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Quality Assurance Specifications

This letter addresses your recent request for information about our Quality Assurance procedures used in the manufacture of disposable, plastic, serological pipettes. Please find below information applicable to our processes:

Visual Inspection: a 100% visual inspection is done on all pipets as they come off the production line by an operator solely dedicated to this. Afterwards, QA personnel visually inspect a random sample taken according to AQL sample size standards. The pipettes are checked for visual defects such as missing/unclear print, incorrect coloring, incorrect text or numbering, misalignment of text, missing cotton plug and physical damage to the pipette.

Pyrogen Test: this test is done on 10 pieces from each finished good lot. The maximum limit is 20 EU per device. An EU is an endotoxin unit, an endotoxin being any object or organism that causes disease or death. The test is performed using the FDA-recommended LAL method. This method is a simple pass/fail to test if the device does or does not have less than 20 EU of endotoxin. Lots that do not pass the test are discarded.

Volumetric Test: this test is done in the QC lab using a volume comparison to a traceable standard. The standard is a Kimble manufactured glass tube precisely marked at different levels of volume (mL). The lab test itself is done at the start of the production run and several times during the shift. At the same time that the test is done a height gauge is calibrated and used on the line by the operator to check imprint height every 30 minutes. Volumetrics must be within a +/- 2% range.