

ISO 15883-5:2021 (E)

Washer-disinfectors — Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy

Contents

	Foreword
	Introduction
1	Scope
2	Normative references
3	Terms and definitions
4	Performance requirements
4.1	General
4.2	Test soil considerations
4.3	Load considerations
4.4	Cleaning efficacy test criteria
4.4.1	General
4.4.2	Visual examination
4.4.3	Assay criteria
4.4.3.1	General
4.4.3.2	Protein assay criteria
4.4.3.3	Assay criteria for other analytes
4.4.4	Process residuals
5	Testing for conformity
5.1	Cleaning test method validation
5.1.1	General
5.1.2	Load soiling method
5.1.3	Detection method(s)
5.1.4	Analyte assay method
5.2	Washer-disinfectors requirements
5.3	Cleaning type test
5.3.1	Principle
5.3.2	Reagents/materials
5.3.3	Procedure
5.3.4	Acceptance criteria
5.4	Cleaning performance qualification test
5.4.1	Principle
5.4.2	Reagents/materials
5.4.3	Procedure
5.4.4	Acceptance criteria
5.5	Process residuals
5.5.1	General
5.5.2	Risk analysis
5.5.3	Cytotoxicity
5.5.4	Sampling methods
5.5.5	Acceptance criteria
Annex A	(informative) Examples of test soils
Annex B	(normative) Protein-based test soil performance assessment
B.1	Principle
B.1.1	Test background
B.1.2	Test protocol

- B.2 Acceptance criteria
- B.3 STP preparation
 - B.3.1 General
 - B.3.1.1 Number of STPs required
 - B.3.1.2 Material and size
 - B.3.2 Stainless steel preparation
 - B.3.2.1 Stainless steel foil surface preparation
 - B.3.2.2 Cleaning of stainless-steel foil
 - B.3.2.3 Procedure
 - B.3.3 STP coating
 - B.3.3.1 Precautions
 - B.3.3.2 Procedure
 - B.3.4 Negative control STPs
 - B.3.4.1 Procedure
 - B.3.5 STP conditioning
- B.4 Immersion test apparatus
 - B.4.1 General
 - B.4.2 Apparatus
- B.5 Immersion test procedure
 - B.5.1 General
 - B.5.2 Procedure
- B.6 STP elution procedure
 - B.6.1 General
 - B.6.2 Procedure
- B.7 UV-Vis ortho-phthalaldehyde (OPA) method
 - B.7.1 General
 - B.7.2 Equipment
 - B.7.3 Calibration curves
 - B.7.4 BSA stock solution preparation
 - B.7.4.1 General
 - B.7.4.2 Procedure
 - B.7.5 UV-Vis system and reagent compatibility for the OPA method
 - B.7.5.1 General
 - B.7.5.2 System suitability controls
 - B.7.5.3 Reagent controls
 - B.7.6 Constructing a BSA calibration curve
 - B.7.6.1 Procedure for sample preparation and UV data acquisition
 - B.7.6.2 Corrected Normalised Mean Sample Absorbances (NEBSA)
 - B.7.6.3 Plotting the BSA calibration curve
- B.8 Negative & positive controls
 - B.8.1 Negative control STPs
 - B.8.1.1 Measuring the protein content of negative control STPs
 - B.8.1.2 Corrected Normalised negative control Sample Absorbances
 - B.8.2 Positive control STPs
 - B.8.2.1 Measuring the protein content of positive control STPs
 - B.8.2.2 Corrected Normalised positive control Sample Absorbances (NE_n)
- B.9 Determination of residual protein for immersion tested STPs – UV-Vis analysis procedure
- B.10 Determination of STP coat weight
 - B.10.1 Cleaning of processed STPs
 - B.10.2 Procedure
 - B.10.3 STP coat weight (gravimetric analysis)
- B.11 Calculation of protein remaining on STP following the immersion procedure
- B.12 Preparation of solutions
 - B.12.1 General
 - B.12.2 Preparation of 1 % SDS solution
 - B.12.3 Preparation of processed STPs cleaning solution
 - B.12.4 Preparation of 20 % (w/w) SDS solution
 - B.12.5 Preparation of 0,1 M borate solution
 - B.12.6 Preparation of SDS/borate solution
 - B.12.7 Preparation of OPA reagent

Annex C (informative) Examples of test methods for the detection and assessment of residual proteinaceous contamination

- C.1** **General**
- C.1.1** **Sampling**
- C.1.2** **Calibration of protein detection method used**
- C.2** **Modified OPA method for the assessment of residual protein contamination**
- C.2.1** **Principle**
- C.2.2** **Procedure**
- C.2.3** **Calculation of the protein content**
- C.2.4** **Acceptance criteria/interpretation of results**
- C.3** **BCA method for the assessment of residual protein contamination**
- C.3.1** **Principle**
- C.3.2** **Materials/solutions**
- C.3.3** **Procedure**
- C.3.4** **Calculation of the total protein content**
- C.3.5** **Acceptance criteria/interpretation of results**

Annex D (informative) Examples of test methods for the detection of haemoglobin for the assessment of cleaning efficacy

- D.1** **Haemoglobin detection methods**
- D.1.1** **Principle**
- D.1.2** **Sampling**
- D.2** **Semi-quantitative detection of haemoglobin using microhematuria test strips**
- D.2.1** **Principle**
- D.2.2** **Procedure**
- D.2.3** **Acceptance criteria/interpretation of results**
- D.3** **Quantitative detection of haemoglobin using a spectrophotometer**
- D.3.1** **General**
- D.3.2** **Calibration and calculation of haemoglobin concentration**
- D.3.3** **Calculation of total residual haemoglobin**
- D.3.4** **Drabkin's Reagent**
- D.3.5** **Methods based on the pseudoperoxidase activity of haemoglobin**
- D.3.5.1** **General**
- D.3.5.2** **Procedure**

Annex E (informative) Test soil performance assessment – Sample results sheets