CERTIFICATE OF ANALYSIS

No QA090128

FITkit® TESTING SERVICES

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

Description of sample: syringe (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 testing process was altered. Extraction solution (0.5 mL of PBS solution, +4°C) was withdrawn into syringe and ejected immediately. Extraction solutions of three syringes were mixed into one sample.

Test Results

Icosagen code	Sample code	Hev b 1 µg/L	Hev b 3 µg/L	Hev b 5 µg/L	Hev b 6.02 µg/L	Total µg/L
LAT09106	sample 1	UD	UD	UD	UD	UD

UD – Undetectable

Detection limits:
Hev b 1 < 0.050 µg/g; Hev b 3 < 0.050 µg/g; Hev b 5 < 0.025 µg/g; Hev b 6.02 < 0.025 µg/g

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.

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