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Certificate of Analysis

Product Collagenase/Elastase Vial (CLSH)
Source Clostridium histolyticum
Country of Manufacture USA
All products from animal sources are produced from starting material of USDA-approved origin, collected in United States Department of Agriculture (USDA) or equivalent approved facilities, inspected to be free of disease and suitable for exportation. Certificates of Origin are available upon request.
Storage Store at 2-8°C.
Code CLSH
Lot Number
Re-Assay Date
Description Enzyme vial of HIS kit that contains 20,000 units of collagenase (Code: CLS-1) and 30 units of elastase (Code: ESL), filtered through 0.22 micron membrane and lyophilized.

Unit Definition

<u>Parameter</u>	<u>Result</u>	<u>Acceptance Criteria</u>
u/mg dw Collagenase	197	≥125 units per mg dry weight
u/vial Collagenase	21,880	≥20,000 units per vial
u/mg dw Caseinase	652	≥200 units per mg dry weight
u/mg dw Clostripain	1.89	≤4.00 units per mg dry weight
u/mg dw Tryptic	0.28	≤0.50 units per mg dry weight
Colony Count	No cfu's detected	≤1.0 cfu per ml
u/mg dw Elastase	0.30	Report assay value.
u/vial Elastase	33.5	≥30 units per vial
Endotoxin EU/mg dw	7.37	Report Assay Value.

Approved by: Thomas R. Ryan, Quality Control Manager (signature on file)

Date: 12/9/20