CERTIFICATE OF ANALYSIS

No QA090129

FITkit® TESTING SERVICES

Customer: **Therapeutic Goods Administration**
Office of Laboratories and Scientific Services
136 Narrabundah Lane, Symonston ACT 2609, Australia

Description of samples: syringes (inner surface)
Arrival date: 19 October 2009
Testing method: Capture enzyme immunoassay method (EIA; IEMA)
Compliant with: EN 455-3:2006; ASTM D7427 – 08

Note: On request of customer the extraction step of the testing process was altered. Extraction solution (0.5 mL of PBS solution, +4°C) was withdrawn into syringe and ejected after 2, 4 or 6 hours incubation at temperature +4°C. Surface of rubber tip of the plunger was exposed to the extraction solution throughout the incubation. Extraction solutions of three identically incubated syringes were mixed into one sample.

Test Results

Icosagen code	Sample code	Incubation time/ hours	Hev b 1 µg/L	Hev b 3 µg/L	Hev b 5 µg/L	Hev b 6.02 µg/L	Total µg/L
LAT09107	sample 2	2	UD	UD	UD	UD	UD
LAT09108	sample 3	2	UD	UD	UD	UD	UD
LAT09109	sample 4	4	UD	UD	UD	UD	UD
LAT09110	sample 5	4	UD	UD	UD	UD	UD
LAT09111	sample 6	6	UD	UD	UD	UD	UD
LAT09112	sample 7	6	UD	UD	UD	UD	UD

UD – Undetectable
Detection limits: Hev b 1 < 10 µg/L; Hev b 3 < 10 µg/L; Hev b 5 < 5 µg/L; Hev b 6.02 < 5 µg/L

30 October 2009

Ranno Rätsep
Proxy Quality Manager

As of 02 March 2009, Icosagen AS is the new business name of the former Quattromed AS.

Note:

The results related only to the tested item.
The test certificate shall not be reproduced except in full, without written approval of Icosagen AS laboratory.

Icosagen AS
Nooruse 9, 50411 Tartu, Estonia
Phone +372 737 7070, Fax +372 737 7077, info@icosagen.com
Reg No: 10565884, VAT No: EE100573055
www.icosagen.com