DRAFT TANZANIA STANDARD

Textiles – Method for evaluation of the bacterial filtration efficiency for surgical face mask

TANZANIA BUREAU OF STANDARDS

FOREWORD

This Draft Tanzania Standard is being developed by the Hospital Textiles Technical Committee under supervision of the Textile and Leather Divisional Standards Committee and it is in accordance with the procedures of the Bureau.

In the preparation of this standard assistance has been obtained from the following standards:

IS 16288:2014 *Medical Textiles — Method for evaluation of the bacterial filtration efficiency of surgical face masks.*

In reporting the result of a test or analysis made in accordance with this Draft Tanzania Standard if the final value, calculated or observed is to be rounded off, it shall be done in accordance with TZS 4 *Rounding off numerical values.*

1. SCOPE

This Draft Tanzania Standard prescribes a method for evaluation of the bacterial filtration efficiency of the medical face mask materials, employing the ratio of the upstream bacterial challenge to downstream residual concentration to determine filtration efficiency of medical face mask materials.

2. TERMS AND DEFINITIONS

For the purpose of this Draft Tanzania Standard, the following definitions shall apply:

2.1 Bacterial Filtration Efficiency (BFE)

effectiveness of a medical face mask material in preventing the passage of aerosolized bacteria; expressed in the percentage of a known quantity that does not pass the medical face mask at a given aerosol flow rate.

2.2 bacterial aerosol

suspension of articles containing biological agents which have been dispersed in the gas.

3. PRINCIPLE

3.1 The fabric samples are clamped between a six stage cascade impactor and an aerosol chamber. The bacteria aerosol is introduced into the aerosol chamber using a nebulizer and a culture suspension of staphylococcus aureus. The aerosol is drawn through the medical face mask material using a vacuum attached to the cascade impactor. The six stage cascade impactor uses six agar plates to collect aerosol droplets which penetrate the medical face mask material. Control samples are collected with no test specimen clamped in the test apparatus to determine the upstream aerosol counts.

3.2 The agar plates from the cascade impactor are incubated for 48 h ± 4 and counted to determine the number of viable particles collected. The ratio of the upstream counts to downstream counts collected for the test specimen are calculated and reported as present bacterial filtration efficiency.

4. APPARATUS

4.1 Autoclave, capable of maintaining temperature of 121-123 °C.

4.2 Incubator, capable of maintaining temperature of 37 + 2 °C.

4.3 Analytical Balance, capable of weighing 0.001 g.

4.4 Vortex Mixer, capable of mixing the contents of 16 mm × 150 mm test tubes.

4.5 Orbital Shaker, capable of achieving 100 – 250 rev/min.

4.6 Refrigerator, capable of maintaining 2-8 °C.

4.7 Six stage viable particle cascade impactor.

4.8 Vacuum Pump, capable of 57 liter/min.

4.9 Air pump/Compressor, capable of 1.1 kg/cm^2.

4.10 Peristatic Pump, capable of delivering 0.01 ml/min.

4.11 Nebulizer, capable of delivering mean particle size of 3.0 micrometer and a challenge level of 2200 particles per test.

4.12 Glass Aerosol Chamber, 60 cm × 8 cm diameter tube.

4.13 Colony Counter, manual or automatic, capable of counting up to 400 colonies per plate.

4.14 Automatic Pipette, capable of delivering 1.0 + 0.05 ml.

4.15 Flow Meters, capable of 28.3 litre/min.

4.16 Pressure Gauges, capable of 35 + 1 kPa.

4.17 Air Regulator

5. REAGENTS

5.1 *Staphylococcus aureus*, ATCC#6358

5.2 Tryptic soy Agar (TSA) 6

5.3 Tryptic soy broth (TSB) 6

5.4 Peptone Water

6. MEDIA PREPARATION

6.1 Prepare media using standard microbiological techniques.

6.2 Prepare agar plates for cascade impactor as specified by the manufacturer of each cascade impactor.

7. SPECIMEN

Test specimens shall be taken from manufactured medical face masks, with all layers arranged in proper order.

Note: the size of the specimen shall fit to the aerosol chamber.

8. CONDITIONING OF THE TEST SPECIMENS

Condition each test specimen for a minimum of 4 h by exposure to a temperature 21 + 5 °C and relative humidity 85 + 5 %.

9. PREPARATION OF THE BACTERIAL CHALLENGE

9.1 Inoculate an appropriate volume of tryptic soy broth with and incubate with mild shaking at 37+ 2 °C for 24 + 2 h.

9.2 Dilute the culture in peptone water to achieve a concentration of approximately 5 × 105 CFU/ml.

9.3 The challenge delivery rate will be maintained at 2200 + 500 viable particles per test.

10. PROCEDURE

10.1 Deliver the challenge to the nebulizer using peristaltic pump. Connect tubing to nebulizer and peristaltic pump and into the challenge suspension; purge tubing and nebulizer of air bubbles.

10.2 Perform positive control run without a test specimen clamped into the test system to determine the number of viable aerosol particles being generated. The mean particle size of the aerosol will be calculated from the results of these positive control plates. Initiate the aerosol challenge by turning on the air pressure and pump connected to the nebulizer. Immediately begin sampling the aerosol using the cascade impactor. Adjust the flow rate through cascade impactor to 28.3 liter/min.

10.3 Time the challenge suspension to be delivered the nebulizer for 1 min. Time the air pressure and cascade impactor to run for 2 min. At the conclusion of the positive control run, remove plates from the cascade impactor. Label each plate with the corresponding stage number.

10.4 Place the new agar plates into the cascade impactor and clamp the test specimen into the top of the cascade impactor with either the inside or outside oriented toward the challenge as intended.

10.5 Initiate the aerosol challenge as outlined above. Repeat the challenge procedure for each test specimen. Repeat a positive control sample after completion of the test sample test. Perform a negative control sample by collecting a two minute samples of air from the aerosol chamber. No bacterial challenge should be pumped into the nebulizer during the collection of the negative control sample.

10.6 Incubate the agar plates at 37 + 2 °C for 48 h Count each of the six agar plates for the test specimens and positive controls, as specified by the manufacturer of the cascade impactor.

10.7 The filtration efficiency is calculated by:

$$C - T/C \times 100$$

Where

C = average plate count total for test controls, and

T = plate count total for test sample.

11. REPORT

Bacterial filtration efficiency in percentage.