



Test Report

Date.

Dec 11th 2020

Report No.

YJ-QT-20-0167

TEST REPORT

CMT CHECK-19 PATCH

 Copper Medical Team
Put Your Safety Strides On It

Check-19^{PATCH}



YJ Lab Co., Ltd.

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CEO Young Jo, PARK



YJ LAB Co., Ltd.



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Manufacturing (Lot) No. : MG – T0L0G0 – MD

1. Finished Production capacity : 150,000 Products
2. Semi-Finished Production capacity : 4,500,000 Patches

Functional area representatives

Division	Department	Name	Date	Signature
Authored by	Quality control team Leader of MGK	Ki Mo Yu	Dec. 11. 2020	
Reviewed by	CEO of MGK	Yong Min Hwang	Dec. 11. 2020	
Approved by	CEO of YJ LAB	Young Jo Park	Dec. 11. 2020	

Preparation, Review and Approval of the document was performed by the organization that had been approved by our company

Manufacturer : YJ LAB Co.,Ltd.

Corporate registration number : 475-88-00202

Address : 802, B-dong, Hyundai J.S. Center 70 Dusan-ro, Geumcheon-gu, Seoul, Republic of Korea.

Factory : MGK

Corporate registration number : 868-33-00404



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1. DESCRIPTION OF PRODUCT

1.1 Model(type)

CMT Check-19 Patch

1.2 Product Description

This product is a disposable medical patch, measures the user's body temperature continuously with illustrating patch color changing according to body temperature.

1.3 Materials

No.	Part	Ingredients of raw materials	Content	Note
1	Hardener	Toluene	98.8%	Contact with skin
		Tetraglycidyl-m-xylenediamine	1.2%	Contact with skin
2	Adhesive	Hexane	39~41%	Contact with skin
		Isopropyl Alcohol	54~56%	Contact with skin
		Ethyl Acetate	3~5%	Contact with skin
		Acrylic Copolymer	0.1~1%	Contact with skin
3	Urethane film	Polyurethane	100%	None
4	Release film	Polyethylene terephthalic acid	100%	None
5	Ink	Urea	20%	None
		WATER	55%	None
		T-Blue dye	10%	None
		Melamine Polymer	15%	None

1.4 Standard dimension





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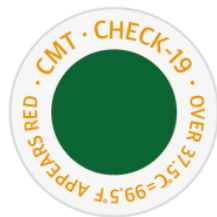
1.5 Standard Color Guide

For Fahrenheit,

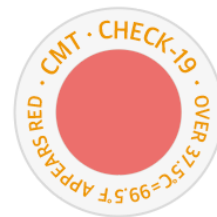
Unused or Normal temperature under 99.5°F is **GREEN**

Fever temperature over 99.5°F is **RED**

COLOR GUIDE (FOR Fahrenheit/°F)



Unused or Normal temperature
(under 99.5°F)



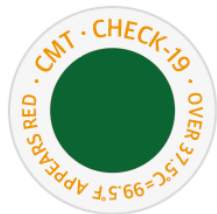
Fever temperature
(over 99.5°F)

For Celsius,

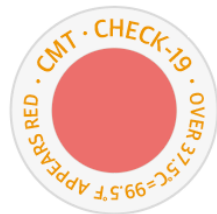
Unused or Normal temperature under 37.5°C is **GREEN**

Fever temperature over 37.5°C is **RED**

COLOR GUIDE (FOR Celsius/°C)



Unused or Normal temperature
(under 37.5°C)



Fever temperature
(over 37.5°C)



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2. TEST STANDARD

In accordance with the standards of Korea MFDS.

2.1 Standard

Test Items	Standard / Norm	Test Lab.	Test Methods
Appearance	It should be smooth without any apparent blemishes, breaks, irregularities, sharp edges, etc. that could cause injury or damage. But, in the case of surface treatment, there should be no irregularly coated, peeled, or cracked parts.	MGK	See 2.2.1
Dimension	Product dimensions must be within $\pm 5\%$ of the standard value set by the manufacturer. But the manufacturer can set the tolerance if it proves its validity due to the characteristics of the product.		See 2.2.2
Accuracy	Color tone display - Unused or Normal temperature under 99.5°F(37.5°C) is GREEN - Fever temperature over 99.5°F(37.5°C) is RED Response time is within 10 seconds.		See 2.2.3
Stability	The finished product must meet the standards of “KFDA” a KOREA standard organization that certifies harmless to humans.		See 2.2.4
Safety	The finished product must meet the standards of “SGS”, an international standard organization that certifies harmless to humans.		See 2.2.5



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2.2 Test Methods

2.2.1 Appearance test

Visually observe to determine compliance with surfaces and edges. But, if it is difficult to check with the naked eye or medical devices that have been surface-treated (limited to coating, plating, and painting), lighting and magnifying devices can be used.

2.2.2 Dimension test

Measure using calibrated measuring instruments such as straight ruler, vernier caliper, and digital gauge. The unit of measurement must be within the range of the reference value.

2.2.3 Accuracy test

Color tone display

- Determine the expressed color of a given temperature condition in a thermostatic experimental oven or water tank.
- Condition of oven or water tank : Temperature should drop at a constant rate without exceeding 0.5°C in 3 minutes.

Response time

- It is judged by whether the response time is satisfied until the color change is completed during the experiment.

2.2.4 Stability test

It must meet the standards of “KFDA”, a KOREA standards organization that certifies harmless to humans.

2.2.5 Safety test

It must meet the standards of “SGS”, an international standards organization that certifies harmless to humans.



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3. TEST RESULT

Tested using randomly selected **15 products** from Manufacturing (Lot) No. MG – T0L0G0 – MD

* 15 Products = 450 Patches

3.1. Visual Inspection Result.

Test Items	Acceptance : O / Reject : X					Result
	#1	#2	#3	#4	#5	
Appearance	O	O	O	O	O	■ Acceptance □ Reject
Lack of quantity	O	O	O	O	O	■ Acceptance □ Reject
Empty packing and part deficit	O	O	O	O	O	■ Acceptance □ Reject
Product and packing damage	O	O	O	O	O	■ Acceptance □ Reject
Foreign material	O	O	O	O	O	■ Acceptance □ Reject

Test Items	Acceptance : O / Reject : X					Result
	#6	#7	#8	#9	#10	
Appearance	O	O	O	O	O	■ Acceptance □ Reject
Lack of quantity	O	O	O	O	O	■ Acceptance □ Reject
Empty packing and part deficit	O	O	O	O	O	■ Acceptance □ Reject
Product and packing damage	O	O	O	O	O	■ Acceptance □ Reject
Foreign material	O	O	O	O	O	■ Acceptance □ Reject

Test Items	Acceptance : O / Reject : X					Result
	#11	#12	#13	#14	#15	
Appearance	O	O	O	O	O	■ Acceptance □ Reject
Lack of quantity	O	O	O	O	O	■ Acceptance □ Reject
Empty packing and part deficit	O	O	O	O	O	■ Acceptance □ Reject
Product and packing damage	O	O	O	O	O	■ Acceptance □ Reject
Foreign material	O	O	O	O	O	■ Acceptance □ Reject



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3.2. Functional, Performance and Dimension Inspection Result.

Test Items	Acceptance : O / Reject : X					Result
	#1	#2	#3	#4	#5	
Dimension	O	O	O	O	O	■ Acceptance □ Reject
Accuracy	O	O	O	O	O	■ Acceptance □ Reject
Stability	O	O	O	O	O	■ Acceptance □ Reject
Safety	O	O	O	O	O	■ Acceptance □ Reject

Test Items	Acceptance : O / Reject : X					Result
	#6	#7	#8	#9	#10	
Dimension	O	O	O	O	O	■ Acceptance □ Reject
Accuracy	O	O	O	O	O	■ Acceptance □ Reject
Stability	O	O	O	O	O	■ Acceptance □ Reject
Safety	O	O	O	O	O	■ Acceptance □ Reject

Test Items	Acceptance : O / Reject : X					Result
	#11	#12	#13	#14	#15	
Dimension	O	O	O	O	O	■ Acceptance □ Reject
Accuracy	O	O	O	O	O	■ Acceptance □ Reject
Stability	O	O	O	O	O	■ Acceptance □ Reject
Safety	O	O	O	O	O	■ Acceptance □ Reject

MGK

Yongmin Hwang



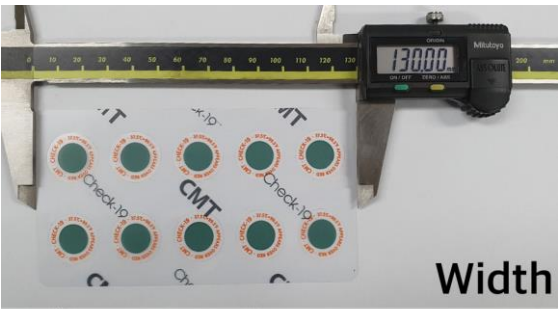

Yongmin Hwang / President

Final Judgment

■ Pass / □ Fail

4. APPENDIX

4.1 Photos of Test Conducting

Inspection for Dimension	
<p style="text-align: center;">Inner diameter (thermometer section)</p> <p style="text-align: center;">Unit : mm</p>	
<p style="text-align: center;">Outer diameter (full diameter)</p> <p style="text-align: center;">Unit : mm</p>	
<p style="text-align: center;">Backing film (10patches) Width / Length</p> <p style="text-align: center;">Unit : mm</p>	 <p style="text-align: right; font-weight: bold; font-size: 1.2em;">Width</p>  <p style="text-align: right; font-weight: bold; font-size: 1.2em;">Length</p>



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Accuracy Test (For Fahrenheit / °F)



Unused or under 97.8°F: **GREEN**

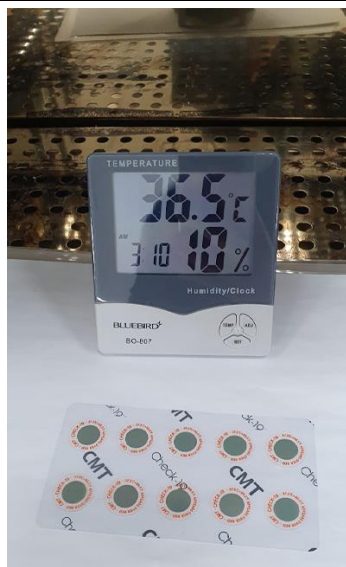


Over 99.5°F: **RED**



Over 120.0°F: **Transparent**

Accuracy Test (For Celsius / °C)



Unused or under 37.5°C: **GREEN**



Over 37.5°C: **RED**



Over 49.0°C: **Transparent**



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