DIN EN 1499:2017-10 (E)

Chemical disinfectants and antiseptics - Hygienic handwash - Test method and requirements (phase 2/step 2)

Contents

Page

Foreword 3

1 Scope 4

2 Normative references 4

3 Terms and definitions 4

4 Requirements 4

5 Test methods 5
5.1 Principle 5
5.2 Materials and reagents 5
5.2.1 Test organisms 5
5.2.2 Culture media and reagents 5
5.3 Apparatus and glassware 7
5.3.1 General 7
5.3.2 Usual microbiological laboratory equipment 7
5.4 Preparation of test organism suspensions and product test solutions 9
5.4.1 Test organism suspensions (test and validation suspension) 9
5.4.2 Product test solutions 10
5.5 Procedure for assessing the bactericidal activity of the product on volunteers' hands 11
5.5.1 General 11
5.5.2 Neutralization - control and validation 12
5.5.3 Test procedure with volunteers 13
5.5.4 Incubation and counting of the test mixture and the control and validation mixtures 15
5.6 Experimental data and calculation 15
5.6.1 Explanation of terms and abbreviations 15
5.6.2 Calculation 15
5.7 Verification of the methodology - Test validation 18
5.7.1 Acceptance criteria for test results 18
5.7.2 Control of weighted mean counts 19
5.7.3 Basic limits 19
5.8 Statistical evaluation (significance testing), expression of results and precision 19
5.9 Conclusion 19
5.10 Test report 19

Annex A (normative) Standard handwash procedure 22

Annex B (informative) Neutralizers and rinsing liquids 23

Annex C (informative) Graphical representation of neutralizer control and method validation 25

Annex D (informative) Quality control of soft soap 26

Annex E (informative) Examples of reporting of results and significance testing 27

Annex F (normative) WILCOXON'S matched-pairs signed-ranks test 31

Bibliography 32