Environmental monitoring report, Building 3

Sterile fill-finish, filling lines FL-3 (RABS) and FL-5 (isolator), lyophilisers LY-2/LY-4 · reporting period 01.04.–30.09.2026

Prepared by Dr. Lena Imboden (QC

Samples analysed	Alert-level results	Action-level results	Viable results within limits	Open investigations
10,507	28	15	99.67%	5
Apr–Sep 2026, 27 locations	of which 7 in September	of which 4 in September	target 99.0 % (all grades)	oldest opened 17.09.2026

Excursions by month

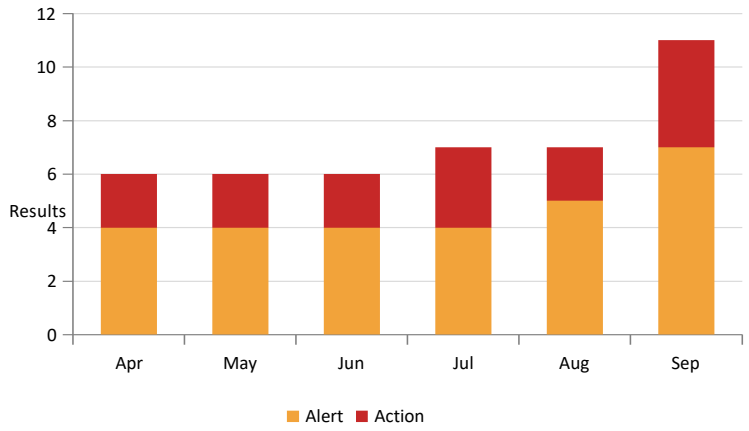
Month	Alert	Action	Total	2025 total
April 2026	4	2	6	3
May 2026	4	2	6	5
June 2026	4	2	6	4
July 2026	4	3	7	7
August 2026	5	2	7	6
September 2026	7	4	11	5
Total	**28**	**15**	**43**	**30**

Viable excursions by grade

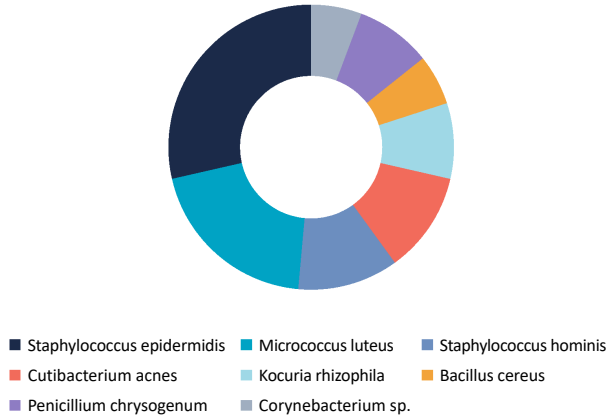
Grade	Viable samples	Excursions	Rate
A	5,764	9	0.16%
B	4,192	21	0.50%
C	551	5	0.91%

Most frequent organism: Staphylococcus epidermidis
Root cause most often cited: Personnel intervention

Excursions per month by level



Identified organisms



Identified organisms (viable excursions)

Organism	Count	Share
Staphylococcus epidermidis	10	29%
Micrococcus luteus	7	20%
Staphylococcus hominis	4	11%
Cutibacterium acnes	4	11%
Kocuria rhizophila	3	9%
Bacillus cereus	2	6%
Penicillium chrysogenum	3	9%
Corynebacterium sp.	2	6%

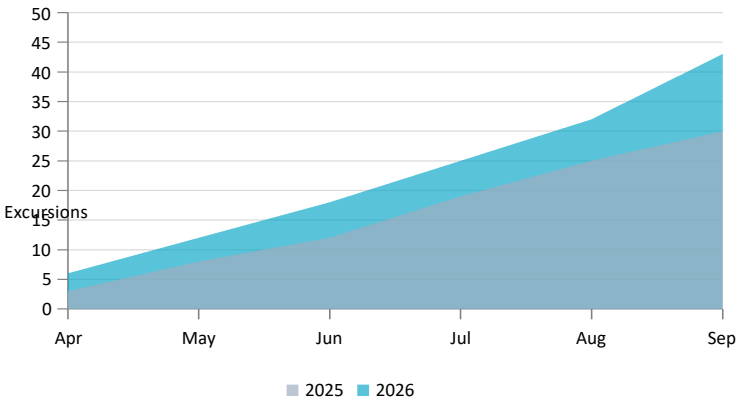
Cumulative excursions 2025 vs 2026

Month	2025	2026
Apr	3	6
May	8	12
Jun	12	18
Jul	19	25
Aug	25	32
Sep	30	43

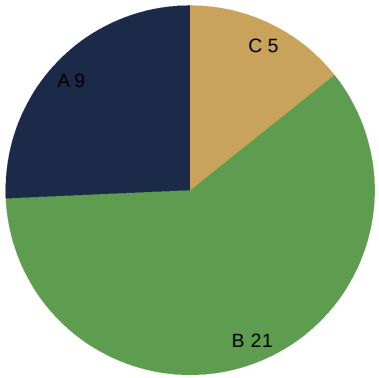
Contents

Limits	Limits and sampling locations
Viable	Active air matrix, September
Particles	Grade A particle counts, September
Samples	Samples by month, room and method
Excursions	Excursion log and Pareto
Statistics	Statistics per location and point
Pivot	DataPilot by room and month

Cumulative excursions, April to September



Viable excursions by grade



Limits and sampling locations

EU GMP Annex 1 (2022) maximum limits and site alert limits, SOP QC-EM-0311 rev. 7 (effective 01.03.2026).

A. Action limits (excursion when the result is above the limit)

Grade	Active air	Settle plate	Contact plate	Glove print	Particles ≥0.5 µm	Particles ≥5 µm
A	no growth	no growth	no growth	no growth	3,520	29
B	10	5	5	5	352,000	2,930
C	100	50	25	–	3,520,000	29,300
D	200	100	50	–	–	–
Unit	*CFU/m³*	*CFU/4 h*	*CFU/plate*	*CFU/glove*	*particles/m³*	*particles/m³*

B. Site alert limits

Grade	Active air	Settle plate	Contact plate	Glove print	Particles ≥0.5 µm	Particles ≥5 µm
A	any growth	any growth	any growth	any growth	1,000	10
B	5	3	3	3	100,000	1,000
C	50	25	13	–	1,000,000	10,000
D	100	50	25	–	–	–

C. Non-viable limits at rest (particles/m³)

Grade	≥0.5 µm	≥5 µm	Classification	Recovery time
A	3,520	not specified	ISO 5	–
B	3,520	29	ISO 5	15–20 min
C	352,000	2,930	ISO 7	15–20 min
D	3,520,000	29,300	ISO 8	15–20 min

D. Sampling locations, Building 3

Location	Room	Grade	Line	Description	Particle counter
A301-01	R301	A	FL-3	Needle station	yes
A301-02	R301	A	FL-3	Stopper bowl and track	yes
A301-03	R301	A	FL-3	Vial infeed, tunnel exit	–
A301-04	R301	A	FL-3	Transfer to lyo trolley	–
B302-01	R302	B	FL-3	Operator position, RABS doors 1–2	–
B302-02	R302	B	FL-3	Operator position, RABS doors 3–4	–
B302-03	R302	B	FL-3	Return air grille, east wall	–
B302-04	R302	B	FL-3	Material pass-through	–
C303-01	R303	C	FL-3	Capping machine infeed	–
C303-02	R303	C	FL-3	Tray loading table	–
A311-01	R311	A	FL-5	Filling needles	yes
A311-02	R311	A	FL-5	Stopper bowl	yes
A311-03	R311	A	FL-5	Mouse-hole outfeed	–
A311-04	R311	A	FL-5	RTP port, tub transfer	–
C312-01	R312	C	FL-5	Isolator glove area	–
C312-02	R312	C	FL-5	Decontamination hatch	–
C321-01	R321	C	Formulation	Weighing booth	–
C321-02	R321	C	Formulation	Formulation vessel V-310	–
C321-03	R321	C	Formulation	Filter integrity bench	–
B322-01	R322	B	Logistics	MAL-3 inner door	–
B322-02	R322	B	Logistics	MAL-3 transfer table	–
B323-01	R323	B	Personnel	Gowning bench, B side	–
B323-02	R323	B	Personnel	Exit to corridor	–
A331-01	R331	A	LY-4	Shelf loading zone	yes
A331-02	R331	A	LY-4	Transfer cart docking	yes
B332-01	R332	B	LY-2/LY-4	Corridor at LY-4 door	–
B332-02	R332	B	LY-2/LY-4	Corridor at LY-2 door	–

Room register

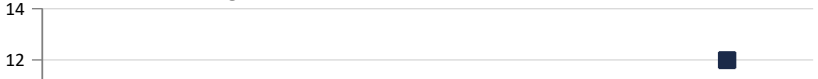
Room	Name	Grade	Line	Locations
R301	FL-3 filling zone (RABS)	A	FL-3	4
R302	FL-3 cleanroom, RABS background	B	FL-3	4
R303	FL-3 capping and tray loading	C	FL-3	2
R311	FL-5 isolator	A	FL-5	4
R312	FL-5 isolator room	C	FL-5	2
R321	Compounding suite	C	Formulation	3
R322	Material airlock MAL-3	B	Logistics	2
R323	Gowning room PAL-3, B side	B	Personnel	2
R331	LY-4 loading zone (UDAF)	A	LY-4	2
R332	Lyophilisation corridor	B	LY-2/LY-4	2

Viable monitoring, active air sampling – September 2026

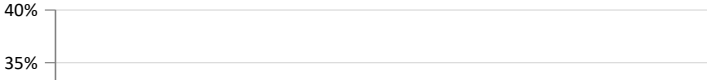
CFU/m³ per sample (1 m³, MAS-100 NT), grade A and B locations of Building 3; empty cells: no production, no sampling. Excursion = result above the alert or action limit.

	Location	Room	Alert	Action	Day of month (September 2026)																													n	Mean	Max	> alert	> action
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30					
					Tue	Wed	Thu	Fri	Sat	Sun	Mon	Tue	Wed	Thu	Fri	Sat	Sun	Mon	Tue	Wed	Thu	Fri	Sat	Sun	Mon	Tue	Wed	Thu	Fri	Sat	Sun	Mon	Tue	Wed					
Grade A	A301-01	R301	0	0	0	0	0	0			0	0	0	0	0			0	1	0	0	0			0	0	0	0	0			0	0	0	22	0.05	1	0	1
	A301-02	R301	0	0	0	0	0	0			0	0	0	0	0			0	0	0	0	0			0	0	0	0	0			0	0	0	22	0.00	0	0	0
	A301-03	R301	0	0	0	0	0	0			0	0	0	0	0			0	0	0	0	0			0	0	0	0	0			0	0	0	22	0.00	0	0	0
	A301-04	R301	0	0	0	0	0	0			0	0	0	0	0			0	0	0	0	0			0	0	0	0	0			0	0	0	22	0.00	0	0	0
	A311-01	R311	0	0	0	0	0	0			0	0	0	0	0			0	0	0	0	0			0	0	0	0	0			0	0	0	22	0.00	0	0	0
	A311-02	R311	0	0	0	0	0	0			0	0	0	0	0			0	0	0	0	0			0	0	0	0	0			0	0	0	22	0.00	0	0	0
	A311-03	R311	0	0	0	0	0	0			0	0	0	0	0			0	0	0	0	0			0	0	0	0	0			0	0	0	22	0.00	0	0	0
	A311-04	R311	0	0	0	0	0	0			0	0	0	0	0			0	0	0	0	0			0	0	1	0	0			0	0	0	22	0.05	1	0	1
	A331-01	R331	0	0	0	0	0	0			0	0	0	0	0			0	0	0	0	0			0	0	0	0	0			0	0	0	22	0.00	0	0	0
	A331-02	R331	0	0	0	0	0	0			0	0	0	0	0			0	0	0	0	0			0	0	0	0	0			0	0	0	22	0.00	0	0	0
Grade B	B302-01	R302	5	10	1	0	0	0			1	7	0	0	0			0	0	0	0	0			0	0	0	1	0			0	1	0	22	0.50	7	1	0
	B302-02	R302	5	10	0	0	0	1			1	1	0	1	1			0	0	1	12	1			1	0	0	0	0			1	0	0	22	0.95	12	0	1
	B302-03	R302	5	10	0	0	0	0			0	0	0	0	0			0	0	0	0	0			0	0	0	0	0			0	0	0	22	0.00	0	0	0
	B302-04	R302	5	10	0	0	0	0			0	0	0	0	2			0	0	0	0	0			0	0	0	0	0			0	0	0	22	0.09	2	0	0
	B322-01	R322	5	10	0	0	0	0			2	0	0	0	0			0	0	0	0	0			0	0	0	1	0			0	0	1	22	0.18	2	0	0
	B322-02	R322	5	10	0	0	1	0			0	0	0	0	0			0	0	0	0	0			1	0	0	1	0			1	0	0	22	0.18	1	0	0
	B323-01	R323	5	10	0	1	0	0			2	0	0	0	0			0	0	0	0	2			0	0	0	6	0			0	0	0	22	0.50	6	1	0
	B323-02	R323	5	10	0	1	0	0			1	0	0	0	0			0	0	0	0	0			1	0	0	0	0			0	0	1	22	0.18	1	0	0
	B332-01	R332	5	10	0	0	0	0			1	0	1	6	0			0	0	0	0	0			0	0	0	0	0			0	1	0	22	0.41	6	1	0
	B332-02	R332	5	10	0	1	0	0			0	0	1	0	0			1	0	0	0	1			0	0	0	1	0			1	0	1	22	0.32	1	0	0
	Interventions	R301			2	9	9	9			4	13	2	5	8			5	11	2	16	7			9	3	6	5	4			5	5	2	22	6.4	16		
	Σ B302 CFU/m³	R302			1	0	0	1			2	8	0	1	3			0	0	1	12	1			1	0	0	1	0			1	1	0	22	1.5	12		

FL-3 interventions vs. summed R302 counts (production days)



Grade B samples with growth, by week



Relation between FL-3 interventions and grade B counts (R302)

Slope	Intercept	R^2	Days
0.535	**-1.88**	**0.48**	**22**

Each additional intervention adds about 0.54 CFU/m³ to the summed grade B result of the four R302 locations (R^2 = 0.48). The two excursions of 08.09. and 17.09. fall on the days with the most interventions.

Week	Samples B	With growth	Rate
Week 36	40	6	15%
Week 37	50	14	28%
Week 38	50	6	12%
Week 39	50	8	16%
Week 40	30	8	27%

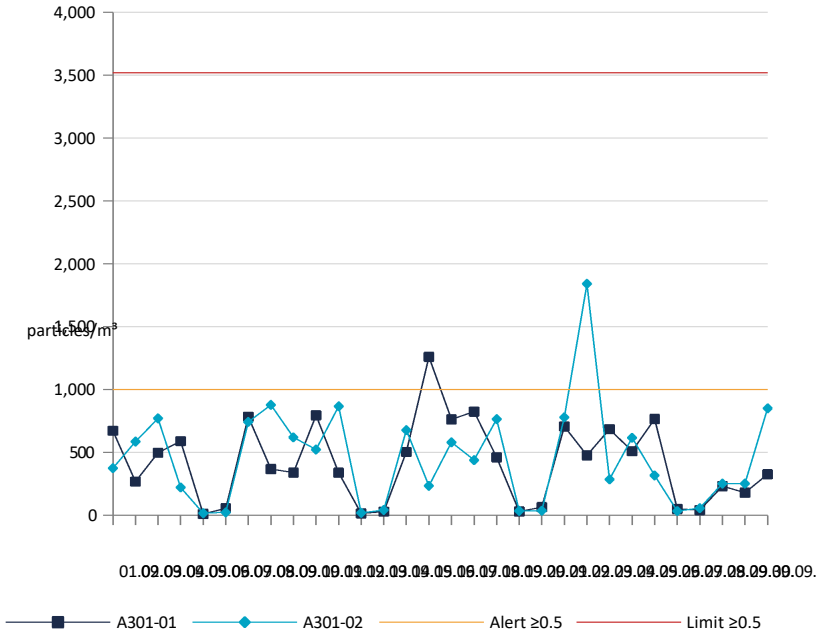
Non-viable particle monitoring, grade A – September 2026

Daily maxima of the continuous monitoring system (1-min samples, 28.3 l/min, MetOne 3400+), particles/m³. Operation on production days, at rest on weekends.

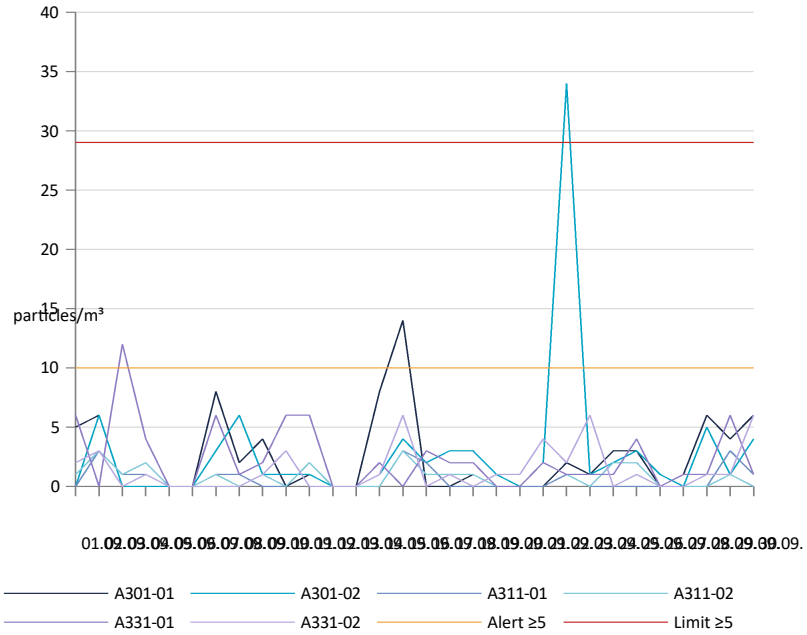
Date	State	≥0.5 µm						≥5 µm						Limits			
		A301-01	A301-02	A311-01	A311-02	A331-01	A331-02	A301-01	A301-02	A311-01	A311-02	A331-01	A331-02	Alert ≥0.5	Limit ≥0.5	Alert ≥5	Limit ≥5
Tue 01.09.2026	Operation	672	375	120	138	263	342	5	0	0	1	6	2	1,000	3,520	10	29
Wed 02.09.2026	Operation	268	586	185	125	158	429	6	6	3	3	0	3	1,000	3,520	10	29
Thu 03.09.2026	Operation	497	770	207	147	720	581	0	0	1	1	12	0	1,000	3,520	10	29
Fri 04.09.2026	Operation	590	222	95	39	445	410	1	0	1	2	4	1	1,000	3,520	10	29
Sat 05.09.2026	At rest	11	17	9	30	17	54	0	0	0	0	0	0	1,000	3,520	10	29
Sun 06.09.2026	At rest	55	24	18	26	20	12	0	0	0	0	0	0	1,000	3,520	10	29
Mon 07.09.2026	Operation	783	743	110	173	379	391	8	3	1	1	6	0	1,000	3,520	10	29
Tue 08.09.2026	Operation	368	878	43	45	197	122	2	6	1	0	1	0	1,000	3,520	10	29
Wed 09.09.2026	Operation	340	620	165	27	454	395	4	1	0	1	2	1	1,000	3,520	10	29
Thu 10.09.2026	Operation	795	523	175	68	101	522	0	1	0	0	6	3	1,000	3,520	10	29
Fri 11.09.2026	Operation	339	867	32	49	85	359	1	1	2	2	6	0	1,000	3,520	10	29
Sat 12.09.2026	At rest	15	19	10	11	33	23	0	0	0	0	0	0	1,000	3,520	10	29
Sun 13.09.2026	At rest	29	42	20	22	50	20	0	0	0	0	0	0	1,000	3,520	10	29
Mon 14.09.2026	Operation	504	678	189	16	187	226	8	1	0	0	2	1	1,000	3,520	10	29
Tue 15.09.2026	Operation	1,260	234	82	210	209	323	14	4	3	3	0	6	1,000	3,520	10	29
Wed 16.09.2026	Operation	763	581	179	22	601	168	0	2	2	1	3	0	1,000	3,520	10	29
Thu 17.09.2026	Operation	825	440	115	133	168	417	0	3	0	1	2	1	1,000	3,520	10	29
Fri 18.09.2026	Operation	461	765	131	44	462	490	1	3	0	1	2	0	1,000	3,520	10	29
Sat 19.09.2026	At rest	30	35	12	22	28	35	0	1	0	0	0	1	1,000	3,520	10	29
Sun 20.09.2026	At rest	65	36	7	14	29	30	0	0	0	0	0	1	1,000	3,520	10	29
Mon 21.09.2026	Operation	707	780	136	63	588	442	0	2	0	2	2	4	1,000	3,520	10	29
Tue 22.09.2026	Operation	477	1,840	43	204	546	224	2	34	1	1	1	2	1,000	3,520	10	29
Wed 23.09.2026	Operation	685	286	106	199	136	281	1	1	0	0	1	6	1,000	3,520	10	29
Thu 24.09.2026	Operation	510	617	181	66	330	599	3	2	0	2	1	0	1,000	3,520	10	29
Fri 25.09.2026	Operation	766	317	15	85	487	418	3	3	0	2	4	1	1,000	3,520	10	29
Sat 26.09.2026	At rest	51	34	20	3	9	31	0	1	0	0	0	0	1,000	3,520	10	29
Sun 27.09.2026	At rest	41	57	24	15	13	7	1	0	0	0	1	0	1,000	3,520	10	29
Mon 28.09.2026	Operation	232	253	175	203	291	600	6	5	0	0	1	1	1,000	3,520	10	29
Tue 29.09.2026	Operation	180	253	60	129	308	328	4	1	3	1	6	1	1,000	3,520	10	29
Wed 30.09.2026	Operation	326	851	15	130	475	441	6	4	1	0	1	6	1,000	3,520	10	29

Mean in operation		561	613	116	105	345	387	3	4	1	1	3	2				
95th percentile		812	873	187	204	595	591	8	6	3	3	6	6				
Maximum		1,260	1,840	207	210	720	600	14	34	3	3	12	6				
Days above alert		1	1	0	0	0	0	1	1	0	0	1	0				
Days above limit		0	0	0	0	0	0	0	1	0	0	0	0				

≥0.5 µm daily maximum, FL-3 RABS, with alert and limit



≥5 µm daily maximum, all grade A points, with alert and limit



Samples by month, room and method

Monthly totals per room and method. Alert- and action-level counts are counted from the excursion log; September active air of grade A/B rooms is linked to the Viable sheet.

Month	Room	Grade	Method	Samples	With growth	Mean CFU	Max CFU	Alert-level	Action-level	Excursions	Within limits	Recovery rate
Apr 2026	R301	A	Active air	88	0	0.00	0	0	0	0	100.0%	0.0%
Apr 2026	R301	A	Settle plate	88	0	0.00	0	0	0	0	100.0%	0.0%
Apr 2026	R301	A	Contact plate	44	0	0.00	0	0	0	0	100.0%	0.0%
Apr 2026	R301	A	Glove print	132	1	0.01	1	0	1	1	99.2%	0.8%
Apr 2026	R302	B	Active air	88	22	0.35	2	0	0	0	100.0%	25.0%
Apr 2026	R302	B	Settle plate	88	23	0.33	1	0	0	0	100.0%	26.1%
Apr 2026	R302	B	Contact plate	66	15	0.36	1	0	0	0	100.0%	22.7%
Apr 2026	R303	C	Active air	9	4	0.67	41	0	0	0	100.0%	44.4%
Apr 2026	R303	C	Contact plate	18	5	0.49	6	0	0	0	100.0%	27.8%
Apr 2026	R311	A	Active air	88	0	0.00	0	0	0	0	100.0%	0.0%
Apr 2026	R311	A	Settle plate	88	1	0.01	1	0	1	1	98.9%	1.1%
Apr 2026	R311	A	Contact plate	44	0	0.00	0	0	0	0	100.0%	0.0%
Apr 2026	R311	A	Glove print	132	0	0.00	0	0	0	0	100.0%	0.0%
Apr 2026	R312	C	Active air	9	4	0.67	40	0	0	0	100.0%	44.4%
Apr 2026	R312	C	Contact plate	18	6	0.46	5	0	0	0	100.0%	33.3%
Apr 2026	R321	C	Active air	13	6	0.70	25	0	0	0	100.0%	46.2%
Apr 2026	R321	C	Contact plate	26	9	0.43	16	1	0	1	96.2%	34.6%
Apr 2026	R322	B	Active air	44	10	0.33	3	0	0	0	100.0%	22.7%
Apr 2026	R322	B	Settle plate	44	7	0.27	4	1	0	1	97.7%	15.9%
Apr 2026	R322	B	Contact plate	66	16	0.40	4	1	0	1	98.5%	24.2%
Apr 2026	R323	B	Active air	44	7	0.23	7	1	0	1	97.7%	15.9%
Apr 2026	R323	B	Settle plate	44	11	0.38	1	0	0	0	100.0%	25.0%
Apr 2026	R323	B	Contact plate	66	14	0.35	2	0	0	0	100.0%	21.2%
Apr 2026	R331	A	Active air	44	0	0.00	0	0	0	0	100.0%	0.0%
Apr 2026	R331	A	Settle plate	44	0	0.00	0	0	0	0	100.0%	0.0%
Apr 2026	R331	A	Contact plate	44	0	0.00	0	0	0	0	100.0%	0.0%
Apr 2026	R331	A	Glove print	132	0	0.00	0	0	0	0	100.0%	0.0%
Apr 2026	R332	B	Active air	44	7	0.28	2	0	0	0	100.0%	15.9%
Apr 2026	R332	B	Settle plate	44	11	0.45	2	0	0	0	100.0%	25.0%
Apr 2026	R332	B	Contact plate	66	18	0.41	1	0	0	0	100.0%	27.3%
May 2026	R301	A	Active air	84	1	0.01	1	0	1	1	98.8%	1.2%
May 2026	R301	A	Settle plate	84	0	0.00	0	0	0	0	100.0%	0.0%
May 2026	R301	A	Contact plate	42	0	0.00	0	0	0	0	100.0%	0.0%
May 2026	R301	A	Glove print	126	0	0.00	0	0	0	0	100.0%	0.0%
May 2026	R302	B	Active air	84	18	0.35	3	0	0	0	100.0%	21.4%
May 2026	R302	B	Settle plate	84	17	0.36	1	0	0	0	100.0%	20.2%
May 2026	R302	B	Contact plate	63	13	0.25	6	0	1	1	98.4%	20.6%
May 2026	R303	C	Active air	8	4	0.64	58	1	0	1	87.5%	50.0%
May 2026	R303	C	Contact plate	17	9	0.85	5	0	0	0	100.0%	52.9%
May 2026	R311	A	Active air	84	0	0.00	0	0	0	0	100.0%	0.0%
May 2026	R311	A	Settle plate	84	0	0.00	0	0	0	0	100.0%	0.0%
May 2026	R311	A	Contact plate	42	0	0.00	0	0	0	0	100.0%	0.0%
May 2026	R311	A	Glove print	126	0	0.00	0	0	0	0	100.0%	0.0%
May 2026	R312	C	Active air	8	3	0.61	22	0	0	0	100.0%	37.5%
May 2026	R312	C	Contact plate	17	6	0.44	10	0	0	0	100.0%	35.3%
May 2026	R321	C	Active air	13	7	0.94	38	0	0	0	100.0%	53.8%
May 2026	R321	C	Contact plate	25	11	0.54	8	0	0	0	100.0%	44.0%
May 2026	R322	B	Active air	42	10	0.39	2	0	0	0	100.0%	23.8%
May 2026	R322	B	Settle plate	42	6	0.18	2	0	0	0	100.0%	14.3%

Month	Room	Grade	Method	Samples	With growth	Mean CFU	Max CFU	Alert-level	Action-level	Excursions	Within limits	Recovery rate
May 2026	R322	B	Contact plate	63	10	0.23	1	0	0	0	100.0%	15.9%
May 2026	R323	B	Active air	42	11	0.34	2	0	0	0	100.0%	26.2%
May 2026	R323	B	Settle plate	42	10	0.30	1	0	0	0	100.0%	23.8%
May 2026	R323	B	Contact plate	63	9	0.25	1	0	0	0	100.0%	14.3%
May 2026	R331	A	Active air	42	0	0.00	0	0	0	0	100.0%	0.0%
May 2026	R331	A	Settle plate	42	0	0.00	0	0	0	0	100.0%	0.0%
May 2026	R331	A	Contact plate	42	0	0.00	0	0	0	0	100.0%	0.0%
May 2026	R331	A	Glove print	126	0	0.00	0	0	0	0	100.0%	0.0%
May 2026	R332	B	Active air	42	9	0.31	8	2	0	2	95.2%	21.4%
May 2026	R332	B	Settle plate	42	10	0.37	1	0	0	0	100.0%	23.8%
May 2026	R332	B	Contact plate	63	11	0.30	1	0	0	0	100.0%	17.5%
Jun 2026	R301	A	Active air	88	0	0.00	0	0	0	0	100.0%	0.0%
Jun 2026	R301	A	Settle plate	88	0	0.00	0	0	0	0	100.0%	0.0%
Jun 2026	R301	A	Contact plate	44	0	0.00	0	0	0	0	100.0%	0.0%
Jun 2026	R301	A	Glove print	132	0	0.00	0	0	0	0	100.0%	0.0%
Jun 2026	R302	B	Active air	88	20	0.31	2	0	0	0	100.0%	22.7%
Jun 2026	R302	B	Settle plate	88	18	0.27	2	0	0	0	100.0%	20.5%
Jun 2026	R302	B	Contact plate	66	10	0.18	4	1	0	1	98.5%	15.2%
Jun 2026	R303	C	Active air	9	3	0.58	32	0	0	0	100.0%	33.3%
Jun 2026	R303	C	Contact plate	18	8	0.74	14	1	0	1	94.4%	44.4%
Jun 2026	R311	A	Active air	88	0	0.00	0	0	0	0	100.0%	0.0%
Jun 2026	R311	A	Settle plate	88	0	0.00	0	0	0	0	100.0%	0.0%
Jun 2026	R311	A	Contact plate	44	1	0.02	1	0	1	1	97.7%	2.3%
Jun 2026	R311	A	Glove print	132	0	0.00	0	0	0	0	100.0%	0.0%
Jun 2026	R312	C	Active air	9	5	0.79	31	0	0	0	100.0%	55.6%
Jun 2026	R312	C	Contact plate	18	8	0.72	10	0	0	0	100.0%	44.4%
Jun 2026	R321	C	Active air	13	4	0.52	30	0	0	0	100.0%	30.8%
Jun 2026	R321	C	Contact plate	26	9	0.59	10	0	0	0	100.0%	34.6%
Jun 2026	R322	B	Active air	44	11	0.35	4	0	0	0	100.0%	25.0%
Jun 2026	R322	B	Settle plate	44	11	0.45	2	0	0	0	100.0%	25.0%
Jun 2026	R322	B	Contact plate	66	18	0.41	2	0	0	0	100.0%	27.3%
Jun 2026	R323	B	Active air	44	11	0.38	3	0	0	0	100.0%	25.0%
Jun 2026	R323	B	Settle plate	44	9	0.35	4	1	0	1	97.7%	20.5%
Jun 2026	R323	B	Contact plate	66	16	0.37	2	0	0	0	100.0%	24.2%
Jun 2026	R331	A	Active air	44	0	0.00	0	0	0	0	100.0%	0.0%
Jun 2026	R331	A	Settle plate	44	0	0.00	0	0	0	0	100.0%	0.0%
Jun 2026	R331	A	Contact plate	44	0	0.00	0	0	0	0	100.0%	0.0%
Jun 2026	R331	A	Glove print	132	0	0.00	0	0	0	0	100.0%	0.0%
Jun 2026	R332	B	Active air	44	8	0.23	6	1	0	1	97.7%	18.2%
Jun 2026	R332	B	Settle plate	44	7	0.23	2	0	0	0	100.0%	15.9%
Jun 2026	R332	B	Contact plate	66	10	0.26	2	0	0	0	100.0%	15.2%
Jul 2026	R301	A	Active air	92	0	0.00	0	0	0	0	100.0%	0.0%
Jul 2026	R301	A	Settle plate	92	1	0.01	1	0	1	1	98.9%	1.1%
Jul 2026	R301	A	Contact plate	46	0	0.00	0	0	0	0	100.0%	0.0%
Jul 2026	R301	A	Glove print	138	0	0.00	0	0	0	0	100.0%	0.0%
Jul 2026	R302	B	Active air	92	20	0.35	2	0	0	0	100.0%	21.7%
Jul 2026	R302	B	Settle plate	92	14	0.25	2	0	0	0	100.0%	15.2%
Jul 2026	R302	B	Contact plate	69	16	0.39	1	0	0	0	100.0%	23.2%
Jul 2026	R303	C	Active air	9	3	0.59	21	0	0	0	100.0%	33.3%
Jul 2026	R303	C	Contact plate	18	8	0.70	11	0	0	0	100.0%	44.4%
Jul 2026	R311	A	Active air	92	0	0.00	0	0	0	0	100.0%	0.0%
Jul 2026	R311	A	Settle plate	92	0	0.00	0	0	0	0	100.0%	0.0%
Jul 2026	R311	A	Contact plate	46	0	0.00	0	0	0	0	100.0%	0.0%
Jul 2026	R311	A	Glove print	138	0	0.00	0	0	0	0	100.0%	0.0%

Month	Room	Grade	Method	Samples	With growth	Mean CFU	Max CFU	Alert-level	Action-level	Excursions	Within limits	Recovery rate
Jul 2026	R312	C	Active air	9	3	0.54	21	0	0	0	100.0%	33.3%
Jul 2026	R312	C	Contact plate	18	7	0.61	10	0	0	0	100.0%	38.9%
Jul 2026	R321	C	Active air	14	4	0.47	54	1	0	1	92.9%	28.6%
Jul 2026	R321	C	Contact plate	28	11	0.70	10	0	0	0	100.0%	39.3%
Jul 2026	R322	B	Active air	46	7	0.18	11	0	1	1	97.8%	15.2%
Jul 2026	R322	B	Settle plate	46	11	0.29	4	1	0	1	97.8%	23.9%
Jul 2026	R322	B	Contact plate	69	17	0.42	4	1	0	1	98.6%	24.6%
Jul 2026	R323	B	Active air	46	10	0.37	3	0	0	0	100.0%	21.7%
Jul 2026	R323	B	Settle plate	46	11	0.30	2	0	0	0	100.0%	23.9%
Jul 2026	R323	B	Contact plate	69	19	0.39	2	0	0	0	100.0%	27.5%
Jul 2026	R331	A	Active air	46	0	0.00	0	0	0	0	100.0%	0.0%
Jul 2026	R331	A	Settle plate	46	0	0.00	0	0	0	0	100.0%	0.0%
Jul 2026	R331	A	Contact plate	46	0	0.00	0	0	0	0	100.0%	0.0%
Jul 2026	R331	A	Glove print	138	1	0.01	2	0	1	1	99.3%	0.7%
Jul 2026	R332	B	Active air	46	8	0.26	6	1	0	1	97.8%	17.4%
Jul 2026	R332	B	Settle plate	46	11	0.33	1	0	0	0	100.0%	23.9%
Jul 2026	R332	B	Contact plate	69	12	0.27	2	0	0	0	100.0%	17.4%
Aug 2026	R301	A	Active air	84	0	0.00	0	0	0	0	100.0%	0.0%
Aug 2026	R301	A	Settle plate	84	0	0.00	0	0	0	0	100.0%	0.0%
Aug 2026	R301	A	Contact plate	42	0	0.00	0	0	0	0	100.0%	0.0%
Aug 2026	R301	A	Glove print	126	0	0.00	0	0	0	0	100.0%	0.0%
Aug 2026	R302	B	Active air	84	17	0.32	7	1	0	1	98.8%	20.2%
Aug 2026	R302	B	Settle plate	84	15	0.29	1	0	0	0	100.0%	17.9%
Aug 2026	R302	B	Contact plate	63	14	0.40	4	1	0	1	98.4%	22.2%
Aug 2026	R303	C	Active air	8	3	0.53	36	0	0	0	100.0%	37.5%
Aug 2026	R303	C	Contact plate	17	6	0.53	10	0	0	0	100.0%	35.3%
Aug 2026	R311	A	Active air	84	0	0.00	0	0	0	0	100.0%	0.0%
Aug 2026	R311	A	Settle plate	84	0	0.00	0	0	0	0	100.0%	0.0%
Aug 2026	R311	A	Contact plate	42	0	0.00	0	0	0	0	100.0%	0.0%
Aug 2026	R311	A	Glove print	126	0	0.00	0	0	0	0	100.0%	0.0%
Aug 2026	R312	C	Active air	8	2	0.35	25	0	0	0	100.0%	25.0%
Aug 2026	R312	C	Contact plate	17	6	0.57	10	0	0	0	100.0%	35.3%
Aug 2026	R321	C	Active air	13	5	0.56	27	0	0	0	100.0%	38.5%
Aug 2026	R321	C	Contact plate	25	9	0.64	15	1	0	1	96.0%	36.0%
Aug 2026	R322	B	Active air	42	10	0.33	2	0	0	0	100.0%	23.8%
Aug 2026	R322	B	Settle plate	42	6	0.20	6	0	1	1	97.6%	14.3%
Aug 2026	R322	B	Contact plate	63	14	0.35	2	0	0	0	100.0%	22.2%
Aug 2026	R323	B	Active air	42	11	0.44	6	1	0	1	97.6%	26.2%
Aug 2026	R323	B	Settle plate	42	10	0.36	1	0	0	0	100.0%	23.8%
Aug 2026	R323	B	Contact plate	63	17	0.47	1	0	0	0	100.0%	27.0%
Aug 2026	R331	A	Active air	42	1	0.02	1	0	1	1	97.6%	2.4%
Aug 2026	R331	A	Settle plate	42	0	0.00	0	0	0	0	100.0%	0.0%
Aug 2026	R331	A	Contact plate	42	0	0.00	0	0	0	0	100.0%	0.0%
Aug 2026	R331	A	Glove print	126	0	0.00	0	0	0	0	100.0%	0.0%
Aug 2026	R332	B	Active air	42	11	0.38	3	0	0	0	100.0%	26.2%
Aug 2026	R332	B	Settle plate	42	6	0.22	2	0	0	0	100.0%	14.3%
Aug 2026	R332	B	Contact plate	63	13	0.36	2	0	0	0	100.0%	20.6%
Sep 2026	R301	A	Active air	88	1	0.01	1	0	1	1	98.9%	1.1%
Sep 2026	R301	A	Settle plate	88	0	0.00	0	0	0	0	100.0%	0.0%
Sep 2026	R301	A	Contact plate	44	0	0.00	0	0	0	0	100.0%	0.0%
Sep 2026	R301	A	Glove print	132	0	0.00	0	0	0	0	100.0%	0.0%
Sep 2026	R302	B	Active air	88	16	0.39	12	1	1	2	97.7%	18.2%
Sep 2026	R302	B	Settle plate	88	24	0.43	2	0	0	0	100.0%	27.3%
Sep 2026	R302	B	Contact plate	66	17	0.36	1	0	0	0	100.0%	25.8%

Month	Room	Grade	Method	Samples	With growth	Mean CFU	Max CFU	Alert-level	Action-level	Excursions	Within limits	Recovery rate
Sep 2026	R303	C	Active air	9	3	0.58	24	0	0	0	100.0%	33.3%
Sep 2026	R303	C	Contact plate	18	8	0.61	7	0	0	0	100.0%	44.4%
Sep 2026	R311	A	Active air	88	1	0.01	1	0	1	1	98.9%	1.1%
Sep 2026	R311	A	Settle plate	88	0	0.00	0	0	0	0	100.0%	0.0%
Sep 2026	R311	A	Contact plate	44	0	0.00	0	0	0	0	100.0%	0.0%
Sep 2026	R311	A	Glove print	132	0	0.00	0	0	0	0	100.0%	0.0%
Sep 2026	R312	C	Active air	9	3	0.58	26	0	0	0	100.0%	33.3%
Sep 2026	R312	C	Contact plate	18	9	0.65	7	0	0	0	100.0%	50.0%
Sep 2026	R321	C	Active air	13	4	0.48	32	0	0	0	100.0%	30.8%
Sep 2026	R321	C	Contact plate	26	11	0.56	9	0	0	0	100.0%	42.3%
Sep 2026	R322	B	Active air	44	7	0.18	2	0	0	0	100.0%	15.9%
Sep 2026	R322	B	Settle plate	44	10	0.33	1	0	0	0	100.0%	22.7%
Sep 2026	R322	B	Contact plate	66	10	0.25	1	0	0	0	100.0%	15.2%
Sep 2026	R323	B	Active air	44	8	0.34	6	1	0	1	97.7%	18.2%
Sep 2026	R323	B	Settle plate	44	9	0.31	2	0	0	0	100.0%	20.5%
Sep 2026	R323	B	Contact plate	66	17	0.31	2	0	0	0	100.0%	25.8%
Sep 2026	R331	A	Active air	44	0	0.00	0	0	0	0	100.0%	0.0%
Sep 2026	R331	A	Settle plate	44	0	0.00	0	0	0	0	100.0%	0.0%
Sep 2026	R331	A	Contact plate	44	0	0.00	0	0	0	0	100.0%	0.0%
Sep 2026	R331	A	Glove print	132	0	0.00	0	0	0	0	100.0%	0.0%
Sep 2026	R332	B	Active air	44	11	0.36	6	1	0	1	97.7%	25.0%
Sep 2026	R332	B	Settle plate	44	11	0.42	1	0	0	0	100.0%	25.0%
Sep 2026	R332	B	Contact plate	66	18	0.34	2	0	0	0	100.0%	27.3%
Total				**10,507**	**1,127**			**22**	**13**	**35**	**99.7%**	**10.7%**

Excursion log, April – September 2026

All results above an alert or action limit (viable and non-viable). Action-level results are handled as deviations; affected batches are on hold until the investigation is closed.

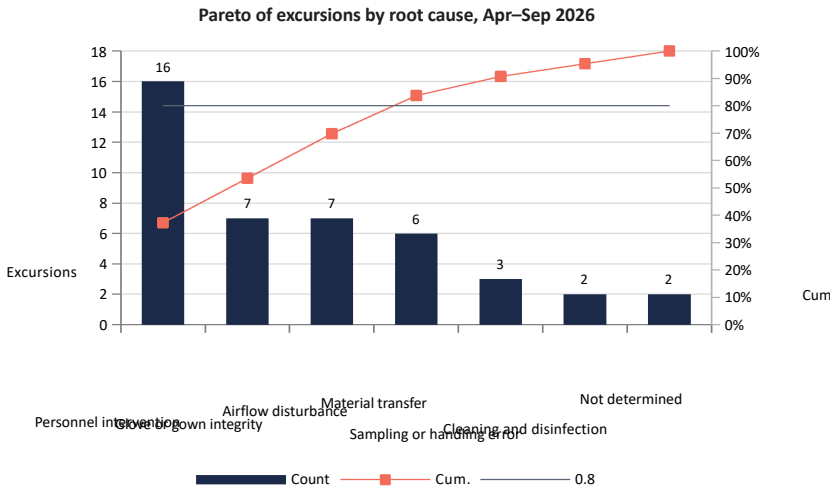
ID	Date	Time	Month	Location	Room	Grade	Method	Result	Unit	Alert	Action	Organism / finding	Root cause	Deviation	Batch	Value on hold CHF	Status	Closed on	Level
EM-26-041	02.04.2026	07:42	Apr 2026	B323-02	R323	B	Active air	**7**	*CFU/m³*	5	10	*Staphylococcus epidermidis*	Personnel intervention	–	–		Closed	19.04.2026	Alert
EM-26-042	06.04.2026	09:05	Apr 2026	B322-02	R322	B	Contact plate	**4**	*CFU/plate*	3	5	*Micrococcus luteus*	Sampling or handling error	–	–		Closed	06.05.2026	Alert
EM-26-043	13.04.2026	10:30	Apr 2026	B322-01	R322	B	Settle plate	**4**	*CFU/4 h*	3	5	*Staphylococcus hominis*	Personnel intervention	–	–		Closed	11.05.2026	Alert
EM-26-044	20.04.2026	08:15	Apr 2026	A301-02	R301	A	Glove print	**1**	*CFU/glove*	0	0	*Staphylococcus epidermidis*	Glove or gown integrity	DEV-26-0421	CVB0217-26-009	CHF 1,740,000	Closed	30.04.2026	Action
EM-26-045	21.04.2026	11:12	Apr 2026	A311-04	R311	A	Settle plate	**1**	*CFU/4 h*	0	0	*Cutibacterium acnes*	Personnel intervention	DEV-26-0424	CVB0217-26-009	CHF 1,865,000	Closed	21.05.2026	Action
EM-26-046	22.04.2026	09:48	Apr 2026	C321-02	R321	C	Contact plate	**16**	*CFU/plate*	13	25	*Bacillus cereus*	Cleaning and disinfection	–	–		Closed	14.05.2026	Alert
EM-26-047	04.05.2026	16:02	May 2026	B332-02	R332	B	Active air	**8**	*CFU/m³*	5	10	*Penicillium chrysogenum*	Airflow disturbance	–	–		Closed	29.05.2026	Alert
EM-26-048	04.05.2026	21:20	May 2026	A301-02	R301	A	Particles ≥5 µm	**13**	*particles/m³*	10	29	*Non-viable*	Material transfer	–	CVB0217-26-013		Closed	13.05.2026	Alert
EM-26-049	08.05.2026	14:25	May 2026	B302-04	R302	B	Contact plate	**6**	*CFU/plate*	3	5	*Staphylococcus epidermidis*	Glove or gown integrity	DEV-26-0436	–		Closed	25.05.2026	Action
EM-26-050	14.05.2026	15:10	May 2026	A301-02	R301	A	Active air	**1**	*CFU/m³*	0	0	*Staphylococcus epidermidis*	Personnel intervention	DEV-26-0439	CVB0217-26-012	CHF 1,940,000	Closed	28.05.2026	Action
EM-26-051	21.05.2026	18:35	May 2026	C303-01	R303	C	Active air	**58**	*CFU/m³*	50	100	*Penicillium chrysogenum*	Airflow disturbance	–	–		Closed	08.06.2026	Alert
EM-26-052	26.05.2026	13:40	May 2026	B332-01	R332	B	Active air	**6**	*CFU/m³*	5	10	*Micrococcus luteus*	Material transfer	–	–		Closed	21.06.2026	Alert
EM-26-053	05.06.2026	08:15	Jun 2026	A311-02	R311	A	Contact plate	**1**	*CFU/plate*	0	0	*Staphylococcus hominis*	Glove or gown integrity	DEV-26-0448	CVB0217-26-014	CHF 1,965,000	Closed	06.07.2026	Action
EM-26-054	16.06.2026	09:48	Jun 2026	B332-01	R332	B	Active air	**6**	*CFU/m³*	5	10	*Corynebacterium sp.*	Personnel intervention	–	–		Closed	11.07.2026	Alert
EM-26-055	19.06.2026	09:05	Jun 2026	B302-04	R302	B	Contact plate	**4**	*CFU/plate*	3	5	*Staphylococcus epidermidis*	Glove or gown integrity	–	–		Closed	16.07.2026	Alert
EM-26-056	22.06.2026	07:42	Jun 2026	B323-01	R323	B	Settle plate	**4**	*CFU/4 h*	3	5	*Kocuria rhizophila*	Personnel intervention	–	–		Closed	09.07.2026	Alert
EM-26-057	26.06.2026	10:30	Jun 2026	A301-02	R301	A	Particles ≥5 µm	**31**	*particles/m³*	10	29	*Non-viable*	Material transfer	DEV-26-0460	CVB0217-26-014		Closed	10.07.2026	Action
EM-26-058	26.06.2026	11:12	Jun 2026	C303-01	R303	C	Contact plate	**14**	*CFU/plate*	13	25	*Micrococcus luteus*	Sampling or handling error	–	–		Closed	26.07.2026	Alert
EM-26-059	02.07.2026	21:20	Jul 2026	A331-02	R331	A	Glove print	**2**	*CFU/glove*	0	0	*Staphylococcus hominis*	Glove or gown integrity	DEV-26-0466	CVB0217-26-019	CHF 1,840,000	Closed	17.07.2026	Action
EM-26-060	06.07.2026	13:40	Jul 2026	B322-02	R322	B	Active air	**11**	*CFU/m³*	5	10	*Staphylococcus epidermidis*	Personnel intervention	DEV-26-0469	–		Closed	26.07.2026	Action
EM-26-061	06.07.2026	16:02	Jul 2026	B332-02	R332	B	Active air	**6**	*CFU/m³*	5	10	*Micrococcus luteus*	Not determined	–	–		Closed	26.07.2026	Alert
EM-26-062	06.07.2026	18:35	Jul 2026	C321-01	R321	C	Active air	**54**	*CFU/m³*	50	100	*Penicillium chrysogenum*	Airflow disturbance	–	–		Closed	24.07.2026	Alert
EM-26-063	09.07.2026	07:42	Jul 2026	B322-01	R322	B	Settle plate	**4**	*CFU/4 h*	3	5	*Staphylococcus epidermidis*	Personnel intervention	–	–		Closed	18.07.2026	Alert
EM-26-064	16.07.2026	14:25	Jul 2026	A301-02	R301	A	Settle plate	**1**	*CFU/4 h*	0	0	*Cutibacterium acnes*	Personnel intervention	DEV-26-0481	CVB0217-26-019	CHF 1,915,000	Closed	29.07.2026	Action
EM-26-065	27.07.2026	15:10	Jul 2026	B322-02	R322	B	Contact plate	**4**	*CFU/plate*	3	5	*Bacillus cereus*	Material transfer	–	–		Closed	14.08.2026	Alert
EM-26-066	07.08.2026	08:15	Aug 2026	B302-01	R302	B	Active air	**7**	*CFU/m³*	5	10	*Kocuria rhizophila*	Material transfer	–	–		Closed	25.08.2026	Alert
EM-26-067	10.08.2026	13:40	Aug 2026	B322-01	R322	B	Settle plate	**6**	*CFU/4 h*	3	5	*Cutibacterium acnes*	Personnel intervention	DEV-26-0490	–		Closed	13.09.2026	Action
EM-26-068	11.08.2026	10:30	Aug 2026	A301-02	R301	A	Particles ≥0.5 µm	**1,210**	*particles/m³*	1,000	3,520	*Non-viable*	Airflow disturbance	–	CVB0217-26-020		Closed	28.08.2026	Alert
EM-26-069	18.08.2026	11:12	Aug 2026	C321-01	R321	C	Contact plate	**15**	*CFU/plate*	13	25	*Corynebacterium sp.*	Cleaning and disinfection	–	–		Closed	09.09.2026	Alert
EM-26-070	20.08.2026	09:48	Aug 2026	B302-01	R302	B	Contact plate	**4**	*CFU/plate*	3	5	*Staphylococcus epidermidis*	Glove or gown integrity	–	–		Closed	09.09.2026	Alert
EM-26-071	24.08.2026	09:05	Aug 2026	A331-02	R331	A	Active air	**1**	*CFU/m³*	0	0	*Micrococcus luteus*	Sampling or handling error	DEV-26-0502	CVB0217-26-022	CHF 1,990,000	Closed	26.09.2026	Action
EM-26-072	27.08.2026	14:25	Aug 2026	B323-02	R323	B	Active air	**6**	*CFU/m³*	5	10	*Micrococcus luteus*	Not determined	–	–		Closed	19.09.2026	Alert
EM-26-073	03.09.2026	10:13	Sep 2026	A331-01	R331	A	Particles ≥5 µm	**12**	*particles/m³*	10	29	*Non-viable*	Personnel intervention	–	CVB0217-26-026		Closed	09.09.2026	Alert
EM-26-074	08.09.2026	15:10	Sep 2026	B302-01	R302	B	Active air	**7**	*CFU/m³*	5	10	*Cutibacterium acnes*	Personnel intervention	–	–		Closed	20.09.2026	Alert
EM-26-075	10.09.2026	18:35	Sep 2026	B332-01	R332	B	Active air	**6**	*CFU/m³*	5	10	*Kocuria rhizophila*	Airflow disturbance	–	–		Closed	22.09.2026	Alert
EM-26-076	15.09.2026	10:25	Sep 2026	A301-01	R301	A	Particles ≥5 µm	**14**	*particles/m³*	10	29	*Non-viable*	Personnel intervention	–	CVB0217-26-027		Closed	21.09.2026	Alert
EM-26-077	15.09.2026	10:27	Sep 2026	A301-01	R301	A	Particles ≥0.5 µm	**1,260**	*particles/m³*	1,000	3,520	*Non-viable*	Personnel intervention	–	CVB0217-26-027		Closed	21.09.2026	Alert
EM-26-078	15.09.2026	16:02	Sep 2026	A301-01	R301	A	Active air	**1**	*CFU/m³*	0	0	*Staphylococcus epidermidis*	Personnel intervention	DEV-26-0523	CVB0217-26-027	CHF 1,865,000	Closed	27.09.2026	Action
EM-26-079	17.09.2026	21:20	Sep 2026	B302-02	R302	B	Active air	**12**	*CFU/m³*	5	10	*Staphylococcus epidermidis*	Personnel intervention	DEV-26-0526	–		Open		Action
EM-26-080	22.09.2026	10:32	Sep 2026	A301-02	R301	A	Particles ≥5 µm	**34**	*particles/m³*	10	29	*Non-viable*	Airflow disturbance	DEV-26-0529	CVB0217-26-028		Open		Action
EM-26-081	22.09.2026	10:34	Sep 2026	A301-02	R301	A	Particles ≥0.5 µm	**1,840**	*particles/m³*	1,000	3,520	*Non-viable*	Airflow disturbance	–	CVB0217-26-028		Open		Alert
EM-26-082	23.09.2026	11:12	Sep 2026	A311-04	R311	A	Active air	**1**	*CFU/m³*	0	0	*Micrococcus luteus*	Material transfer	DEV-26-0535	CVB0217-26-028	CHF 1,865,000	Open		Action
EM-26-083	24.09.2026	07:42	Sep 2026	B323-01	R323	B	Active air	**6**	*CFU/m³*	5	10	*Staphylococcus hominis*	Glove or gown integrity	–	–		Open		Alert

Pareto of excursions by root cause

Root cause	Count	Share	Cum.	0.8
Personnel intervention	16	37%	37%	80%
Glove or gown integrity	7	16%	53%	80%
Airflow disturbance	7	16%	70%	80%
Material transfer	6	14%	84%	80%
Sampling or handling error	3	7%	91%	80%
Cleaning and disinfection	2	5%	95%	80%
Not determined	2	5%	100%	80%

Excursions by grade and level

Grade	Alert	Action	Total
A	6	11	17
B	17	4	21
C	5	0	5
Total	**28**	**15**	**43**



Statistics, September 2026

Active air per location (Viable sheet) and particle counts per point (Particles sheet); percentages computed with array formulas.

A. Active air per location

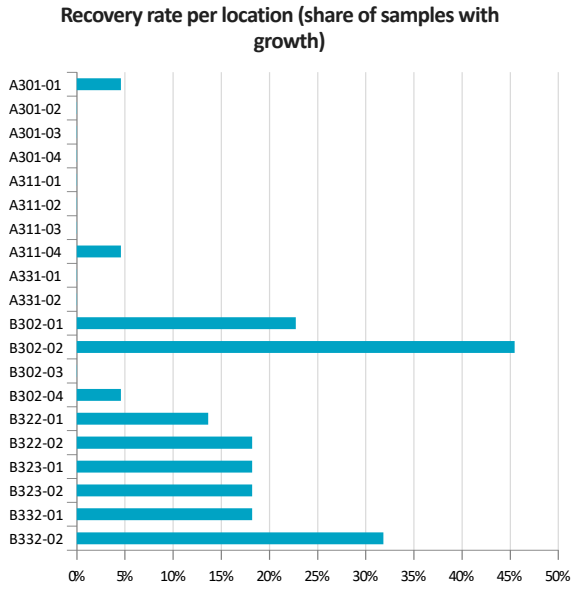
Location	Room	Grade	Samples	Mean	Median	P90	P95	Max	Recovery rate	Above alert
A301-01	R301	A	22	0.05	0.00	0.00	0.00	1	4.5%	4.5%
A301-02	R301	A	22	0.00	0.00	0.00	0.00	0	0.0%	0.0%
A301-03	R301	A	22	0.00	0.00	0.00	0.00	0	0.0%	0.0%
A301-04	R301	A	22	0.00	0.00	0.00	0.00	0	0.0%	0.0%
A311-01	R311	A	22	0.00	0.00	0.00	0.00	0	0.0%	0.0%
A311-02	R311	A	22	0.00	0.00	0.00	0.00	0	0.0%	0.0%
A311-03	R311	A	22	0.00	0.00	0.00	0.00	0	0.0%	0.0%
A311-04	R311	A	22	0.05	0.00	0.00	0.00	1	4.5%	4.5%
A331-01	R331	A	22	0.00	0.00	0.00	0.00	0	0.0%	0.0%
A331-02	R331	A	22	0.00	0.00	0.00	0.00	0	0.0%	0.0%
B302-01	R302	B	22	0.50	0.00	1.00	1.00	7	22.7%	4.5%
B302-02	R302	B	22	0.95	0.00	1.00	1.00	12	45.5%	4.5%
B302-03	R302	B	22	0.00	0.00	0.00	0.00	0	0.0%	0.0%
B302-04	R302	B	22	0.09	0.00	0.00	0.00	2	4.5%	0.0%
B322-01	R322	B	22	0.18	0.00	0.90	1.00	2	13.6%	0.0%
B322-02	R322	B	22	0.18	0.00	1.00	1.00	1	18.2%	0.0%
B323-01	R323	B	22	0.50	0.00	1.90	2.00	6	18.2%	4.5%
B323-02	R323	B	22	0.18	0.00	1.00	1.00	1	18.2%	0.0%
B332-01	R332	B	22	0.41	0.00	1.00	1.00	6	18.2%	4.5%
B332-02	R332	B	22	0.32	0.00	1.00	1.00	1	31.8%	0.0%

B. Particles per point (operation days)

Point	Mean ≥0.5	P95 ≥0.5	Mean ≥5	P95 ≥5	Compliance
A301-01	561	824	3.4	8.0	96.7%
A301-02	613	877	3.8	6.0	96.7%
A311-01	116	189	0.9	3.0	100.0%
A311-02	105	204	1.1	3.0	100.0%
A331-01	345	600	3.1	6.0	96.7%
A331-02	387	598	1.8	6.0	100.0%

C. Within-limit rate by grade (Apr–Sep)

Grade	Samples	Excursions	In limits	Target
A	5,764	9	99.84%	99.90%
B	4,192	21	99.50%	99.00%
C	551	5	99.09%	98.00%



Excursions by room and month

DataPilot tables on the Samples and Excursions sheets (Data ▸ Pivot Table ▸ Refresh after changes).

Excursions by room and month (count)

Level - all -

Excursions	Month						
Room	Apr 2026	May 2026	Jun 2026	Jul 2026	Aug 2026	Sep 2026	**Total Result**
R301	1	2	1	1	1	5	**11**
R302		1	1		2	2	**6**
R303		1	1				**2**
R311	1		1			1	**3**
R321	1			1	1		**3**
R322	2			3	1		**6**
R323	1		1		1	1	**4**
R331				1	1	1	**3**
R332		2	1	1		1	**5**
Total Result	**6**	**6**	**6**	**7**	**7**	**11**	**43**

Excursions by root cause and grade

Method - all -

Excursions	Grade			
Root cause	A	B	C	**Total Result**
Airflow disturbance	3	2	2	**7**
Cleaning and disinfection			2	**2**
Glove or gown integrity	3	4		**7**
Material transfer	3	3		**6**
Not determined		2		**2**
Personnel intervention	7	9		**16**
Sampling or handling error	1	1	1	**3**
Total Result	**17**	**21**	**5**	**43**

Viable samples by room and month

Method - all -

Samples	Month						
Room	Apr 2026	May 2026	Jun 2026	Jul 2026	Aug 2026	Sep 2026	**Total Result**
R301	352	336	352	368	336	352	**2,096**
R302	242	231	242	253	231	242	**1,441**
R303	27	25	27	27	25	27	**158**
R311	352	336	352	368	336	352	**2,096**
R312	27	25	27	27	25	27	**158**
R321	39	38	39	42	38	39	**235**
R322	154	147	154	161	147	154	**917**
R323	154	147	154	161	147	154	**917**
R331	264	252	264	276	252	264	**1,572**
R332	154	147	154	161	147	154	**917**
Total Result	**1,765**	**1,684**	**1,765**	**1,844**	**1,684**	**1,765**	**10,507**

Grades	Methods	Root causes	Status	Organisms
A	Active air	Personnel intervention	Open	Staphylococcus epidermidis
B	Settle plate	Glove or gown integrity	Closed	Micrococcus luteus
C	Contact plate	Material transfer		Staphylococcus hominis
D	Glove print	Airflow disturbance		Cutibacterium acnes
	Particles ≥0.5 µm	Sampling or handling error		Kocuria rhizophila
	Particles ≥5 µm	Cleaning and disinfection		Bacillus cereus
		Not determined		Penicillium chrysogenum
				Corynebacterium sp.
				Non-viable