



ALCOHOL ARTICLE SUMMARIES

EN 1500: 1997. Chemical disinfectants and antiseptics—Hygienic handrub—Test method and requirements (phase 2/step2).

The EN 1500 is utilized in Europe for *in vivo* testing of hygienic handrubs that are designed to reduce the level of transient flora on the hands. It applies to leave-on products for use in hospitals, clinics, nursing homes, and other areas.

The method involves artificially contaminating the hands, applying the product, and determining the reduction in bacteria. To pass the EN 1500, the mean log reduction of the handrub may not be significantly smaller than the mean log reduction of the reference handrub, 60% isopropanol (v/v). The products must also have at least bactericidal efficacy in accordance with EN 12054.

The test method uses the Gram negative microorganism *E. coli* K12 (NCTC 10538). The subjects contaminate their hands by immersing their fingers in a dense culture. Their hands are allowed to dry in the air for 3 minutes. Then their fingertips are rubbed for one minute on the base of a Petri plate for containing TSB (1 hand per plate). The TSB is diluted and plated and the bacterial counts are used to determine the pre values. Immediately afterward and without recontamination, the handrub product is applied. The product is rubbed according to the manufacturer's instructions or in the case of the reference product, in accordance with the 5.6.4.2. After the application, the fingers are rinsed for 5 s under running tap water and excess water is shaken off. Immediately following this step, the fingertips are rubbed for 1 minute on a fresh Petri plate containing TSB with neutralizers. The TSB is diluted and plated and the bacterial counts are used to determine the post values.

(Procedure for reference handrub is two applications of 3 mL of IPA (60% v/v), rub 30 s each time, rinse 5 s afterwards)

Rotter, M., Simpson, R., and Koller, W. Surgical hand disinfection with alcohols at various concentrations: parallel experiments using the new proposed European standard methods. *Infect Control Hosp Epidemiol.* 1998; 19:778-781.

The researchers evaluated concentrations of IPA in an *in vivo* surgical scrub test. The control product was a reference alcohol, 60% v/v n-propanol. The study used fingertip sampling; one hand was sampled immediately and the other hand was sampled after 3 hours. **The authors found that “The results of this study demonstrate the rapid and strong effect of isopropanol and n-propanol to reduce the release of skin flora from the hands.” (p. 780).** Higher concentrations of isopropanol were more effective, with 90% IPA equivalent to 60% n-propanol and 80% IPA not significantly different. Seventy percent IPA was significantly lower than the reference alcohol but it still produced an average immediate log reduction of 2.0.

Note: The goal of this study was to find the level of IPA that is as effective as n-propanol to allow the use either as a reference in EN studies. Concentrations lower than 70% were not evaluated in the study.

Larson, E. et al. Assessment of alternative hand hygiene regimens to improve skin health among neonatal intensive care unit nurses. *Heart and Lung*. 2000; 29(2): 136-142.

The study evaluated the effects of 2 hand care regimens on skin microbiology and condition of the hands in a sample of nurses. Skin condition was assessed using the Visual Scoring of Skin Condition scale and the Hand Skin Assessment Form; skin microbiology determine using glove juice sampling followed by plating on selective media and microbial identification. One group of nurses used CHG products and a CHG-compatible lotion while the other group used nonantimicrobial soap, Cal Stat (62% IPA), and an oil-based moisturizer. During the 4-week study, there were no significant differences between the two groups in the level of colonizing flora or types of microorganisms present. However, the skin condition of the group using Cal Stat showed significant improvement compared to the group using CHG products (p.140 Table).

The mild soap and isopropanol regimen had comparable effectiveness with traditional antiseptic handwashing and improved skin condition.

Bryce, E.A., D. Spence, and F.J. Roberts. An in-use evaluation of an alcohol-based pre-surgical hand disinfectant. *Infect. Control Hosp. Epidemiol*. 2001; 22(10): 635-9.

An isopropanol hand disinfectant (70%) was compared to a 4% CHG scrub and a 7.5% povidone-iodine scrub in an in-use surgical scrub study. The sampling methods included imprinting and glove juice sampling and they sampled pre and post surgery. The study also included an assessment of the skin condition for each subject.

There was no significant difference in the microbial hand counts after use of the isopropanol disinfectant or the other two products; this was true for both the immediate sampling and the sampling after surgery. The alcohol hand rinse was also equivalent to the two scrubs in terms of skin condition and user acceptability.

Rotter, M.L. Arguments for alcoholic hand disinfection. *J. Hosp. Infect*. 2001; 48 (Supp. A): S4-S8.

This article is a summary supporting alcohol rubs. The author states “. . . there is also a clear ranking of order in the efficacy of the alcohols: ethanol is less effective than isopropanol, the performance of which is inferior to that of n-propanol” (p. S4). The evidence is provided in Table I (p. S5), which summarizes the effectiveness of various actives in tests involving hand contamination with *E. coli*. Isopropanol is more effective than CHG and ethanol. It requires between 70 and 80% ethanol to be as effective as 60% isopropanol. In Table II various treatments are compared for effectiveness in reducing

resident flora (surgical scrub). Isopropanol is not as effective as n-propanol but it demonstrates comparable efficiency with other current products (p. S6).

(There is also discussion of flammability issues on p. S7. Ethanol is slightly more flammable than isopropanol at concentrations with antimicrobial effect.)

Pietsch, H. Hand antiseptics: rubs versus scrubs, alcoholic solutions versus alcoholic gels. *J. Hosp. Infect.* 2001; 48(Supp. A): S33-36.

One of the studies discussed in this paper tested alcohol gels according to EN 1500, hygienic hand disinfection protocol. The reference alcohol for this protocol is 60% IPA. None of the hand gels met the EN 1500 at 30s, they all had reduction factors significantly lower than 60% IPA (Table II p. S36).

Notes: The reference alcohol is two applications of 3 mL with a 30 s rub-in time after each application. In this study the authors use 1 application of 3 mL and a 30s rub-in time for the hand gels. Supposedly this is because most "alcohol-based liquid hand disinfectants used in the hospital meet the EN 1500 requirement with 3mL and within 30 s".

Kampf, G. Ostermeyer, C. Intra-laboratory reproducibility of the hand hygiene reference procedures of EN 1499 (hygienic handwash) and EN 1500 (hygienic hand disinfection). *J Hosp Infect.* 2002; 52(3): 219-224.

The EN 1500 standard for hygienic hand disinfection (leave-on products) compares test products to a reference alcohol, 60 % (w/w) IPA (2 apps.X 3mL). This article looks at values obtained for IPA from 23 different experiments in the same lab utilizing *E. Coli* as the standard organism. The mean reduction factor for IPA was 4.64 ± 0.93 and the lowest RF was 4.05 (p. 220-221 plus Fig. 1). The article indicates that IPA is both effective and a reliable standard in the procedure.

Kramer, A. et al. Limited efficacy of alcohol-based hand gels. *Lancet.* 2002; 359: 1489-1490.

Alcohol hand gels and rinses were evaluated using EN 1500. The hand gels were significantly less effective than the reference alcohol, 60% IPA. Looking at their data and Rotter's data they conclude that ethanol gels need to have at least 80% ethanol to be as effective as 60% IPA (p. 1490).

Pittet, D. Compliance with hand disinfection and its impact on hospital-acquired infections. *J. Hosp. Inf.* 2001; 48(Supp. A): S40-S46.

The paper discusses some of the barriers to hand-hygiene compliance and risk factors for non-compliance. The author recommends alcoholic-based hand-rubs for several reasons, including their anti-microbial spectrum, fast action, and ease of use. He also states "... alcohol-based formulations for hand disinfection (whether isopropyl, ethyl, or n-propanol, at 60%-90% v/v) are less irritating on skin than any antiseptic or non-antiseptic detergents ..." (p. S43).

(The results of the paper below (Lancet, 356: 1307-1312) are also summarized in this paper.)

Pittet, D. et al. Effectiveness of a hospital-wide programme to improve compliance with hand hygiene. *Lancet*. 2000; 356: 1307-1312.

The researchers implemented a hand-hygiene campaign in a teaching hospital by distributing individual bottles of handrub (alcohol-based + 0.5% CHG) and displaying hand-hygiene educational posters in target areas. Before and during the campaign, hand-hygiene compliance was monitored. Nosocomial infections, handrub usage, and MRSA (multi-resistant *S. aureus*) transmission rates were also monitored during the study. From 1994 to 1997, hand hygiene improved from 48% to 66% and alcohol-based handrub use increased from 4.1 L per 1000 patient days to 10.9 L per 1000 patient days (p. 1309). During this time period, nosocomial infection rates declined from 16.9% to 9.9% and MRSA transmission rates declined from 2.16 to 0.93 episodes per 10000 patient days (p. 1309).

The increase in compliance and decrease in infection rates was attributed to the promotion of alcohol-based handrubs (p. 1307).

BOOKS

Russell, A.D., W.B. Hugo, and G.A.J. Ayliffe. Principles and Practice of Disinfection, Preservation, and Sterilization. Third Edition. Russell AD, Hugo WB, Ayliffe GAJ. (editors). Blackwell Scientific Publications. Oxford, England. 1999: pp 51-53.

Isopropyl alcohol is more effective than ethanol (p. 52 –cites some old references).

Rotter, M. Infection Prevention for Skin and Burns. In Disinfection, Sterilization, and Preservation. Fifth Edition, Block SS (ed). Lippincott, Williams & Wilkins, Philadelphia, PA, 2001; pp 997-1010.

There is a summary table on p. 1002 that shows the efficacy of n-propanol, isopropanol, and ethanol at various concentrations against resident skin flora. This table has a lot of the same summaries as other tables, although this one does include contact time. Isopropanol is more effective than ethanol but less effective than n-propanol. Activity is concentration dependent.

Ali Y, Doaln MJ, Larson EL. Alcohols. In Disinfection, Sterilization, and Preservation. Fifth Edition, Block SS (ed). Lippincott, Williams & Wilkins, Philadelphia, PA, 2001; pp 229-254.

This chapter comprises a summary of a large body of work on alcohols from a wide variety of sources. It includes data on the active ingredient and its use in formulations

and clinical settings. The activity is compared to a number of other antimicrobials including CHG and Iodine in Surgical Scrub, Surgical Preoperative Skin Preparations and as Healthcare Personnel Handwashes (rubs). Its activity is shown to be equivalent or greater than these antimicrobials in these applications.

Additionally the data demonstrates that isopropanol has greater activity than ethanol as indicated by the following:

Table 12.4 Isopropanol is bactericidal at a lower concentration than ethanol, against both *S. aureus* and *E. coli* in suspension tests. (*S. aureus*: IPA 45 % , Ethanol 50%; *E. coli* IPA 26%, Ethanol 45-50%) (p.235)

Table 12.5 Isopropanol is bactericidal at a lower concentration than ethanol, against *S. aureus*, *E. coli*, and *M. tuberculosis* in carrier tests. (*S. aureus*: IPA 50 % , Ethanol 60%; *E. coli* IPA 50%, Ethanol 80%; *M. tuberculosis*: IPA 20%, Ethanol 80%) (p.235).

(Both tables are adapted from Rotter)

The efficacy of isopropanol is also discussed on p. 238 where it is stated, "The bactericidal action of isopropanol is slightly greater than that of ethanol." (p. 238) Isopropanol is also effective against lipophilic, enveloped viruses with activity equal to or better than ethanol. Table 12.10 indicates that when compared to ethanol, lower or equal concentrations of isopropanol are required to inactivate vaccinia, herpes simplex, and influenza (p.239). Other types of viruses are more resistant to inactivation by alcohols.

Isopropanol has been shown to have significant activity on both transient and normal flora of the skin. Table 12.15 shows that 70% isopropanol against transient flora has a mean log reduction of 3.3 after a 30s application; against normal flora the mean log reduction is about 2.5. (p.247) (Data from Rotter 1981, Ayliffe, 1988)

Rotter, ML. Hand washing and hand disinfection. In: Mayhall CG, ed. Hospital epidemiology and infection control, 2nd edn. Philadelphia: Lippincott, Williams, & Wilkins, 1999: 1339-55.

There is a summary table of efficacy of various agents against artificially contaminated hands on p. 1344. The table is similar to the one in his article from 2001 however some of the tests were done with other organisms.

The summary table on p. 1347 shows efficacy against resident skin flora. Isopropanol is shown to be as effective, if not more effective than ethanol. The sustained effect (3 hr) is demonstrated. There is no return to baseline values for any of the IPA concentrations, although the lower the concentration the lower the log reduction.

The graph on p. 1349 indicates that 60% isopropanol has an immediate log reduction just under 2.5. This is one of the most effective products, second only to n-propanol and a combination of IPA and CHG. The graph also indicates a persistence effect, with the 3

hour log reduction right around 2. The efficacy of 60% isopropanol is not as great – although it is still shown as more effective than CHG.

The bactericidal activity is summarized again on p. 1350: “ 42% n-propanol = 60% isopropanol = 77% ethanol.”

Calfee, D.P. and B.M. Farr. Comparison of four antiseptic preparations for skin in the prevention of contamination of percutaneously drawn blood cultures: a randomized trial. *J. Clin. Micro.* 2002; 40(5): 1660-1665.

The study evaluated blood culture contamination after use of one of four skin antiseptics: povidone-iodine, tincture of iodine, isopropyl alcohol, and povidone-iodine with alcohol. The study found some evidence to support less contamination with alcohol-based products. They believe this is due to the more rapid antimicrobial activity compared to iodophors (p.1663). Based on effectiveness and cost analysis they believe IPA may be the best antiseptic for percutaneous blood cultures (p.1664).