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Hygienic standard for disinfection in hospitals

医院消毒卫生标准

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Hygienic standard for disinfection in hospitals

1 Scope

This Standard specifies hygienic standard for disinfection in hospitals, requirements for disinfection management in hospitals as well as inspection methods.

This Standard is applicable to medical institutions at all levels. Disease prevention and control institutions at all levels and blood collection and supply institutions shall refer to this Standard for implementation.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

GB 4789.3, *Microbiological examination of food hygiene - Detection of Coliform bacteria*

GB 4789.4, *National food safety standard - Microbiological examination of food - Examination of salmonella*

GB/T 4789.11, *Microbiological Examination of Food - Hygiene-Examination of Streptococcus hemolyticus*

GB 5749, *Standards for drinking water quality*

GB 7918.4, *Standard methods of microbiological examination for cosmetics; Pseudomonas aeruginosa*

GB 7918.5, *Standard methods of microbiological examination for cosmetics; Staphylococcus aureus*

GB 18466, *Discharge standard of water pollutants for medical organization*

GB 19082, *Technical requirements for single-use protective clothing for medical use*

GB 19083, *Technical requirements for protective face mask for medical use*

infection during use, it is divided into critical device/items, semi-critical device/items and no-critical device/items

3.2.1 critical device/items

equipment that enters normal sterile tissues, vasculature, or has sterile body fluids (such as blood) flowing through, once it is contaminated by microorganisms, it will cause a high risk of infection

3.2.2 semi-critical device/items

equipment that directly or indirectly touches the mucosa

3.2.3 no-critical device/items

equipment that only comes into contact with intact skin and not mucosa

3.3 sterilization

treatment to kill or remove all microorganisms on medical equipment; the sterility assurance level of sterilization shall reach 10^{-6}

3.4 high-level disinfection

disinfection treatment to kill various bacterial propagules, viruses, fungi and their spores and most bacterial spores

3.5 intermediate-level disinfection

disinfection treatment to kill various pathogenic microorganisms except bacterial spores

3.6 low-level disinfection

disinfection treatment that can only kill bacterial propagules (except mycobacteria) and lipophilic viruses

3.7 multidrug-resistant organism; MDRO

bacteria that are resistant to three or more types of antibacterial drugs in clinical use; common multidrug-resistant organism includes methicillin-resistant staphylococcus aureus (MRSA), vancomycin-resistant enterococcus (VRE), extended-spectrum β-lactamase (ESBLs) producing bacteria, carbapenem-resistant enterobacteriaceae (CRE) (such as enterobacteriaceae that produce type I New-Delhi metal β-lactamase [NDM-1] or carbapenemase [KPC]), carbapenem-resistant antibacterial drugs Acinetobacter baumannii (CR-AB), multidrug-resistant/pan-resistant pseudomonas aeruginosa (MDR/PDR-PA) and multidrug-resistant mycobacterium tuberculosis.

4.3.1 Critical device/items shall be sterile.

4.3.2 The total number of colonies of semi-critical device/items shall be ≤20CFU/piece (CFU/g or CFU/100cm^2). No pathogenic microorganisms must be detected.

4.3.3 The total number of colonies of no-critical device/items shall be ≤200CFU/piece (CFU/g or CFU/100cm^2). No pathogenic microorganisms must be detected.

4.4 Treatment water

Hemodialysis-related treatment water shall meet the requirements of YY 0572. Other treatment water shall meet the corresponding sanitary standards.

4.5 Protective supplies

Protective supplies such as medical protective masks, surgical masks and disposable protective clothing shall meet the requirements of GB 19083, YY 0469 and GB 19082.

4.6 Disinfectant

4.6.1 Sterilizers, skin and mucous membrane disinfectants shall be prepared with purified water or sterile water that complies with the *Pharmacopoeia of the People's Republic of China*. The preparation water of other disinfectants shall meet the requirements of GB 5749.

4.6.2 The effective concentration of the disinfectant in use shall meet the use requirements. Continuously used disinfectant shall be monitored for effective concentration before daily use.

4.6.3 The total number of colonies of the disinfectant for sterilization shall be 0CFU/mL. The total number of colonies of the skin and mucous membrane disinfectant shall meet the requirements of the corresponding standards. The total number of colonies of other disinfectants in use shall be ≤100CFU/mL. No pathogenic microorganisms must be detected.

4.7 Disinfection equipment

4.7.1 The intensity of the sterilization factor of the disinfection equipment in use shall meet the requirements of use. UV lamps shall meet the requirements of GB 19258. The radiation illuminance value of the ultraviolet lamp (30W) in use shall be ≥70μW/cm^2.

4.7.2 The concentration (strength) of harmful substances generated by disinfection equipment in the working environment shall comply with relevant

hydrogen peroxide disinfectant shall be prepared as needed. Peracetic acid, chlorine dioxide and other binary and multi-package disinfectants shall be used immediately after being activated. Use chemically disinfected and sterilized medical device/items. Before use, use sterile water (use filtered drinking water for high-level sterilized endoscopes) to rinse thoroughly to remove residue. Do not use expired and ineffective disinfectants. The natural fumigation of formaldehyde shall not be used to disinfect medical device/items. The glutaraldehyde fumigation method shall not be used to disinfect and sterilize medical device/items such as lumen device/items.

5.2.3 If the sterilizer needs to be verified for the sterilization effect, it shall be tested by the disinfection identification laboratory recognized by the health administrative department above the provincial level. The sterility inspection of sterilized items shall be carried out in accordance with the requirements of the "Law of Sterility Inspection" in the *Pharmacopoeia of the People's Republic of China*. Disinfection staff who use disinfection equipment for sterilization shall be trained and qualified before they can work.

5.3 Cleaning of reusable medical device/items

The cleaning procedures shall be executed according to WS 310.2. Medical device/items contaminated by infectious disease pathogens with special requirements shall be disinfected and then cleaned.

5.4 Selection principle for disinfection and sterilization methods

5.4.1 Critical device/items shall be sterilized before use. High-level disinfection or intermediate-level disinfection shall be selected before use of semi-critical device/items. Choose intermediate-level and low-level disinfection or keep clean before using no-critical device/items.

5.4.2 Pressure steam sterilization shall be the first choice for medical device/items that is resistant to humidity and heat. The device/items with lumens and/or valves shall adopt the sterilization procedures confirmed by the sterilization process verification device (PCD) or the sterilization method provided by the external device supplier.

5.4.3 Dry heat sterilization shall be the first choice for glass device/items, oils and dry powder items. Other methods shall meet the requirements of "Disinfection technical specifications".

5.4.4 Medical device/items not heat-resistant or moisture-resistant shall be sterilized at low temperatures approved by the national health administration department.

5.4.5 Reusable oxygen humidification bottles, suction bottles, baby incubator water bottles and heating and humidification tanks shall be disinfected at high-

Annex A

(normative)

Sampling and inspection methods

A.1 Sampling and inspection principle

A.1.1 The samples shall be tested for corresponding indicators as soon as possible after sampling. The time for submission of testing shall not exceed 4h. If the sample is stored at 0°C~4°C, the i time for submission of testing shall not exceed 24h.

A.1.2 It is not recommended that hospitals routinely carry out sterility inspections of sterilized items. When epidemiological investigations suspect that nosocomial infections are related to sterilized items, perform a sterility inspection of the corresponding items. Routine supervision and inspection may not be tested for pathogenic microorganisms. When involving a suspected nosocomial infection outbreak, investigation of a nosocomial infection outbreak, or suspected microbial contamination at work, target microorganisms shall be tested.

A.1.3 The verified on-site rapid detection instrument can be used to monitor and screen the environment, surface and other microbial contamination and the cleanliness of medical device/items. It can also be used for inspection of hospital cleaning effect and cleaning procedure evaluation and verification.

A.2 Inspection method for air microbial pollution

A.2.1 Sampling time

Conduct sampling in Class I environment after self-cleaning of the clean system and before engaging in medical activities. Conduct sampling in II, III and IV environments after disinfection or prescribed ventilation and before engaging in medical activities.

A.2.2 Testing methods

A.2.2.1 Panel exposure method and air sampler method can be selected for class I environment. Refer to requirements of GB 50333 "Architectural technical code for hospital clean operating department" for testing. Level-six impact air sampler or other verified air samplers can be chosen for air sampler method. Place the sampler in the center of the room at a height of 0.8 m~1.5 m during testing. Operate according to the sampler instruction manual. Each sampling time shall not exceed 30min. For rooms larger than 10m^2, add a sampling point

$$\text{Total number of bacterial colonies in the hands of medical staff (CFU/m}^2\text{)} = \frac{\text{Average number of colonies per dish} \times \text{dilution factor of sampling solution}}{30 \times 2} \quad \cdots\cdots (A.3)$$

A.5 Inspection method for medical device/items

A.5.1 Sampling time

After disinfection or sterilization, conduct sampling during storage period.

A.5.2 Inspection method for sterilized medical device/items

A.5.2.1 Samples that can be sampled by destructive methods, such as disposable infusion (blood) devices, syringes, and injection needles, shall be conducted in accordance with the "Sterile Inspection Method" in the *Pharmacopoeia of the People's Republic of China*. For medical device/items that cannot be sampled by destructive methods, it shall be in a one-way air area or an isolation system with a local cleanliness of level 100 and an environmental cleanliness of level 10000. Use a cotton swab soaked with sterile saline sampling solution to apply on the surface of the test object. Take the whole surface or not less than 100cm^2 for sampling. Then take the cotton swab of which the hand contact part is removed for sterility inspection.

A.5.2.2 Dental mobile phone: It shall be in a one-way air area or an isolation system with a local cleanliness of level 100 and an environmental cleanliness of level 10000. Put each mobile phone in a sterile large test tube (inner diameter is 25mm) containing 20mL~25mL of sampling solution. The height of the liquid level shall be greater than 4.0cm. Wash and shake on a vortex mixer for more than 30s. Take the eluate for sterility inspection.

A.5.3 Inspection method for disinfection medical device/items

A.5.3.1 If the whole piece can be put into a sterile test tube, oscillate for more than 30s after immersion in eluent. Take 1.0 mL of eluate to inoculate into a petri dish. Pour 15mL~20mL of molten nutrient agar medium cooled to 40°C~45°C per dish. Inoculate in 36°C±1°C incubator for 48h. Count the number of colonies (CFU/piece). Separate pathogenic microorganisms when necessary.

A.5.3.2 For those can be sampled by destructive method, weigh 1g~10g of sample on a level-100 ultra-clean workbench. Put it into a test tube containing 10mL of sample solution for elution. Take 1.0mL of eluate to inoculate into a petri dish. Count the number of colonies (CFU/g). Separate pathogenic microorganisms when necessary. For medical device/items that cannot be sampled by destructive method, on the level-100 ultra-clean workbench, use a cotton swab soaked with sterile saline sampling solution to apply on the surface of the object to be sampled. When the sampled surface is <100cm^2, take the

A.8.3 Inspection method for irradiance value of in-use UV lamp

A.8.3.1 Instrument method. After turning on the UV lamp for 5min, place the UV radiometer probe with a measuring wavelength of 253.7nm at the center of the tested UV lamp at a vertical distance of 1m. After the meter is stable, the data shown is the irradiance value of the ultraviolet lamp.

A.8.3.2 Indicator card method. After turning on the UV lamp for 5min, place the indicator card at a vertical distance of 1m under the UV lamp. The patterned side faces up. Irradiate for 1min. Observe the color of the indicator card. Compare it with the standard color patches.

A.8.4 Precautions

The ultraviolet irradiance meter should be used within the validity period verified by the metrology department. The ultraviolet monitoring indicator card shall be approved by the national health administration department and used within the validity period of the product.

A.9 Inspection method for disinfection equipment

A.9.1 Determination of bactericidal factor strength: test according to the methods specified in the "Disinfection technical specifications" or corporate standards.

A.9.2 Determination of concentration (strength) of harmful substances in the working environment: test according to the method specified in the "Disinfection technical specifications" or relevant standards.

A.10 Inspection method for hospital sewage

Test according to GB 18466.

A.11 Testing method for disinfection effect of epidemic spot (area)

Test according to GB 19193.

A.12 Inspection method for coliform

Test according to GB 4789.3.

A.13 Inspection method for salmonella

Test according to GB 4789.4.

A.14 Inspection method for streptococcus hemolyticus

Test according to GB/T 4789.11.

Annex B

(normative)

Reagents and mediums

B.1 0.03mol/L phosphate buffer (0.03mol/LPBS)

Weigh 2.84g of disodium hydrogen phosphate and 1.36g of potassium dihydrogen phosphate. Add into 1000mL of distilled water. After they are completely dissolved, adjust the pH to 7.2~7.4. Sterilize under pressure steam at 121°C for 20min.

B.2 Eluent

Weigh 10.00g of peptone, 8.50g of sodium chloride, 1.0mL of Tween-80. Add to 1000mL of 0.03mol/L phosphate buffer. After heating and dissolving, adjust the pH to 7.2~7.4. Sterilize under pressure steam at 121°C for 20min.

B.3 Normal saline

Weigh 8.50g of sodium chloride and dissolve it in 1000mL of distilled water. Sterilize under pressure steam at 121°C for 20min.

B.4 Gram staining solution and staining method

B.4.1 Crystal violet staining solution: Weigh 1.00g of crystal violet and dissolve it in 20mL of 95% alcohol. Then mix with 80mL of 1% ammonium oxalate aqueous solution.

B.4.2 Gram iodine solution: Weigh 1.00g of iodine and 2.00g of potassium iodide. Add a little distilled water after mixing. Fully shake. After they are completely dissolved, add distilled water to 300mL. Mix well.

B.4.3 Sand yellow counterstain solution: Weigh 0.25g of sand yellow and dissolve it in 10mL of 95% alcohol solution. Then add 90mL of distilled water. Mix well.

B.4.4 The dyeing method is as follows:

a) Fix the smear on the flame;

b) Add crystal violet staining solution dropwise. Act for 1min. Wash with water;

c) Drip gram iodine solution. Act for 1min. Wash with water;

B.9.1 Components: 17g of casein peptone, 3g of soy peptone, 2.5g of glucose, 5g of sodium chloride, 2.5g of dipotassium hydrogen phosphate, 1g of lecithin, 7g of Tween-80, 1000mL of distilled water.

B.9.2 Production method: Mix various components (such as casein-free peptone and soy peptone can be replaced by Japanese polypeptone). After heating to dissolve, adjust the pH to 7.2~7.3. Dispense and sterilize at 121°C for 20min under pressure steam. Shake well. Cool to 25°C for use.

B.10 Eosin methylene blue medium

B.10.1 Components: 10g of peptone, 10g of lactose, 2g of potassium dihydrogen phosphate, 2mL of 2% eosin solution, 1mL of 0.65% methylene blue solution, 17g of agar, 1000mL of distilled water.

B.10.2 Production method: Dissolve peptone, phosphate and agar in distilled water. Adjust pH to 7.1. After dispensing, sterilize at 121°C for 20min under pressure steam. When it is required to use, add lactose aseptically and heat to melt agar. When it is cooled to 50°C, add eosin and methylene blue solution and shake well. Pour the petri dish. Store in a refrigerator at 4°C for later use.

B.11 0.5% dextrose broth medium

B.11.1 Components: 10g of peptone, 5g of sodium chloride, 5g of glucose, 1000mL of meat extract.

B.11.2 Production method: Add peptone and sodium chloride into the meat extract. After dissolving at low temperature, adjust pH to weak alkaline. Boil. Add glucose to dissolve. Shake well. Filter. Adjust pH to 7.0~7.4. Sterilize at 115°C for 30min under pressure steam.

B.12 Mannitol medium

B.12.1 Components: 10g of peptone, 5g of beef extract, 5g of sodium chloride, 10g of mannitol, 12mL of 0.2% bromothymol blue solution, 1000mL of distilled water.

B.12.2 Add peptone, sodium chloride, beef extract to distilled water. Heat to dissolve. Adjust pH to 7.4. Add mannitol and bromothymol blue. Mix well. Dispense. Sterilize at 115°C for 20min under pressure steam.

B.13 Lactose bile salt fermentation tube

B.13.1 Components: 20g of peptone, 5g of porcine bile salt (or cattle, sheep bile salt), 10g of lactose, 25mL of 0.04% bromocresol purple aqueous solution, 1000mL of distilled water.

B.13.2 Production method: Dissolve peptone, bile salt and lactose in distilled water. Adjust pH to 7.4. Add 0.04% bromocresol purple aqueous solution. Dispense (10mL per tube). And put it in a fermentation tube. Sterilize at 115°C for 15min under pressure steam.

B.14 Lactose fermentation tube

B.14.1 Components: 20g of peptone, 10g of lactose, 25mL of 0.04% bromocresol purple aqueous solution, 1000mL of distilled water.

B.14.2 Production method: Dissolve peptone and lactose in distilled water. Adjust pH to 7.4. Add 0.04% bromocresol purple aqueous solution. Dispense (10mL per tube). And put it in a fermentation tube. Sterilize at 115°C for 15min under pressure steam.

B.15 Bromocresol purple glucose peptone aqueous medium

B.15.1 Components: 10g of peptone, 5g of glucose, 0.6mL of 2% bromocresol purple alcohol solution, 1000mL of distilled water.

B.15.2 Production method: Dissolve peptone and glucose in distilled water. Adjust pH to 7.0~7.2. Add 2% bromocresol purple alcohol solution. Shake well. Dispense (5mL per tube). And put it in a fermentation tube. Sterilize at 115°C for 30min under pressure steam. Store in a refrigerator at 4°C for later use.

B.16 Medium for determination of pyocyanin

B.16.1 20g of peptone, 1.4g of magnesium chloride (anhydrous), 10g of potassium sulfate, 10mL of glycerol, 18g~20g of agar, 1000mL of distilled water.

B.16.2 Production method: Take peptone, magnesium chloride, potassium sulfate and add to water. Dissolve at a low temperature. Adjust pH to 7.2~7.4 after sterilization. Dispense into small test tubes. Conduct sterilization.

B.17 Gelatin medium

B.17.1 5g of peptone, 120g of gelatin, 3g of beef extract powder, 1000mL of distilled water.

B.17.2 Add the above components into water. Soak for about 20min. Stir anytime. Heat to dissolve. Adjust the pH value to 7.2~7.4 after sterilization. Dispense into small test tubes. Conduct sterilization.

B.18 Precautions

B.18.1 In the double-material lactose bile salt fermentation tube, except distilled water, other components are twice as much as lactose bile salt fermentation tube. In the 3 times concentrated lactose bile salt fermentation tube, except

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