



Unravelling Cell Isolation

CERTIFICATE OF ORIGIN

Clzyme Collagenase HA

Version 22 May 2018

COUNTRY OF ORIGIN

Collagenase HA, Catalog # 001-1000, 001-1050 and 001-1070 are manufactured entirely within the United States by VitaCyte LLC.

STATEMENT OF ANIMAL ORIGIN

None of the components used in the formulation of Collagenase HA use or come into contact with any ingredient of bovine origin during the manufacturing process. The only animal sourced material used in the manufacture of Collagenase HA is gelatin peptone derived from porcine skin. This peptone is a culture media component used to stimulate collagenase biosynthesis from *Clostridium histolyticum*. Prior to inoculation with the organism, the culture media is sterilized for 30 minutes at 121°C, a process shown to inactivate many viruses.¹ Other biochemical contaminants in the culture supernatant are removed during the purification process.

RISK OF TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHY

The use of porcine derived gelatin represents a minimal risk of Transmissible Spongiform Encephalopathy (TSE). No evidence exists for naturally occurring TSE in pigs or transmission to pigs from infected tissue.² Furthermore, no brain-heart infusion media is used at any stage of the Clzyme Collagenase HA manufacturing process.

Signatures:

A handwritten signature in black ink, appearing to read "R. McCarthy".

Robert McCarthy Ph.D.
President

A handwritten signature in blue ink, appearing to read "A. Breite".

Andrew Breite M.S., M.B.A.
Director of Quality Assurance

¹ International Federation for Animal Health Europe. Viral Inactivation Related to Steam Sterilisation of Biological Products. <http://www.ifaheurope.org/ifah-media/publications/215-viral-inactivation-1.html>; 2012 (Retrieved 19 Dec 2016)

² Wells, G.A.H.; et al. Portrait of experimental BSE in Pigs. In: Hornlimann, B.; Riesner, D.; Kretzschmar, H., eds. Prions in humans and animals. New York/Berlin: Walter de Gruyter; 2007: 275-278.

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