

## **Certificate of Analysis**

## LONG®EGF Freeze-Dried Product (FD)

Repligen Sweden AB product name:		LONG®EGF Freeze-dried Product (FD)	
Repligen article number:		10-1021-20	
Media grade			
Batch number	•		
Date of filling	(MMM YYYY):		
	MMM YYYY):		
Storage conditions:		Minus 20 °C ± 5 °C	
Packaging:		Clear glass-vials with stoppers	
Quantity:		20 mg/vial	
Intended use:		For further manufacturing use. Not for human administration.	
(21-1010) and Site of Manuf	Repligen Sweden AB (acturing: Repligen Swed	lance with the manufacturing formulative Policy, (01-1100). Hen AB, Box 965, SE-220 09 Lumunder dry $N_2$ at slight vacuum.	
Category	Test Method	Acceptance criteria	Result
Category Appearance	Test Method Visual inspection	Acceptance criteria White powder	Result
Appearance Molecular weight			Result
Appearance Molecular weight Biological	Visual inspection	White powder	Result
Appearance Molecular weight	Visual inspection  Mass Spectrometry	White powder  12296-12300 Da  ED <sub>50</sub> LT 20 ng/mL  LT 0.10 EU/μg	Result
Appearance  Molecular weight Biological Activity	Visual inspection  Mass Spectrometry  Stimulation of cell growth	White powder  12296-12300 Da  ED <sub>50</sub> LT 20 ng/mL  LT 0.10 EU/µg  NLT 95% single band between	Result
Appearance  Molecular weight Biological Activity Endotoxin	Visual inspection  Mass Spectrometry  Stimulation of cell growth  LAL	White powder  12296-12300 Da  ED <sub>50</sub> LT 20 ng/mL  LT 0.10 EU/μg	Result
Appearance  Molecular weight Biological Activity Endotoxin Purity  Identity	Visual inspection  Mass Spectrometry  Stimulation of cell growth  LAL  SDS-PAGE	White powder  12296-12300 Da  ED <sub>50</sub> LT 20 ng/mL  LT 0.10 EU/µg  NLT 95% single band between 6000 and 14400 Da  Conforms to reference standard by retention time and	Result
Appearance  Molecular weight Biological Activity Endotoxin Purity  Identity	Visual inspection  Mass Spectrometry  Stimulation of cell growth  LAL  SDS-PAGE  RP-HPLC	White powder  12296-12300 Da  ED <sub>50</sub> LT 20 ng/mL  LT 0.10 EU/µg  NLT 95% single band between 6000 and 14400 Da  Conforms to reference standard by retention time and	Result
Appearance  Molecular weight Biological Activity Endotoxin Purity  Identity	Visual inspection  Mass Spectrometry  Stimulation of cell growth  LAL  SDS-PAGE  RP-HPLC  fills the specification.	White powder  12296-12300 Da  ED <sub>50</sub> LT 20 ng/mL  LT 0.10 EU/µg  NLT 95% single band between 6000 and 14400 Da  Conforms to reference standard by retention time and	Result