



CERTIFICATE OF ANALYSIS
FITkit® TESTING SERVICES

No QA090130

Customer:

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

Description of samples: syringe plunger pistons
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. Rubber tips of plungers from three syringes were cut into pieces and handled as one sample. Incubation was performed at temperature +4°C for 2, 4 or 6 hours, accordingly

Test Results

Icosagen code	Sample code	Incubation time/ hours	Hev b 1 µg/g	Hev b 3 µg/g	Hev b 5 µg/g	Hev b 6.02 µg/g	Total µg/g
LAT09113	sample 8	2	UD	UD	UD	UD	UD
LAT09114	sample 9	2	UD	UD	UD	UD	UD
LAT09115	sample 10	4	UD	UD	UD	UD	UD
LAT09116	sample 11	4	UD	UD	UD	UD	UD
LAT09117	sample 12	6	UD	UD	UD	UD	UD
LAT09118	sample 13	6	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.

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

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