

	Certificate of Analysis	Record #: PEX-00000083
		Version: 1.0
TITLE: CERTIFICATE OF ANALYSIS FOR HYDROKARMA REJUVENATE SERUM™ 70 BILLION		Effective Date: 14 Aug 2025

Product Name HydroKarma Rejuvenate Serum™ 70 Billion

Product Description **HydroKarma Rejuvenate Serum™ 70 Billion** is a premium regenerative aesthetics formulation designed to elevate natural harmony and refinement. Developed using **precision-isolated cell secretions** and **extracellular vesicles**, it delivers an advanced composition that supports balance, renewal, and the pursuit of optimal aesthetic outcomes. Crafted from **clinical-grade amniotic fluid**, each batch contains **amniotic fluid-derived exosomes** and **extracellular matrix proteins**, preserved through stringent, multi-stage quality assurance processes to ensure **safety, identity, strength, purity, and consistency**. This meticulous approach safeguards the unique profile and intended performance of the formulation. Presented in **high-grade glass vials** engineered for **low particulate levels** and **minimal interaction** between product and container, the serum is protected from leachable compounds and protein adsorption—maintaining its integrity from preparation to application. The result is an **exceptionally pure and precisely curated aesthetic formulation** that empowers practitioners to integrate innovation into diverse disciplines, from luxury beauty experiences to advanced professional care.

Part # **KH-HKS0.030**

Lot # **KH-0006DE**

Shipping Ship with dry ice

Storage Conditions Store at -20°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 Rejuvenate Serum™ 70 Billion 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 standards for quality and effectiveness. Environmental monitoring, including aerobic and anaerobic, endotoxin, and sterility testing is performed on all lots to ensure the product is free from contamination and is safe for human use.

Disclaimer

HydroKarma Rejuvenate Serum™ 70 Billion is intended for aesthetics applications, 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.

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GENERAL INFORMATION			
PRODUCT NAME	Hydrokarma Rejuvenate Serum™ 70 Billion		
MANUFACTURER	KWEHEALTH, LLC	LOT NUMBER	KH-0006DE
SITE/LOCATION	Alachua, FL 32615	DATE OF MANUFACTURE	23 July 2025
DONOR CONSENT	☒ Yes ☐ No	DATE OF RELEASE	14 Aug 2025
PRODUCT PROTEIN/EXOSOME STABILITY (UPON THAW)	Room Temperature: 12H 4°C: 48H	DATE OF EXPIRY	23 July 2027
PRODUCT LABELS			
KEY NOTES	HydroKarma Rejuvenate Serum™ (HRS) 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 Rejuvenate Serum adheres to stringent regulatory and ethical standards. Donors must be over 18 (or have guardian consent), undergo a healthy, live birth via scheduled Cesarean section, and provide amniotic fluid that is free from meconium or red in color—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 certain history of genetic, autoimmune, neurological, or systemic disorders. All tissue collection, storage, and transport are conducted under controlled procedures, with procedures in place for any deviation from protocol or regulatory requirements to assess tissue suitability and eligibility.

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FINAL PRODUCT TESTING					
TEST		RESULT		SPECIFICATION	TEST LOCATION; TEST METHOD
SAFETY – RELEASE TESTING					
Endotoxin		<0.001 EU/mL		≤4.5 EU/mL	Eurofins; LAL Method
Sterility		No Growth, Day 14		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	68nm	70 billion EV/ml	≥ 70 billion per 1ml Vial	Spectradyne; Fluorescence Microfluidic Resistive Pulse Sensing (F-MRPS)
	D50	78nm			
	D90	152nm			
Total Protein		2.5 mg/ml		≥ 2.0 mg/ml	KWEHEALTH; BCA Assay
EV Count / Total Protein		2.8 × 10 ⁷ particles/μg		≥ 2.0 × 10 ⁷ particles/μg	KWEHEALTH; Calculation
PURITY – CHARACTERIZATION					
Color		Clear, tinted yellow 0.077AU		Clear to light amber or 0.002 – 0.200 AU @420nm	KWEHEALTH; Visual Observation; Synergy HTX Multimode Reader
Total Cell Count		0 cells/mL		0 cells/mL	KWEHEALTH; NC3000
Turbidity		21 NTU		< 30 NTU	KWEHEALTH; Turbidity meter
QUALITY – CHARACTERIZATION					
pH		7.5		6.8 – 7.6	KWEHEALTH; pH Meter
Conductivity		13.1mS/cm		12 – 20 mS/cm	KWEHEALTH; Conductivity Meter
Salinity		7.21 ppt		7 – 11 ppt	KWEHEALTH; Conductivity-derived
HIRPT		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	CytoViva; Microscopic Analysis
	≥ 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 tests if the product is free from viable microorganisms, ensuring each lot meets the highest 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.
Color	Visual indicator of product quality and purity. Amniotic fluid is typically clear with a slight yellow or amber tint.
Turbidity	Turbidity is a parameter that can indicate the presence of particles, cellular debris, or other components that might affect a product's purity, stability, and efficacy.
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.
pH	Important for understanding product stability, efficacy, and compatibility.
Conductivity	Reflects ionic strength/osmolarity; impacts colloidal stability. Too low/high ionic content can cause aggregation or protein precipitation.
Salinity	Specific measure of dissolved salts (e.g., NaCl) driving osmolarity. Hyper/hypo-saline conditions can disrupt vesicles.
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 a 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	Chief Quality Officer		14 Aug 2025