

- Linearity (*ISO 13366-2 for each cell count level $r_C \leq 2$ %*) 1,7 %
- Lower limit of quantification (L_Q): 37.10³ cells/mL
- Upper limit of quantification: 10 000.10³ cells/mL
- Intra-laboratory reproducibility ($R_{intra-lab}$) per cell count level:
 - Low (ca. 140.10³ cells/mL) 16 % (*ISO 13366-2 19 %*)
 - Medium (ca. 450.10³ cells/mL) 11 % (*ISO 13366-2 14 %*)
 - High (ca. 1 450.10³ cells/mL) 7 % (*ISO 13366-2 11 %*)
- Fossomatic™ FC functions stable through the working day
- High fat and protein content of the milk do not influence the somatic cell count results
- The overall accuracy standard deviation $s_{y,x}$ is (*EURL MMP $s_{y,x} < 10$ %*):
 - Individual cow milk samples 3 %
 - Herd bulk cow milk samples 1 %

3.2. Interlaboratory study

The interlaboratory study was performed according to ISO 5725-2 and IDF Bulletin 453/2012. The overall precision characteristics of Fossomatic™ FC are:

- The interlaboratory standard deviation of repeatability $s_r = 20.10^3$ cells/mL = 1 % (*ISO 13366-2 $s_r = 5$ %*)
- The between-laboratory standard deviation $s_L = 15.10^3$ cells/mL = 1 %.
- The interlaboratory standard deviation of reproducibility $s_R = 24.10^3$ cells/mL = 2 % (*ISO 13366-2 $s_R = 5$ %*)

4. Final conclusion validation study

The Method Comparison Study and the Interlaboratory Study show that the alternative method results obtained with Fossomatic™ FC (FOSS Analytical A/S) comply with all criteria in the EURL MMP document.