



## VWR® PCR 8-WELL TUBE STRIPS

As per the manufacturer the below product meets the following criteria:

<b>NA Catalog Number:</b>	93001-118
<b>Lot Number:</b>	20283
<b>Description:</b>	VWR Strip PCR RT NAT PK120
<b>Date of Manufacture:</b>	June 2020
<b>Date of Expiration:</b>	June 2025

### Quality System Compliance

The product conforms to written material specifications and was manufactured under a registered and audited ISO 9001 quality system and underwent lot testing as outlined in the manufacturer's laboratory procedures. These products come with the highest standard of quality assurance.

### QC Testing

It is produced in a tightly controlled environment and subjected to rigorous testing and performance procedures. The products meet all stated standards for precision, clarity, warp, and freedom from contamination.

### Product Specifications

<b>Material:</b>	Polypropylene Certified free of Bisphenol A (BPA), phthalates and cytotoxic effects. Plastic resins used in product manufacturing have been tested for heavy metals using the prescribed USP method and confirmed to have levels lower than 100 PPM. Resins are USP Class-VI certified, RoHS, FDA regulation CFR 21, and are free of Substances of Very High Concern (SVHC), REACH compliant, and are FDA approved for food contact.
<b>Non-Pyrogenic Statement:</b>	Product samples are exposed to endotoxin-free water and the resulting extraction fluid is tested for contamination using the kinetic turbidimetric Limulus Amoebocyte Lysate (LAL) assay protocol and USP guidelines. All products tested must display less than 0.05 EU/ml to be certified free of endotoxin.
<b>ATP Assay:</b>	Product is certified as ATP-free.
<b>DNase &amp; RNase Free:</b>	Product samples are exposed to nuclease-free water and the resulting extraction fluid is tested for nuclease activity on commercially available 7.5 kb Poly(A) tailed RNA (1ug) and HindIII-digested DNA (1ug) with a one hour 37 °C incubation in appropriate buffers. Results are visualized on an agarose gel with appropriate positive and negative controls. Extraction fluid samples must show no degradation of the nucleic



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acids by the extraction fluid has occurred for the product to be certified as RNase-free and DNase-free.

**BSE/TSE Statement:** (Bovine Spongiform Encephalopathy/Transmissible Spongiform Encephalopathy)

The product above is free from and manufactured from materials that do not contain any raw materials or substances derived from animal origin as defined in EC Directive 97/534/EC and EC Directive 76/768/EEC and Amendment 419 Annex II.

The manufacturer does not store any products of animal origin, including animal proteins, in any manufacturing areas of their facility or warehouse

**DNA Contamination Assay:** Product samples are exposed to DNA-free water and the resulting extraction fluid is tested for the presence of human DNA using primers for known DNA sequences in a PCR reaction. Amplification products are examined by Agarose gel electrophoresis with appropriate positive and negative controls. PCR reactions using extraction fluid must show no PCR- amplified product compared to a positive control containing one picogram of human genomic DNA for the product to be certified as DNA-free.

**Protease Assay:** Product samples are exposed to protease-free water and the resulting extraction fluid is tested for the presence of protease activity by examining test protein degradation in the extraction fluid compared to a negative control and positive control reactions supplemented with 2 nanograms of Proteinase K or Trypsin. Extraction fluid samples must show no test protein degradation relative to the negative control for the product to be certified as protease- free.

**Latex Statement:** No Latex was used in the manufacturing of the product. This also includes all the packaging and shipping materials used in the production of all items.

The only time the product or packaging may come in contact with Latex would be from the Latex gloves that production employees are required to wear for the purpose of clean handling and to avoid biological contamination of the products.

**Disclaimer:** This declaration will not discharge the user from his obligation to ensure the product is suitable for the intended use.

**Signed:**



Jamie Ethier  
VP Global Quality  
VWR, Part of Avantor

**Date:** October 12, 2020