KWEHEALTH

Certificate of Analysis – HydroKarma ExoPure™

Product Name	**HydroKarma ExoPure™**
Product Description	HydroKarma ExoPure™ is a premium cosmetic product meticulously manufactured to enhance cosmetic procedures. Crafted from clinical-grade amniotic fluid, it contains amniotic fluid-derived exosomes and extracellular matrix proteins and undergoes stringent quality assurance testing to meet predefined specifications for safety, identity, strength, purity and quality. The serum is packaged in high-quality glass vials with industry-leading low particle levels and minimal product-container interaction, reducing leachable chemicals and minimizing protein adsorption.
Part #	**KH-HKEP50-0.10**
Lot #	**KH-0007DE**
Shipping	Ship with dry ice
Storage Conditions	Store at -20^{0}C or below
Manufacturer	KWEHEALTH, LLC 13800 Tech City Circle, Suite 314 Alachua, FL 32615 www.kwehealth.com

Certification

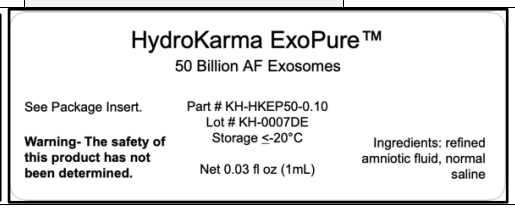
KWEHEALTH, LLC products are manufactured using aseptic techniques from pre-screened donor tissues and go through comprehensive clinical and laboratory testing to ensure they are safe and effective for end use. Medical records for each donor are screened for information pertaining to risk factors for relevant communicable diseases by a licensed medical doctor. The screening includes a serology panel for communicable diseases, medical history interview, physical examination, behavioral risk assessment, and information from other sources or records which may pertain to donor suitability. HydroKarma ExoPure™ is manufactured in an ISO certified controlled environment using aseptic techniques to prevent contamination and cross-contamination. Quality assurance testing is performed on all products to ensure they meet regulations for quality and effectiveness. Environmental monitoring, including aerobic, anaerobic, and sterility testing is performed on all lots to ensure the product is free from contamination and is safe for human use.

Samples from this lot were tested and the manufacturer certifies this product was processed in accordance with its quality program, which complies with the FDA's regulations contained in Title 21 CFR and Current Good Manufacturing Practices (cGMP).

Disclaimer

HydroKarma ExoPure™ is intended for use as a cosmetic only, as reflected by the labeling, advertising, and other indications of the manufacturer's objective intent. It may not be transferred to third parties, resold, modified, or mixed for resale. There is no claim that treatment using this product is a cure for any condition, disease or injury.

KWEHEALTH	**Certificate of Analysis**	**Record #:** PEX-00000119
		Version: 1.0
Certificate Of Analysis for HydroKarma ExoPure™		**Issuance Date:** October 14, 2025

GENERAL INFORMATION				
PRODUCT NAME	HydroKarma ExoPure™			
MANUFACTURER	KWEHEALTH, LLC		**LOT NUMBER**	KH-0007DE
SITE/LOCATION	Alachua, FL 32615		**DATE OF MANUFACTURE**	September 24, 2025
DONOR CONSENT	☒ Yes ☐ No		**DATE OF RELEASE**	October 14, 2025
PRODUCT/PROTEIN/EXOSOME STABILITY (UPON THAW)	Room Temperature: **12H**	4^{O}C: **48H**	**DATE OF EXPIRY**	September 24, 2027
PRODUCT LABEL	 			
KEY NOTES	Secondary label (on right) states incorrect fill volume of 1mL – fill volume is 3mL, as all other labeling reflects. HydroKarma ExoPure™ has been dermatologically tested and clinically proven to be hypoallergenic, safe, and non-irritating.			

DONOR SEROLOGY INFECTIOUS DISEASE SCREENING			
TEST	**RESULTS**	**SPECIFICATION**	**TEST LOCATION; TEST ID**
HIV I/II	Non-Reactive	Non-Reactive	Eurofins CellTX; 35210
Hepatitis B (Surface Antigen)	Non-Reactive	Non-Reactive	Eurofins CellTX; 32140
Hepatitis B (Virus Core)	Non-Reactive	Non-Reactive	Eurofins CellTX; 32110
Hepatitis C (Encoded Antigens)	Non-Reactive	Non-Reactive	Eurofins CellTX; 32210
HIV-1/HCV/HBV Nucleic Acid Test (NAT)	Non-Reactive	Non-Reactive	Eurofins CellTX; 2771, 2772, 2773
Syphilis	Non-Reactive	Non-Reactive	Eurofins CellTX; 3991
HTLV I/II	Non-Reactive	Non-Reactive	Eurofins CellTX; 35460
CMV	IgM: Non-Reactive	IgM: Non-Reactive	Eurofins CellTX; 35030, 31040, 31050
WNV Nucleic Acid Test (NAT)	Non-Reactive	Non-Reactive	Eurofins CellTX; 2722
COVID-19 illness or Vaccination (within 30 days)	Negative	Negative	Tissue Acquisition Company; Donor Eligibility Questionnaire

KWEHEALTH's donor eligibility criteria for sourcing amniotic fluid for HydroKarma ExoPureTM adheres to stringent regulatory and ethical standards, including FDA 21 CFR Part 1271, CDC, and AATB guidelines. Donors must be over 18 (or have guardian consent), undergo a healthy, live birth via scheduled Cesarean section, and provide amniotic fluid that is never from aborted tissue. Extensive screening excludes any donor with infectious diseases (e.g., HIV, Hepatitis, HTLV, WNV), high-risk behaviors (e.g., drug use, unsafe sexual activity), recent illnesses or vaccinations (e.g., COVID-19), or a history of genetic, autoimmune, neurological, or systemic disorders. All amniotic fluid collection, storage, and transport are conducted under tightly controlled procedures, with automatic disqualification for any deviation from protocol or regulatory requirements.

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FINAL PRODUCT TESTING					
TEST		**RESULT**		**SPECIFICATION**	**TEST LOCATION; TEST METHOD**
SAFETY – RELEASE TESTING					
Endotoxin		<0.1 EU/mL		≤4.5 EU/mL	Eurofins; LAL Method
Sterility		No Growth		No Growth	Eurofins; 14-day Sterility
IDENTITY – CHARACTERIZATION					
PAMG-1 (Amniotic Fluid)		Positive		Positive	KWEHEALTH; Lateral Flow Immunoassay (LFIA)
CD9, CD63, CD81 (Exosomes)		Positive		Positive	Spectradyne; Fluorescence Microfluidic Resistive Pulse Sensing (F-MRPS)
STRENGTH – CHARACTERIZATION					
Extracellular Vesicles (EV)	D10	68.0 nm	**50** billion EV per 3mL Vial	≥ 50 billion per 3mL Vial	Spectradyne; Fluorescence Microfluidic Resistive Pulse Sensing (F-MRPS)
	D50	78.7 nm			
	D90	122.6 nm			
Total Protein		0.599 mg/mL		≥ 0.10 mg/mL	KWEHEALTH; BCA Assay
EV Count / Total Protein		2.8×10^{10} particles/µg		≥ 4.0×10^{7} particles/µg	KWEHEALTH; Calculation
PURITY – CHARACTERIZATION					
Color		Clear, light yellow 0.054 AU @420nm		Clear to light amber or 0.000 – 0.200 AU @420nm	KWEHEALTH; Visual Observation BioTek Synergy HTX Plate Reader
Total Cell Count		0 cells/mL		0 cells/mL	KWEHEALTH; NC3000
QUALITY – CHARACTERIZATION					
Osmolality		290 mOsm/kg		260 – 310 mOsm/kg	KWEHEALTH; Osmometer
HRIPT		Hypoallergenic, non-irritating		Hypoallergenic, non-irritating	PCR Corp; PCRRIP1
Zeta Potential	Mean	-19.2 mV		-30 mV to -10 mV	Izon; Tunable Resistive Pulse Sensing (TRPS)
	Mode	-16.7 mV			
Sub-Visible Particulate	≥ 10 µm	0 particles/mL		NMT 25 particles/mL	Spectradyne; Fluorescence Microfluidic Resistive Pulse Sensing (F-MRPS)
	≥ 25 µm	0 particles/mL		NMT 3 particles/mL	

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TEST SUMMARY DESCRIPTION

TEST	RELEVANCE
Endotoxin	Endotoxins can cause inflammatory responses and potentially serious adverse reactions, even in small amounts.
Sterility	Critical quality control measure that ensures the product is free from viable microorganisms, ensuring product meets safety standards before distribution.
COVID-19	Tests if the product is free from SARS-CoV-2 contamination, an important safety measure, especially given the global impact of the SARS-CoV-2 pandemic.
HRIPT (Human Repeat Insult Patch Test)	To assess the potential of the product to cause irritation, sensitization, and allergic contact on the skin.
CD81, CD63, CD9 (Tetraspanin)	These tetraspanins are considered canonical markers for exosomes. Tetraspanins are important in mutual cell contact, exosome uptake, gamete maturation, fertilization, and embryo development.
PAMG-1	Placental Alpha Microglobulin-1 (PAMG-1) is highly specific to human amniotic fluid. It is produced by the decidual cells of the placenta and is present in high concentrations. Used for identity and strength analysis, ensuring product is derived from human amniotic fluid.
Exosome Size Distribution	Exosome size distribution provides crucial insights into the exosomes' properties, functional capabilities, and overall quality of the amniotic fluid preparation. Exosome size can influence their uptake, biodistribution, cargo content, and ultimately their beneficial potential. D10, D50, and D90 are key parameters used to describe the particle size distribution of exosomes within a sample. ***D10*** represents the particle diameter below which 10% of exosomes are found, reflecting the finer vesicle population. ***D50***, or the median particle size, indicates the point at which 50% of exosomes are smaller and 50% are larger, providing a measure of the predominant vesicle size within the sample. ***D90*** denotes the particle diameter below which 90% of exosomes are contained, corresponding to the larger vesicle population. Together, these parameters provide a comprehensive assessment of the exosome size range and distribution uniformity, which are critical indicators of product consistency, purity, and manufacturing quality.
Color	Visual indicator of product quality and purity. Amniotic fluid is typically clear with a slight yellow or amber tint.
Total Cell Count	To ensure complete removal of cells and confirm acellular nature of product.
Total Protein	This provides total protein count of product, a quantitative measure for potency, quality control and batch consistency.
EV Count / Total Protein	Reflects product quality and offers a potency metric.
Zeta Potential	Zeta potential provides important information about the stability and overall surface charge of particles in a suspension, like exosomes in amniotic fluid. It can help predict the tendency of the exosomes to aggregate in amniotic fluid, which can impact safety and efficacy of the product.
Sub-Visible Particulate	Subvisible particle specifications help ensure quality and safety of a product. These specifications help control the presence of particles that are too small to be seen with the naked eye but have the potential to cause adverse effects.

Certification

This product has been tested in compliance with applicable company procedures, and all specifications have been met unless otherwise noted.

Name	Title	Signature	Date
Casey McCormack	CQO		14 Oct 2025

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