

Case Study: Verified 24-Month Stability of Exocellure Exosome Serum

Comprehensive third-party verification of encapsulated exosome stability over 24 months

Overview

A comprehensive third-party analysis was commissioned to verify the long-term stability and potency of Exocellure's Exosome Serum (Reference: 162-2019-09-47, Lot 20210112). Testing was conducted over a 24-month period under controlled ambient conditions by Applied Consumer Services Inc. (Hialeah Gardens, FL) and Alpha Nano Tech LLC (Durham, NC).

The objective was to confirm that Exocellure's encapsulated exosomes remain structurally intact, biologically active, and microbiologically safe after two years of shelf storage at room temperature.

Study Design

Testing Laboratories

Applied Consumer Services Inc. – Physical, chemical, and microbiological stability testing

Alpha Nano Tech LLC – Western blot electrophoresis and CD81 ELISA quantification of exosomal markers

Storage Conditions

25 ± 2 °C / 60 ± 5 % RH for 24 months in preliminary 15 mL marketing containers

Sampling Schedule

0 mo | 1 mo | 3 mo | 6 mo | 9 mo | 12 mo | 18 mo | 24 mo

Physical & Chemical Stability

Parameter	Method	Specification	0 mo	24 mo	Result
Appearance	Visual	Liquid, homogeneous	Pass	Pass	Stable
Color	Visual	Light yellow	Pass	Pass	Stable
Odor	Organoleptic	Characteristic	Pass	Pass	Stable
pH (25 °C)	USP <791>	5.30 – 8.30	7.39	5.94	Within range
Specific Gravity	USP <841>	0.9858 – 1.0268	1.0064	1.0042	Within range
Total Plate Count	USP <61>	< 100 CFU/g	< 100	< 10	Pass
Yeast & Mold	USP <61>	< 100 CFU/g	< 100	< 10	Pass

All parameters remained within specification for the full 24 months, confirming no physical degradation, pH drift beyond limits, or microbial growth. ACS concluded the serum “passes the stability study specification” and “has a shelf life of 24 months from the date of production.”

Biochemical Integrity

Alpha Nano Tech electrophoresis verified retention of key exosomal surface and cytoplasmic markers:

CD81 $\approx$ 23 kDa | +2% retention

TSG101 $\approx$ 46 kDa | –19% (within expected variance)

Calnexin $\approx$ 90 kDa | Not detected (purity confirmed)

A complementary CD81 ELISA quantified the total exosome count in the 24-month sample at approximately 2.8 billion exosomes, consistent with the original baseline reading at the start of the study. This demonstrates that no measurable exosome loss or aggregation occurred over the 24-month storage period.

Conclusion

The combined findings from Applied Consumer Services and Alpha Nano Tech confirm that Exocellure's encapsulated exosomes:

- Remain structurally and biochemically intact after 24 months
- Maintain pH stability, physical homogeneity, and sterility
- Exhibit no degradation of key markers CD81 and TSG101
- Retain a consistent 2.8 billion exosome concentration verified by CD81 ELISA
- Demonstrate a validated 24-month shelf stability without lyophilization

Verified by:

Applied Consumer Services Inc. | Test Report No. 41366/A | Jan 2023

Alpha Nano Tech LLC | Report No. APC01-002 | Jul 2025

CD81 marker verification confirmed via ELISA assay

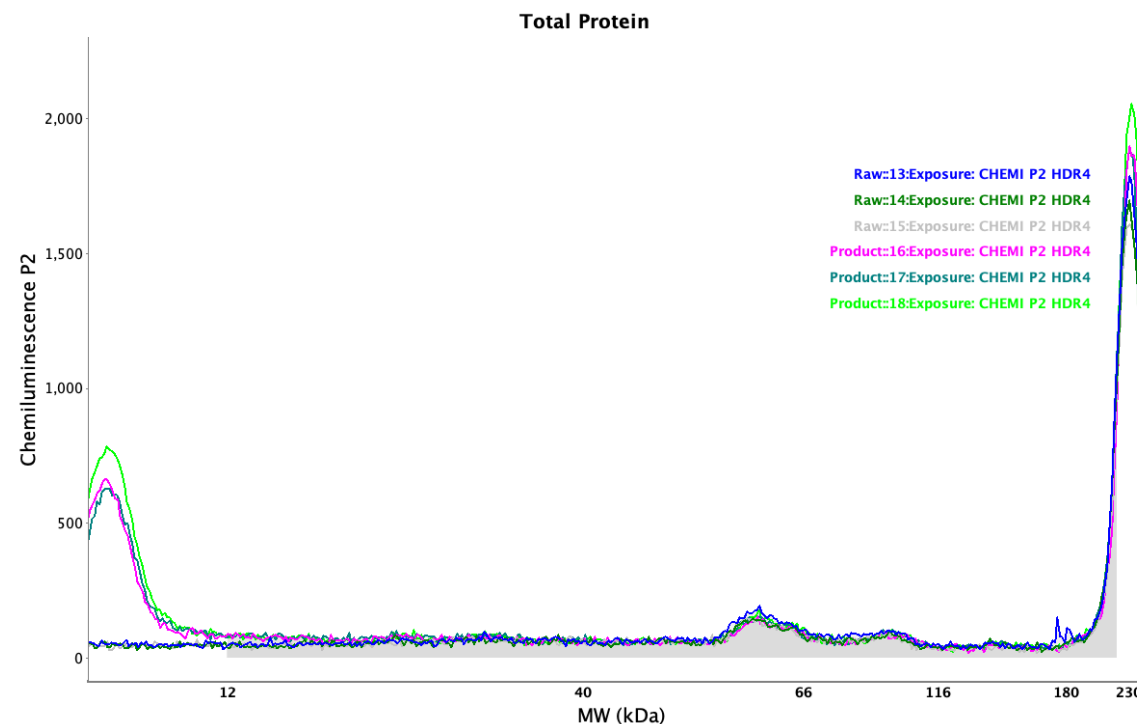
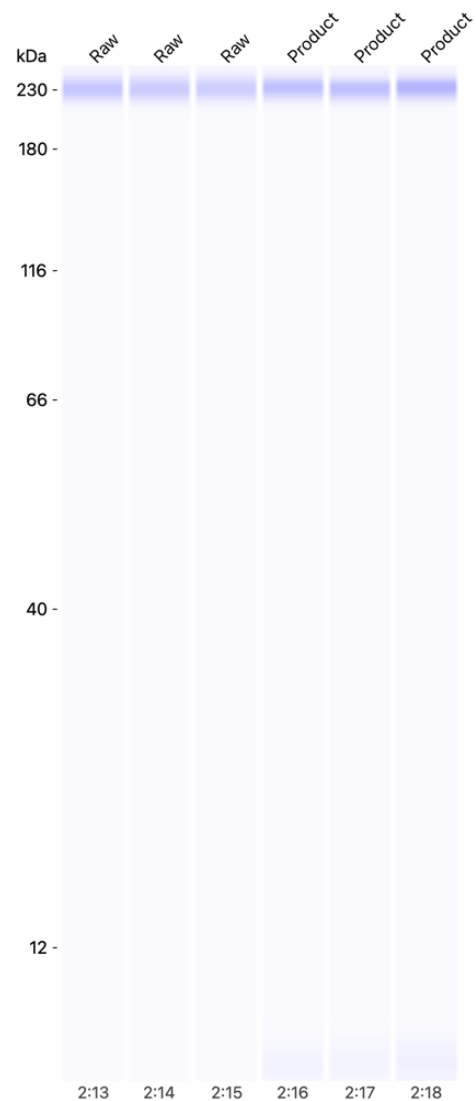
	Alpha Nano Tech, LLC 3624 Shannon Rd STE 103 Durham, NC 27707 Phone: (919) 884-8376	Document Number	Report Date
		APC01-002	7/27/25

Client	Applied consumer service
Contact	Galina Tuninskaya 11890 NW 87 th court Unit #8 Hialeah Gardens, FL 33018 (305)821-1677

Antibody	Vendor	Concentration	Dilution	Species
TSG101	Novus Biologicals	1 mg/mL	1:10	rabbit
CD81	Novus Biologicals	1 mg/mL	1:20	rabbit
Calnexin	Novus Biologicals	1 mg/mL	1:25	mouse

Sample ID	Concentration, µg/mL (BCA)	Loading concentration, µg/mL
Raw	-	As is
Product	-	As is

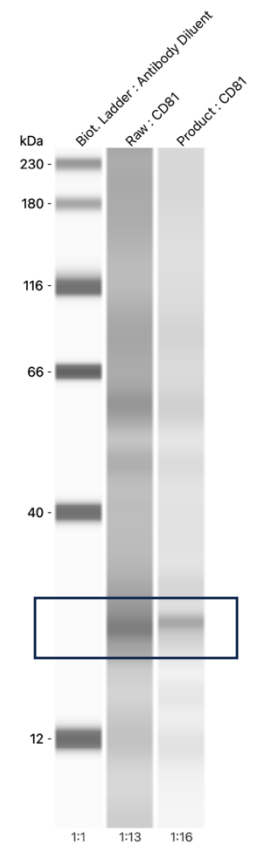
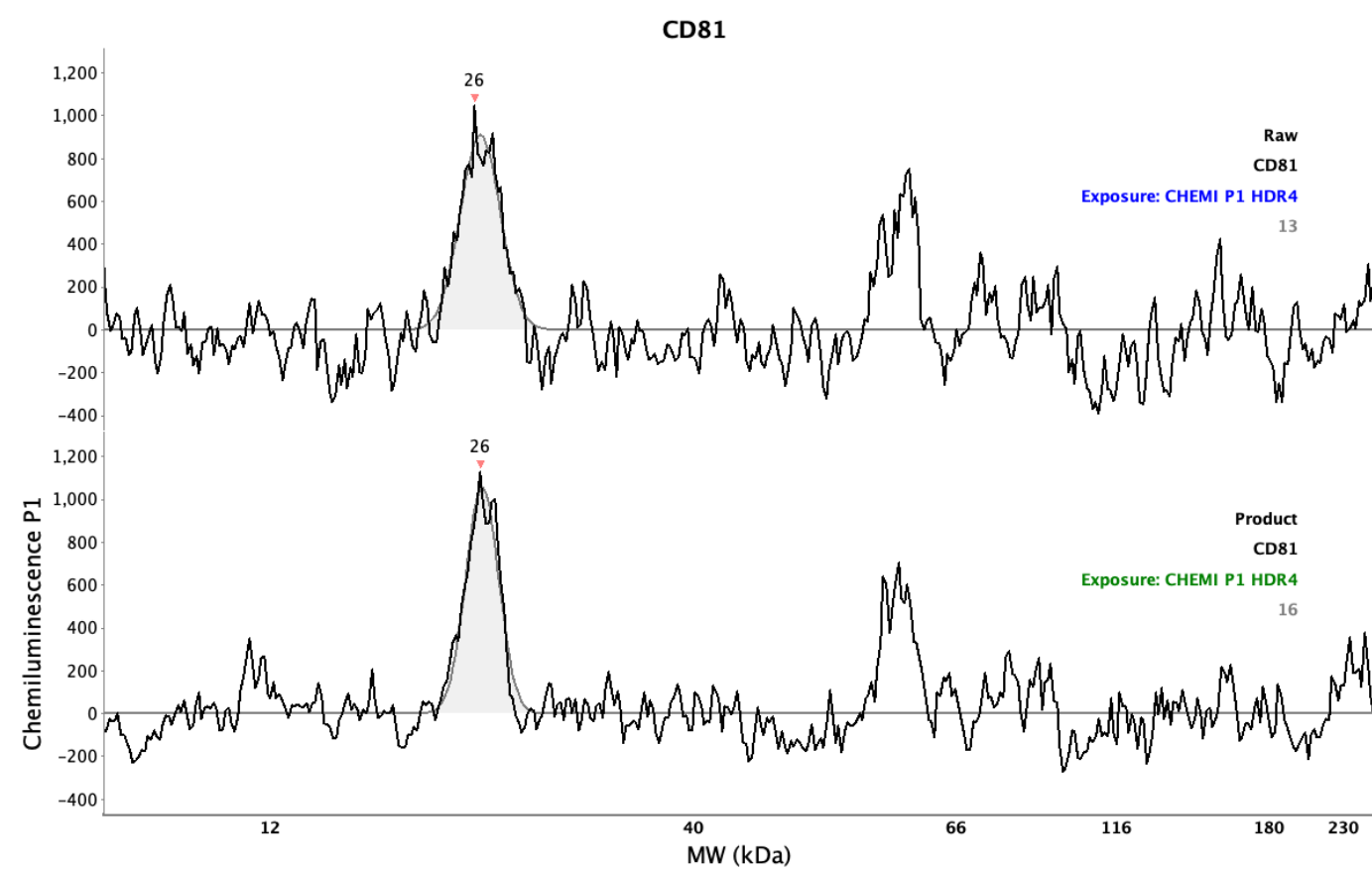
Run summary: Total protein loading



Sample	Cap	Area	Baseline	Channel
Raw	P2:13	29365.9	137.8	CHEMI
Raw	P2:14	26273.8	129.6	CHEMI
Raw	P2:15	25495	124.5	CHEMI
Product	P2:16	27123.9	116.5	CHEMI
Product	P2:17	29500.4	112.5	CHEMI
Product	P2:18	28884	124.7	CHEMI

Expected MW: 23 kDa

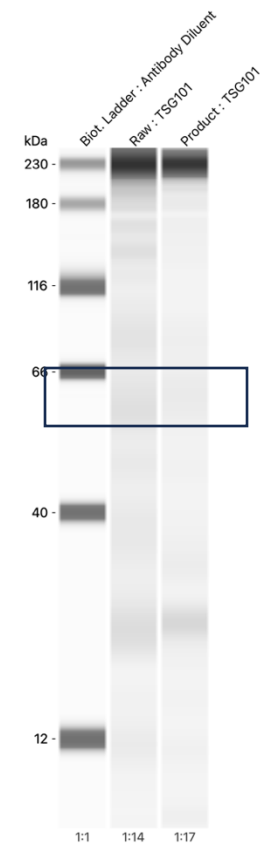
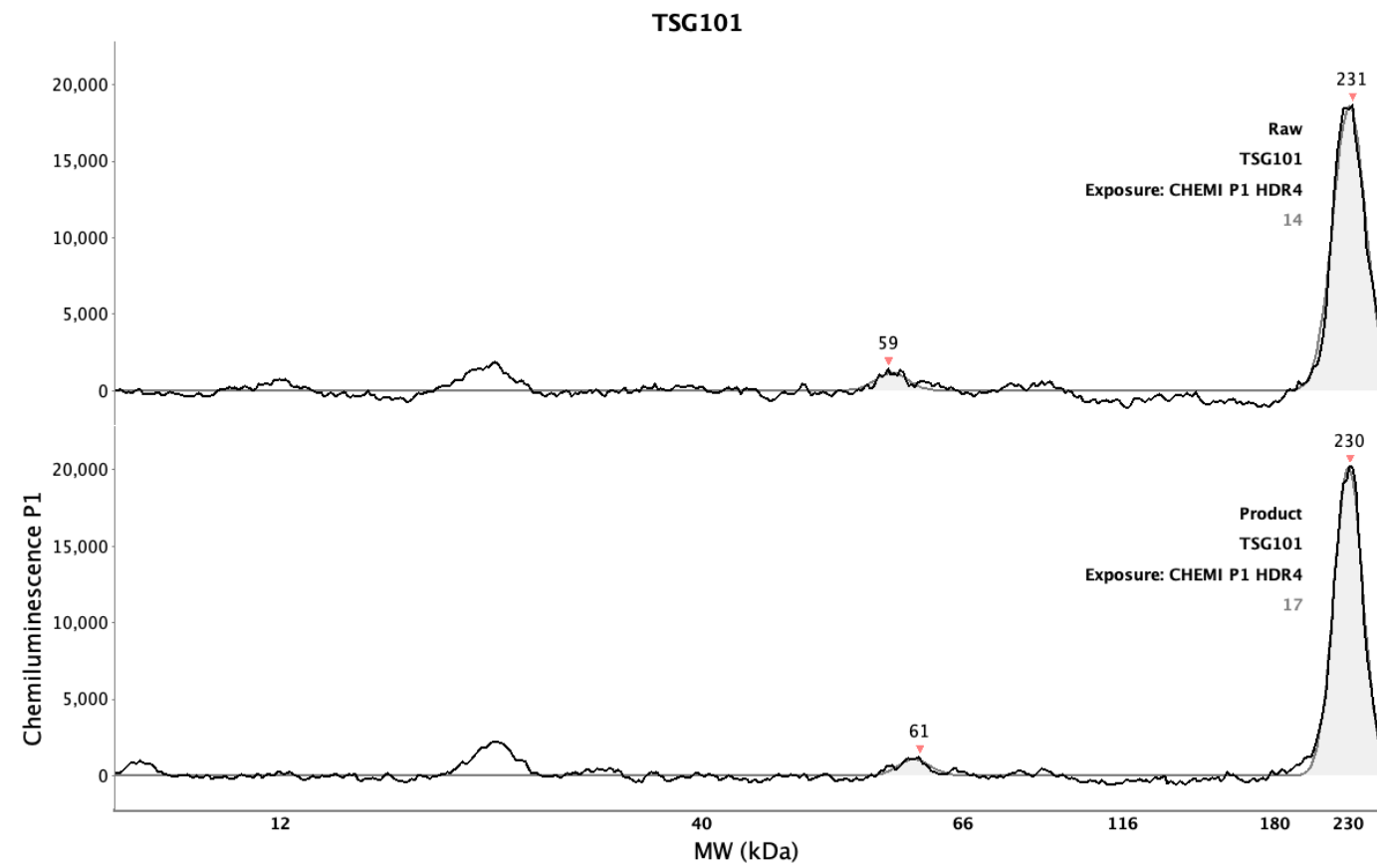
CD81



Sample	Primary	Secondary	Cap	Peak	Name	Position	MW (kDa)	Height	Area	% Area	Corr. Area	Width	S/N	Baseline	Channel
Raw	CD81	Secondary Probe 1	P1:13	1		231	26	911.5	15376.1		134607.6	15.8	6.3	1514.8	CHEMI
Product	CD81	Secondary Probe 1	P1:16	1		234	26	1057.6	14483.3		137272.8	12.9	17.3	895.9	CHEMI

TSG101

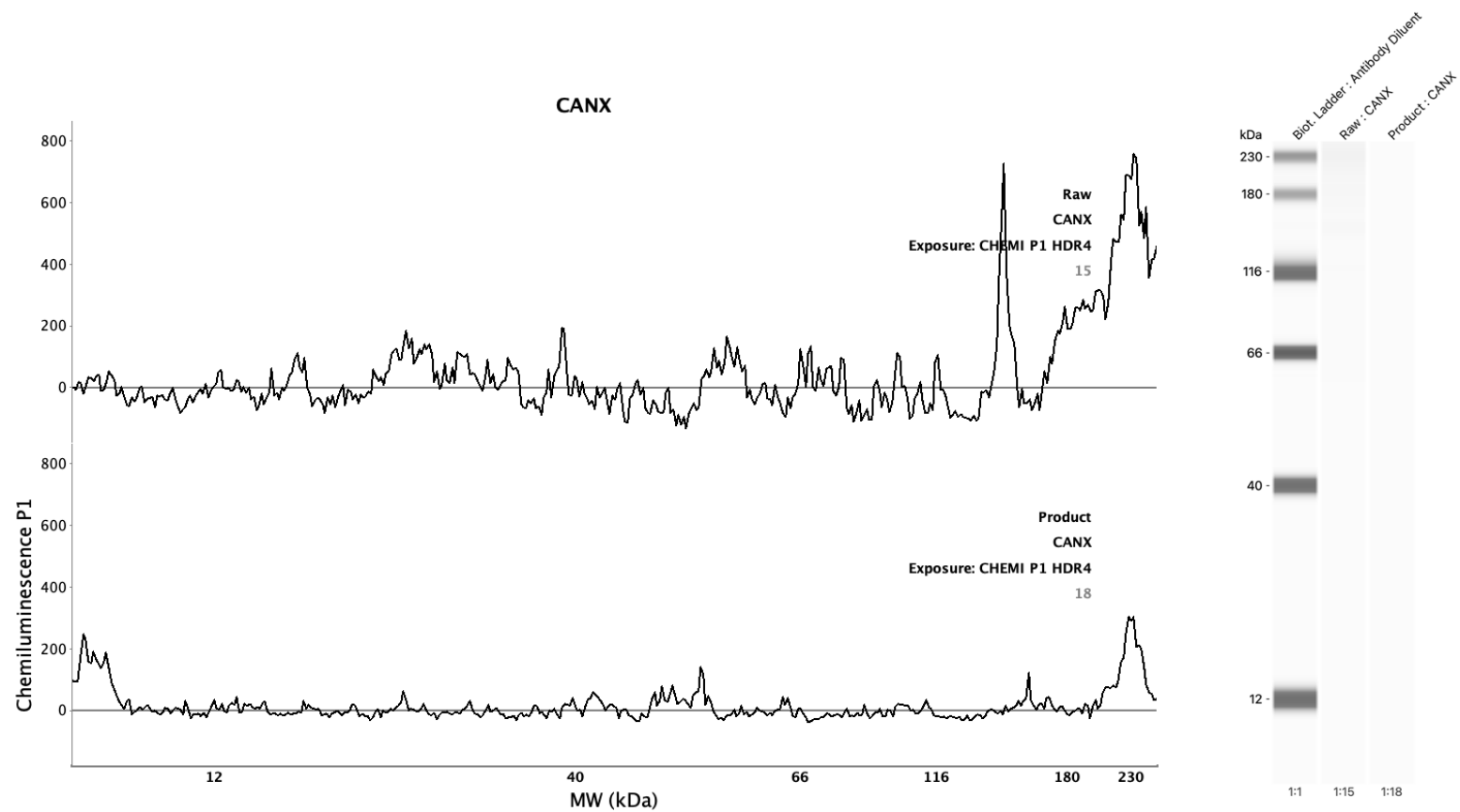
Expected MW: 23-46 kDa



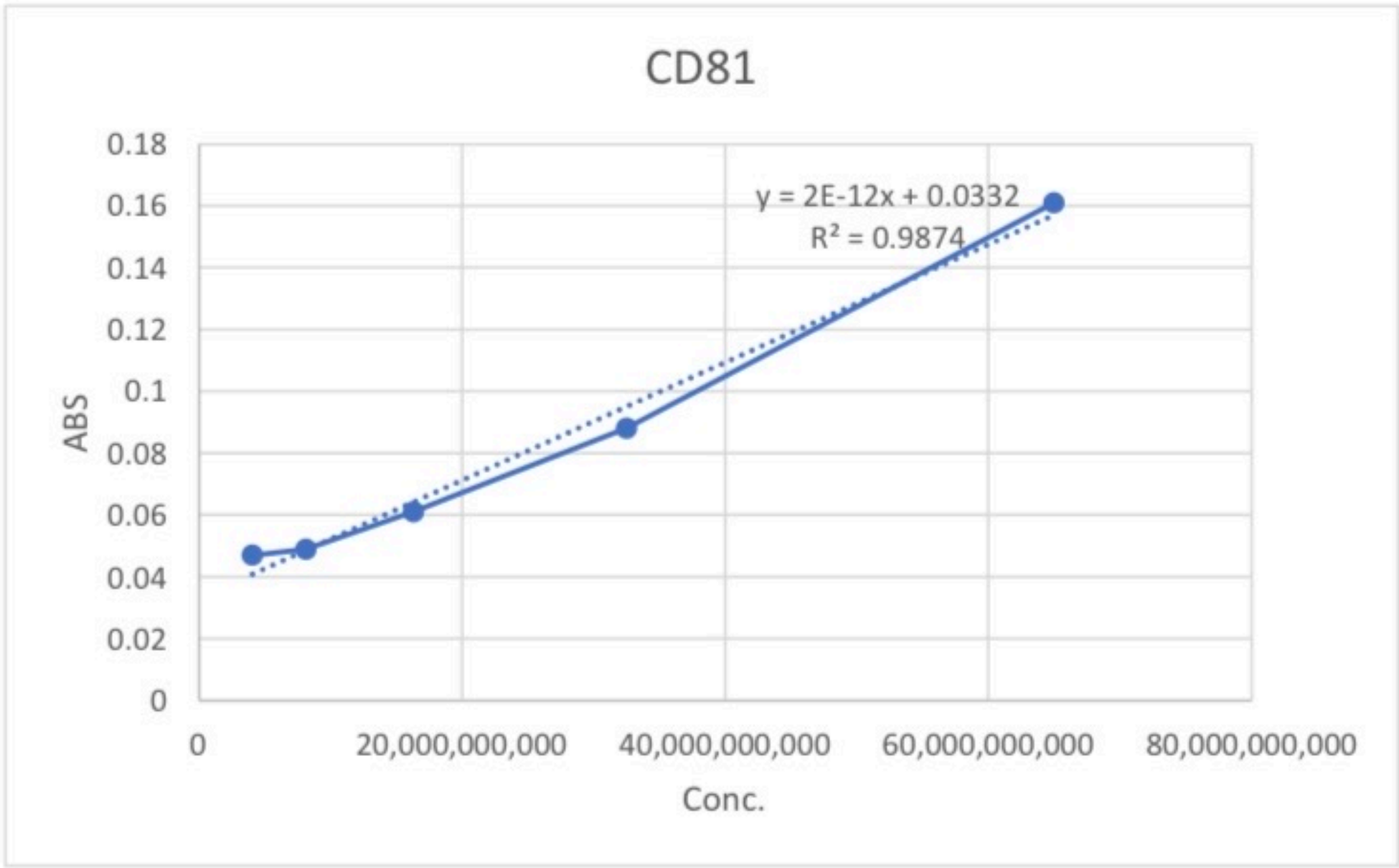
Sample	Primary	Secondary	Cap	Peak	Name	Position	MW (kDa)	Height	Area	% Area	Corr. Area	Width	S/N	Baseline	Channel
Raw	TSG101	Probe 1	P1:14	1		367	59	1253	15619.4		152830.2	11.7	5.9	3000.5	CHEMI
Product	TSG101	Probe 1	P1:17	1		375	61	1108.6	14265.3		124314.2	12.1	7	2394.5	CHEMI

Expected MW: 90 kDa;

Calnexin (EV negative control)



CD81 ELISA Analysis Results



Samples Submitted for Testing:

Serum Lot#20250623
Serum with Exosomes Lot# 20250623-E

Sample:	No. of Exosomes (Normalized)
Serum (No Exosomes)	0
Serum + Exosomes	2875000000

APPLIED CONSUMER SERVICES, INC.

11890 N.W. 87 COURT, UNIT #8, HIALEAH GARDENS, FL 33018

Phone: (305) 821-1677 Fax: (305) 821-0155 Website: appliedconsumer.com

Test Report

N° 41366/A

Client: Ms. Rita Vaccaro
7X ENTERPRISES
270 Arthur Avenue
Englewood Cliffs, NJ 07632

Analysis Type: Stability Study
Sampled by: Client
Stability Study at: 24 Months
Storage Condition: Temperature $25 \pm 2^{\circ}\text{C}$ / Relative Humidity: $60 \pm 5\%\text{RH}$
Beginning of the Study: 1/20/2021
End of the Study: 1/20/2023
Sample Information: Exosome Serum, Reference: 162-2019-09-47
Sample Description: Sample in preliminary marketing container, white plastic of approx. 15mL
Lot Number: 20210112
Manufacturer Date: N/Av
Expiration Date: N/Av
Analysis Date: 1/20/2023 to 1/27/2023
Current Lab Number: 41366/A
Original Lab Number: 36962/A
Reference: Q11192020-ACS1

INTRODUCTION

Samples of "Exosome Serum, Reference: 162-2019-09-47, Lot: 20210112, Exp. Date: N/Av" were submitted for room temperature stability study. The procedure would include physical, chemical and microbiology analysis at the end of each of testing periods (0, 1, 3, 6, 9, 12, 18, and 24 months). Based on the final analysis results, the expiration day of the product would be determined.

RESULTS

Results of the current testing are summarized in the Table.

COMMENTS

According to the stability study result, the product "Exosome Serum, Reference: 162-2019-09-47, Lot: 20210112, Exp. Date: N/Av" passes the stability study specification.

Our stability study that includes physical, chemical, and microbiological analysis confirms that the product "Exosome Serum, Reference: 162-2019-09-47, Lot: 20210112, Exp. Date: N/Av" has a shelf-life of 24-months from the date of production.



Ernesto Melgarejo, B.S.
Quality Manager
January 30, 2023

Galina Tuninskaya (oc)

Galina Tuninskaya, M.S.
President
January 30, 2023

January 30, 2023
L/N 41366/A - 36962/A (24 Months)

TABLE (24 Months)

SUMMARY OF CHEMICAL, PHYSICAL & MICROBIOLOGICAL ANALYSIS RESULTS FOR ROOM TEMPERATURE (*) STABILITY TESTING OF
EXOSOME SERUM, REFERENCE: 162-2019-09-47
(Lot: 20210112, Exp. Date: N/Av)

Analysis	Method	Specification	Unit	Results							
				0 Day	1 Month	3 Months	6 Months	9 Months	12 Months	18 Months	24 Months
Appearance	Visual	Liquid	N/A	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Color	Visual	Light Yellow	N/A	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Odor	Organoleptic	Characteristic	N/A	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Consistency	Visual	Homogeneous	N/A	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
pH at 25°C	USP <791>	5.30 – 8.30	N/A	7.39	7.23	7.43	7.04	6.66	6.54	6.16	5.94
Specific Gravity	USP <841>	0.9858 – 1.0268	N/A	1.0064	1.0095	1.0062	1.0090	1.0042	1.0081	1.0064	1.0042
Total Plate Count	USP <61>	< 100	CFU/g	< 100	< 100	< 100	< 100	< 10	< 10	< 10	< 10
Yeast and Mold	USP <61>	< 100	CFU/g	< 100	< 100	< 100	< 100	< 10	< 10	< 10	< 10

(*) Temperature: 25 ± 2°C/ Relative Humidity: 60 ± 5%RH

Reference: The United States Pharmacopeia/The National Formulary Ed. 2022, Issue 1

Note: CFU: Colony Forming Units
N/A: Not Applicable
N/Av: Not Available
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