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Engineering Study: PRC097288
Revision: A

ENGINEERING STUDY	Document Title				MVP, DP, ECP or SPCR Number
	Mimas Packaging Equivalency Evaluation				ECR0001689
Originator	**Date Originated**	**Account Code**	**Reference Documents** (Link in EPICENTER)	**Batch/Lot Number(s)**	**Product Code/Part Numbers** (Link in EPICENTER)
Matthew Varga	8/17	N/A	MS00003 / PRC096522 / PRC095893	N/A	See Table 1

Engineering Study Document Type and Approval Governance				
Type:	**Engineering Studies - Other**			
Organization Responsible-Governance	☐ **New Product Development** Pre-Launch/Stabilization (CP0258 or CP0150 if applicable)	☒ **Lifecycle Engineering** Post Stabilization (CP0150 if applicable)	☐ **External Manufacturing** (CP0231/CP0150)	☐ **Other**

Are Pre-Execution Approvals Required? (Review WE0020 Appendix I)	☐ **YES** ☒ **NO**

Approval Section (Indicate Approval Status of THIS REVISION)		☐ **Pre-Execution Approval** ☒ **Completion Approval**	
Function	**Name**	**User I.D.**	**Signature/Date**
Originator	Matthew Varga	Mvarga5	eSig in EPICENTER
Lifecycle Design Engineer	Brian Walter	Bwalte16	eSig in EPICENTER
Lifecycle Quality Engineer	Ihsan Samara	Isamara	eSig in EPICENTER
LCE or PM Development Engineer	Thomas No	Tno	eSig in EPICENTER

Additional Completion Approvals (N/A If Not Applicable) (LEAVE THESE SPACES BLANK AT PRE-APPROVAL PHASE)			
Function	**Name**	**User I.D.**	**Signature/Date**
Test Conducted By	N/A	N/A	N/A
Data Authentication	N/A	N/A	N/A
Product Destroyed By	N/A	N/A	N/A

Revision	Change Description
A	Original

PURPOSE

The purpose of this study is to document and compare the wall thickness data from current flexible forms produced at Draper, Utah and new flexible forms produced on new equipment in Juarez, MX regarding Megadyne packaged product. Additionally, it is to analyze seal strength data between the two sites and document objective data that shows the packages produced at Juarez, MX are equivalent or better from both a material thickness and seal strength standpoint therefore providing justification that transit testing is not required for new product produced under the referenced package configurations.

SCOPE

The scope of this engineering study includes data from flexible forms produced from the following in Juarez, MX:

Product Codes	Tool Number	Maximo Tool
0014, 0014A, 0014AM and 0014M	T02769	ES3221
0012, 0012A, 0012AM, 0012M, 0013, 0013M, 0118 and 0118A	T02770	ES4036

Table 1 Tooling

Additionally, it includes data from flexible forms produced the equivalent packaging tools and footprints from Draper, Utah.

Testing Location:

- ☒ **Cincinnati Campus (all buildings): Ethicon Endo-Surgery, Inc. 4545 Creek Road, Cincinnati, OH, 45242
- ☐ Albuquerque: Ethicon Endo-Surgery, 3801 University Blvd, S.E., Albuquerque, NM, 87106
- ☐ Torres: Ethicon Endo-Surgery, S.A. de C.V., Avenida De Las Torres No 7125, Colonia Salvarcar 118, Ciudad Juarez, Chihuahua, 32580, Mexico
- ☐ Independencia: Ethicon Endo-Surgery, S.A. de C.V. Planta II, Calle Durango No. 2751, Colonia Lote Bravo, Ciudad Juarez, Chihuahua, 32575, Mexico
- ☐ Other (please specify):

CRITERIA FOR SUCCESS

Objectively show functionally equivalent wall thickness and seal strength data show that new packages referenced in this protocol that are produced in Juarez, MX are equivalent or more robust to those produced in Draper, Utah.

STRATEGIES AND ASSUMPTIONS

1. The same exact roll stock materials were used to produce the parts evaluated in this study. (Part number, size and material).

2. The Draper, UT sample data for both material thickness and seal strength is gathered from PRC095893B and data sheets can be referenced there.

3. The Juarez, MX sample data for both material thickness and seal strength is gathered from PRC096522A which was the engineering study to gather data from the Multivac OQ and data sheets can be referenced there.

4. While the exact model of Multivac equipment differs between both sets, they are fundamentally the same flexible form fill seal process for producing the packages being evaluated. The Juarez Multivac (E19592) is a newer R245 model with improvements. The Draper Multivac (Machine #74) is an older R230.

5. The same thickness points were measured for all the samples evaluated, based on evaluating three points per cavity per one index. More information can be found in applicable protocol.

6. For Draper, UT seal strength, seal pull points were pulled from four different spots per index to acquire 32 total data points per package index. For Juarez, MX seal strength seal pull points were pulled from each side of each cavity per index to acquire 60 total data points per package index. More information can be found in applicable protocol.

7. The Draper, UT samples for material thickness were produced using nominal production settings.

8. The Juarez, MX samples for material thickness were produced using low production, nominal and high production settings. Only those produced under high for thickness and low for seal strength will be evaluated.

    a. For material thickness, Juarez OQ high samples will be compared to Draper, Utah nominal. High forming parameters generally apply the most time, temperature and pressure during the forming process and therefore produce generally thinner samples. This is being done for a worst-case comparison.

    b. For seal strength, Juarez OQ low samples will be compared to Draper, Utah nominal. Low sealing parameters generally apply the least amount of time, temperature and pressure during the sealing process and therefore produce generally lower or weaker seal strength samples. This is being done for a worst-case comparison.

PROCEDURE (Use Attachments if Necessary) Training Applicable (Check One) ☐ **Yes** ☒ **No**

Analyze the applicable data gathered from PRC095893B & PRC096522A.

EQUIPMENT AND MATERIAL

For equipment information, reference applicable protocol.

Table 2: Material Information

Material	Part Number
Tyvek 12.00 wide	3600014-01
Eva-Surlyn-Eva 10 mil x 12.75 wide	3600019-01

PRODUCT DISPOSITION ☐ Destroy (Sign Approval Section) ☒ Other (Detail Below)

N/A

RESULTS / RECOMMENDATIONS

12x1 Analysis

Table 4: 12x1 Utah Thickness Nominal (inches)

12x1 Draper, UT				
Cavity Number	Thickness 1 (closest to pull tab)	Thickness 2 (middle)	Thickness 3 (furthest from pull tab)	Average
1	0.0032	0.0047	0.0033	0.00373
2	0.0032	0.0048	0.0027	0.00357
3	0.0030	0.005	0.0031	0.00370
4	0.0032	0.0047	0.0034	0.00377
5	0.0033	0.005	0.0034	0.00390
6	0.0032	0.0049	0.0031	0.00373
7	0.0030	0.0049	0.0030	0.00363
8	0.0032	0.0051	0.0033	0.00387
9	0.0030	0.0050	0.0030	0.00367
10	0.0029	0.0052	0.0033	0.00380
11	0.0034	0.0050	0.0032	0.00387
12	0.0029	0.0049	0.0032	0.00367
Average	0.00313	0.00493	0.00317	

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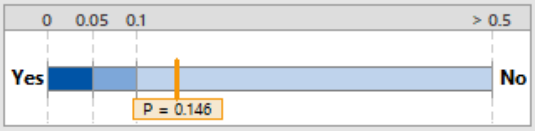
Table 5: 12x1 Juarez Thickness High (inches)

12x1 Juarez High				
Cavity Number	**Thickness 1 (closest to pull tab)**	**Thickness 2 (middle)**	**Thickness 3 (furthest from pull tab)**	**Average**
1	0.0028	0.0050	0.0031	0.00363
2	0.0030	0.0050	0.0030	0.00367
3	0.0028	0.0051	0.0031	0.00367
4	0.0028	0.0053	0.0031	0.00373
5	0.0030	0.0051	0.0030	0.00370
6	0.0029	0.0052	0.0032	0.00377
7	0.0029	0.0053	0.0032	0.00380
8	0.0031	0.0058	0.0033	0.00407
9	0.0031	0.0057	0.0036	0.00413
10	0.0032	0.0058	0.0034	0.00413
11	0.0034	0.0056	0.0035	0.00417
12	0.0032	0.0051	0.0031	0.00380
Average	0.00302	0.00533	0.00322	

12x1 2-Sample T-Test between Thickness 1 (Utah & Juarez)

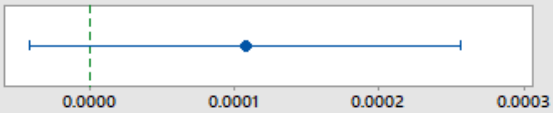
2-Sample t Test for the Mean of Thickness _1 and Thickness _2
Summary Report

Do the means differ?

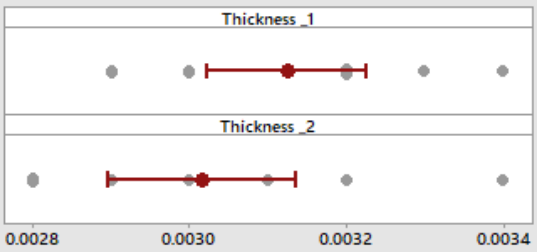


The mean of Thickness _1 is not significantly different from the mean of Thickness _2 (p > 0.05).

95% CI for the Difference
Is the entire interval above or below zero?



Distribution of Data
Compare the data and means of the samples.



Individual Samples

Statistics	Thickness _1	Thickness _2
Sample size	12	12
Mean	0.003125	0.0030167
95% CI	(0.0030, 0.0032)	(0.00290, 0.00314)
Standard deviation	0.00016026	0.00018990

Difference Between Samples

Statistics	*Difference
Difference	0.00010833
95% CI	(-4.084E-05, 0.00025750)

*Difference = Thickness _1 - Thickness _2

Comments

- Test: There is not enough evidence to conclude that the means differ at the 0.05 level of significance.
- CI: Quantifies the uncertainty associated with estimating the difference in means from sample data. You can be 95% confident that the true difference is between -4.0837E-05 and 0.00025750.
- Distribution of Data: Compare the location and means of samples. Look for unusual data before interpreting the results of the test.

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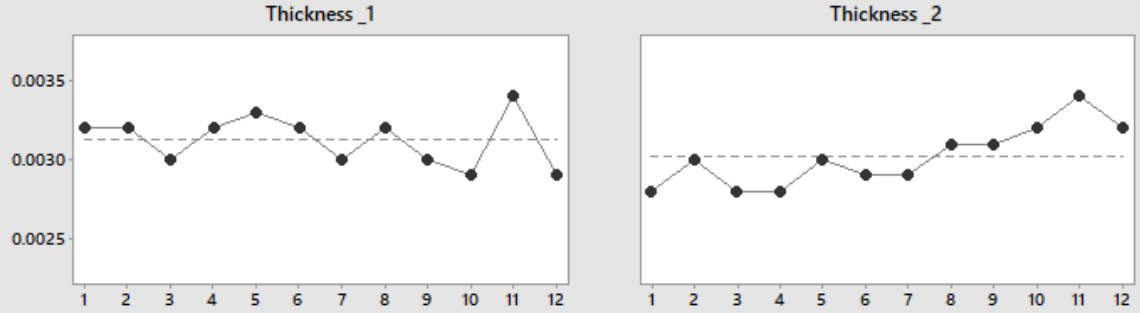
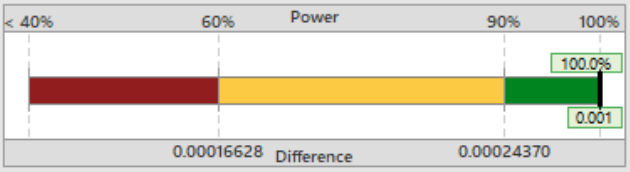
2-Sample t Test for the Mean of Thickness _1 and Thickness _2
Diagnostic Report

Data in Worksheet Order
Investigate any outliers (marked in red).



What is the chance of detecting a difference of 0.001?



For α = 0.05 and sample sizes = 12:
If the true means differed by 0.001, you would have a 100.0% chance of detecting the difference.

What sample sizes are required to detect a difference of 0.001?

Each Sample	Power
2	60%
2	70%
3	80%
3	90%
Your Samples	
12, 12	100.0

Observed difference = 0.00010833

Power is a function of the sample sizes and the standard deviations. If the power is not satisfactory, consider increasing the sample sizes.

2-Sample t Test for the Mean of Thickness _1 and Thickness _2
Report Card

Check	Status	Description
Unusual Data	✓	There are no unusual data points. Unusual data can have a strong influence on the results.
Normality	⚠	Because the sample sizes are less than 15, normality can be an issue. If the data are not normally distributed, the p-value may be inaccurate with small samples. Because normality cannot be reliably checked with small samples, you should use caution when interpreting the test results.
Sample Size	✓	Although the test results are not significant, the power is adequate. Based on your sample sizes, standard deviations, and α, you have a 100.0% chance of detecting a difference of 0.001 between the means. Because the power is adequate, you can conclude that it is unlikely that there is a difference of 0.001 or larger.
Equal Variance	i	Minitab's Assistant uses Welch's method, which does not assume or require that the two samples have equal variances. Research shows that the test performs well with unequal variances, even when the sample sizes are not equal.

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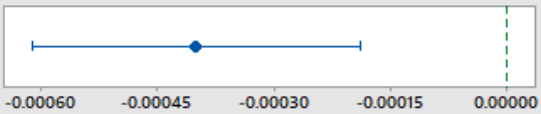
12x1 2-Sample T-Test between Thickness 2 (Utah & Juarez)

2-Sample t Test for the Mean of Thickness _1 and Thickness _2
Summary Report

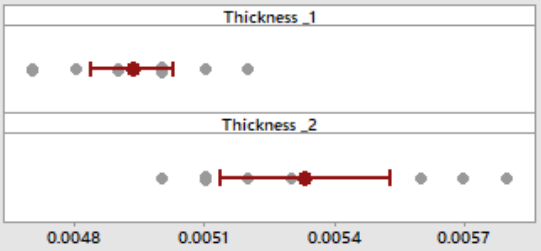
Do the means differ?

The mean of Thickness _1 is significantly different from the mean of Thickness _2 (p < 0.05).

95% CI for the Difference
Is the entire interval above or below zero?



Distribution of Data
Compare the data and means of the samples.



Individual Samples

Statistics	Thickness _1	Thickness _2
Sample size	12	12
Mean	0.0049333	0.0053333
95% CI	(0.0048, 0.0050)	(0.00514, 0.00553)
Standard deviation	0.00014975	0.00030847

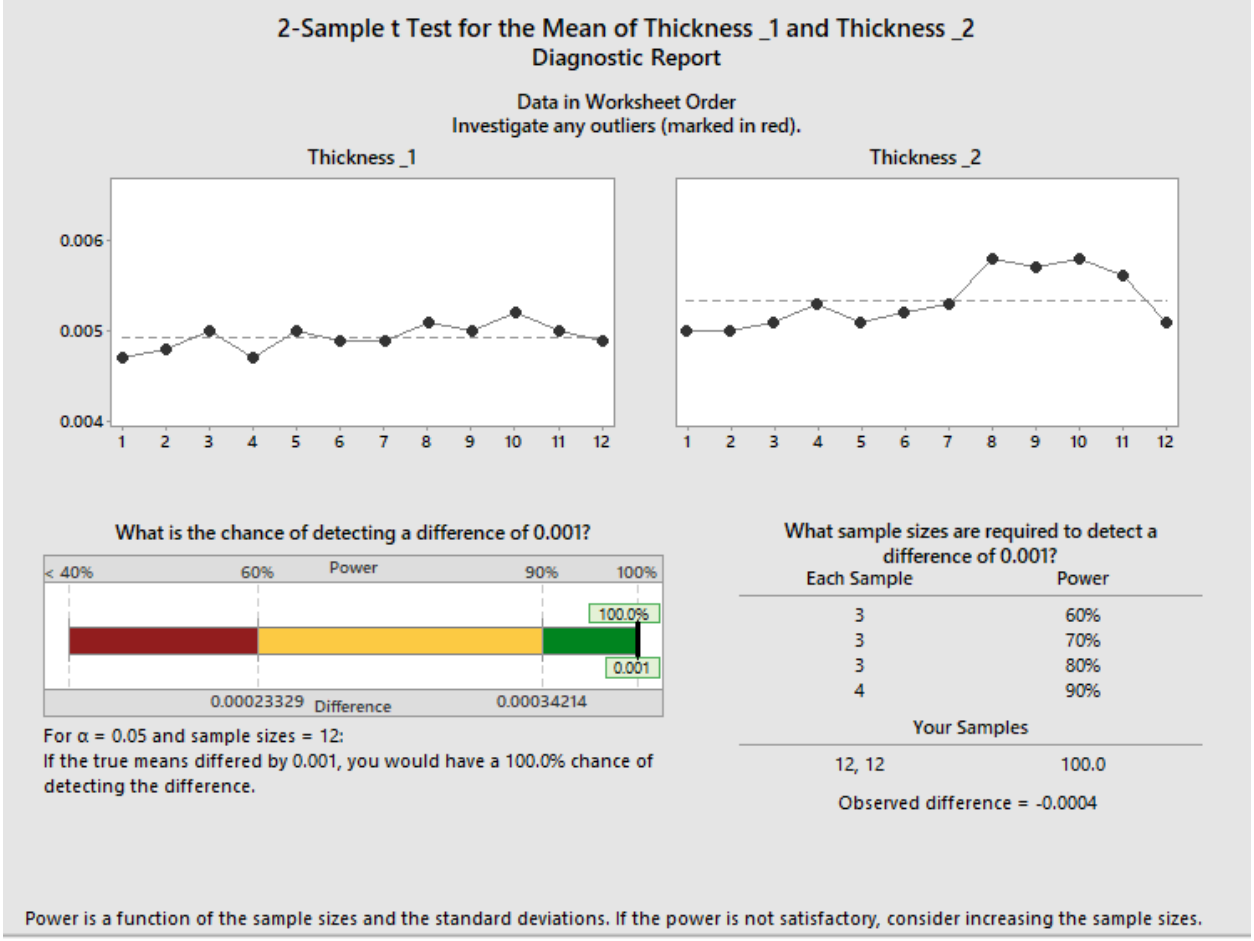
Difference Between Samples

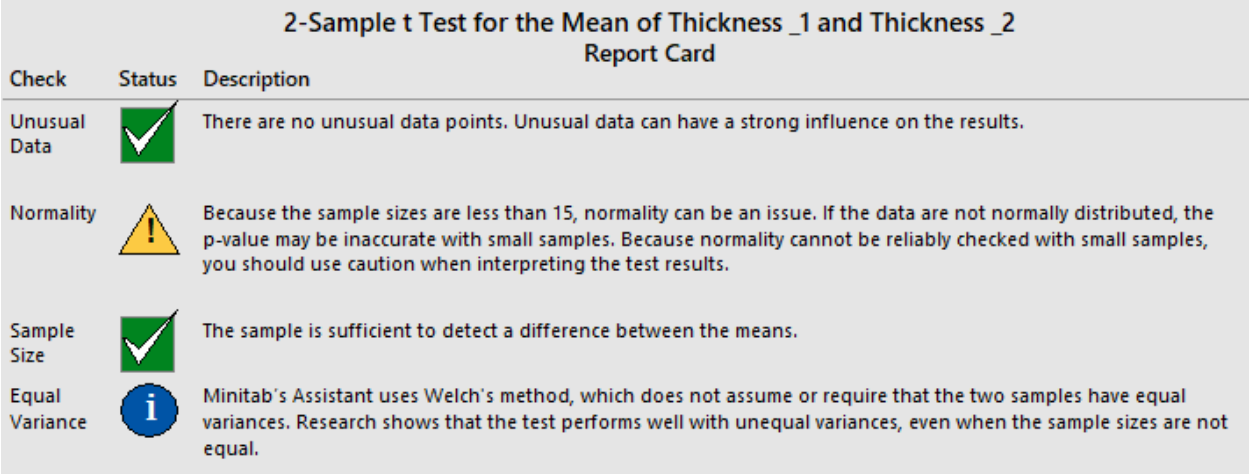
Statistics	*Difference
Difference	-0.0004
95% CI	(-0.0006110, -0.0001890)

*Difference = Thickness _1 - Thickness _2

Comments

- Test: You can conclude that the means differ at the 0.05 level of significance.
- CI: Quantifies the uncertainty associated with estimating the difference in means from sample data. You can be 95% confident that the true difference is between -0.00061098 and -0.00018902.
- Distribution of Data: Compare the location and means of samples. Look for unusual data before interpreting the results of the test.





12x1 2-Sample T-Test between Thickness 3 (Utah & Juarez)

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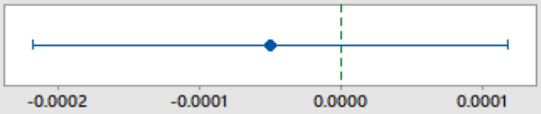
2-Sample t Test for the Mean of Thickness _1 and Thickness _2
Summary Report

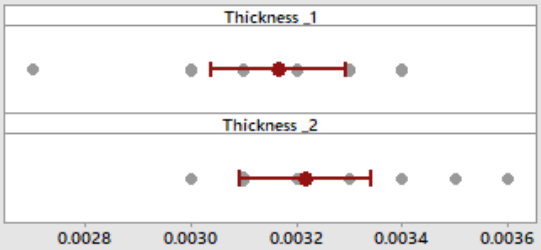
Do the means differ?

The mean of Thickness _1 is not significantly different from the mean of Thickness _2 (p > 0.05).

95% CI for the Difference
Is the entire interval above or below zero?



Distribution of Data
Compare the data and means of the samples.



Individual Samples

Statistics	Thickness _1	Thickness _2
Sample size	12	12
Mean	0.0031667	0.0032167
95% CI	(0.0030, 0.0033)	(0.00309, 0.00334)
Standard deviation	0.00020151	0.00019462

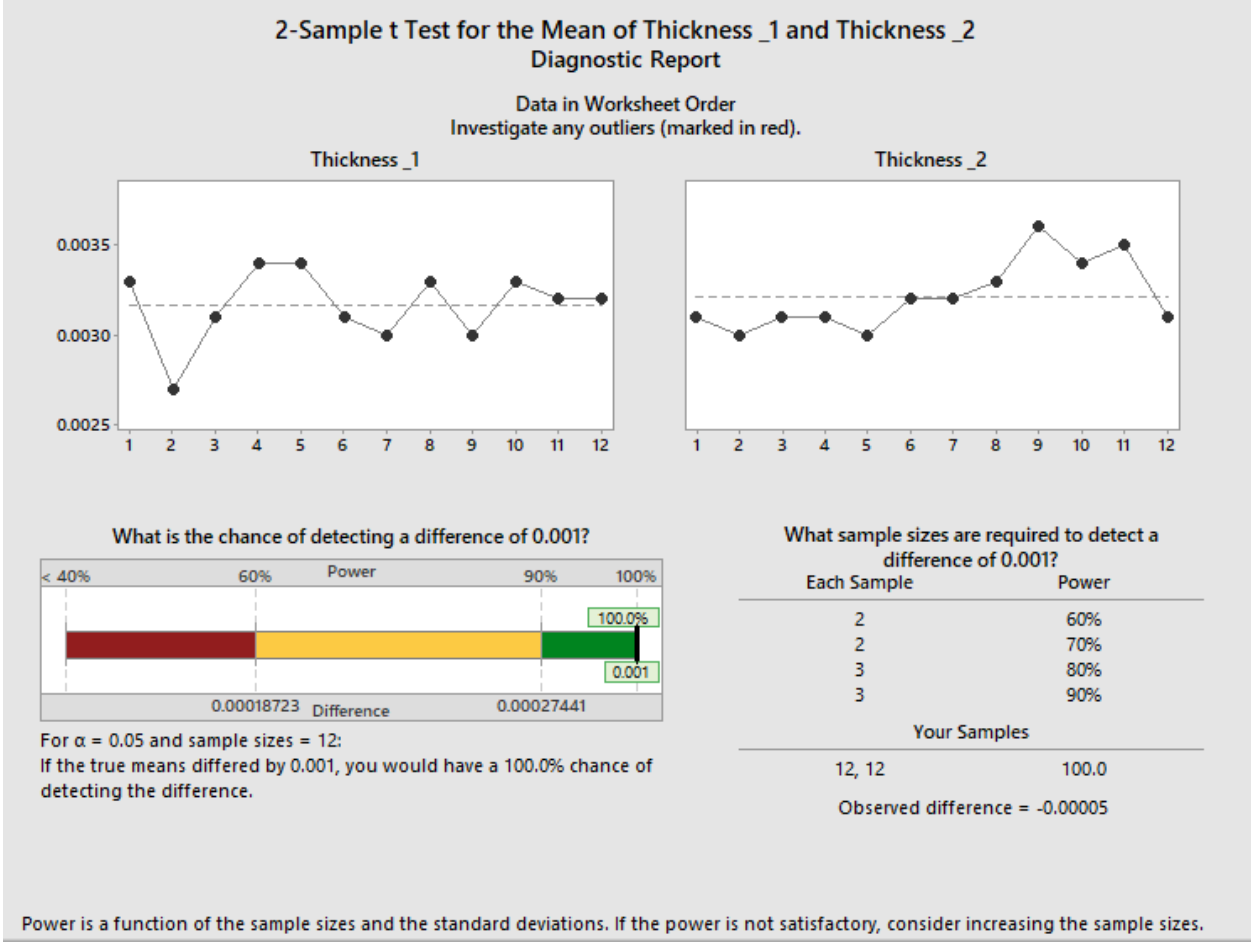
Difference Between Samples

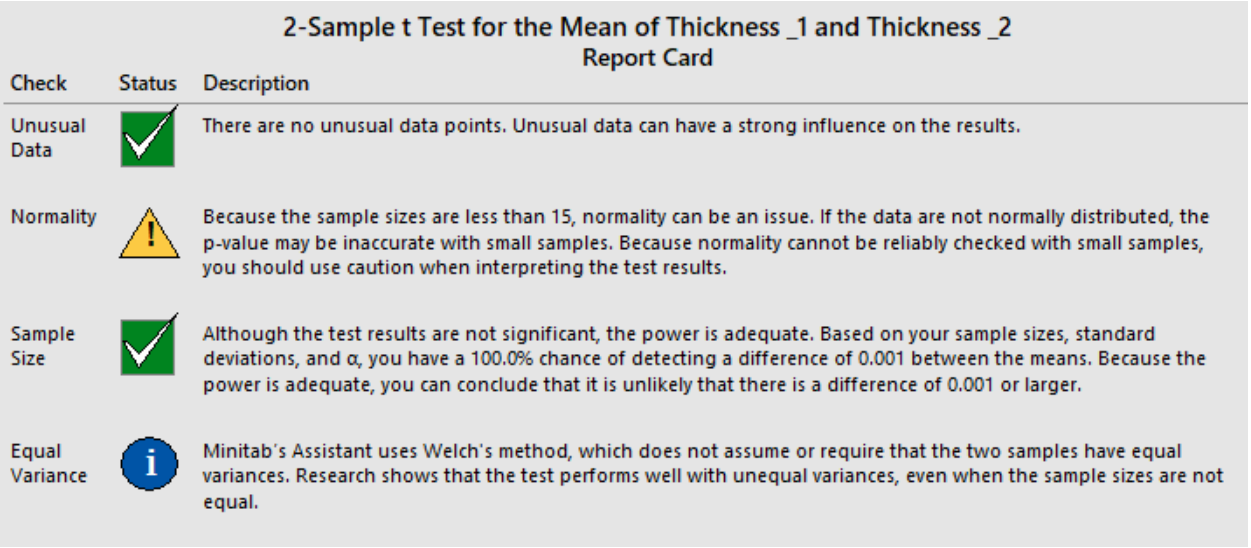
Statistics	*Difference
Difference	-0.00005
95% CI	(-0.0002182, 0.00011818)

*Difference = Thickness _1 - Thickness _2

Comments

- Test: There is not enough evidence to conclude that the means differ at the 0.05 level of significance.
- CI: Quantifies the uncertainty associated with estimating the difference in means from sample data. You can be 95% confident that the true difference is between -0.00021818 and 0.00011818.
- Distribution of Data: Compare the location and means of samples. Look for unusual data before interpreting the results of the test.

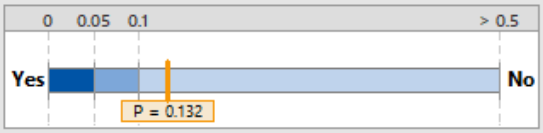




12x1 2-Sample T-Test between Seal Strength (Utah & Juarez)

2-Sample t Test for the Mean of Peak load lb and Jrz Peak Loa
Summary Report

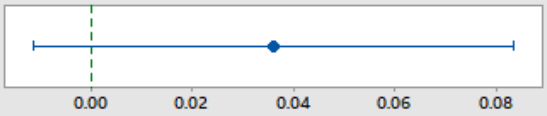
Do the means differ?



The mean of Peak load lb is not significantly different from the mean of Jrz Peak Loa (p > 0.05).

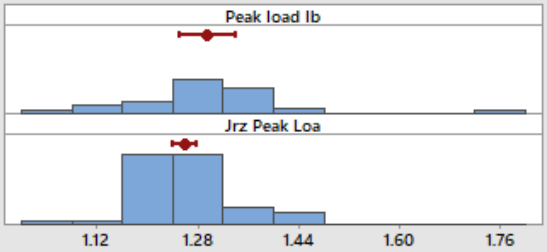
95% CI for the Difference

Is the entire interval above or below zero?



Distribution of Data

Compare the data and means of the samples.



Individual Samples

Statistics	Peak load lb	Jrz Peak Loa
Sample size	32	60
Mean	1.2958	1.2597
95% CI	(1.252, 1.339)	(1.2400, 1.2794)
Standard deviation	0.12077	0.076188

Difference Between Samples

Statistics	*Difference
Difference	0.03605
95% CI	(-0.011322, 0.083422)

*Difference = Peak load lb - Jrz Peak Loa

Comments

- Test: There is not enough evidence to conclude that the means differ at the 0.05 level of significance.
- CI: Quantifies the uncertainty associated with estimating the difference in means from sample data. You can be 95% confident that the true difference is between -0.011322 and 0.083422.
- Distribution of Data: Compare the location and means of samples. Look for unusual data before interpreting the results of the test.

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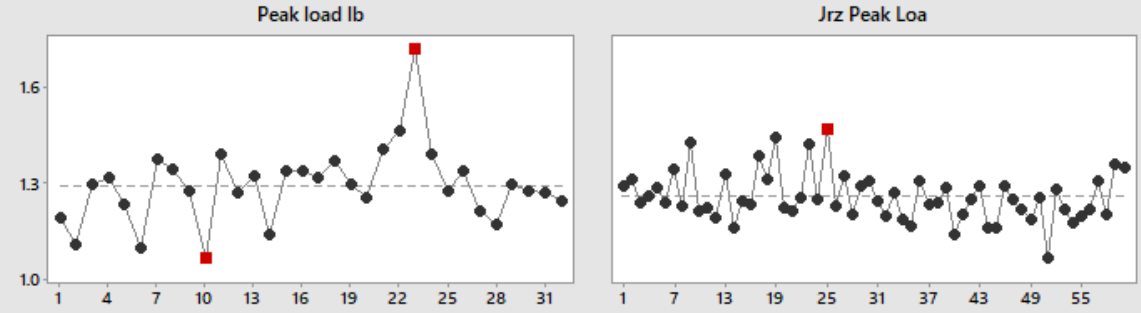
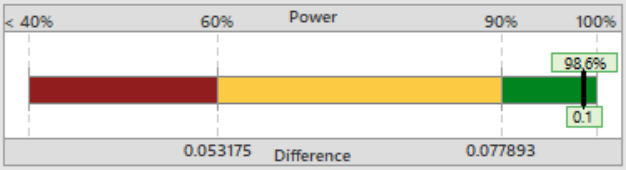
2-Sample t Test for the Mean of Peak load lb and Jrz Peak Loa
Diagnostic Report

Data in Worksheet Order
Investigate any outliers (marked in red).



What is the chance of detecting a difference of 0.1?



For α = 0.05 and sample sizes = 32, 60:
If the true means differed by 0.1, you would have a 98.6% chance of detecting the difference.

What sample sizes are required to detect a difference of 0.1?

Each Sample	Power
12	60%
14	70%
18	80%
23	90%
Your Samples	
32, 60	98.6

Observed difference = 0.03605

Power is a function of the sample sizes and the standard deviations. If the power is not satisfactory, consider increasing the sample sizes.

2-Sample t Test for the Mean of Peak load lb and Jrz Peak Loa
Report Card

Check	Status	Description
Unusual Data	⚠	Some of the data points are unusual compared to the others in the same sample. Because unusual data can have a strong influence on the results, you should try to identify the cause of their unusual nature. These points are marked in red on the Diagnostic Report. You can hover over a point or use Minitab's brushing feature to identify the worksheet row. Correct any data entry or measurement errors. Consider removing data that are associated with special causes and repeating the analysis.
Normality	✓	Because both sample sizes are at least 15, normality is not an issue. The test is accurate with nonnormal data when the sample sizes are large enough.
Sample Size	✓	Although the test results are not significant, the power is adequate. Based on your sample sizes, standard deviations, and α, you have a 98.6% chance of detecting a difference of 0.1 between the means. Because the power is adequate, you can conclude that it is unlikely that there is a difference of 0.1 or larger.
Equal Variance	ℹ	Minitab's Assistant uses Welch's method, which does not assume or require that the two samples have equal variances. Research shows that the test performs well with unequal variances, even when the sample sizes are not equal.

12x2 Analysis

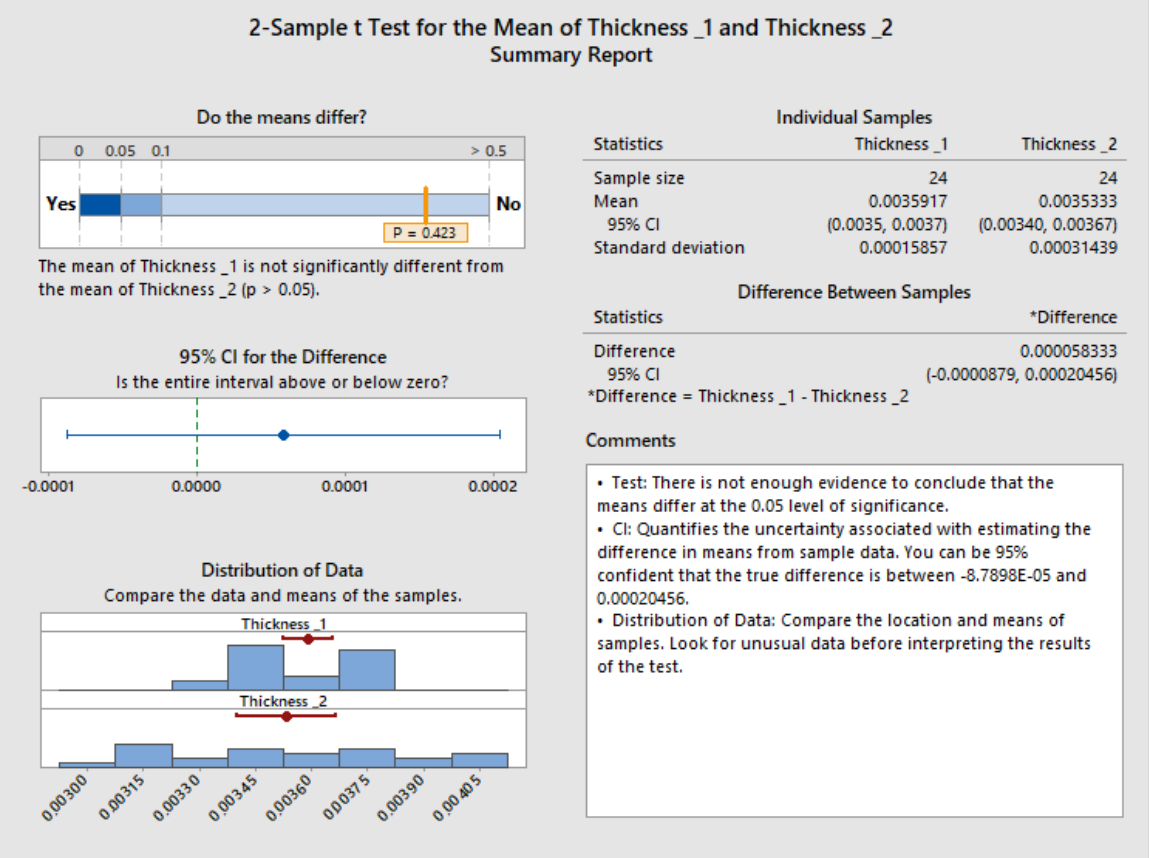
Table 6: 12x2 Utah Thickness Nominal (inches)

12x2 Draper UT				
Cavity Number	Thickness 1 (closest to pull tab)	Thickness 2 (middle)	Thickness 3 (furthest from pull tab)	Average
1	0.0037	0.0052	0.0032	0.00403
2	0.0037	0.0053	0.0033	0.00410
3	0.0038	0.0054	0.0035	0.00423
4	0.0036	0.0054	0.0034	0.00413
5	0.0033	0.0052	0.0033	0.00393
6	0.0035	0.0054	0.0035	0.00413
7	0.0037	0.0053	0.0035	0.00417
8	0.0035	0.0054	0.0035	0.00413
9	0.0035	0.0054	0.0036	0.00417
10	0.0035	0.0056	0.0037	0.00427
11	0.0035	0.0056	0.0039	0.00433
12	0.0035	0.0052	0.0036	0.00410
13	0.0036	0.0052	0.0036	0.00413
14	0.0034	0.0053	0.0038	0.00417
15	0.0035	0.0052	0.0038	0.00417
16	0.0038	0.0053	0.0039	0.00433
17	0.0038	0.0054	0.0034	0.00420
18	0.0038	0.0053	0.0037	0.00427
19	0.0038	0.0053	0.0035	0.00420
20	0.0035	0.0053	0.0037	0.00417
21	0.0036	0.0053	0.0039	0.00427
22	0.0035	0.0054	0.0036	0.00417
23	0.0038	0.0053	0.0034	0.00417
24	0.0033	0.0052	0.0034	0.00397
Average	0.00359	0.00533	0.00357	

Table 7: 12x2 Juarez Thickness High (inches)

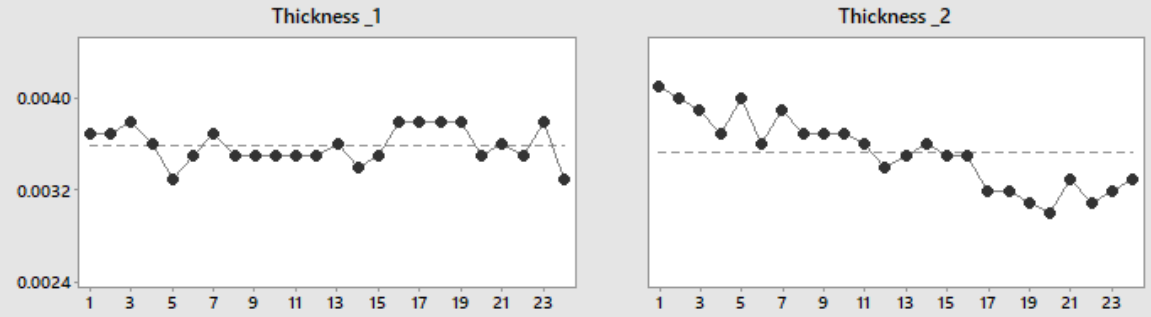
12x2 Juarez High				
Cavity Number	**Thickness 1 (closest to pull tab)**	**Thickness 2 (middle)**	**Thickness 3 (furthest from pull tab)**	**Average**
1	0.0041	0.0059	0.0038	0.00460
2	0.0040	0.0058	0.0043	0.00470
3	0.0039	0.0059	0.0042	0.00467
4	0.0037	0.0058	0.0036	0.00437
5	0.0040	0.0058	0.0035	0.00443
6	0.0036	0.0056	0.0034	0.00420
7	0.0039	0.0055	0.0036	0.00433
8	0.0037	0.0056	0.0037	0.00433
9	0.0037	0.0053	0.0034	0.00413
10	0.0037	0.0054	0.0036	0.00423
11	0.0036	0.0051	0.0038	0.00417
12	0.0034	0.0049	0.0036	0.00397
13	0.0035	0.0056	0.0037	0.00427
14	0.0036	0.0060	0.0041	0.00457
15	0.0035	0.0058	0.0038	0.00437
16	0.0035	0.0059	0.0039	0.00443
17	0.0032	0.0055	0.0037	0.00413
18	0.0032	0.0058	0.0033	0.00410
19	0.0031	0.0061	0.0033	0.00417
20	0.0030	0.0053	0.0036	0.00397
21	0.0033	0.0055	0.0035	0.00410
22	0.0031	0.0056	0.0037	0.00413
23	0.0032	0.0054	0.0039	0.00417
24	0.0033	0.0052	0.0032	0.00390
Average	0.00353	0.00560	0.00368	

12x2 2-Sample T-Test between Thickness 1 (Utah & Juarez)

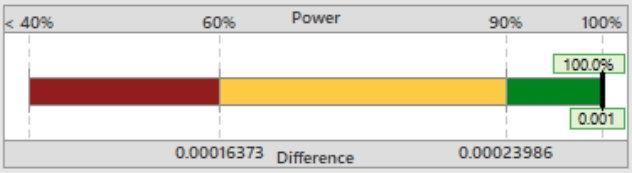


2-Sample t Test for the Mean of Thickness _1 and Thickness _2
Diagnostic Report

Data in Worksheet Order
Investigate any outliers (marked in red).



What is the chance of detecting a difference of 0.001?



For α = 0.05 and sample sizes = 24:
If the true means differed by 0.001, you would have a 100.0% chance of detecting the difference.

What sample sizes are required to detect a difference of 0.001?

Each Sample	Power
3	60%
3	70%
3	80%
4	90%
Your Samples	
24, 24	100.0

Observed difference = 0.000058333

Power is a function of the sample sizes and the standard deviations. If the power is not satisfactory, consider increasing the sample sizes.

2-Sample t Test for the Mean of Thickness _1 and Thickness _2
Report Card

Check	Status	Description
Unusual Data	✓	There are no unusual data points. Unusual data can have a strong influence on the results.
Normality	✓	Because both sample sizes are at least 15, normality is not an issue. The test is accurate with nonnormal data when the sample sizes are large enough.
Sample Size	✓	Although the test results are not significant, the power is adequate. Based on your sample sizes, standard deviations, and α, you have a 100.0% chance of detecting a difference of 0.001 between the means. Because the power is adequate, you can conclude that it is unlikely that there is a difference of 0.001 or larger.
Equal Variance	i	Minitab's Assistant uses Welch's method, which does not assume or require that the two samples have equal variances. Research shows that the test performs well with unequal variances, even when the sample sizes are not equal.

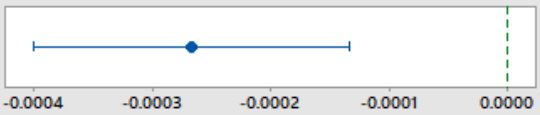
12x2 2-Sample T-Test between Thickness 2 (Utah & Juarez)

2-Sample t Test for the Mean of Thickness _1 and Thickness _2
Summary Report

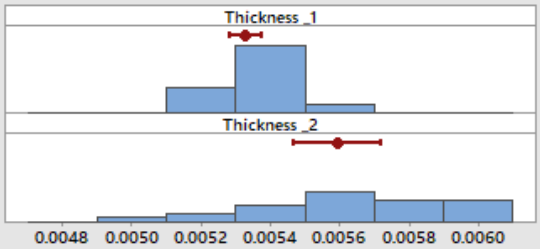
Do the means differ?

The mean of Thickness _1 is significantly different from the mean of Thickness _2 (p < 0.05).

95% CI for the Difference
Is the entire interval above or below zero?



Distribution of Data
Compare the data and means of the samples.



Individual Samples

Statistics	Thickness _1	Thickness _2
Sample size	24	24
Mean	0.0053292	0.0055958
95% CI	(0.0053, 0.0054)	(0.00547, 0.00572)
Standard deviation	0.00011221	0.00029997

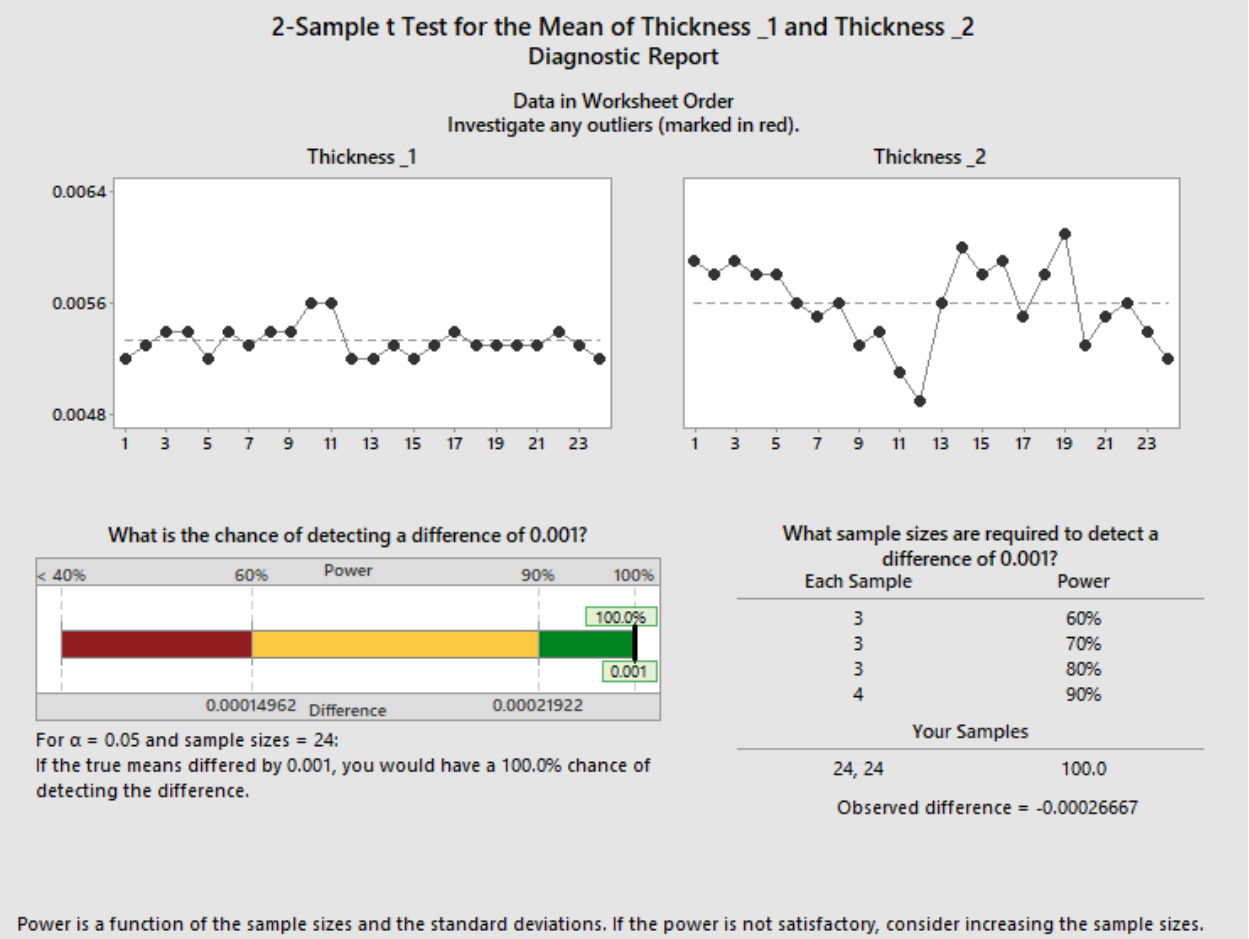
Difference Between Samples

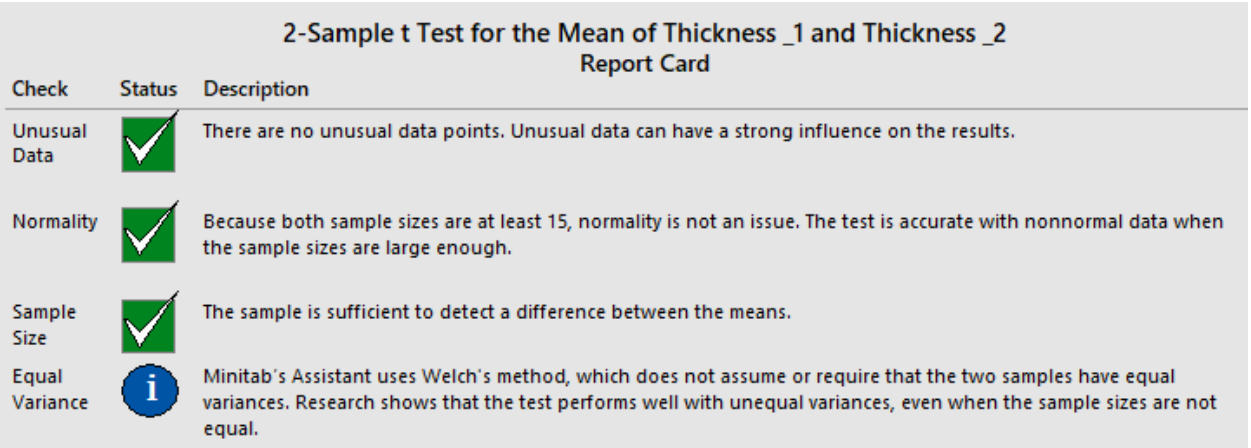
Statistics	*Difference
Difference	-0.00026667
95% CI	(-0.0004004, -0.0001330)

*Difference = Thickness _1 - Thickness _2

Comments

- Test: You can conclude that the means differ at the 0.05 level of significance.
- CI: Quantifies the uncertainty associated with estimating the difference in means from sample data. You can be 95% confident that the true difference is between -0.00040037 and -0.00013296.
- Distribution of Data: Compare the location and means of samples. Look for unusual data before interpreting the results of the test.

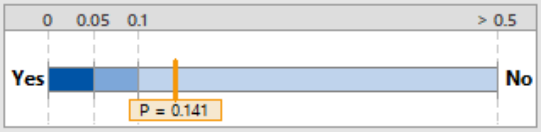




12x2 2-Sample T-Test between Thickness 3 (Utah & Juarez)

2-Sample t Test for the Mean of Thickness _1 and Thickness _2
Summary Report

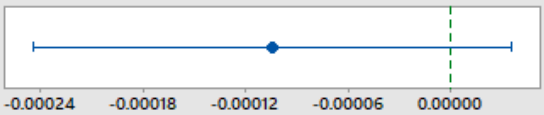
Do the means differ?



The mean of Thickness _1 is not significantly different from the mean of Thickness _2 (p > 0.05).

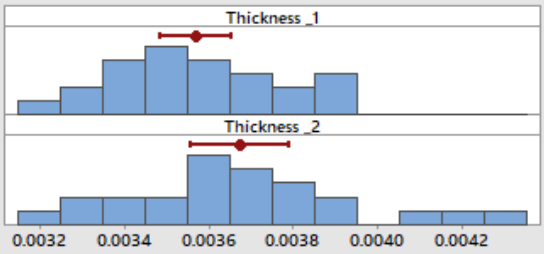
95% CI for the Difference

Is the entire interval above or below zero?



Distribution of Data

Compare the data and means of the samples.



Individual Samples

Statistics	Thickness _1	Thickness _2
Sample size	24	24
Mean	0.0035708	0.003675
95% CI	(0.0035, 0.0037)	(0.00356, 0.00379)
Standard deviation	0.00019886	0.00027544

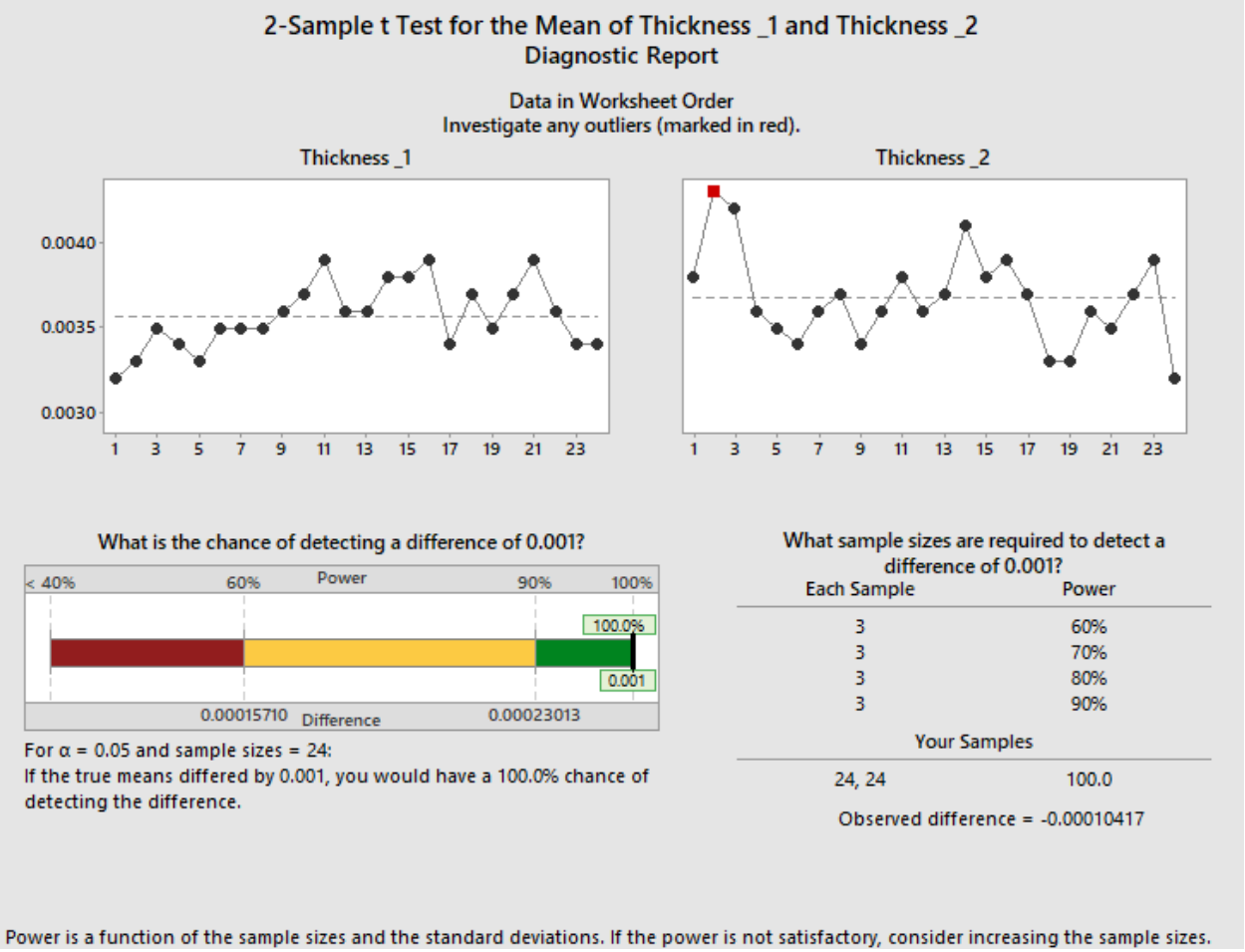
Difference Between Samples

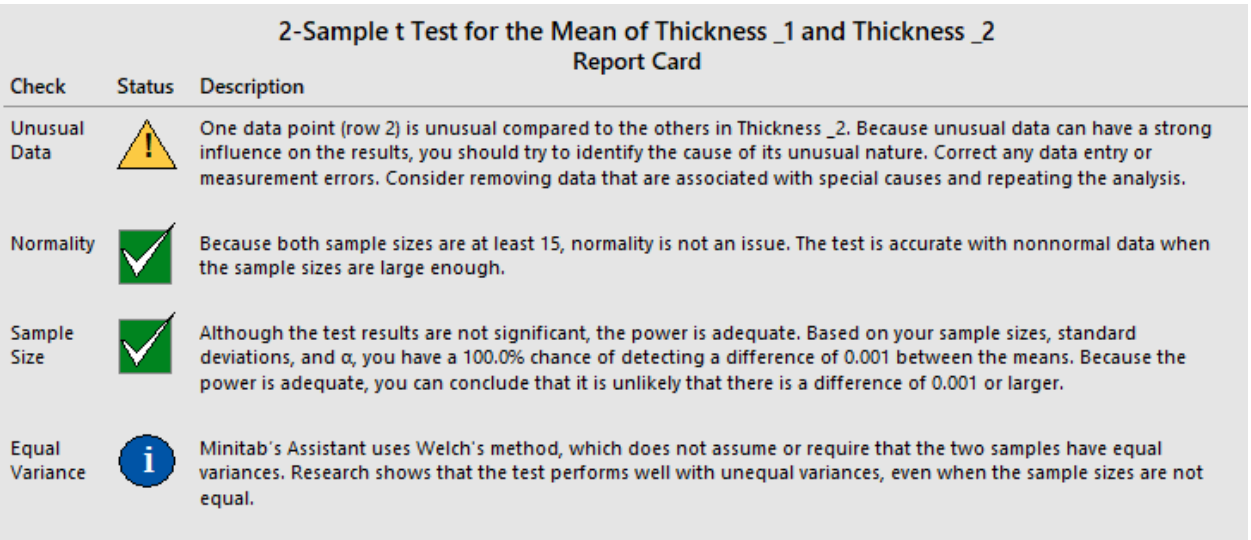
Statistics	*Difference
Difference	-0.00010417
95% CI	(-0.0002442, 3.5883E-05)

*Difference = Thickness _1 - Thickness _2

Comments

- Test: There is not enough evidence to conclude that the means differ at the 0.05 level of significance.
- CI: Quantifies the uncertainty associated with estimating the difference in means from sample data. You can be 95% confident that the true difference is between -0.00024422 and 0.000035883.
- Distribution of Data: Compare the location and means of samples. Look for unusual data before interpreting the results of the test.





12x2 2-Sample T-Test between Seal Strength (Utah & Juarez)

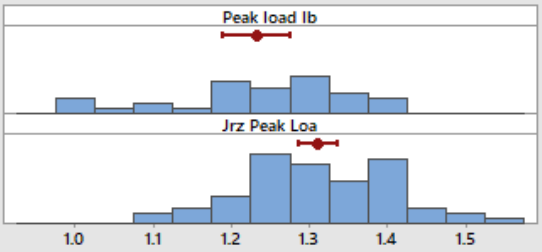
2-Sample t Test for the Mean of Peak load lb and Jrz Peak Loa
Summary Report

Do the means differ?

The mean of Peak load lb is significantly different from the mean of Jrz Peak Loa ($p < 0.05$).

95% CI for the Difference
Is the entire interval above or below zero?

Distribution of Data
Compare the data and means of the samples.



Individual Samples

Statistics	Peak load lb	Jrz Peak Loa
Sample size	32	60
Mean	1.2321	1.3115
95% CI	(1.189, 1.275)	(1.2870, 1.3359)
Standard deviation	0.11993	0.094734

Difference Between Samples

Statistics	*Difference
Difference	-0.079342
95% CI	(-0.12845, -0.030228)

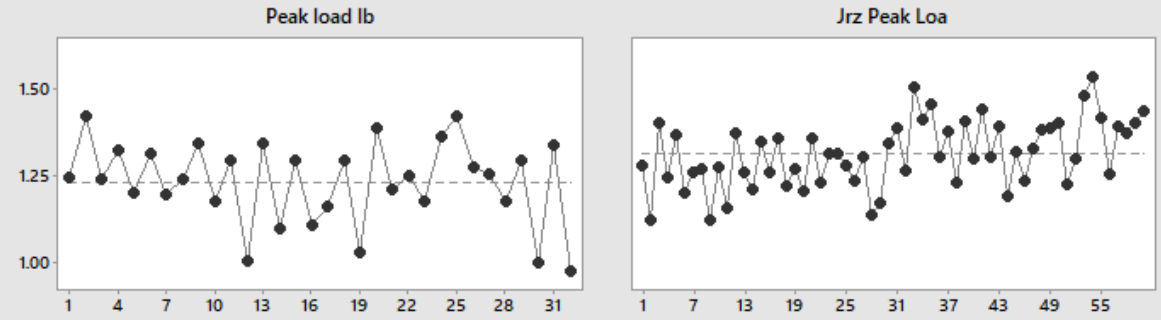
*Difference = Peak load lb - Jrz Peak Loa

Comments

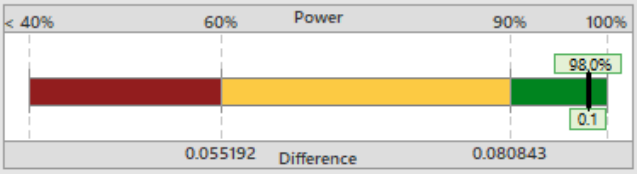
- Test: You can conclude that the means differ at the 0.05 level of significance.
- CI: Quantifies the uncertainty associated with estimating the difference in means from sample data. You can be 95% confident that the true difference is between -0.12845 and -0.030228.
- Distribution of Data: Compare the location and means of samples. Look for unusual data before interpreting the results of the test.

2-Sample t Test for the Mean of Peak load lb and Jrz Peak Loa
Diagnostic Report

Data in Worksheet Order
Investigate any outliers (marked in red).



What is the chance of detecting a difference of 0.1?



For α = 0.05 and sample sizes = 32, 60:
If the true means differed by 0.1, you would have a 98.0% chance of detecting the difference.

What sample sizes are required to detect a difference of 0.1?

Each Sample	Power
13	60%
16	70%
20	80%
26	90%
Your Samples	
32, 60	98.0

Observed difference = -0.079342

Power is a function of the sample sizes and the standard deviations. If the power is not satisfactory, consider increasing the sample sizes.

2-Sample t Test for the Mean of Peak load lb and Jrz Peak Loa
Report Card

Check	Status	Description
Unusual Data	✓	There are no unusual data points. Unusual data can have a strong influence on the results.
Normality	✓	Because both sample sizes are at least 15, normality is not an issue. The test is accurate with nonnormal data when the sample sizes are large enough.
Sample Size	✓	The sample is sufficient to detect a difference between the means.
Equal Variance	i	Minitab's Assistant uses Welch's method, which does not assume or require that the two samples have equal variances. Research shows that the test performs well with unequal variances, even when the sample sizes are not equal.

12x1 Summary

For thickness 1 (closest to the pull tab), Minitab concluded no significant difference between the mean average between samples from Utah nominal and Juarez high.

For thickness 2 (middle), Minitab concluded there is a significant difference between the mean average between samples from Utah nominal and Juarez high. This difference is that the Juarez high samples are slightly thicker on average than Utah's.

For thickness 3 (furthest from pull tab), Minitab concluded no significant difference between the mean average between samples from Utah nominal and Juarez high.

For seal strength, Minitab concluded there is no significant difference between the mean average between samples from Utah nominal and Juarez low.

12x2 Summary

For thickness 1 (closest to the pull tab), Minitab concluded no significant difference between the mean average between samples from Utah nominal and Juarez high.

For thickness 2 (middle), Minitab concluded there is a significant difference between the mean average between samples from Utah nominal and Juarez high. This difference is that the Juarez high samples are slightly thicker on average than Utah's.

For thickness 3 (furthest from pull tab), Minitab concluded no significant difference between the mean average between samples from Utah nominal and Juarez high. There is one unusual data point in the Juarez data set, however it is just slightly higher (.0042 vs .00367 mean) and supports the trend that the Juarez high samples are generally equivalent or thicker.

For seal strength, Minitab concluded there is a significant difference between the mean average between samples from Utah nominal and Juarez low. Minitab shows that the Juarez low samples are on average slightly higher in seal strength than the Utah nominal samples.

CONCLUSION / COMPLETION ACTIVITIES

In conclusion, based on analyzing the material thickness an entire index of samples produced at nominal production in Utah in comparison to those produced at OQ high from Juarez, it can be determined that Juarez's worst case parameter set for production forming will produce equivalent or more robust packages from a thickness for both the 12x1 and 12x2 configurations than those produced in Utah. Additionally, based on comparing seal strengths between Utah nominal and Juarez low, it can be determined that the worst case parameter set for production sealing will produce equivalent or more robust packages from a seal strength standpoint.

Therefore, it can be determined that the packages produced in Juarez are equivalent or more robust than those produced in Utah regarding transit testing characteristics and therefore support the rationale and strategy that no transit testing is necessary as this supports that there is no increased risk by packages produced in Juarez.

ATTACHMENTS

Supporting File 1 – Minitab 12x1 Thickness 1

Supporting File 2 – Minitab 12x1 Thickness 2

Supporting File 3 – Minitab 12x1 Thickness 3

Supporting File 4 – Minitab 12x2 Thickness 1

Supporting File 5 – Minitab 12x2 Thickness 2

Supporting File 6 – Minitab 12x2 Thickness 3

Supporting File 7 – Minitab 12x1 Seal Strength

Supporting File 8 – Minitab 12x2 Seal Strength