Respirator PFE decision rule guide

This document is a guide on PFE testing criteria for analysts and validators. It is imperative that the correct PFE class is used, matching the highest claimed PFE claimed by the manufacture when using this decision-making guide. This document should be used alongside the SOP "Particulate Penetration Efficiency Assessment – Rapid Screening" found D20-3958656.

Initial 10 specimens (specimens 1-10)

If all specimens tested pass – cease testing, sample passes.

If only 1 specimen is within the lower limit of acceptance, another 10 specimens of the same sample must be tested to determine the overall result – continue testing.

If 1 or more specimens less than the lower limit of acceptance – cease testing, sample fails.

If 2 or more specimens within the lower limit of acceptance – cease testing, sample fails.

Follow-up 10 specimens (specimens 11-20)

Test another 10 specimens from the same sample, only if 1 specimen was within the lower limit of acceptance.

If all specimens tested pass – cease testing, sample passes.

If only 1 specimen within the lower limit of acceptance (2 in total) – cease testing, sample passes.

If 1 or more specimens less than the lower limit of acceptance – cease testing, sample fails.

If 2 or more specimens within the lower limit of acceptance (≥3 in total) – cease testing, sample fails.

Initial 10 specimens (specimens 1-10)

PFE Class	Pass first 10 specimens above limit	Indeterminate 1 specimen **within** lower limit of acceptance	Minor Fail ≥2 specimen **within** lower limit of acceptance	Major Fail ≥ 1 specimen **below** lower limit of acceptance
P1	≥ 80 %	79-80 %	79-80 %	< 79 %
KN90	≥ 90 %	89-90 %	89-90 %	< 89 %
P2/FFP2/KF94	≥ 94 %	93-94 %	93-94 %	< 93 %
KN95/N95	≥ 95 %	94-95 %	94-95 %	< 94 %
FFP3/N99	≥ 99 %	98-99 %	98-99 %	< 98 %
P3	≥ 99.95%	98.95-99.95%	98.95-99.95%	< 98.95 %

Follow up 10 specimens (specimens 11-20)

PFE Class	Pass next 10 specimens above limit	Pass 1 follow-up specimen, 2 total, within lower limit of acceptance	Minor Fail ≥3 total speicmens **within** lower limit of acceptance	Major Fail ≥ 1 specimen **below** lower limit of acceptance
P1	≥ 80 %	79-80 %	79-80 %	< 79 %
KN90	≥ 90 %	89-90 %	89-90 %	< 89 %
P2/FFP2/KF94	≥ 94 %	93-94 %	93-94 %	< 93 %
KN95/N95	≥ 95 %	94-95 %	94-95 %	< 94 %
FFP3/N99	≥ 99 %	98-99 %	98-99 %	< 98 %
P3	≥ 99.95%	98.95-99.95%	98.95-99.95%	< 98.95 %

Analyst decision table

Test Initial 10	Failures or lower limit of acceptance	Action	Failures or lower limit of acceptance	Result
Test Initial 10	0 ──▶			**Sample Passes**
	≥ 1 Major Failure ≥ 2 Minor Failure ─────────────────────────────▶			**Sample Fails**
	1 **within** lower limit of acceptance	Test another 10	0 1 lower ─────▶ limit of acceptance	**Sample Passes** (Total of 2 within lower limit of acceptance)
			≥ 1 Major Failure ≥ 2 Minor Failures (in this group of 10) ──▶	**Sample Fails**

Analyst decision tree