

ACCEPTABLE QUALITY LEVEL

(Also known as Acceptance Quality Limit)

Quality medical gloves are essential to protect healthcare workers and patients from potential hazards, and can be measured by Acceptable Quality Level.

What is Acceptable Quality Level (AQL)?

AQL is an industry standard that is a statistical sampling process for evaluating quality. According to the International Standards Organization (ISO) (2859-1: 1999)¹, AQL is “the worst tolerable process average when a continuing series of lots is submitted for acceptance sampling”. Process average is the typical percentage of defective gloves in the lots/batches sampled.

What are the required AQLs?

Various international standards, as shown in Table 1, determine the AQL that manufacturers must comply to. However, manufacturers can set their own standards as long as they are stricter than the international standards. This is the case for Ansell, which has the following AQL Standards:

Ansell surgical gloves adhere to an AQL of 0.65
(Meeting or exceeding recommendations set by ASTM, EN & ISO)

Ansell examination gloves adhere to an AQL of 1.5
(Meeting or exceeding world standards of 1.5-2.5)

The lower the AQL, the higher the level of glove barrier protection and the lower the incidence of finding a defect resulting in a higher quality product.

Technical data sheets containing the AQL for each specific glove are available upon request.

Table 1: International Surgical and Examination Glove Standards

Surgical Gloves Standards	Inspection Level	AQL
AS/NZS 4179: 2014 ² Applicable to Australia/ New Zealand	G1	1.0
ASTM D3577-19 ⁴ Applicable to US & Canada	G1	1.5
EN 455-1:2020 ⁸ Applicable to the European Union	G1	0.65
ISO 10282:2023 ⁹ Adopted by the rest of the World	G1	1.5
JIS T9107: 2018 ¹¹ Applicable to Japan	G1	1.5

Examination Gloves Standards	Inspection Level	AQL
AS/NZS 4011: 2014 ³ Applicable to Australia/ New Zealand	G1	1.5
ASTM D3578-19 ⁵ ASTM D6319-19 ⁶ ASTM D6977-19 ⁷ Applicable to US & Canada	G1	2.5
EN 455-1:2020 ⁸ Applicable to the European Union	G1	1.5
ISO 11193-1:2020 ¹⁰ Adopted by the rest of the World	G1	2.5
JIS T9115:2018 ¹² Applicable to Japan	G1	2.5

How is AQL determined and measured for gloves?



Water Leak Test to determine the AQL level of a glove for pinholes

In this test, the gloves are filled with 1000 ml (1 litre) of water, bound or sealed at the cuff and hung upside down for two minutes and checked for leaks (pinholes) under sustained pressure. This is the recognized test method for global glove standards.

AQL is a pass/fail where a predetermined sample size of a manufactured lot is tested following the sampling plan and protocols established by the various international standards or more stringent standards set by manufacturers to ensure stricter and higher quality is delivered to the customer.

The sampling plan is an inspection procedure of a sample size (which are gloves that are randomly selected from a batch of gloves) that is used to determine acceptance or rejection criteria from an inspection batch or lot. The sample size to be tested is set by:

The lot or batch size

The inspection level - determined by region as reflected in Table 1

The decision on whether or not to release the full production batch to the market will be based on the results obtained from the sample size tested, as set by the AQL value specified in standards for the market, or determined by individual manufacturers. Manufacturers will also decide whether to discard, or rework the lot until the AQL is achieved.

AQL Sampling Plans

To explain how gloves are tested for AQL, this will be determined by the manufacturer based on the lot size. If the lot size is 10,000 and they are following an AQL of 0.65 with inspection level I (determined by the standards), they will need to select a sample test of 80 gloves (see Table 2). The full lot (10,000 gloves) can be released if they find one or less defective gloves in the 80 gloves inspected (that is equivalent to a maximum of 1.25% defective in the tested gloves). However, if your AQL is 1.5, as determined in the majority of standards, the full 10,000 gloves lot will pass if they find 3 or less defective gloves in the 80 inspected (which is equivalent to a maximum of 3.75% defectives in the tested gloves).

A more stringent AQL ensures less defects in the overall lot.

Table 2: Comparison Table for Selected AQL Sampling Plans

AQL	0.65	1.0	1.5	2.5
Inspection Level (General Level 1, G1)	G1	G1	G1	G1
Lot/Batch Size	10,000	10,000	10,000	10,000
Sample Size	80	80	80	80
Maximum Non-Conformance Number Acceptance	1	2	3	5

Operating Characteristic (OC) Curve

According with Statistical Quality Control which is applied to measure and inspect the quality of a product, only a predetermined sample of gloves are tested rather than the whole lot/batch. Based on the sampling test of 80 gloves, 9,920 gloves out of a 10,000 lot will not be tested and there may be a chance that defective gloves may be present. In order to demonstrate the likelihood of accepting a lot with a certain percentage of defects in it, each sampling plan has an Operating Characteristic (OC) curve (see Chart 1). The OC curve shows what the sampling plan will do under particular circumstances. More precisely, the OC curve shows the probability of acceptance for lots with assumed values of defective gloves.

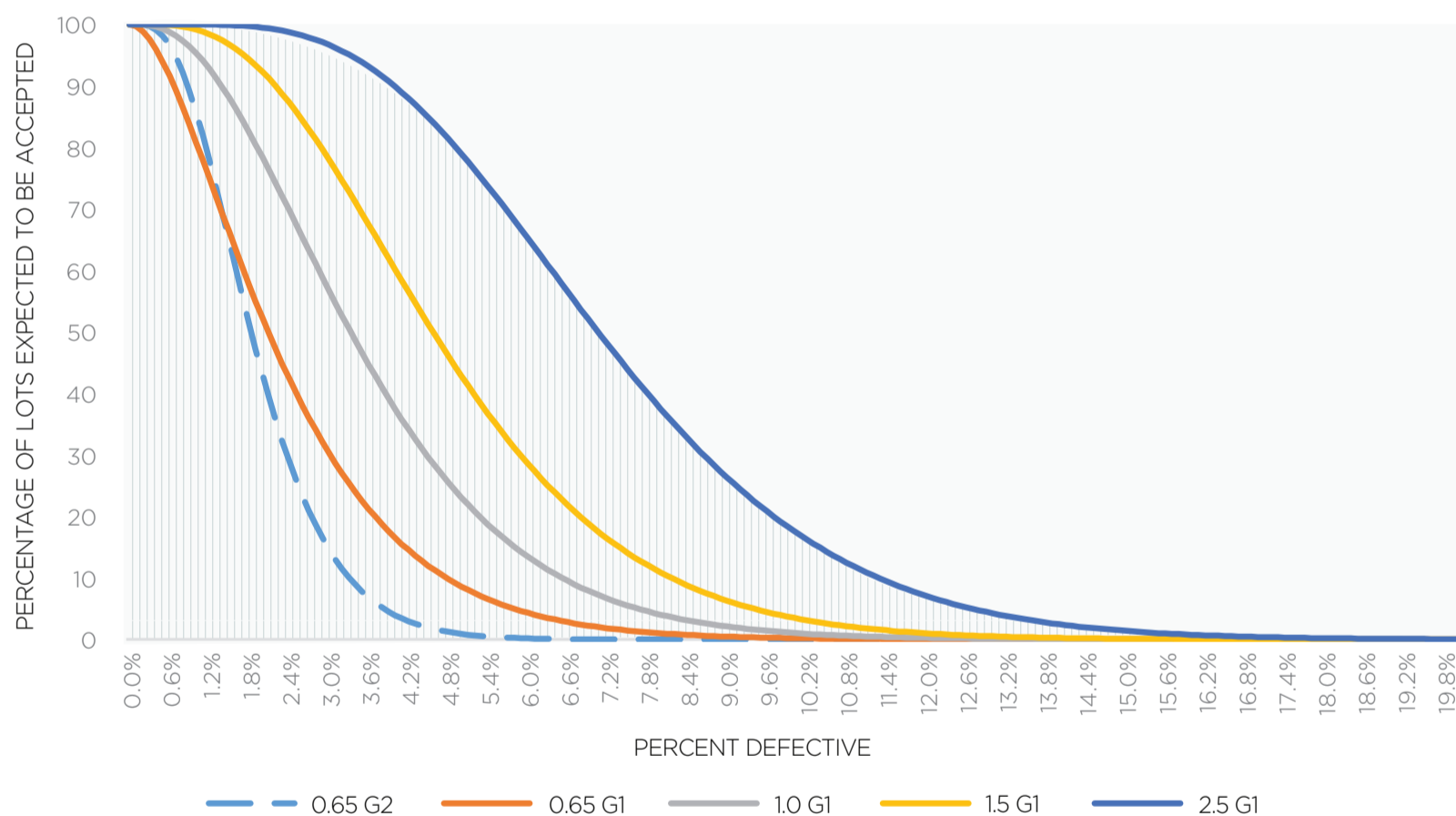
The horizontal scale indicates the percentage of defective gloves in our sample size of 80 (for a 10,000 glove lot). The vertical scale indicates the

corresponding percent of lots which, on average will be accepted from this process if this sampling plan is applied. In summary, the better the quality level from the production process, the higher the lot acceptance will be.

Ansell's Acceptable Quality Level, a guarantee for higher quality and protection.

Medical gloves are critical to protect both patients and healthcare workers and as such, they must be manufactured to a very high standard at all times. Amongst the most critical protective features are the absence of pinholes. The accepted rate of defects allowable to be released after passing through control processes is measured by AQL, and therefore this test is one of the most direct indicators of manufacturers' quality and process standards.

Chart 1: Operating Characteristic (OC) Curve



References:

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3. Standard New Zealand Te Mana Tautikanga O Aotearoa, AS/NZS 4011.1:2014 Single-use medical examination gloves <http://infostore.saiglobal.com/store/Details.aspx?ProductID=1742678> Accessed 4-12-15
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6. American Society for Testing and Materials, ASTM D6319-19 Standard Specification for Nitrile Examination Gloves for Medical Application <http://www.astm.org/Standards/D6319.htm> Accessed 08-03-22

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