ISO 20391-2:2019 (E)

Biotechnology — Cell counting — Part 2: Experimental design and statistical analysis to quantify counting method performance

Contents

		Forew	ord	
		Introduction		
1		Scope		
2		Norma	ative references	
3		Terms, definitions, symbols and abbreviated terms		
	3.1 3.2		Terms and definitions List of abbreviated terms and symbols	
4		Principle		
	4.1 4.2 4.3		General Proportionality Deviation from proportionality	
5		Experimental design		
	5.1 5.2 5.3 5.3.2 5.3.3 5.3.4 5.4 5.5	2 3	General Considerations for the cell counting measurement process Preparation of samples for the experimental design General Stock cell solution Dilution fraction experimental design Considerations for generating dilution fractions Test sample labelling Measurement of the test sample	
6		Statistical methods		
	6.1 6.2 6.3 6.4 6.5 6.6 6.6 6.6 6.6 6.7 6.8 6.8 6.8 6.8 6.8 6.8 6.8 6.8	2 3 1 2 3 4	General Mean cell count Measurement precision Proportional model fit Coefficient of determination Proportionality index (PI) General Calculation of the smoothed residual (esmoothed) Calculation of proportionality index (PI) Additional statistical analysis and quality metrics Data interpretation General Interpretation of %CV Interpretation of R2 Interpretation of PI values Comparison of PI values	
7		Repor	ting	
	7.1 7.2 7.3		Reporting of quality indicators Documentation of experimental design parameters and statistical analysis method Additional reporting elements on the cell counting measurement process	
Annex	Α	(inforr	native) Method to assess pipetting error contributions to dilution integrity	
	A.1		General	

A.2 A.3	using a calibrated scale to obtain accurate volume estimates upon pipetting Example procedure for obtaining a measured DF during the evaluation of PI using a calibrated scale to obtain accurate volume estimates		
Annex B	(normative) Method to calculate smoothed residual (esmoothed) when a set of measured dilution fractions (DFmeasured) is obtained		
Annex C	(informative) Example formulae for calculating PI		
C.1	Detailed example of the calculation of PI based on sum of the absolute value of scaled smoothed residuals		
C.2 C.3	Detailed example of the calculation of PI based on R2 of smoothed residuals Additional examples of the calculation of PI when measured dilution fraction is utilized		
Annex D	(informative) Use case 1 — Evaluating the quality of a single cell counting measurement process		
D.1	General		
D.2	Description of experimental design and statistical analysis		
D.3	Raw data and data analysis for use case 1		
D.4	Example report for use case 1		
D.5	Interpretation		
Annex E	(informative) Use case 2 — Comparing the quality of several cell counting measurement processes		
E.1	General		
E.2	Description of experimental design and statistical analysis		
E.3	Raw data and data analysis for use case 2		
E.4	Example report for use case 2		
E.5	Comparison of cell counting methods evaluated in use case 2		
E.5.			
E.6	Interpretation		
E.7	Consistency of results with underlying simulated model		

Page count: 53