



CERTIFICATE OF ANALYSIS

CTS™ VITRONECTIN (VTN-N) RECOMBINANT HUMAN PROTEIN IN PARTNERSHIP WITH CDI™

Catalog Number: CTS279S3
Lot Number: D1-012211C
Manufacturing Date: 2022-11-03
Expiry Date: 2025-10-24
CoA Issue No.: 497

Volume: 1 mL

Storage temperature: -70 ± 10 °C

Composition: 20 mM K₂HPO₄ 20 mM KH₂PO₄ pH 7.40 (NaOH), 135 mM NaCl, 15 mM KCl, 0.5 mM EDTA, 150 mM L-Arginine, 250 mM Acetyl-L-cysteine, 20% (v/v) Glycerol, DNA-free WMB

For Research Use or Manufacturing of Cell, Gene, or Tissue-Based Products.

CAUTION: Not intended for direct administration into humans or animals.

Testing is listed in alphabetical order

PARAMETER	SPECIFICATION	RESULT	UNIT
¹ Biological activity	Concentration of Test sample at which half maximal attachment of BALB/3T3 cells in serum-free medium is observed (ED ₅₀) ≤1.000 µg/ml	0.641	µg/ml
	Ratio of ED ₅₀ values between IRS and Test samples: 55.00-145.00 %	101.24	%
² Color and clarity	Color: not more intense than Y6 (Yellow palette)	Conforms	
	Clarity: <30 NTU	3	NTU
³ Concentration	0.81-0.99 mg/ml	0.91	mg/ml
⁴ Endotoxins	< 25 EU/mg protein	Conforms	
⁵ Host cell gDNA	<100.00 pg/mg (LOQ – 12 pg/mg)	< LOQ	(LOQ – 12 pg/mg)
⁶ Identity by RP-HPLC	The intact protein chromatographic profiles of the Sample solution are similar to those of the IRS	Conforms	
⁷ Identity by SDS-PAGE	Main band of the test sample corresponds to position of the main band of IRS (≈55 kDa)	Conforms	
⁸ Mycoplasmas	<LOD (LOD – 10 CFU/ml)	Conforms	
⁹ pH	7.4 (7.0 – 7.8)	7.4	
¹⁰ Purity by RP-HPLC	> 95.0 %	98.6	%
¹¹ Sterility	No growth	Conforms	



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CoA is issued by

CoA is verified and approved by

<i>Sreta Mikicic</i>	<i>2023-09-12</i>
Quality Assurance Department	Signature Date
<i>P. Hagonanarayana</i>	<i>2023-09-12</i>
Quality Assurance Manager	Signature Date

REFERENCES:

¹Biological activity: Thermo Fisher Scientific Baltics, In-house method.

²Color and clarity: *Color*: acc. Ph. Eur. 2.2.2. Degree of coloration of liquids. Method I. *Clarity*: acc. Ph. Eur. 2.2.1. Clarity and degree of opalescence of liquids", Instrumental method.

³Concentration, ⁶Identity, ¹⁰Purity: Thermo Fisher Scientific Baltics, In-house method.

⁴Endotoxin testing: USP <85> Bacterial Endotoxins and Ph. Eur. 2.6.14. Bacterial endotoxins. Method A. Gel-clot method: limit test.

⁵Host cell gDNA: Contract Laboratory, In-house method.

⁷Identity by SDS-PAGE: Thermo Fisher Scientific Baltics, In-house method.

⁸Mycoplasmas: Contract Laboratory, In-house method.

⁹pH: USP <791> pH and Ph. Eur. 2.2.3. Potentiometric determination of pH.

¹¹Sterility: Contract Laboratory, Ph. Eur. 2.6.1. Sterility and USP/NF <71> Sterility Test.