

Results Interpretation and implementation of corrective actions

C_{pk}	The lower of the C_{pu} and the C_{pl}
C_{pl}	$C_{pl} = \frac{(\bar{X} - LSL)}{3s}$
C_{pu}	$C_{pu} = \frac{(USL - \bar{X})}{3s}$
C_{pm}	$C_{pm} = \frac{USL - LSL}{6\sqrt{(\bar{X} - T)^2 + s^2}}$
Estimated Sample Standard Deviation	$s \approx \frac{\bar{R}}{d_2}$
Grand Average	$\bar{\bar{X}} = \frac{\sum \bar{X}}{k}$
Mean	$\bar{X} = \frac{\sum X}{n}$
Process Capability Index	$C_p = \frac{USL - LSL}{6s}$
Process Capability Ratio	$C_r = \frac{6s}{USL - LSL} \times 100\%$
Range	R = highest point - lowest point
Sample Standard Deviation	$s = \sqrt{\frac{\sum (X - \bar{X})^2}{n - 1}}$
P_{pk}	The lower of the P_{pu} and the P_{pl}
P_{pl}	$P_{pl} = \frac{\bar{X} - LSL}{3s}$
P_{pu}	$P_{pu} = \frac{USL - \bar{X}}{3s}$
Process Performance Index	$P_p = \frac{USL - LSL}{6s}$

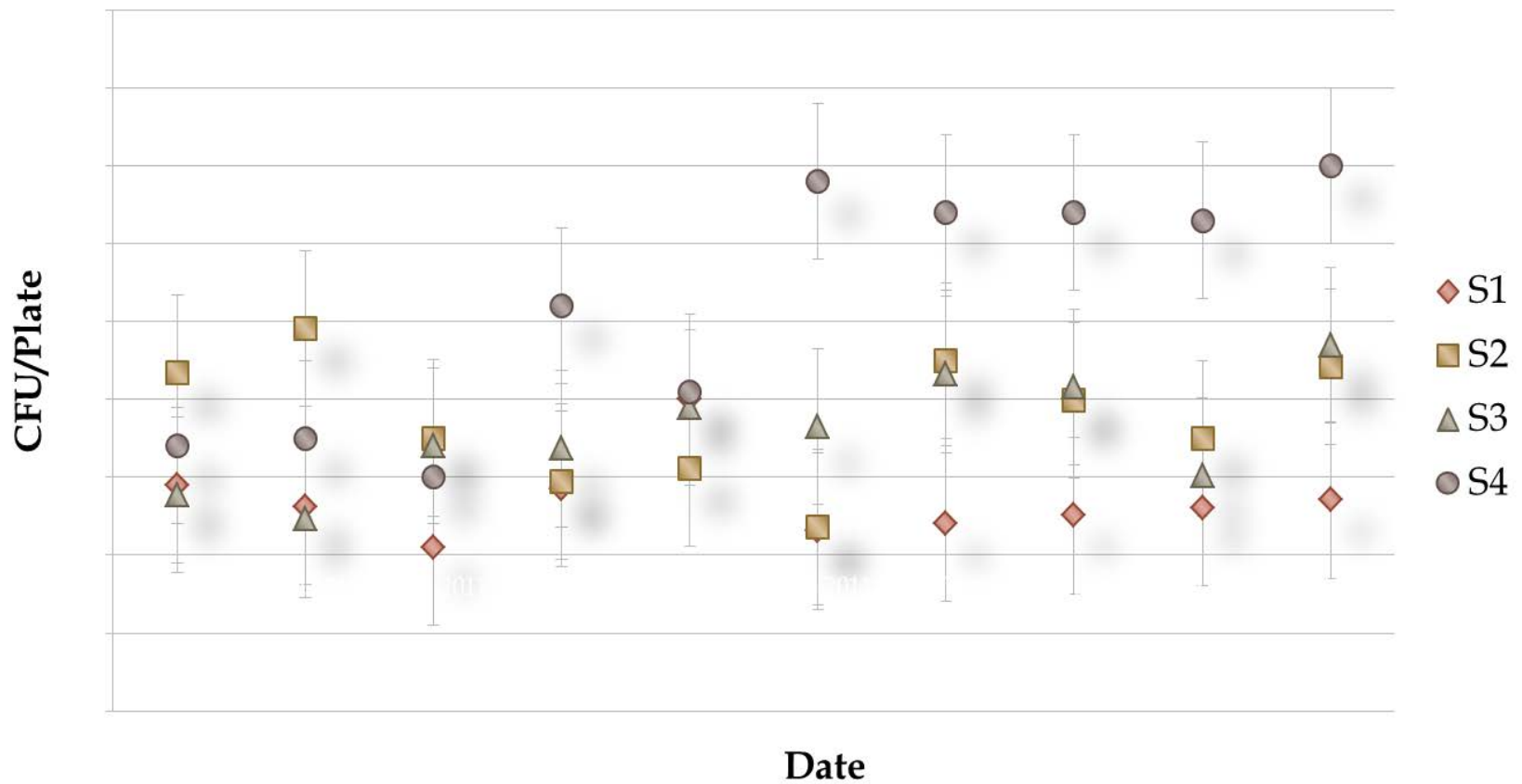
Interpretation - microbiological variation

- “The absolute number of colony forming units has limited significance”
 - The sample is only representative of the matrix at the time of sampling
 - It is recognised that bacteria may be fastidious and that damaged/stressed bacteria may not multiply.
- Variability
 - Sample collection, transportation
 - Methodology – media.
- External Quality Proficiency results August 2012
 -
- Results
 - FEPTU median (MF)* = 52
 - No. results returned = 38
 - Expected Range 16 - 154

Trend Analysis

Week	Sample points						
	S1	S2	S3	S4	S5	S6	S7
1	36	34	40	36	48	54	40
2	47	56	45	21	33	37	11
3	10	27	50	55	44	60	37
4	13	41	23	54	108	60	38
5	50	40	45	45	78	42	59
6	15	54	57	37	85	30	26
7	44	37	15	10	98	39	19
8	12	53	12	10	97	47	39
9	33	56	33	22	105	37	56
10	37	39	44	29	68	11	32
mean	30	44	36	32	76	42	36
SD	16	10	15	16	27	15	15
Lower	-2	23	6	-1	22	12	6
Upper	61	64	67	65	131	71	65

Trend Analysis

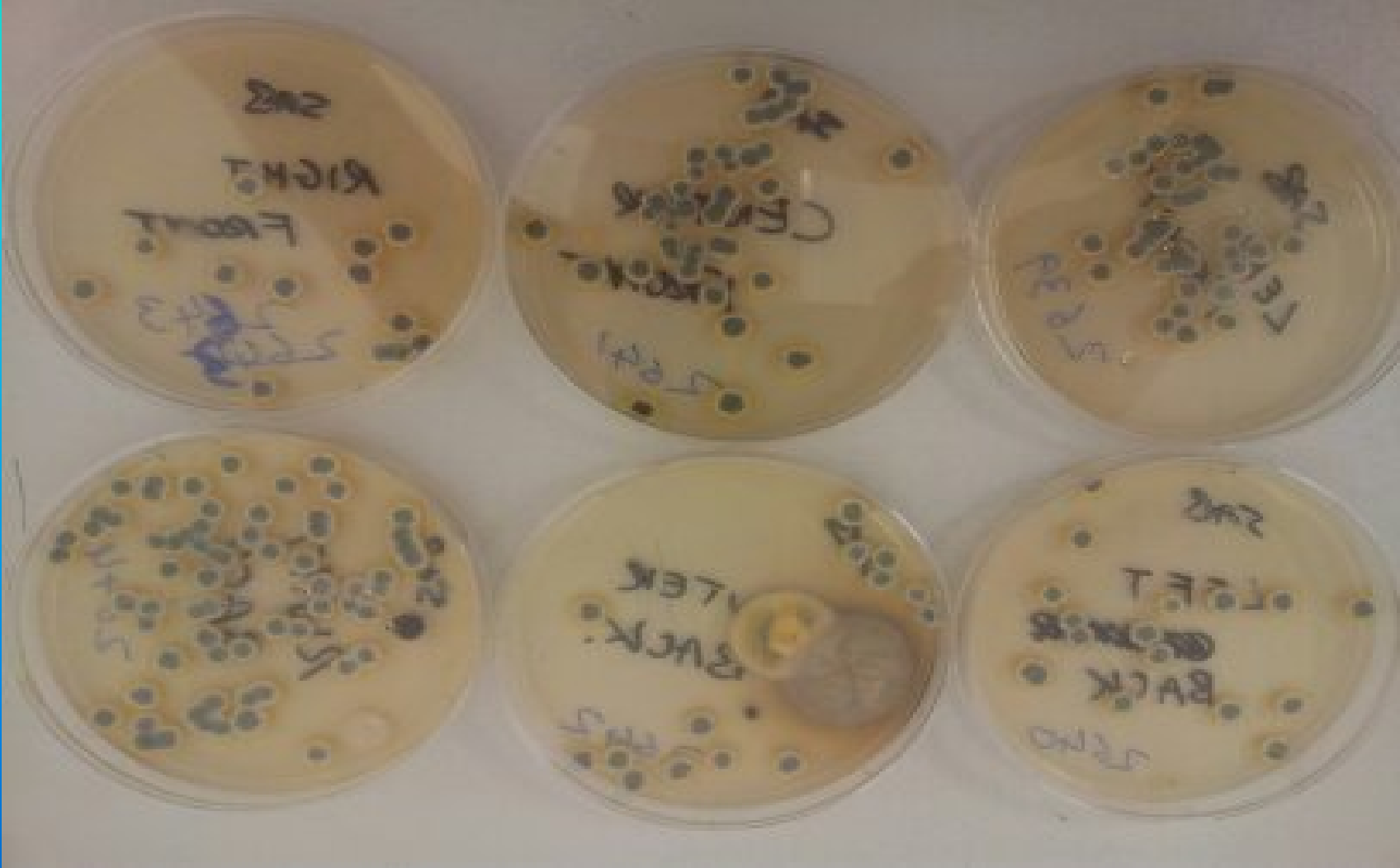


Alert and Action Limits

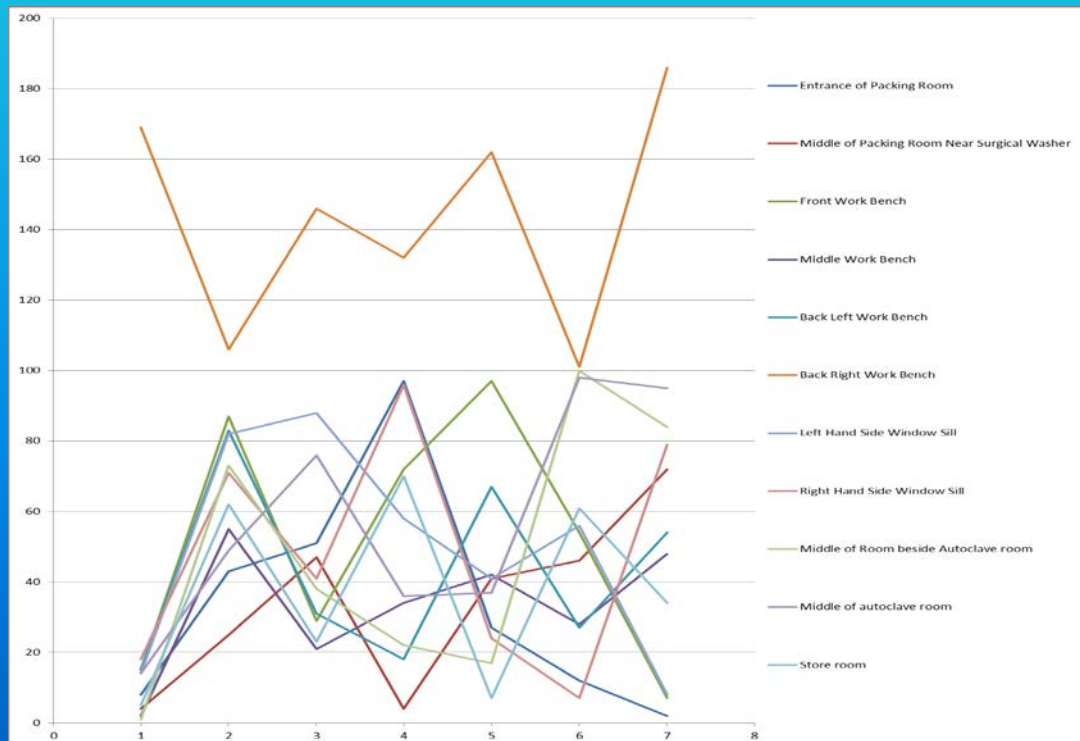
- Should be based on averaged values achieved over at least a six or twelve month period.
- Alert level – CFU Levels that when exceeded, signal a possible deviation from that normally seen.
- Action Level – CFU levels that significantly exceed those normally seen.

Typical microbial 'Action' limit values used in Class 7 or Class 8 cleanrooms

	Contact Plate CFU/plate	Settle Plate CFU/plate
Class 8 Alert	5	5
Class 8 Action	30 (Floor counts)	20
Class 7 Alert	4	3
Class 7 action	5 (10 Floor) (20 Floor, dirty side)	5



	At Rest	1	2	3	4	5	6
Entrance of Packing Room	8	43	51	97	27	12	2
Middle of Packing Room Near Surgical Washer	4	25	47	4	41	46	72
Front Work Bench	15	87	29	72	97	54	7
Middle Work Bench	2	55	21	34	42	28	48
Back Left Work Bench	15	83	31	18	67	27	54
Back Right Work Bench	129	188	174	195	139	156	108
Left Hand Side Window Sill	14	82	88	58	41	56	8
Right Hand Side Window Sill	18	71	41	96	24	7	79



Investigation

- If a single result is it:-
 - An anomaly
 - Possible sampling contamination . Check controls supplied by laboratory
 - Was there unusual activity

Take advice from the microbiologist /Infection control /laboratory

Repeat sampling

Undertake a risk assessment