



## Notification of Change

April 16, 2021

Shenandoah Biotechnology  
103 Steam Whistle Drive, Suite A  
Warminster, PA 18974

To whom it may concern,

Shenandoah Biotechnology, Inc. has eliminated  $\beta$  lactam antibiotics from the recombinant protein manufacturing process in its facility. To achieve this goal, standard molecular biological techniques have been utilized to transfer the DNA coding sequences from the current bacterial expression vector into two new bacterial expression vectors. All other processes and equipment used in the manufacture of the recombinant proteins have not changed.

Shenandoah has confirmed the following:

- 1) DNA sequence by standard DNA sequence methodology
- 2) *in silico* translation of the coding sequence
- 3) Equivalent recombinant protein expression levels after fermentation by SDS-PAGE analysis and comparison to internal standards.
- 4) Purified recombinant protein properties based on comparison to an internal standard by SDS-PAGE, cell-based activity testing and amino acid sequencing (HPLC-MS/MS, N-terminal or C-terminal amino acid sequencing).

This change will affect all new lots manufactured at Shenandoah Biotechnology. All previous product details and documentation, unless expressly noted, will remain unchanged.

Please feel free to contact me if there are any further questions regarding this change.

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cc:

Jazmine George, CQT

A handwritten signature in black ink that reads 'Jazmine George'.

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