
Sampling Procedure	Representative samples are removed from the production process and testing is performed using the protocols described below. All samples must test negative before product is approved for sale.
Testing Certification	All assays are performed by an independent testing laboratory. Certification documentation is on file at Bridge Bioscience Inc. Portsmouth, NH.
RNase Testing	Test articles are incubated with sterile buffer and mRNA is added to the buffer. The test sample is incubated at 37°C alongside controls. The positive control consists of mRNA in sterile buffer, spiked with RNase. The negative control is mRNA in sterile buffer that has not been exposed to RNase. The samples are run on an agarose gel and evaluated. For samples to pass certification, the bands from the test samples must correspond to the negative control. The negative control must show no evidence of degradation (smearing). The positive control must show degradation for the test to be valid. Test sensitivity: 10 ⁻⁹ Kunitz Units/μl.
DNase Testing	Test articles are incubated with sterile buffer and a 1kb DNA ladder is then added to the buffer. The test sample is incubated at 37°C alongside positive controls. The positive control consists of DNA in sterile buffer, spiked with DNase. The negative control is DNA in sterile buffer that has not been exposed to DNase nor incubated. The samples are run on an agarose gel and evaluated. For samples to pass certification, the bands from the test samples must correspond to the negative control. The negative control must show no evidence of degradation. The positive control must show degradation for the test to be valid. Test sensitivity: 10 ⁻⁷ Kunitz Units/μl.
Human DNA Testing	Test articles are incubated with a reaction mix containing primers specific for human DNA. The test sample is subjected to thermal cycling alongside controls. The positive control consists of reaction mix with human DNA added. The negative control is reaction mix with DNA-free water added. The samples are run on an agarose gel and evaluated. For samples to pass certification, the test samples must correspond to the negative control. The positive control must show bands of product in order to be valid. Test sensitivity: 30pg human genomic DNA.
OTHER INFORMATION	<p>The above information is believed correct as of the above date, but does not purport to be all inclusive and shall be used only as a guide.</p> <p>Products from Bridge Bioscience Inc. are intended for research use only.</p> <p>PCR (polymerase chain reaction) is covered by patents owned by Hoffmann-La Roche, Inc. and F. Hoffmann La Roche Ltd. Nothing in this document should be construed as an authorization or implicit license to practice PCR under any patents held by Hoffmann-La Roche.</p>
