

MOLTOX BACTERIOLOGICAL MEDIA FORMULATION & QUALITY CONTROL STATEMENT

PART NO.: <u>21-199</u> ASSEMBLY DATE: <u>July 28, 2020</u> LOT NO.: <u>54844</u> EXPIRATION DATE: <u>September 28, 2020</u>

MEDIA DESIGNATION EC "TRI" PLATES STORE IN REFRIGERATOR

FORMULATION & ASSEMBLY

| FORMULATION & ASSEMBLY | | | | | | | | |
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| 50X VBE SALTS (formulated as described by Maron & Ames (Mut. Res. 113:173, 1983), added at 20 ml/liter | | | | | | | | |
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Note: 50X VBE salts diluted to 2X and the resultant solution sterilized and added to sterile 2X agar solution. 40% D-glucose, L-tryptophan and ampicillin were added as previously sterilized solutions.

QUALITY CONTROL- METHODS & RESULTS

STERILIZATION: Media were steam sterilized at 15 lbs/sq in for 20 min @ 121°C. Temperature sensitive devices (thermocouples) were used to check each cycle.

MEDIA STERILITY TEST: Finished media were incubated for 40 - 48 h at $35 \pm 2^{\circ}\text{C}$. Samples of media from each element (e.g., flask) comprising the production run were uniquely identified and tested as above. The appearance of adventitious agent growth would have led to the rejection of the sampled pool.

EVALUATION OF MEDIA NUTRIENT PROPERTIES (GROWTH TEST): Samples of finished media were inoculated with a *Escherichia coli* WP2 strain (with or without uvrA; - pKM101). Media were judged suitable for release if the resultant cultures exhibited growth characteristic of R factor vs. non-R factor master plate cultures after 40-48 h incubation at 35 \pm 2°C.

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Approved:

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