THE IMPORTANCE OF BIOLOGICAL CONTROL LIMIT SELECTION

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Monitoring 'biological control' subjects forms an integral part of laboratory quality control. Control limits are established using a period of baseline tests. Applying Westgards 'multi-rule' analysis to subsequent data helps determine the quality status of pulmonary function equipment.
We investigated the consequence of altering the baseline data to determine the effect on the frequency of 'out of control' events.
METHODS: FEV_1 for 141 consecutive tests in 3 subjects were analysed using different algorithms to establish baseline control limits.
RESULTS: Each algorithm altered the baseline mean and standard deviation values. The number of tests in which at least 1 'out of control' condition is met (OC) and the coefficient of variation (CV) range are shown in the table.

	Subject 1		Subject 2		Subject 3	
Baseline Algorithm	OC	CV (%)	OC	CV (%)	OC	CV (%)
1st 20 values	7	2.1	49	3.0	7	1.9
Moving average (last 20 values)	5	1.5 – 3.7	5	1.3 – 3.8	3	1.1 – 2.5
Yearly interval (last 20 values)	14	1.8 – 3.6	30	2.3 – 3.6	7	1.6 – 1.9
Fixed interval (last 20 values)	8	1.7 – 3.5	16	1.3 – 3.7	6	1.5 – 2.5
All previous values	7	1.9 – 3.5	14	2.0 – 3.5	6	1.5 – 2.1

Subject 2 showed the most variation ranging from 5 to 49 'out of control' events. Subject 3 had the fewest 'out of control' events for all the algorithms and the narrowest CV range. The moving average algorithm showed the least number of 'out of control' events for all 3 subjects.
CONCLUSION: The choice of data used for calculating control limits will influence the frequency of 'out of control' events within a biological data set.

Keywords: Biological control, quality control, FEV_1, control limits
Nomination for award: Young Investigator