

SUBJECT: Change in denomination of Exosome depleted material, implementation of in-house processing and change in method of measure of E.V. depletion

1- INFORMATION ON PRODUCT CONCERNED BY THE NOTIFICATION:

Catalogue Number: SxxxM
Batch Number: Batches produced since 11/2022
Production date: Not applicable

2- DESCRIPTION OF THE NOTIFICATION:

Description:

I used to subcontract a treatment called "Exosome depletion". This treatment depletes the microvesicles naturally present in the serum i.e. exosomes but also other extravesivular components. In order to better represents the reality of the treatment, I decided to change the denomination of the product from "Serum, Exosome depleted" to "Serum, E.V. Depleted" (where E.V. means ExtraVesicular).

Furthermore, I has invested in equipment to carry out the treatment in-house. The E.V. depletion can now be done in-house or subcontracted under the same level of quality.

I has also developped a test for measurement of depletion efficiency. The depletion rate was previously measured with a nanoparticle tracking analysis apparatus and is now measured with Elisa method. The acceptance criteria remains unchanged : $\geq 95\%$. E.V. values before and after depletion will no more be written on CoA.

Documents linked: Technical data sheet FT.SxxxMan dated 16/01/2023

3- PREVENTIVE / CORRECTIVE ACTION TO REALISE:

Description: Not applicable

Written by: JP Hamon

Position: Quality Manager

Date: 16/01/2023