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## SOP APPENDIX



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Document Title:

### RAW MATERIAL SPECIFICATION, COLLAGENASE NB 1, PREMIUM GRADE

#### 1.0 Requirements:

TEST	METHOD	REQUIREMENT
<b>Identity</b>	Visual Inspection	Container labeling and Certificate of Analysis must specify: "Collagenase NB 1, Premium Grade" and must have same lot number.
<b>Vendor</b>	Visual Inspection	Distributor: SERVA Manufacturer: Nordmark, Cat. #17455
<b>Review of Vendor's Certificate of Analysis</b>	Visual Inspection	The following criteria must be met: Color: Nearly colorless powder Constitution: Lyophilisate Container: Vial PZ (Wünsch) @ 25°C: $\geq 3.0$ U/mg lyophilisate PZ (Wünsch) @ 25°C: $\geq 2,000$ U/vial Neutral protease Activity: $\leq 0.05$ U/mg lyophilisate Trypsin-like activity: Test & Report Bacterial Endotoxins: $\leq 10.0$ EU/mg The Certificate of Analysis must be signed and dated.

#### 2.0 Storage

+ 2°C to + 8°C

#### 3.0 Formulation:

NA