# Advancement of standard *in vivo* hand rub test methods: A critical comparison of the Health Care Personnel Handwash (ASTM E1174) and the Hygienic Handrub (EN1500)

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## Introduction

Recognized standards for evaluating alcohol based hand rubs (ABHR) differ significantly in methodology and success criteria. Hand hygiene authorities including the WHO and U.S. CDC have recognized inherent weaknesses calling out the need for improved *in vivo* efficacy methods.[1,2] The European Standard EN1500 (Hygienic Handrub), ASTM Standard E1174 (Health Care Personnel Handwash), and a recently approved ASTM standard, ASTM E2755-10, were critically compared and contrasted based on the written standards and empirical evidence (i.e. actual performance in practice).

## Conclusions

- Each method fails to represent actual healthcare worker ABHR use.
- None have success criteria based on evidence of clinical benefit or prevention of pathogen transmission.
- A single, globally recognized *in vivo* efficacy standard would be of significant value

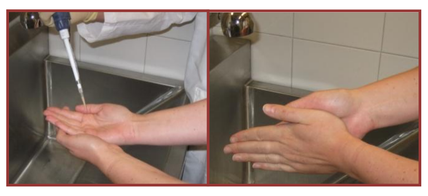
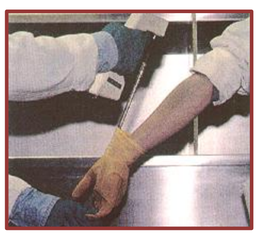
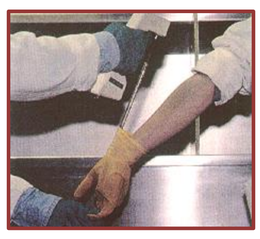
## Thought Provokers

- All current ABHR *in vivo* standard methods have major limitations and issues!
- Industry can exploit the test methods to draw erroneous or biased conclusions.
- ABHR formulations may perform differently based on method (i.e. pass vs. fail).
- Most infection prevention decision makers do not understand the methods & make erroneous assumptions.

**Input, suggestions, and involvement from infection prevention thought leaders like you is welcomed!**

## General Flowchart of *in vivo* test method execution:

**Hands contaminated with test organism** → **ABHR Test product applied** → **Hands sampled to recover surviving test organism** → **Reduction of test organism calculated**

| KEY STEP OR VARIABLE | EN 1500[3] | ASTM E1174[4] | ASTM E2755[5] | COMMENTARY |
|---|---|---|---|---|
| **Test organism:** | *Escherichia coli* 😐 | *Serratia marcescens* 😐 | *Serratia marcescens* or *Staphylococcus aureus* 🙂 | • *Should survive on hands and be representative of organisms known to transfer by hands.*<br>• *Must consider subject safety.* |
| **Method of contamination::** | Hands immersed in contamination fluid to mid-metacarpals for 5s. Air-dry for 3 min. ☹  | 1.5 mL suspension dispensed into subjects' hands and rubbed over entire surface for 20s. Air-dry for 30s. Repeat procedure 2 additional times. Final air dry is 90s. ☹  | 0.2 mL of concentrated suspension dispensed into subjects' hands and rubbed over entire surface for 30s. Hands are dry. 😐  | • *HCW hands typically become contaminated through touch.*<br>• *Contamination with large volumes introduces moisture and soil to the hands.*<br>• *90% of the bacteria do not survive the drying step.*  |
| **Baseline Recovery or Pretest value:** | $>10^7$ CFU /hand 😐 | $10^9$ CFU /hand 😐 | $10^9$ CFU /hand 😐 | • *Hand contaminated in clinical practice is typically much lower.* |
| **Recontamination prior to product application:** | No ☹ | Yes 🙂 | Yes 🙂 | • *The recovery procedure reduces bacterial load. If hands are not re-contaminated, reduction factors are overestimated.* |
| **Condition of hands prior to ABHR application:** | Heavily soiled and may have moisture 😐 | Heavily soiled and typically wet ☹ | Minimally soiled and dry 🙂 | • *HCW hands are not soiled or wet when using ABHR.*<br>• *Soil and wetness inhibit activity of ABHR.* |
| **Test article rub-in technique:** | Test article applied to hands using standardized rub-in method 🙂 | Test article applied to hands and rubbed over all surfaces (not standardized). 😐 | Test article applied to hands and rubbed over all surfaces (not standardized). 😐 | • *Standardized rub-in technique may reduce variability.* |
| **Test article rub-in duration and completion:** | Test article rubbed-in for a prescribed time and then rinsed with tap water to inactivate and remove remaining product. ☹ | Test article rubbed-in until completely dry. (Tends to be unrealistically long due to hand wetness remaining from contamination step.) ☹ | Test article rubbed-in until completely dry. (Reflective of in-use product rub-in time.) 🙂 | • *In practice ABHR are rubbed until dry. Because dry time can vary between test articles and test subject, rinsing before product is dry prevents accurate estimation of activity.* |
| **ABHR Dosing Practices:** | Typically 3 mL 🙂 | Typically 5 mL ☹ | Representative of in-use volumes (1.2-3 mL) 🙂 | • *Product should be tested at volume used by HC workers.*<br>• *The ideal volume remains unknown.* |
| **Hand sampling recovery method:** | Finger tips rubbed in broth ☹  | "Glove juice" sampling of entire hand 🙂  | "Glove juice" sampling of entire hand 🙂  | • *Sampling of the entire hand ensures that all surviving organism are recovered.* |
| **Single &/or Multiple use Evaluation:** | Single use 😐 | Single use and multiple use evaluation 🙂 | Single use and multiple use evaluation 🙂 | • *Efficacy of some ABHR formulations may either increase or decline over repeated use.* |
| **Internal reference:** | 60% 2-Propanol internal reference (3 mL rubbed for 30s followed by 3 mL rubbed for 30s; 6mL total) 🙂 | None ☹ | None ☹ | • *Internal reference controls for inter-experimental variability.*<br>• *Internal reference dose is unrealistically high.* |
| **Study Design:** | Crossover design – Each subject uses both internal reference and test article 🙂 | Random assignment of test subjects to a single test article 😐 | Random assignment of test subjects to a single test article 😐 | • *Crossover design controls for inter-experimental and inter-subject variability.* |
| **Success Criteria:** | Reference must not be significantly better than test article. 😐 | Application 1: 2 log reduction<br>Application 10: 3 log reduction<br>(Established by U.S. FDA[6]) 😐 | Not currently established ☹ | • *None of the current success criteria have been validated to correspond to the threshold for clinical effectiveness.* |

☹ limitation or major issue; 😐 not ideal but not a major limitation; 🙂 ideal or strength of method




## References

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