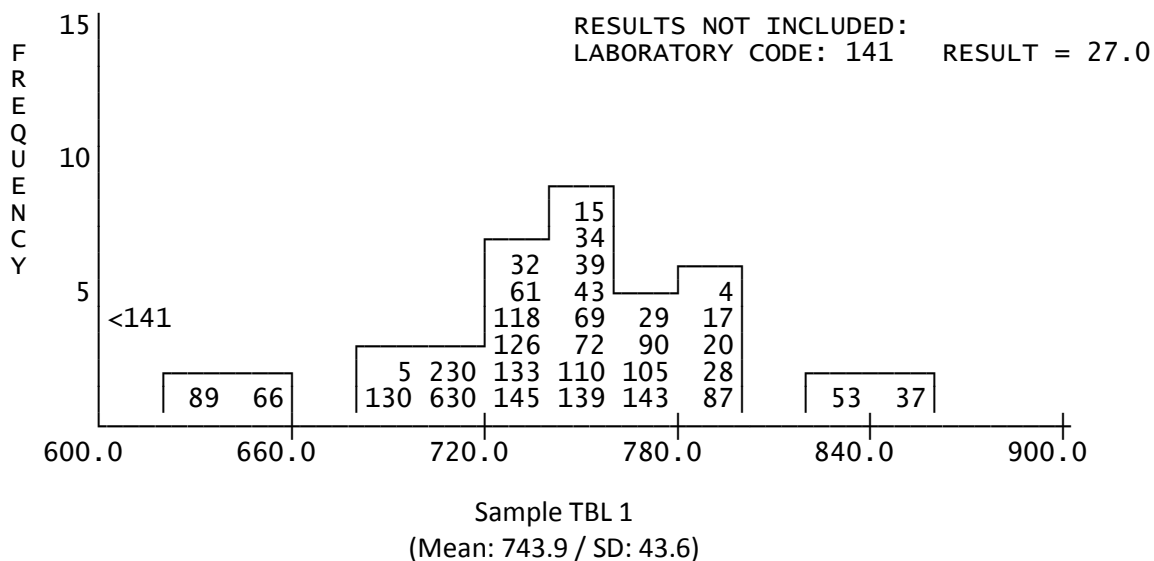
PRECISION ACHIEVED (after removal of extreme results)

FORCE (N)

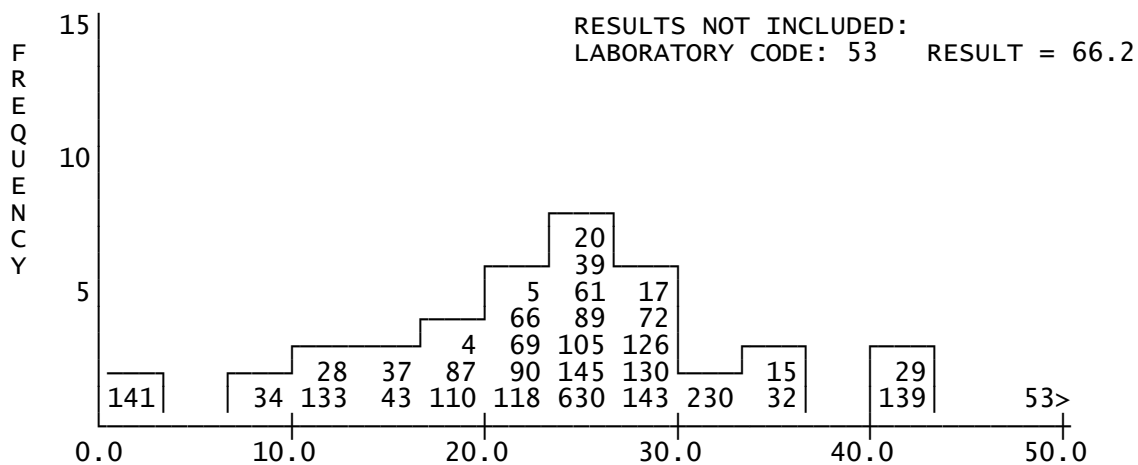
Sample : TCE 3
 Number of Laboratories : 29
 Consensus Mean : 77.8
 Repeatability Estimate : 24.7 ± 3.2
 Reproducibility Estimate : 25.2 ± 3.2

Sample : TTE 4
 Number of Laboratories : 31
 Consensus Mean : 76.4
 Repeatability Estimate : 34.4 ± 4.4
 Reproducibility Estimate : 42.3 ± 7.4

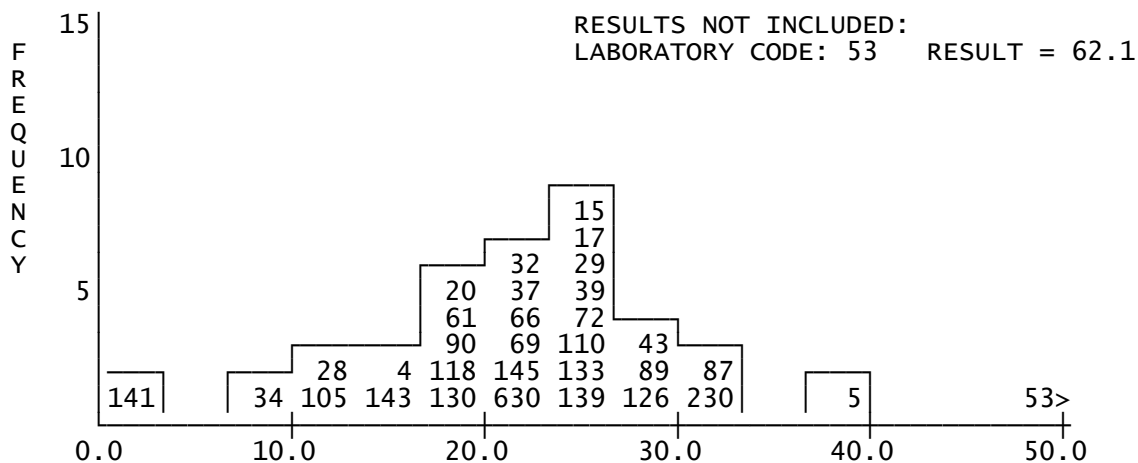
Elongation at Break (%) - Laboratory Means



Elongation at Break (%) - Laboratory Standard Deviations



Sample TBL 1



Sample TBL 2

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SUMMARY STATISTICS for Elongation at Break (%)

Sample TBL 1:

Statistical Parameters	Before Removing Extreme Results	After Removing Extreme Results	Extreme Results (Laboratory code no's)	
			No. Labs	32
Mean	724.1	743.9	Repeatability Outliers	53
Std Dev'n	134.8	43.6	Reproduc'ility Stragglers	None
Std Error	23.8	8.0	Reproduc'ility Outliers	141
Coef Var'n	18.6	5.9		
Minimum	27.0	638.1		
Maximum	848.8	848.8		
Range	821.8	210.7		

Sample TBL 2:

Statistical Parameters	Before Removing Extreme Results	After Removing Extreme Results	Extreme Results (Laboratory code no's)	
			No. Labs	32
Mean	749.6	769.6	Repeatability Outliers	53
Std Dev'n	135.6	39.3	Reproduc'ility Stragglers	None
Std Error	24.0	7.2	Reproduc'ility Outliers	141
Coef Var'n	18.1	5.1		
Minimum	41.2	669.0		
Maximum	856.4	832.9		
Range	815.2	163.9		

PRECISION ACHIEVED (after removal of extreme results)

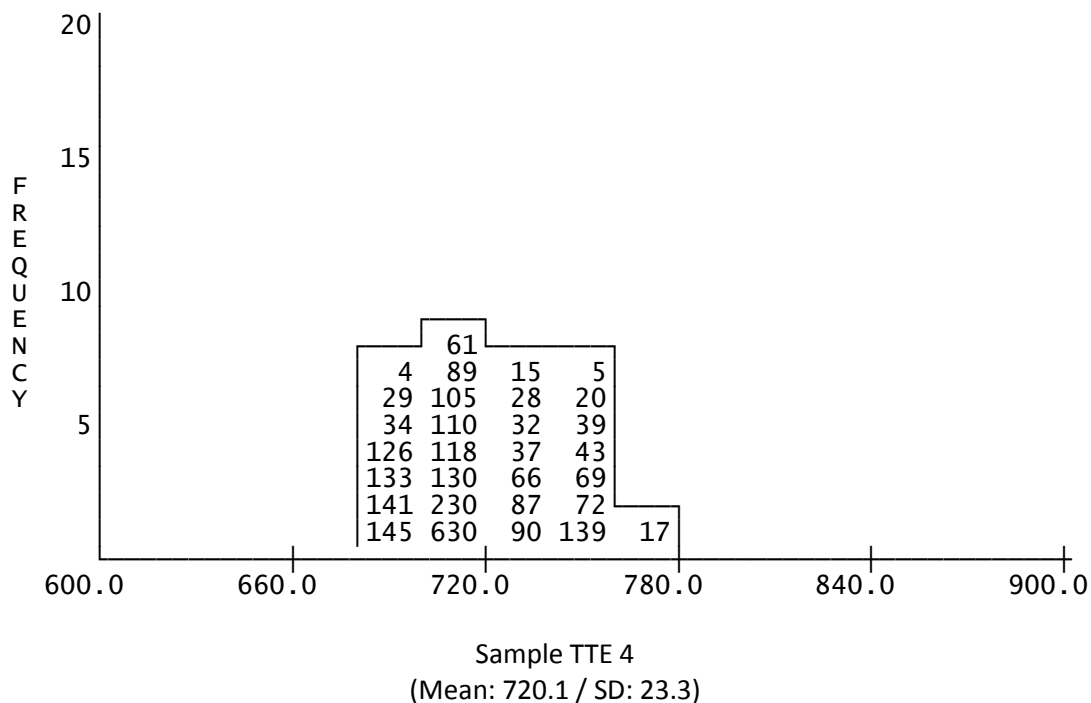
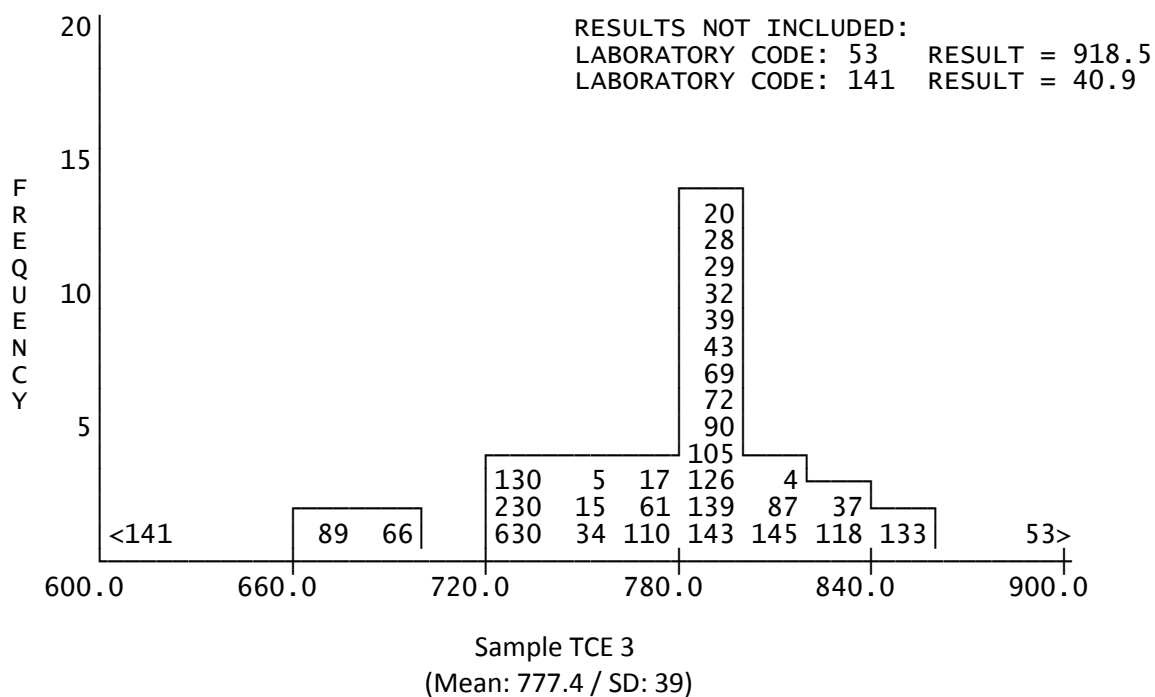
ELONGATION (%)

Sample : TBL 1
 Number of Laboratories : 30
 Consensus Mean : 743.9
 Repeatability Estimate : 71.4 ± 9.2
 Reproducibility Estimate : 140.6 ± 42.7

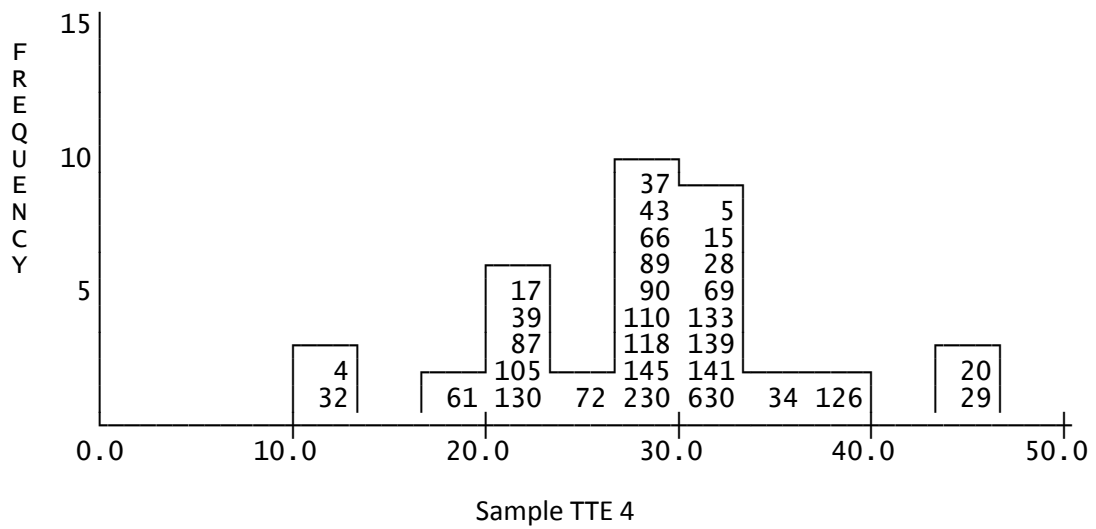
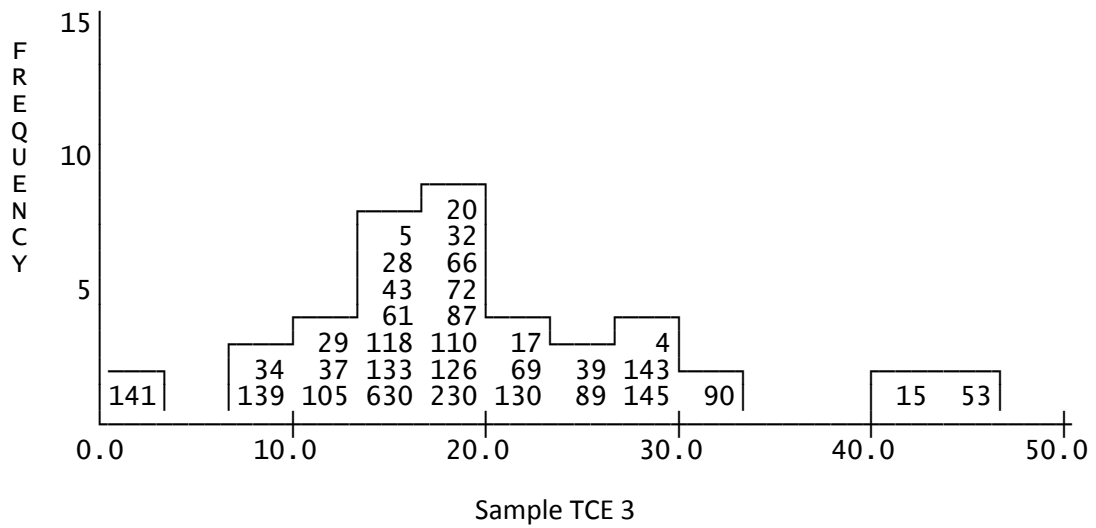
Sample : TBL 2
 Number of Laboratories : 30
 Consensus Mean : 769.6
 Repeatability Estimate : 66.0 ± 8.5
 Reproducibility Estimate : 127.7 ± 38.4

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Elongation at Break (%) - Laboratory Means



Elongation at Break (%) - Laboratory Standard Deviations



ENERSOL Interlaboratory Proficiency Trial of Condom Testing Laboratories, 2011

SUMMARY STATISTICS for Elongation at Break (%)

Sample TCE 3:

Statistical Parameters	Before Removing Extreme Results	After Removing Extreme Results
No. Labs	32	29
Mean	758.0	777.4
Std Dev'n	138.4	39.0
Std Error	24.5	7.2
Coef Var'n	18.3	5.0
Minimum	40.9	674.6
Maximum	918.5	842.4
Range	877.6	167.8

Extreme Results (Laboratory code no's)	
Repeatability Stragglers	None
Repeatability Outliers	15,53
Reproduc'ility Stragglers	53
Reproduc'ility Outliers	141

Sample TTE 4:

Statistical Parameters	Before Removing Extreme Results	After Removing Extreme Results
No. Labs	30	30
Mean	720.1	720.1
Std Dev'n	23.3	23.3
Std Error	4.3	4.3
Coef Var'n	3.2	3.2
Minimum	682.1	682.1
Maximum	766.0	766.0
Range	83.9	83.9

Extreme Results (Laboratory code no's)	
Repeatability Stragglers	None
Repeatability Outliers	None
Reproduc'ility Stragglers	None
Reproduc'ility Outliers	None

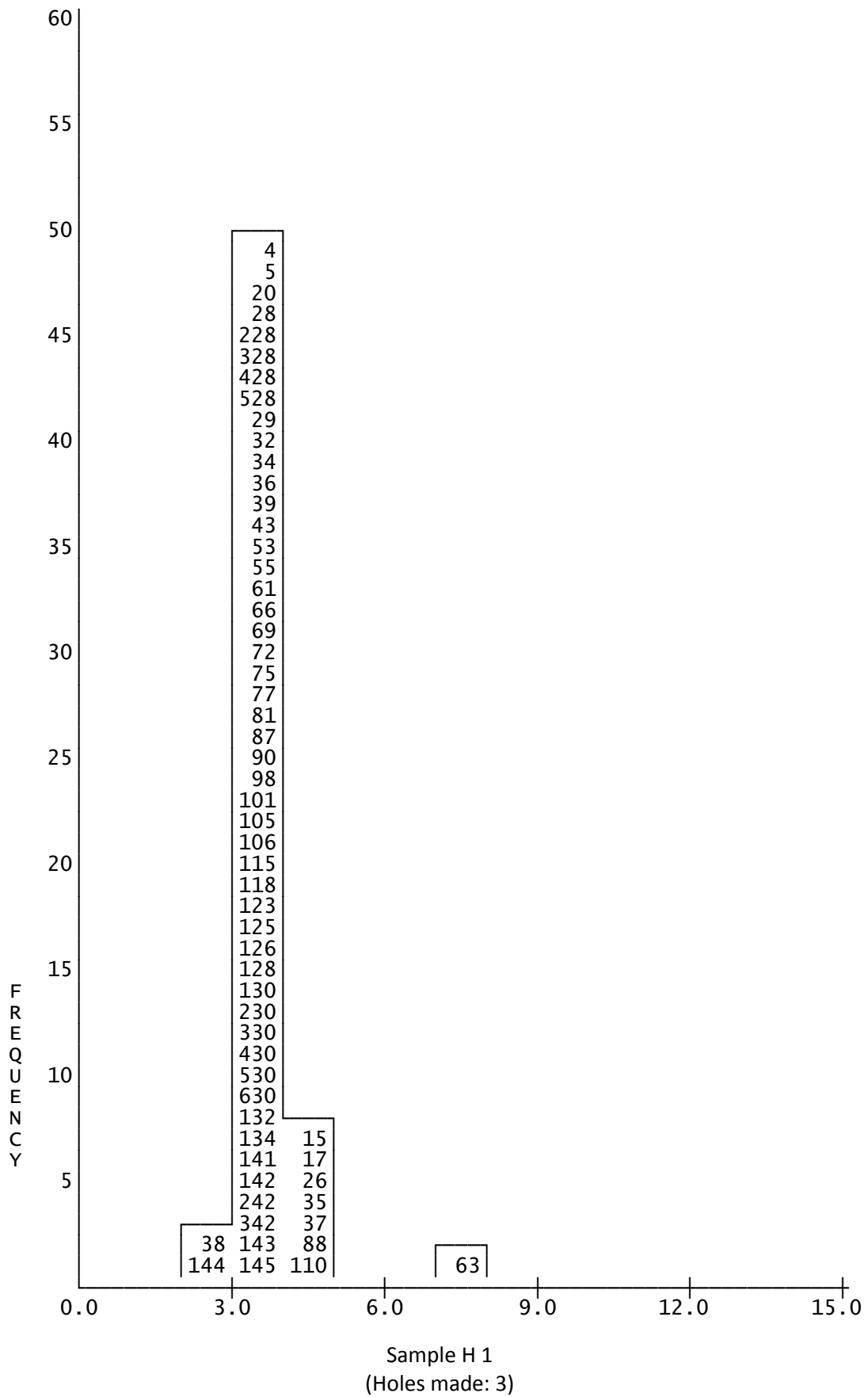
PRECISION ACHIEVED (after removal of extreme results)

ELONGATION (%)

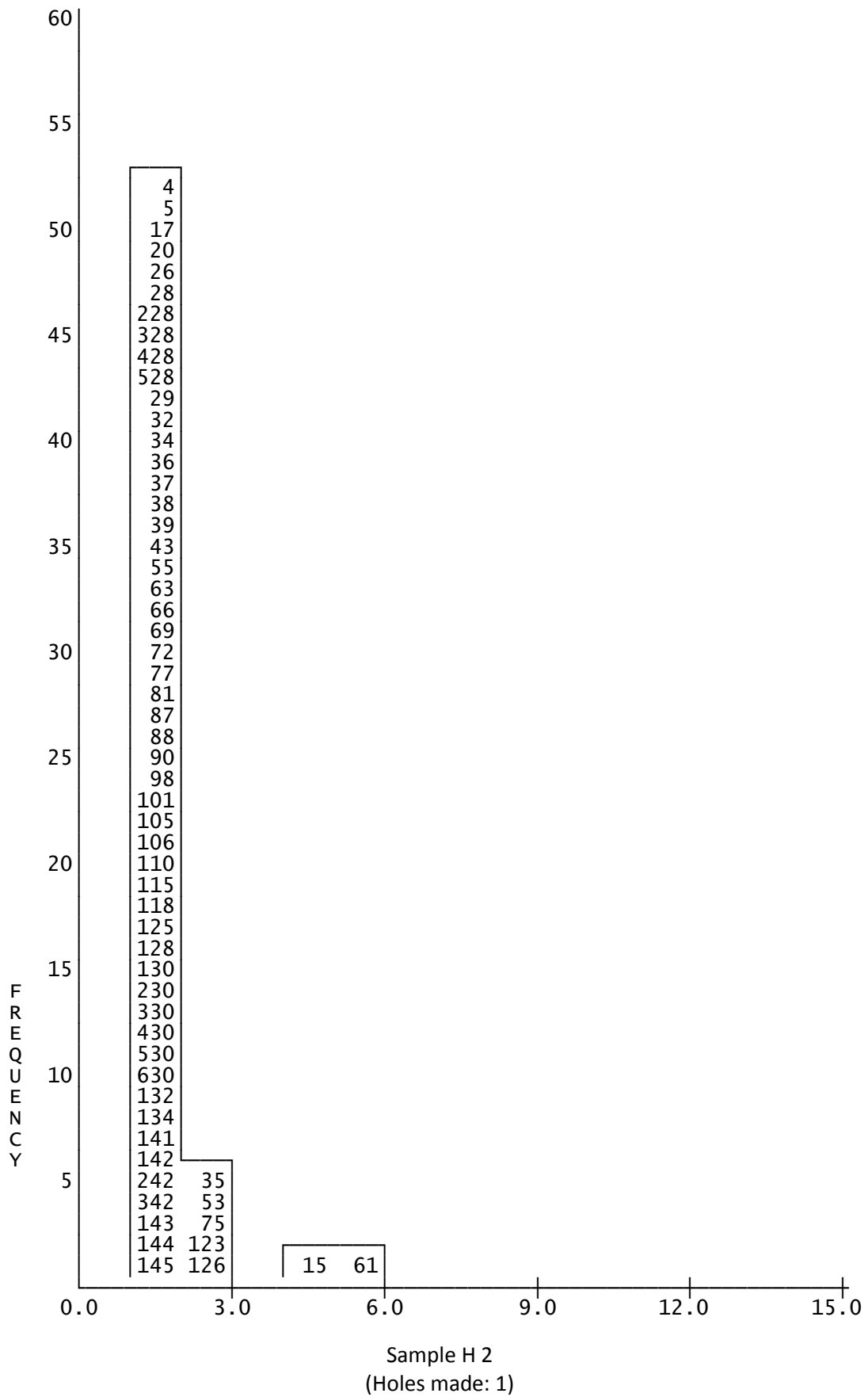
Sample : TCE 3
 Number of Laboratories : 29
 Consensus Mean : 777.4
 Repeatability Estimate : 55.6 ± 7.3
 Reproducibility Estimate : 122.2 ± 40

Sample : TTE 4
 Number of Laboratories : 30
 Consensus Mean : 720.1
 Repeatability Estimate : 82.7 ± 10.7
 Reproducibility Estimate : 102.5 ± 18.5

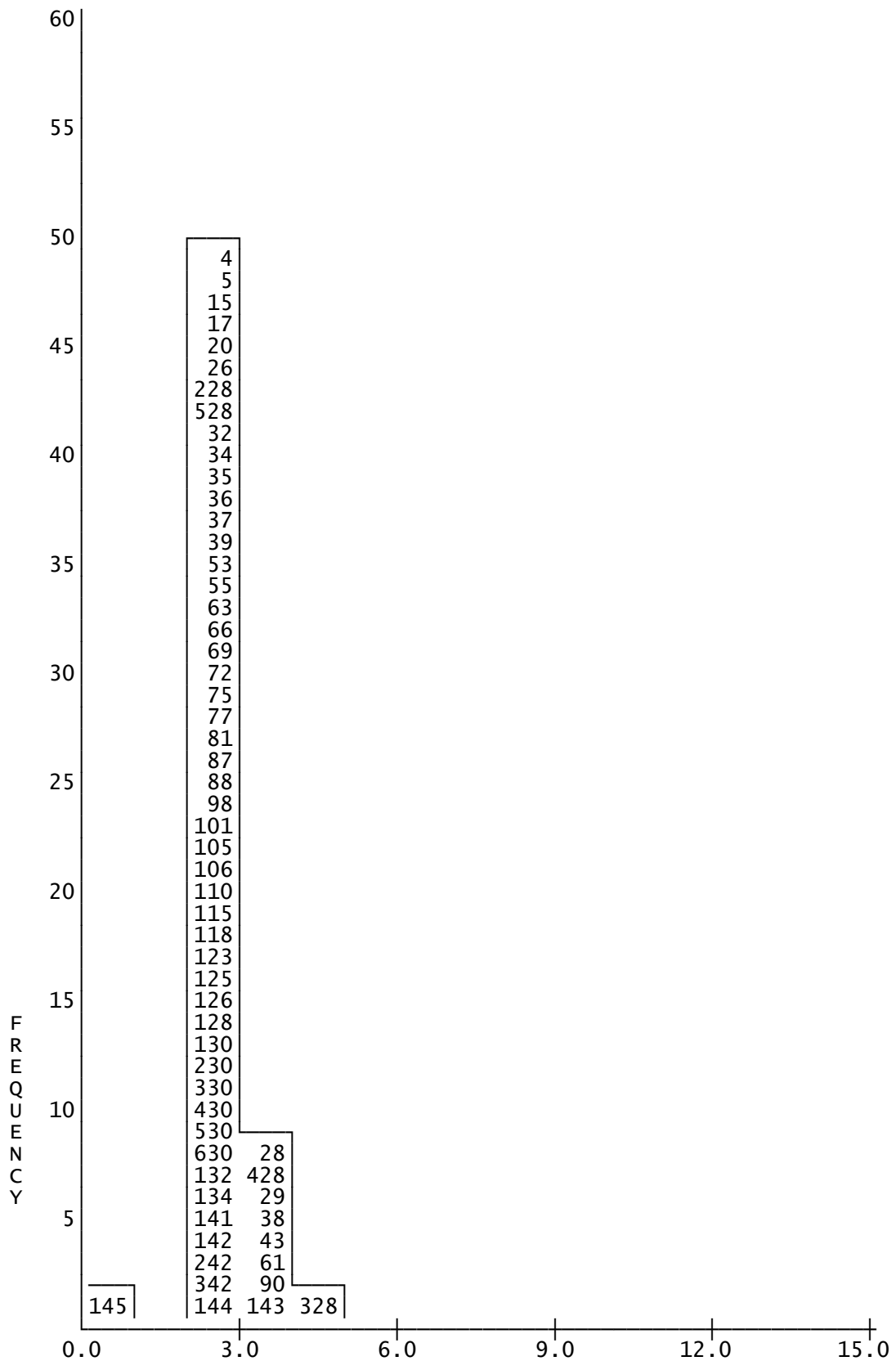
Freedom from Holes (Visual Method) - Total Holes Found



Freedom from Holes (Visual Method) - Total Holes Found (Continued)



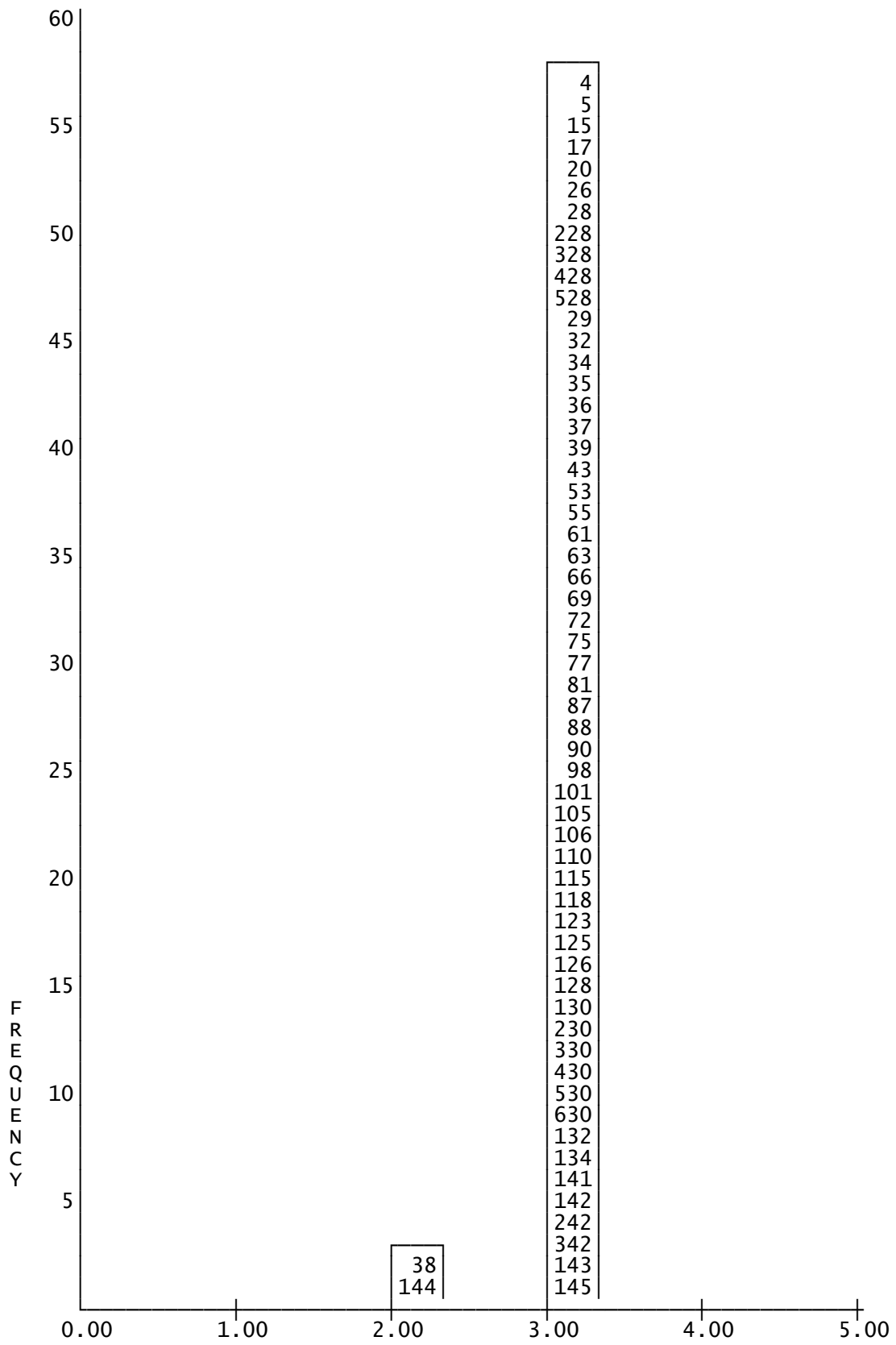
Freedom from Holes (Visual Method) - Total Holes Found (Continued)



Sample H 3
(Holes made: 2)

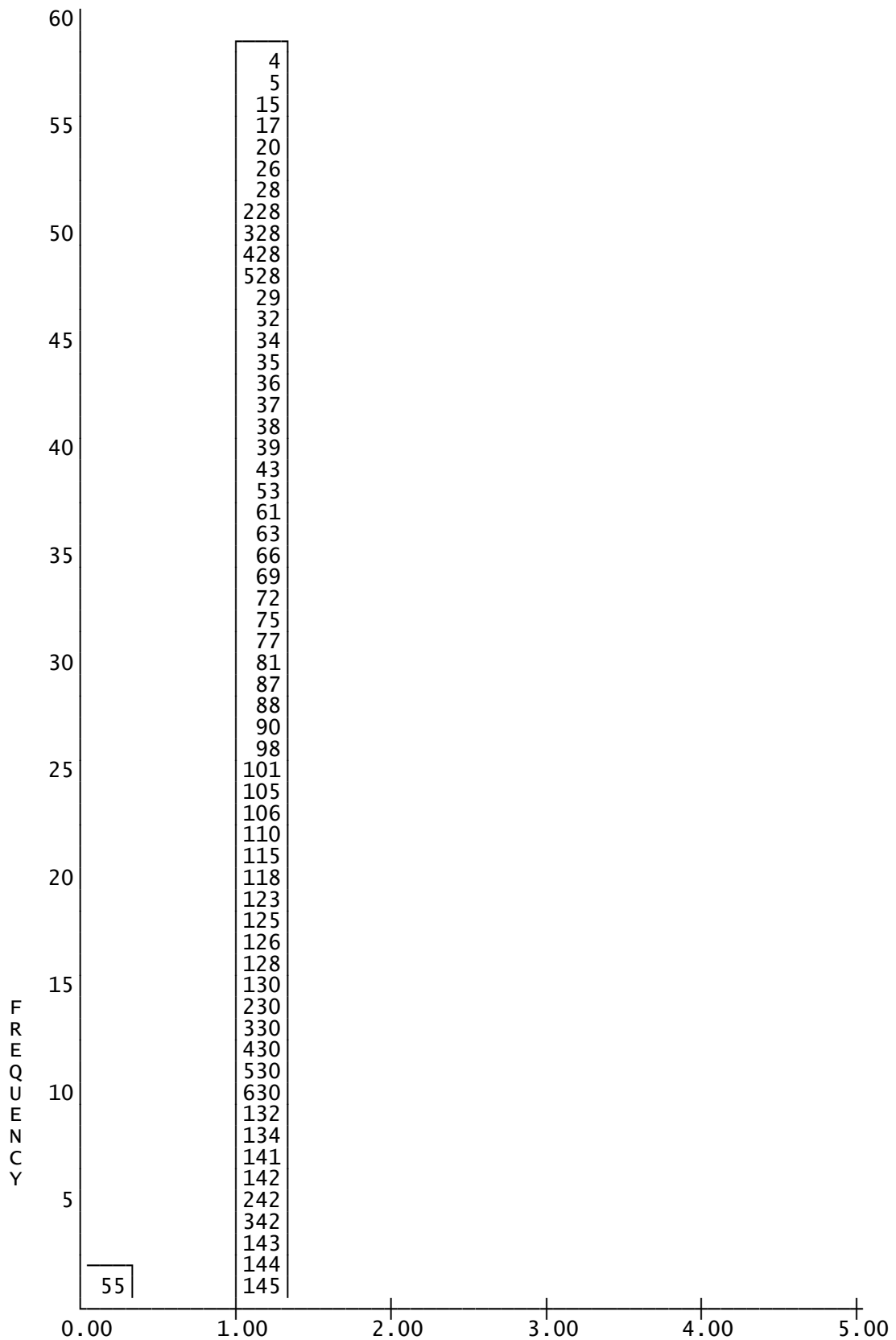
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Freedom from Holes (Visual Method) - Holes Found in Selected Regions



Sample H 1
(Holes made: 3)

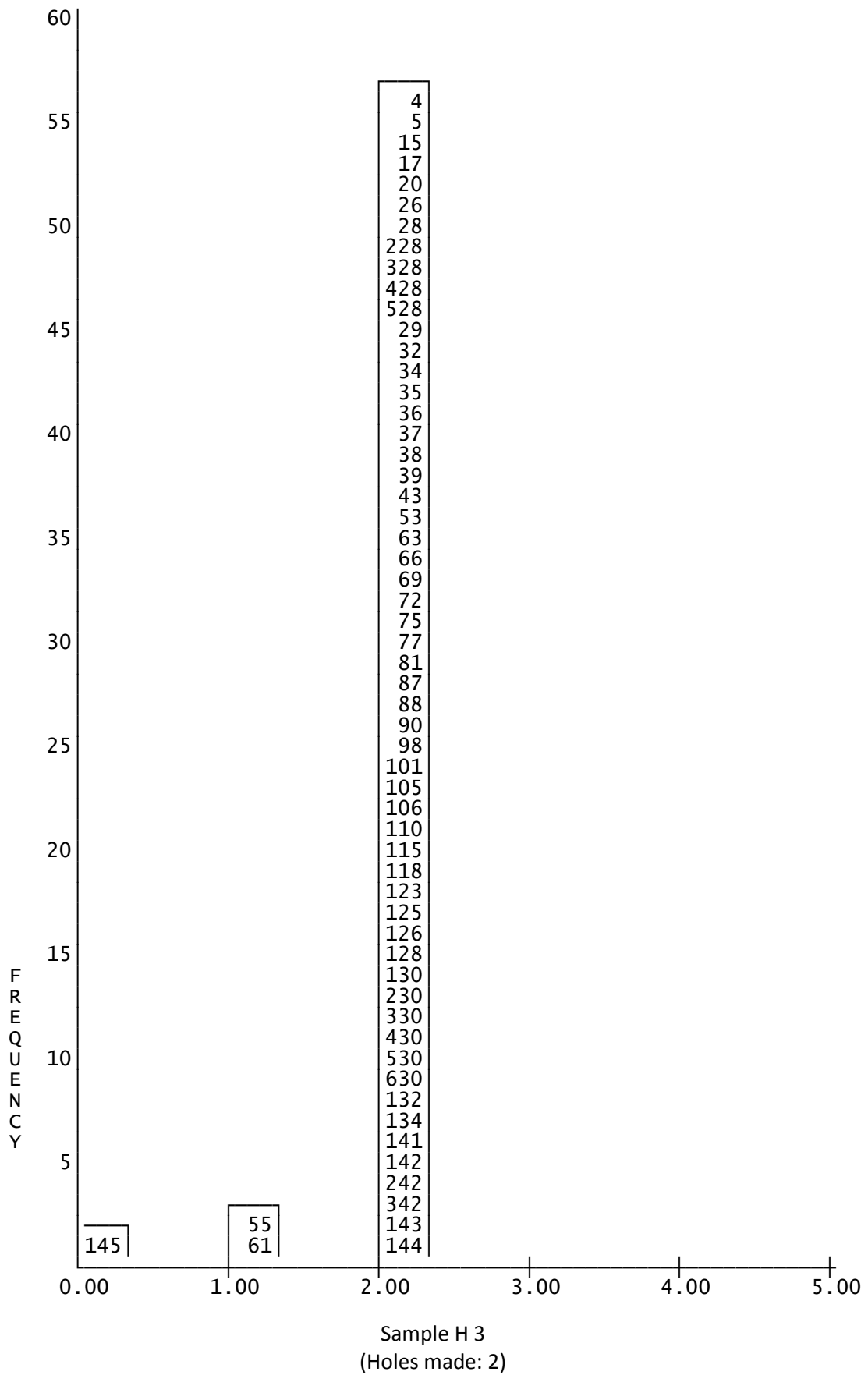
Freedom from Holes (Visual Method) - Holes Found in Selected Regions (Continued)



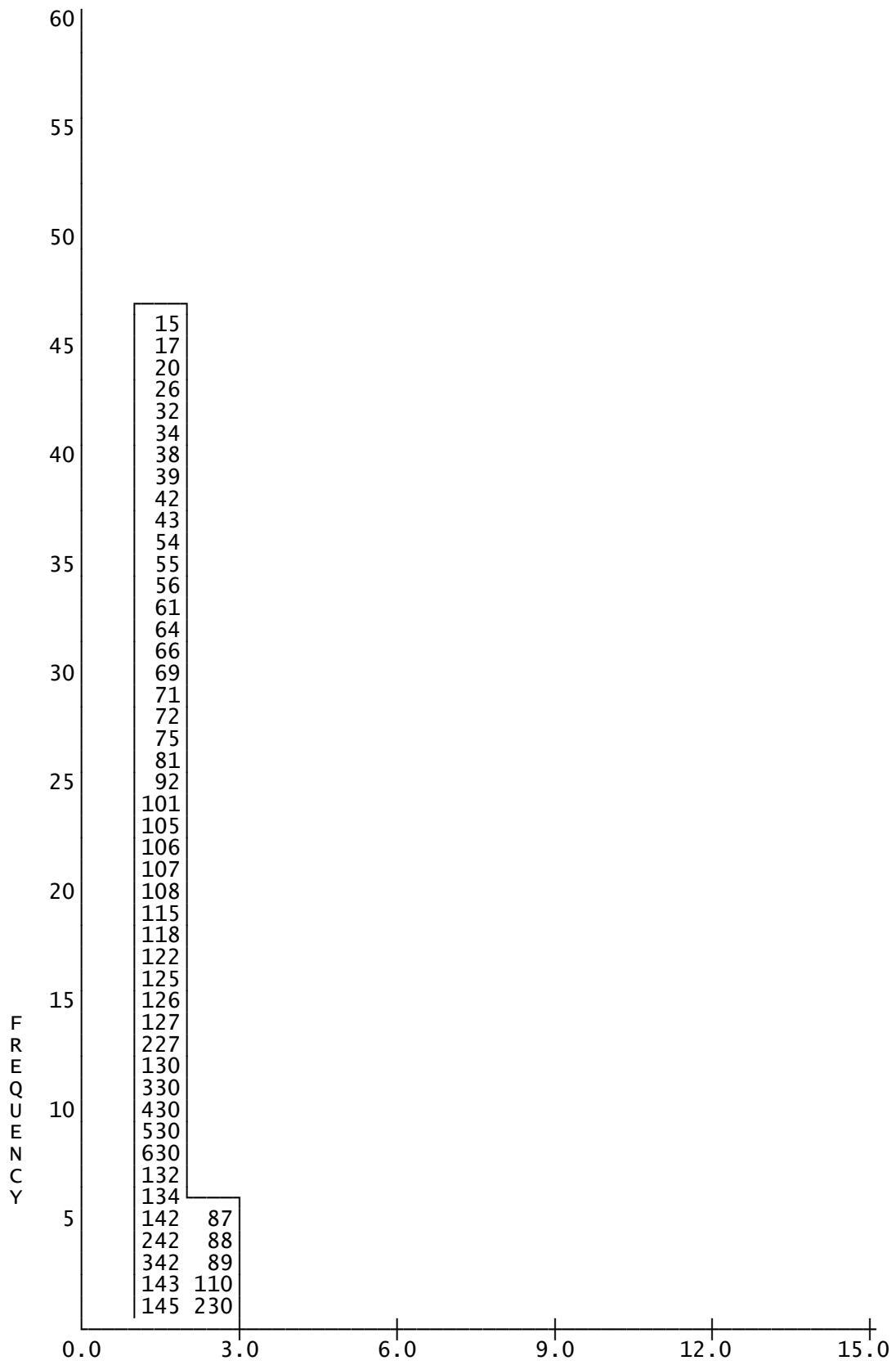
Sample H 2
(Holes made: 1)

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Freedom from Holes (Visual Method) - Holes Found in Selected Regions (Continued)

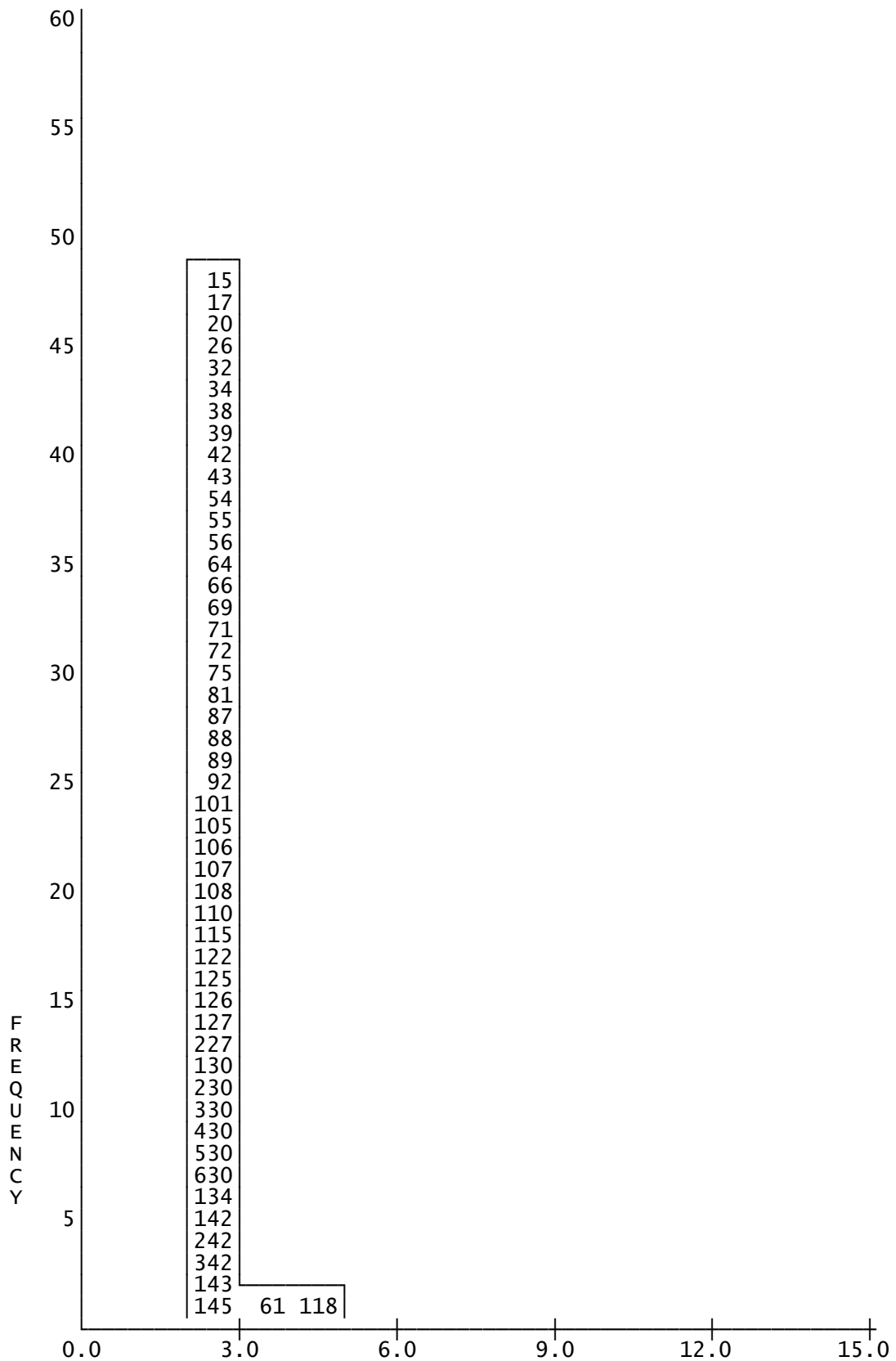


Freedom from Holes (Conductivity Method) - Total Holes Found



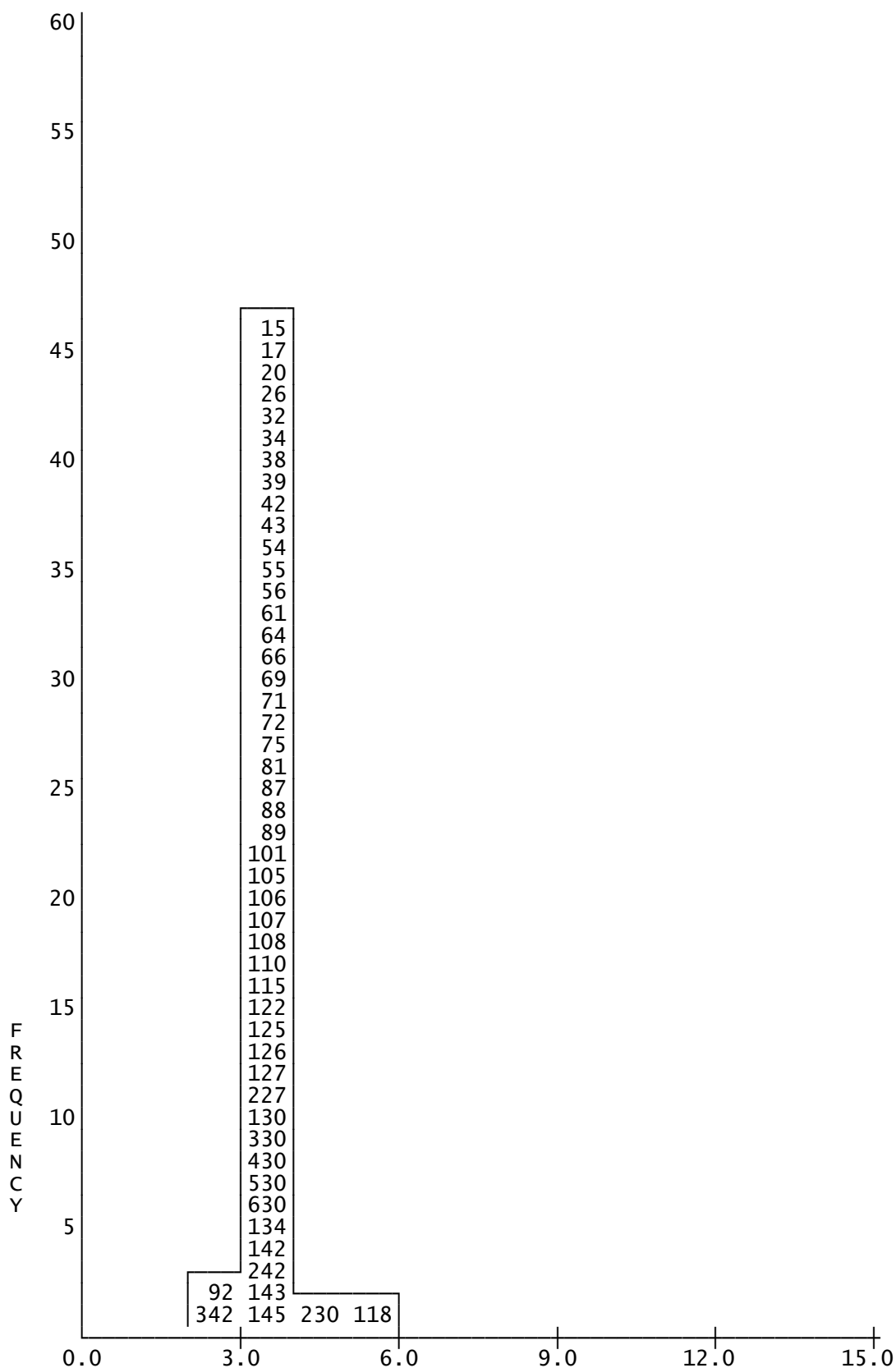
Sample H 4
(Holes made: 1)

Freedom from Holes (Conductivity Method) - Total Holes Found (Continued)



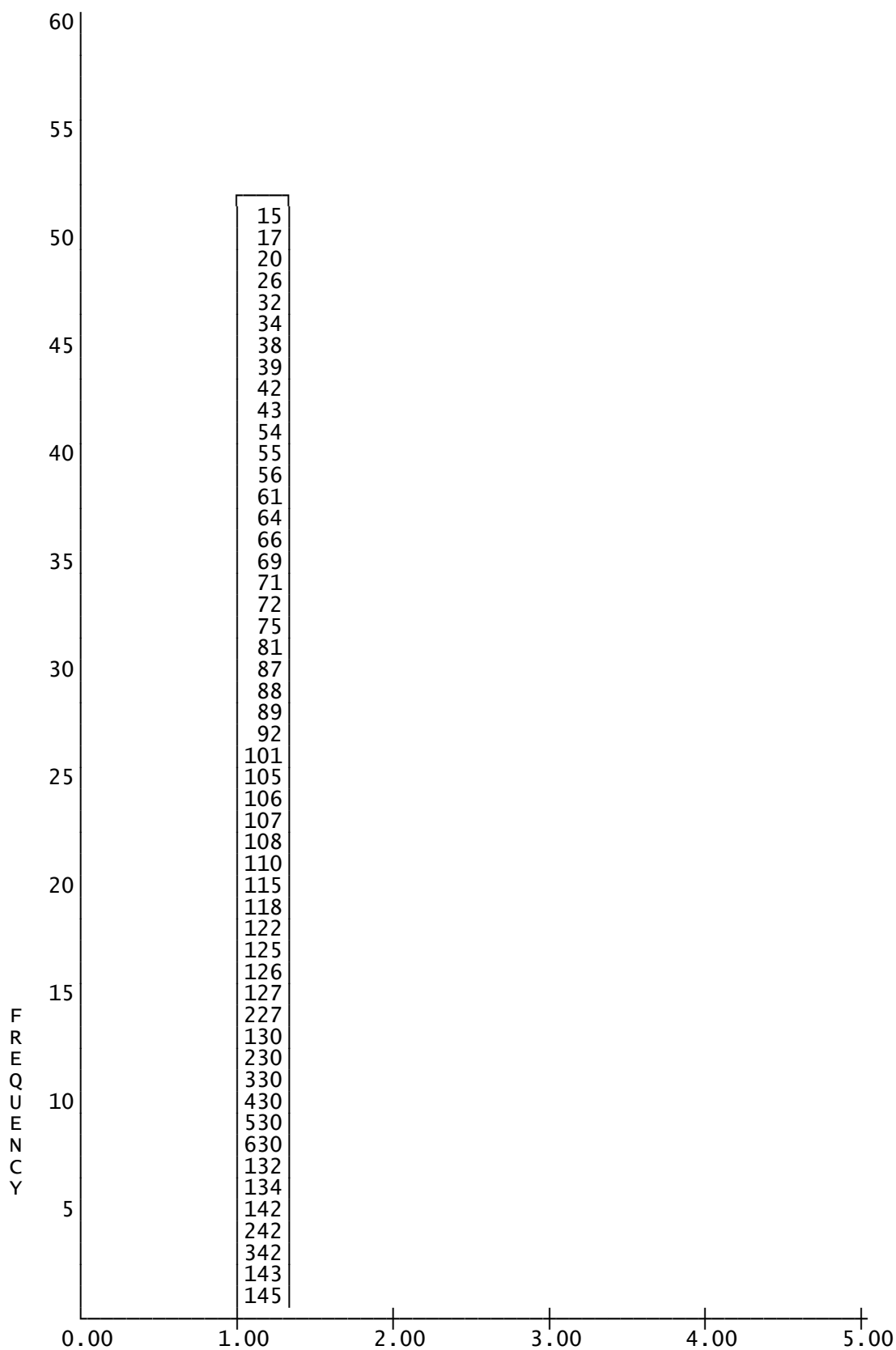
Sample H 5
(Holes made: 2)

Freedom from Holes (Conductivity Method) - Total Holes Found (Continued)



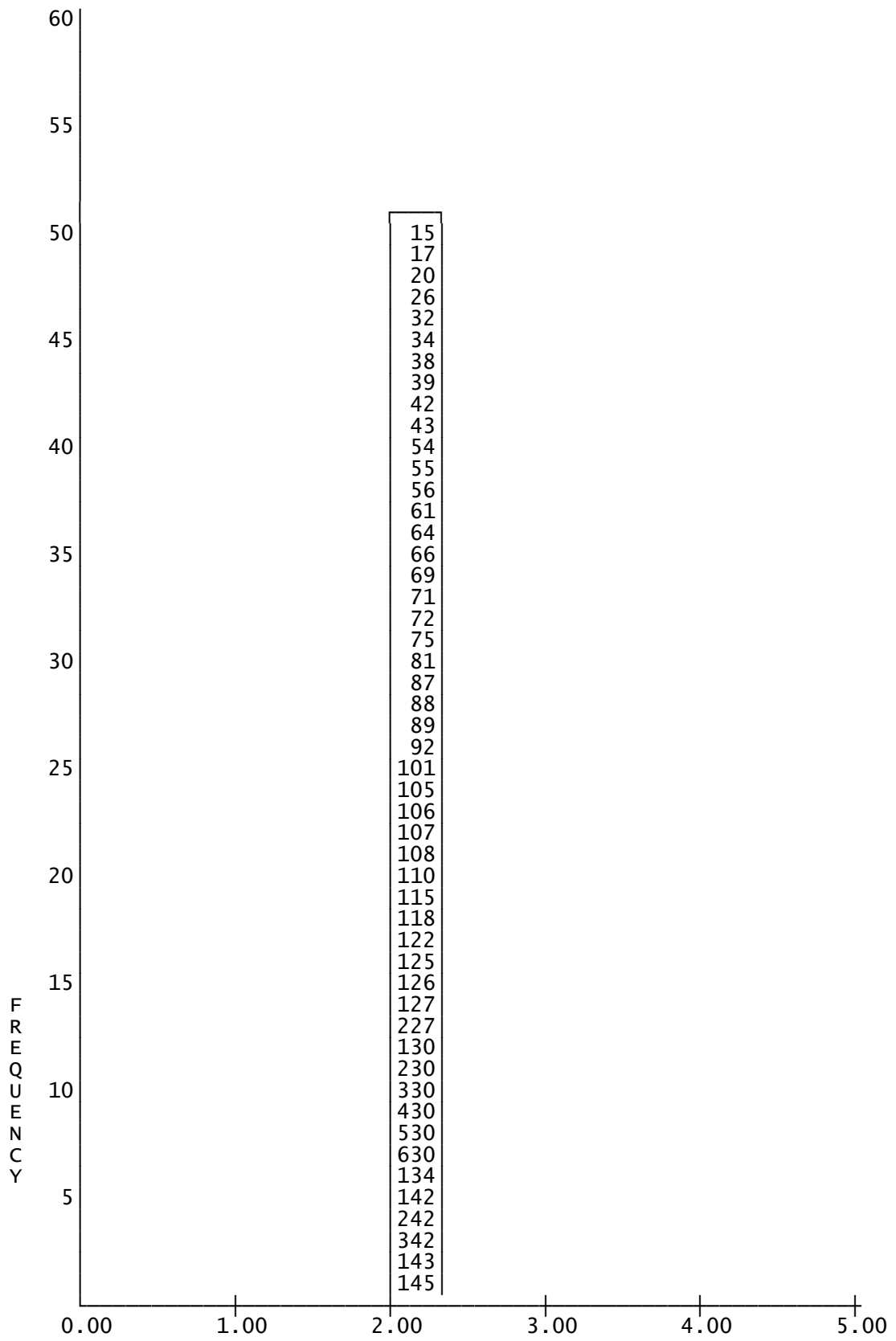
Sample H 6
(Holes made: 3)

Freedom from Holes (Conductivity Method) - Holes Found in Selected Regions



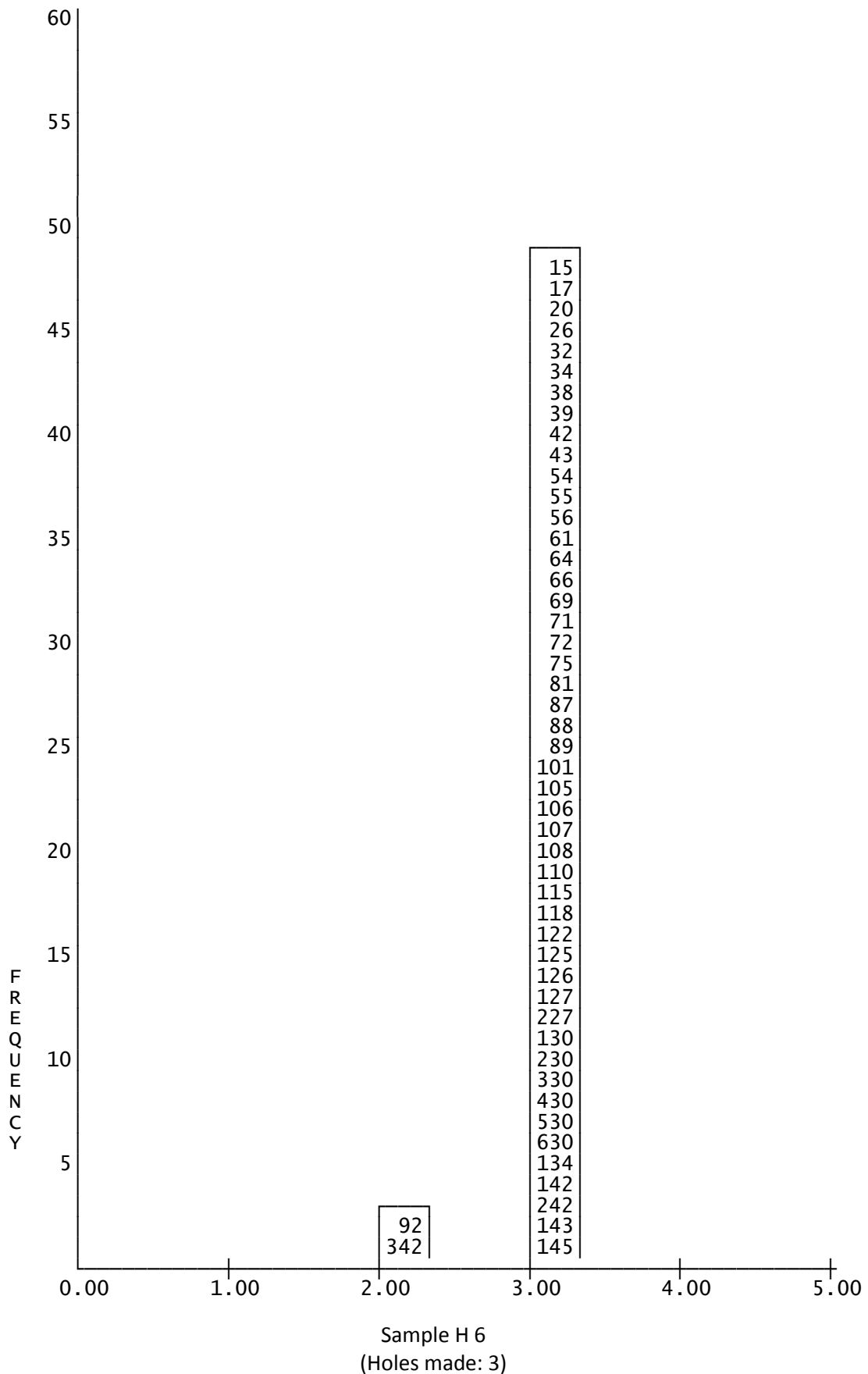
Sample H 4
(Holes made: 1)

Freedom from Holes (Conductivity Method) - Holes Found in Selected Regions (Continued)

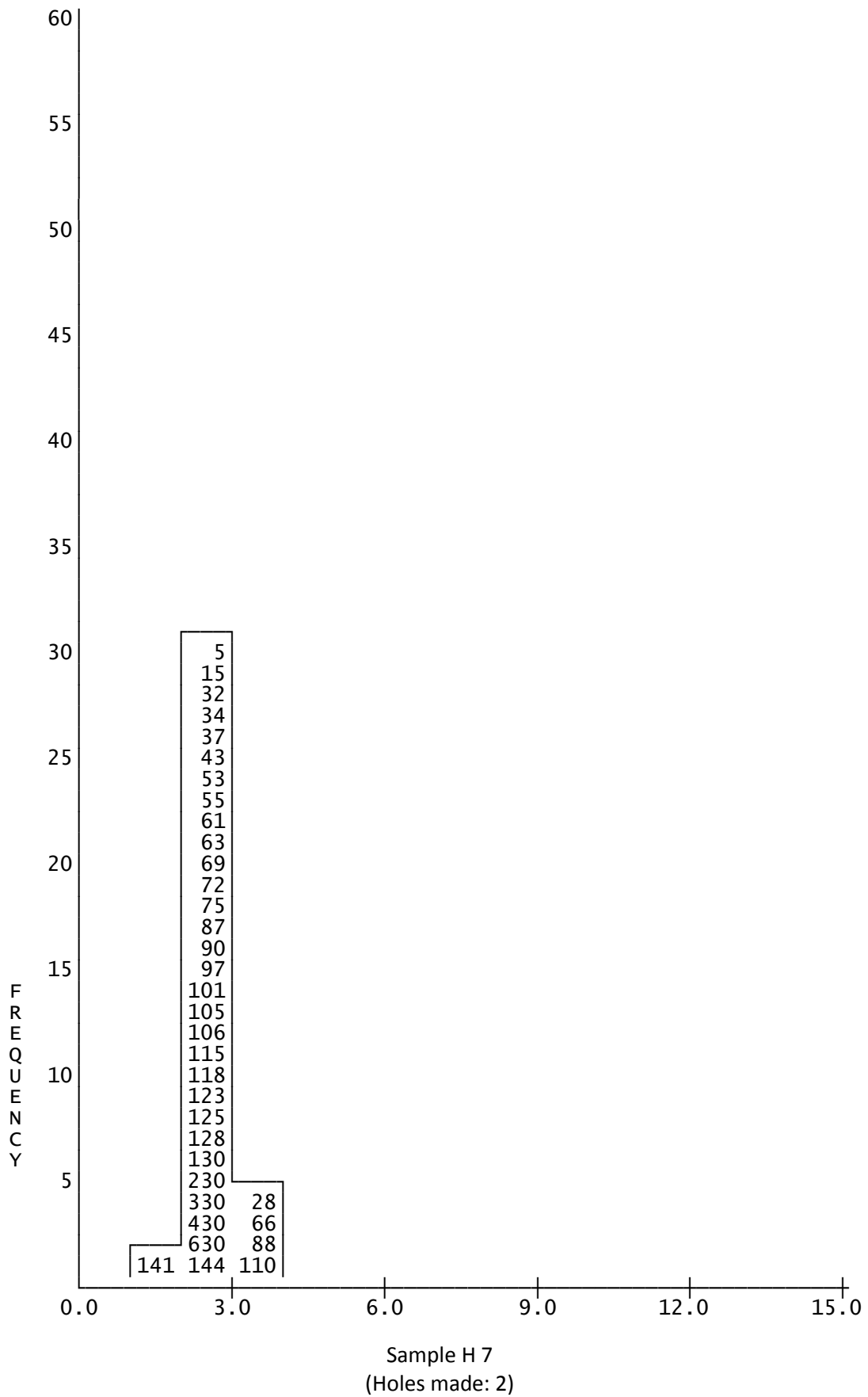


Sample H 5
(Holes made: 2)

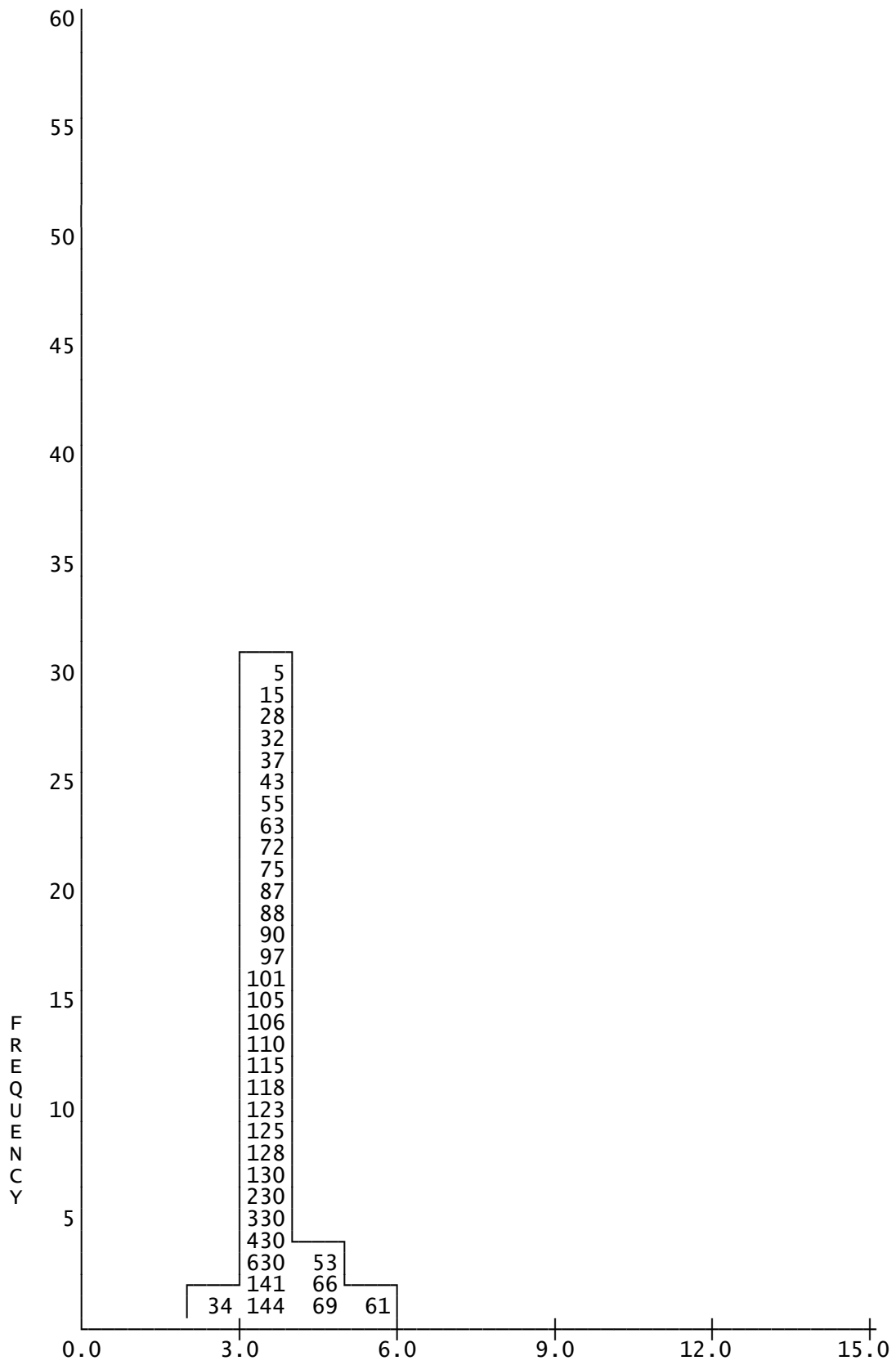
Freedom from Holes (Conductivity Method) - Holes Found in Selected Regions (Continued)



Freedom from Holes (ASTM Hang & Squeeze Method) - Total Holes Found

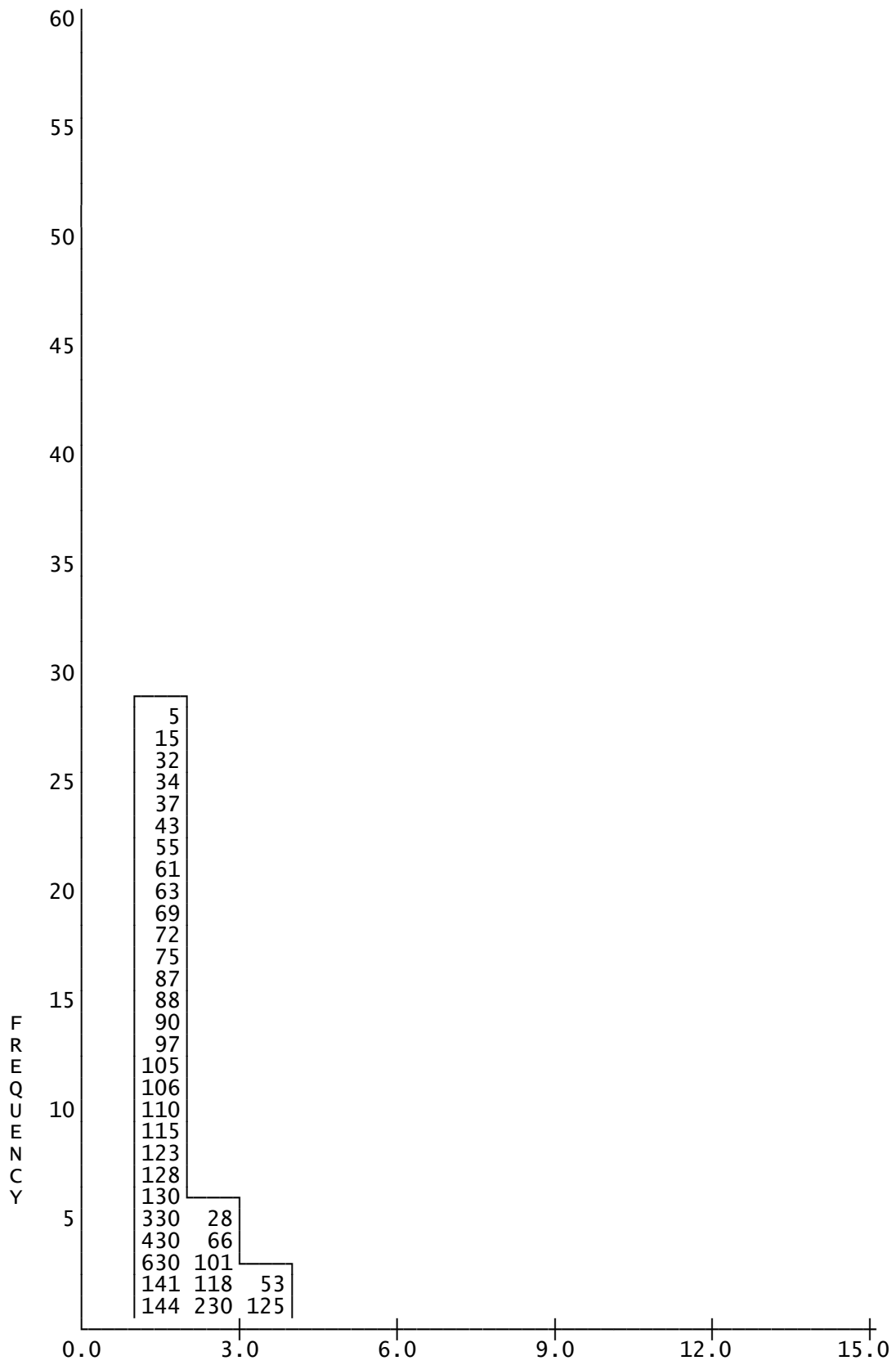


Freedom from Holes (ASTM Hang & Squeeze Method) - Total Holes Found (Continued)



Sample H 8
(Holes made: 3)

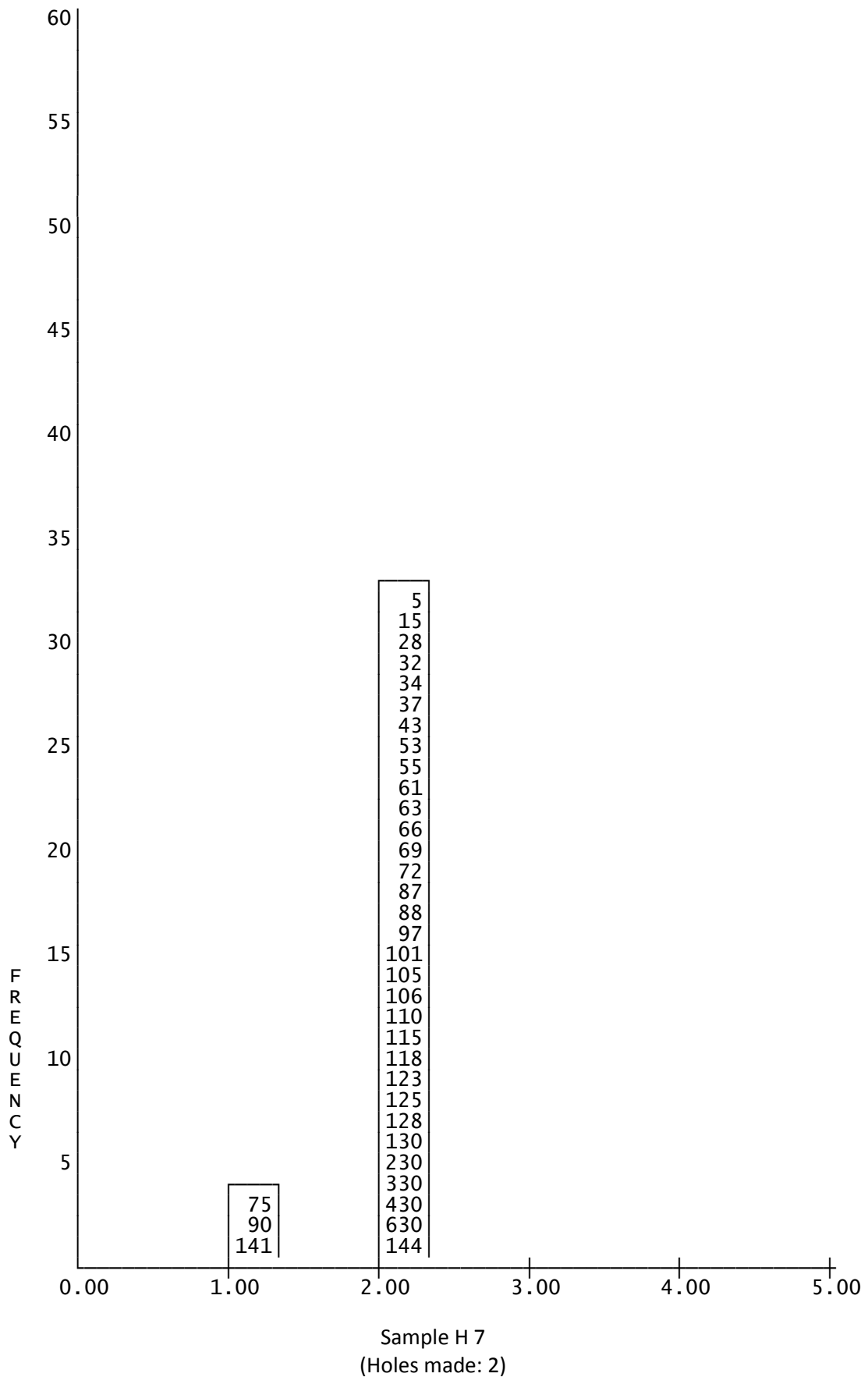
Freedom from Holes (ASTM Hang & Squeeze Method) - Total Holes Found (Continued)



Sample H 9
(Holes made: 1)

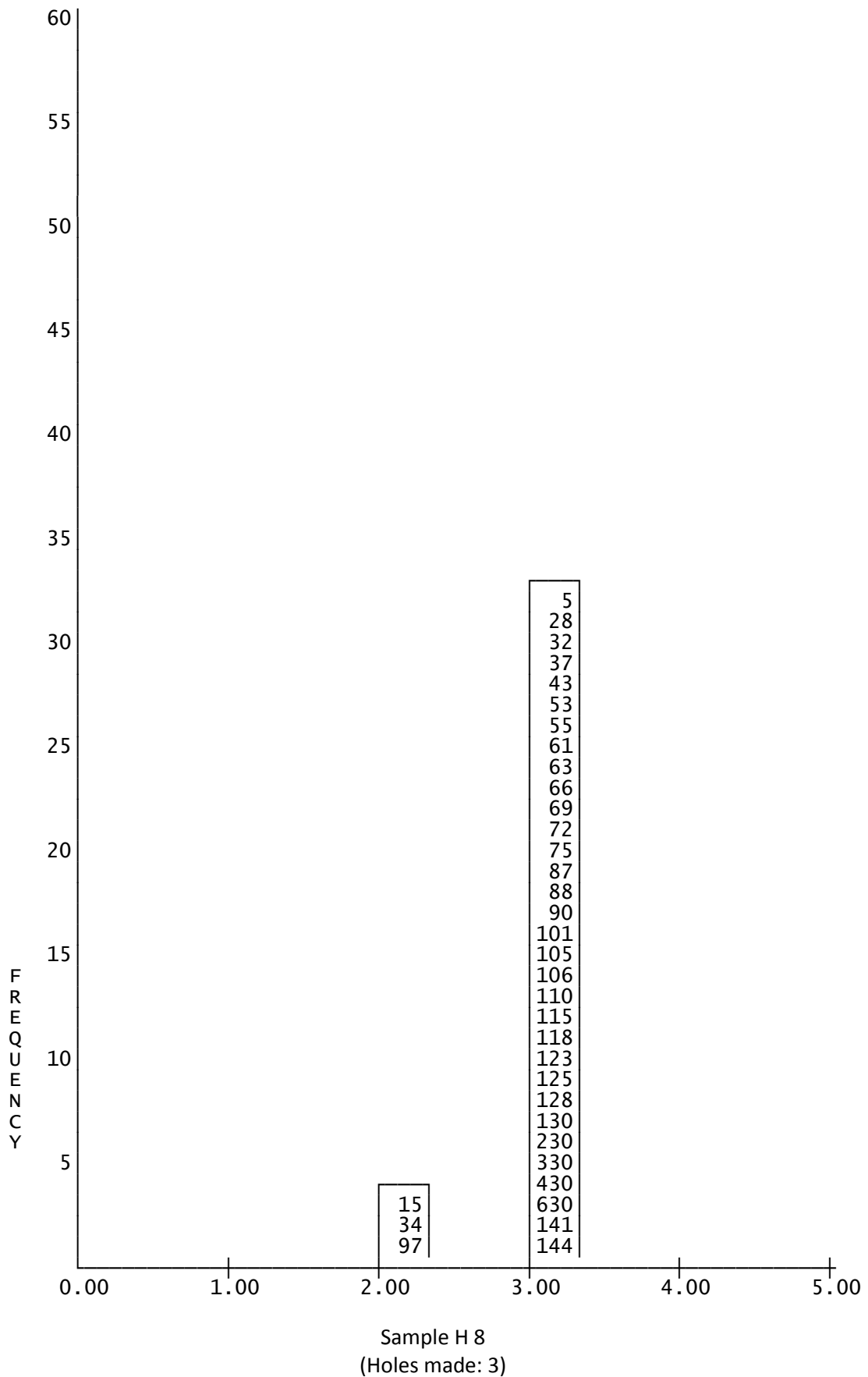
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Freedom from Holes (ASTM Hang & Squeeze Method) - Holes Found in Selected Regions

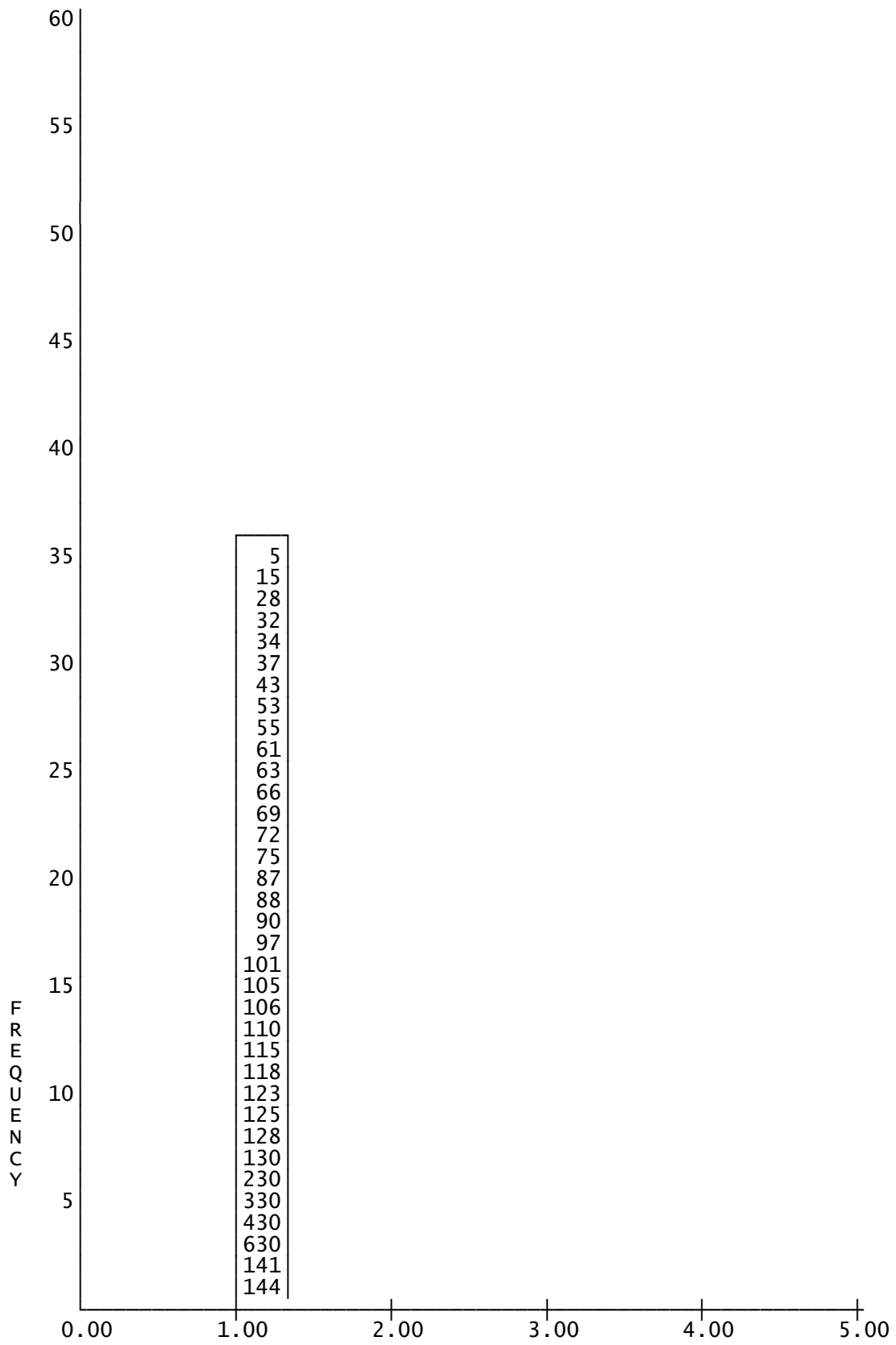


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Freedom from Holes (ASTM Hang & Squeeze Method) - Holes Found in Selected Regions (Continued)



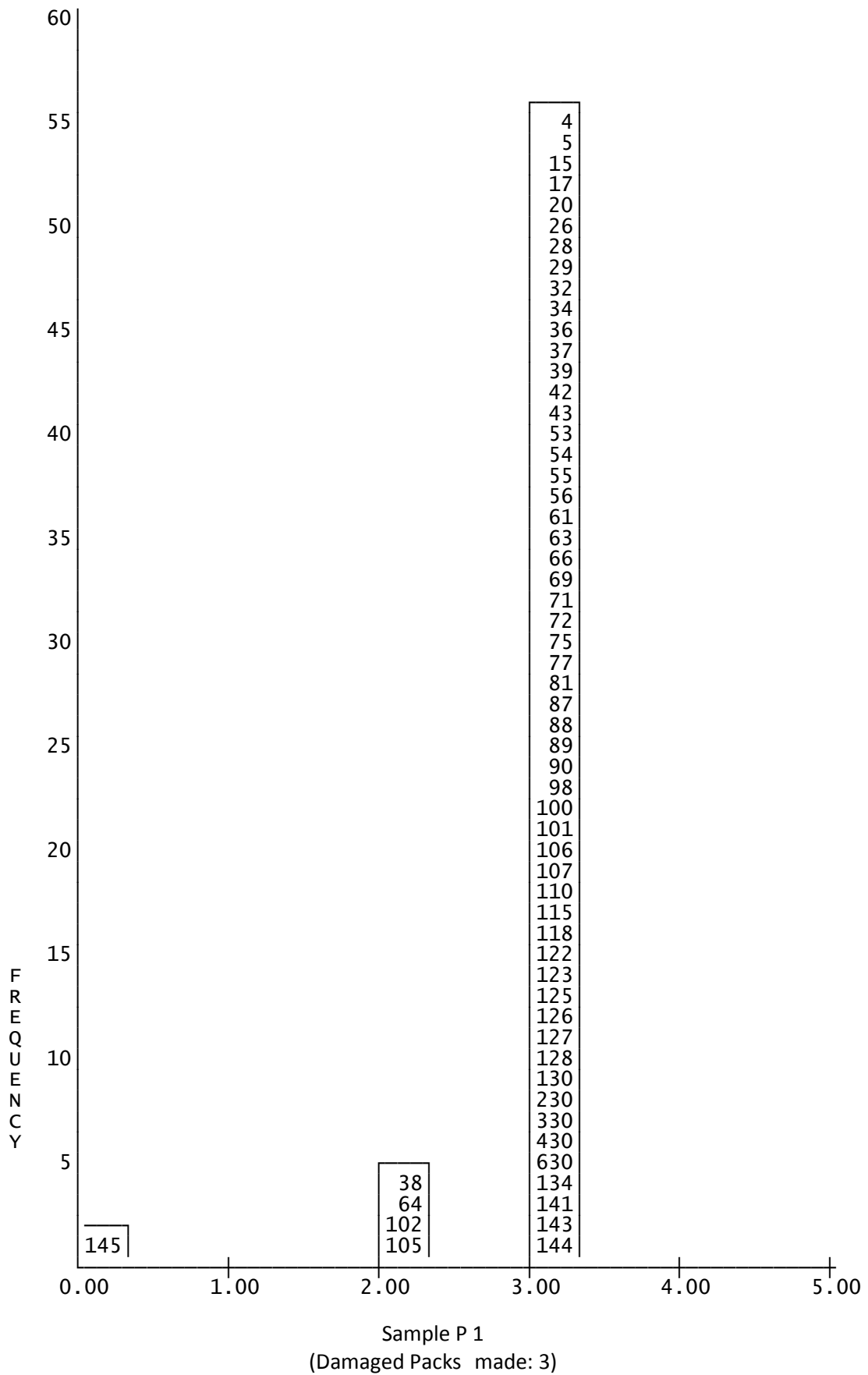
Freedom from Holes (ASTM Hang & Squeeze Method) - Holes Found in Selected Regions (Continued)



Sample H 9
(Holes made: 1)

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Package Seal Integrity – Introduced Holes Found



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Package Seal Integrity – Introduced Holes Found (continued)

