

# ISO 16297:2020-01 (E)

## Milk - Bacterial count - Protocol for the evaluation of alternative methods

---

	Contents	Page
Foreword .....	iv	
Introduction .....	vi	
1 Scope .....	1	
2 Normative references .....	1	
3 Terms and definitions .....	1	
4 Transformation of results .....	1	
5 Attributes of the alternative method .....	2	
5.1 General .....	2	
5.2 Description of the method to be evaluated .....	2	
5.2.1 Description .....	2	
5.2.2 Checklist .....	2	
5.3 Measuring range .....	2	
5.3.1 Lower limit of quantification .....	2	
5.3.2 Upper limit of quantification .....	3	
5.3.3 Linearity of the instrument signal .....	3	
5.4 Carry-over .....	4	
5.5 Stability .....	5	
5.6 Precision .....	6	
5.6.1 General .....	6	
5.6.2 Repeatability .....	6	
5.6.3 Reproducibility .....	6	
5.6.4 Evaluation of factors affecting the results .....	6	
6 Alternative method as an estimate of the anchor method .....	6	
6.1 General .....	6	
6.2 Evaluation of factors affecting the estimation .....	7	
6.3 Measurement protocol .....	7	
6.4 Calculations .....	7	
6.4.1 General .....	7	
6.4.2 Visual check of a scatter diagram .....	7	
6.4.3 Outliers .....	8	
6.4.4 Accuracy of the estimate and accuracy profile .....	8	
6.5 Attributes of the alternative method expressed in units of the anchor method .....	10	
7 Rating of the elaborated attributes .....	10	
Bibliography .....	11	