Title:

Quality Control Record Sheet ¹²⁵I-labelled MuSK QC Data

72.3

Prepared by: Approved by:

G FLOOD

MuSK labelling date: 04 MARCH 2024

J BRADBURY

Document:

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Kit Lot Number:	KMK248		Kit Expiry Date: 29 APRIL 2024
¹²⁵ I-labelled MuSK:	MK248		Expiry Date: 29 APRIL 2024
Reconstitution Buffer:	171B		Expiry Date:18 JULY 2024
Anti Human IgG:	181Gm		Expiry Date: 10 DECEMBER 2024
Precipitation Enhancer:	PE193		Expiry Date: 29 OCTOBER 2024
Wash Solution:	439W		Expiry Date: <u>18 JULY 2024</u>
Negative Control:	MKN41p		Expiry Date: 10 SEPTEMBER 2024
Positive Control:	MKP42g		Expiry Date: 10 SEPTEMBER 2024
Specific activity of ¹²⁵ I-labelled MuSK:		1908	Ci/mmol (34.7 μCi/μg)
Total cpm in 50 μL of labelled MuSK:		89 4	

¹²⁵I Decay Table:

% Counter Efficiency: __

QC date	Decay factor		
(weeks after labelling date)			
up to 1 week	1.0		
+1 - 2 weeks	1.1		
+2 - 3 weeks	1.2		
+3 - 4 weeks	1.3		
+4 - 5 weeks	1.4		
+ 5 - 6 weeks	1.5		
+ 6 - 7 weeks	1.6		
+ 7 - 8 weeks	1.75		

Positive Control	Mean cpm	Nmol/L	Range (nmol/L)
Negative Control	362	-	-
Positive Control	13125	0.8211	0.77 ± 0.38

Materials of human origin used in the manufacture of this product have been tested and found non-reactive for HIV1 and 2 and HCV antibodies and HBsAg at the time of testing.

Assay Date:	07 MARCH 2024	Authorised b
Performed by:	Jonathon Davies	Signature: _
Signature:		Position:
Position:	Senior Scientist	Date: '7 T

Authorised by: DR G FLOOD

Signature: 4

Position: Head of Quality Control

Position: Head of Quality Control

Date: 7 MAR 2024