



CTL Documentation

April 05, 2023

HSA (human serum albumin) Usage

The purpose of this letter is to confirm that the HSA liquid Cellular Technology Limited (CTL) buys from commercial sources is not used, and will not be used for direct patient injection.

CTL uses HSA (human serum albumin) in various concentrations for media manufacturing of CTL-Test™ Medium, CTL-Test™ PLUS Medium CTL-Wash™ Supplement, CTL-Cryo™ ABC, and CTL-AntiAggregate™ Wash Supplement.

The above mentioned media products are intended and labeled for laboratory research use only; not used for diagnostics, food or therapeutics.

The following statement had been copied from the HSA vendor's Certificate of Analysis:

Individual donor units used in the preparation of this product have been tested and found negative by tests for antibodies to HIV 1/2, HCV and non-reactive for HBsAg. Pooled samples were found non-reactive for HIV-1 RNA, HBV DNA and HCV RNA by Nucleic Acid Test. All testing performed with kits approved by the FDA. Each donor has been tested and found negative for syphilis according to FDA guidelines.

All donor units were collected at FDA approved donor centers located in the United States.

The pool of source plasma for fractionation from which the product comes from has been tested and found non-reactive for virological markers HBsAg, anti HIV-1/HIV-2 and anti HCV using validated serological tests, and for HCV RNA, HIV-1 RNA and HBV DNA using validated techniques.

ALL BLOOD PRODUCTS SHOULD BE HANDLED AND TREATED AS POTENTIALLY INFECTIOUS

Sincerely,

Prof. Paul V. Lehmann, M.D., Ph.D
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