



201819000873

Guangzhou CAS Test Technical Services Co., Ltd.

Test Report

Test Report Number: JKK20020003A(R)

Sample Name: Hydrogen Peroxide Sterilizer

Commissioned by: Wuxi BioTeke Co., Ltd.

This report replaces the report No. JKK20020003A issued on February 07, 2020. The original report is invalid.

2020.2.20

Description

1. This inspection report is only responsible for the samples submitted for inspection.
2. The alteration, addition, deletion of this inspection report is invalid, and the unseal of the unit's official seal is invalid, and the copy is invalid.
3. If there is any objection to this inspection report, a review application can be submitted within 30 days from the date of receipt of the report, and it will not be accepted after the deadline.
4. This inspection report and the name of the inspection unit shall not be used for product labeling, advertising, evaluation and product promotion.
5. The technical inspection report is made in triplicate, two copies are submitted to the commission company, and one is filed by the inspection agency.

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Guangzhou CAS Test Technical Services Co., Ltd.

Test Report

Sample acceptance number: JKK20020003

| | | | |
|--|--|-----------------------------------|-------------------------------------|
| Sample name | Hydrogen peroxide sterilizer | Number of samples | 1 |
| Production date or batch number | DS1001202001001 | Sample properties | Machine and supporting disinfectant |
| Model specifications | DS1001 | Trademark | BioTeke |
| Commissioned by | Wuxi BioTeke Co., Ltd. | Pick up date | 2020-02-03 |
| Production company | Area A, 4th floor, 1719-5, Huishan Avenue, Wuxi City, Jiangsu Province | Inspection completion date | 2020-02-07 |

Test basis:

《Disinfection Technical Specifications》 (2002 edition) 2.1.1.5、2.1.3.

Evaluation basis:

《Disinfection Technical Specifications》 (2002 edition)

Test conclusions:

1. Neutralizer identification test: The sample "hydrogen peroxide sterilizer" is equipped with a hydrogen peroxide solution as the original solution, and is configured as a hydrogen peroxide solution with a concentration of 8% according to the customer's instructions to contain 1.5% sodium thiosulfate , 0.5% lecithin, 5% Tween 80 in PBS solution as a neutralizer, can effectively neutralize the effect of residual disinfectants on the test bacteria, and the neutralizer and its neutralized products have no adverse effects on the test bacteria and the culture medium .
2. The air simulation field test showed that the sample "hydrogen peroxide sterilizer" started and processed for 60 minutes, repeat 3 times, and the killing rates of Staphylococcus albus were all $\geq 99.90\%$. The results meet the demand of 《Disinfection Technical Specifications》 (2002 edition).
3. The air simulation field test showed that the sample "hydrogen peroxide sterilizer" started and processed for 120 minutes, repeat 3 times, and the killing rates of Staphylococcus albus were all $\geq 99.90\%$. The results meet the demand of 《Disinfection Technical Specifications》 (2002 edition).

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Guangzhou CAS Test Technical Services Co., Ltd.

Test Report

Sample acceptance number: JKK20020003

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|------------------------|---------------------------------|-----------------------------------|------------|
| Sample name | Hydrogen peroxide sterilizer | Pick up date | 2020-02-03 |
| Inspection item | Neutralizer identification test | Inspection completion date | 2020-02-05 |

I. Equipment

- 1 Test strain: Staphylococcus albicans 8032. The generation of the above bacteria is the fourth generation, and the bacterial suspension is configured with 0.03mol / L PBS.
2. Test sample: "Hydrogen peroxide sterilizer" is equipped with a hydrogen peroxide solution as the original solution, and is configured as a hydrogen peroxide solution with a concentration of 8% according to customer instructions.
3. Neutralizer: PBS solution containing 1.5% sodium thiosulfate, 0.5% lecithin, 5% Tween 80
4. Organic interference: 3% bovine serum protein.
5. Graduated pipettes (0.1mL, 1.0mL, 5.0mL, 10.0ml), etc.

II. Method

1. Test basis: 《Disinfection Technical Specifications》 (2002 edition) 2.1.1.5 neutralizer identification test.
2. Preparation of bacterium suspension: A bacterial suspension with a bacterial content of 1×10^8 CFU/ml- 5×10^8 CFU/ml was selected for the neutralizer identification test.
3. Neutralizer identification test: The test bacterium is Staphylococcus albicans. The test groups are: (1) disinfectant + bacterium suspension, (2) (disinfectant + bacterium suspension) + neutralizer, (3) neutralizer + bacterium suspension, (4) (disinfectant+ neutralizer) + bacterium suspension, (5) dilution solution + bacterium suspension, (6) dilution solution + Neutralizer + culture medium. The sample "Hydrogen Peroxide Sterilizer" uses the hydrogen peroxide solution as the original solution, and is diluted and prepared according to customer requirements , react 1 minute. The test was repeated 3 times.

III. Results

Three repeated tests proved that the first group was aseptically grown, the average number of colonies in group 2 was 40 CFU / mL, the average number of colonies in groups 3, 4, and 5 was similar, and the error rate among the three groups was 3.42%. Group 6 sterile growth (see Table I) (see Table 1). No colony growth in group 6. (Table 1.)

Table1. Neutralizer identification test results

| Group | Number of growth colonies in each group (CFU / mL) | | | Average number of growth colonies (CFU / mL) |
|-------|--|-------------------|-------------------|--|
| | 1 | 2 | 3 | |
| 1 | 0 | 0 | 0 | 0 |
| 2 | 23 | 45 | 51 | 40 |
| 3 | 2.6×10^6 | 4.6×10^6 | 4.4×10^6 | 3.9×10^6 |
| 4 | 2.5×10^6 | 4.3×10^6 | 4.2×10^6 | 3.7×10^6 |
| 5 | 2.7×10^6 | 5.0×10^6 | 4.5×10^6 | 4.1×10^6 |
| 6 | 0 | 0 | 0 | 0 |

Note: The negative control grows aseptically.

IV. Conclusion

The sample "hydrogen peroxide sterilizer" is equipped with a hydrogen peroxide solution as the original solution, and is configured as a hydrogen peroxide solution with a concentration of 8% according to the customer's instructions to contain 1.5% sodium thiosulfate, 0.5% lecithin, 5% Tween 80 in PBS solution as a neutralizer, can effectively neutralize the effect of residual disinfectants on the test bacteria, and the neutralizer and its neutralized products have no adverse effects on the test bacteria and the culture medium.

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Guangzhou CAS Test Technical Services Co., Ltd.

Test Report

Sample acceptance number: JKK20020003

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|------------------------|--|-----------------------------------|------------|
| Sample name | Hydrogen peroxide sterilizer | Pick up date | 2020-02-03 |
| Inspection item | Air simulation field disinfection test (Staphylococcus albicans) | Inspection completion date | 2020-02-07 |

I. Equipment

1. Experiment module: 20m³.
2. Test strain: Staphylococcus albus,8032, culture medium: nutrient agar medium containing neutralizing agent, sampler: six-stage sieve air impact sampler.
3. Disinfection equipment: DS100I1 hydrogen peroxide sterilizer.

II. Method

1. Test basis: 《Technical Specifications for Disinfection》 (2002 edition) 2.1.3.
2. Detection environment: temperature: (20-25) °C, relative humidity: (50-70)% RH.
3. Machine running status: Just turn on the equipment.
4. Disinfection method: During the test, the equipment to be tested is placed in the experiment module, and the sample "hydrogen peroxide sterilizer" is equipped with a hydrogen peroxide disinfectant according to the customer's instructions. It is configured into a hydrogen peroxide solution of 8% concentration and poured into the machine. In the experiment, the volume parameter of the machine was set to 20m², the concentration parameter was 10mL / m³, turn on the equipment and react for 60min. The test was repeated 3 times.
5. Sampling method: Set a sampling point 1.0m above the ground in the center of the test chamber and use a six-stage screen air impact sampler to sample. The sampling flow rate is 28.3L / min. Sampling was performed when the disinfection time was 0min and 60min, the sampling time of the control group was 20s and 20s, and the sampling time of the test group was 20s and 7min.

III. Results

The test temperature is (20-25) °C, the relative humidity is (50-70)% RH, the sample "hydrogen peroxide sterilizer" is turned on for disinfection and treatment for 60 minutes, and the kill rate of 3 times for Staphylococcus albus were all > 99.99%.

Table 2. Experimental data of air disinfection effect identification test

| Test Strain | React time (min) | Test number | Control group | | | test group | | Kill rate (%) |
|----------------------|------------------|-------------|--|---|-----------------------|--|---|---------------|
| | | | Colony number before test(CFU/m ³) | Colony number after test(CFU/m ³) | Natural death rate(%) | Colony number before test(CFU/m ³) | Colony number after test(CFU/m ³) | |
| Staphylococcus albus | 60 | 1 | 9.01×10 ⁴ | 6.93×10 ⁴ | 23.09 | 9.60×10 ⁴ | < 5 | > 99.99 |
| | | 2 | 1.05×10 ⁵ | 7.62×10 ⁴ | 27.43 | 1.08×10 ⁵ | < 5 | > 99.99 |
| | | 3 | 9.24×10 ⁴ | 6.94×10 ⁴ | 24.89 | 9.13×10 ⁴ | < 5 | > 99.99 |

IV. Conclusion

The sample "Hydrogen peroxide sterilizer" was sterilized and processed for 60 minutes. The three test results on the killing rate of Staphylococcus albus were $\geq 99.90\%$. They were qualified for disinfection and met the requirements of the 《Technical Specifications for Disinfection》 (2002 edition).

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Guangzhou CAS Test Technical Services Co., Ltd.

Test Report

Sample acceptance number: JKK20020003

| | | | |
|-----------------|---|----------------------------|-------------------|
| Sample name | <u>Hydrogen peroxide sterilizer</u> | Pick up date | <u>2020-02-03</u> |
| Inspection item | <u>Air simulation field disinfection test (Staphylococcus albicans)</u> | Inspection completion date | <u>2020-02-07</u> |

I. Equipment

1. Experiment module: 20m³.
2. Test strain: Staphylococcus albus,8032, culture medium: nutrient agar medium containing neutralizing agent, sampler: six-stage sieve air impact sampler.
3. Disinfection equipment: DS100I1 hydrogen peroxide sterilizer.

II. Method

1. Test basis: 《Technical Specifications for Disinfection》 (2002 edition) 2.1.3.
2. Detection environment: temperature: (20-25) °C, relative humidity: (50-70)% RH.
3. Machine running status: Just turn on the equipment.
4. Disinfection method: During the test, the equipment to be tested is placed in the experiment module, and the sample "hydrogen peroxide sterilizer" is equipped with a hydrogen peroxide disinfectant according to the customer's instructions. It is configured into a hydrogen peroxide solution of 8% concentration and poured into the machine. In the experiment, the volume parameter of the machine was set to 20m², the concentration parameter was 10mL / m³, turn on the equipment and react for 60min. The test was repeated 3 times.
5. Sampling method: Set a sampling point 1.0m above the ground in the center of the test chamber and use a six-stage screen air impact sampler to sample. The sampling flow rate is 28.3L / min. Sampling was performed when the disinfection time was 0min and 60min, the sampling time of the control group was 20s and 20s, and the sampling time of the test group was 20s and 7min.

III. Results

The test temperature is (20-25) °C, the relative humidity is (50-70)% RH, the sample "hydrogen peroxide sterilizer" is turned on for disinfection and treatment for 60 minutes, and the kill rate of 3 times for Staphylococcus albus were all > 99.99%.

Table 3. Experimental data of air disinfection effect identification test

| Test Strain | React time (min) | Test number | Control group | | | test group | | Kill rate (%) |
|----------------------|------------------|-------------|--|---|-----------------------|--|---|---------------|
| | | | Colony number before test(CFU/m ³) | Colony number after test(CFU/m ³) | Natural death rate(%) | Colony number before test(CFU/m ³) | Colony number after test(CFU/m ³) | |
| Staphylococcus albus | 120 | 1 | 9.01×10 ⁴ | 4.77×10 ⁴ | 47.06 | 9.60×10 ⁴ | < 5 | > 99.99 |
| | | 2 | 1.05×10 ⁵ | 5.76×10 ⁴ | 45.14 | 1.08×10 ⁵ | < 5 | > 99.99 |
| | | 3 | 9.24×10 ⁴ | 5.35×10 ⁴ | 42.10 | 9.13×10 ⁴ | < 5 | > 99.99 |

IV. Conclusion

The sample "Hydrogen peroxide sterilizer" was sterilized and processed for 60 minutes. The three test results on the killing rate of Staphylococcus albus were $\geq 99.90\%$. They were qualified for disinfection and met the requirements of the 《Technical Specifications for Disinfection》 (2002 edition).

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