Title:

Quality Control Record Sheet <sup>125</sup>I-labelled MuSK QC Data

Prepared by: Approved by: G FLOOD

J BRADBURY

Document:

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Kit Lot Number:	KMK232		Kit Expiry Date: 03 FEBRUARY 2023		
<sup>125</sup> I-labelled MuSK:	MK232		Expiry Date: 03 FEBRUARY 2023		
Reconstitution Buffer:			Expiry Date: 01 SEPTEMBER 2023		
Anti Human IgG:	180Gm		Expiry Date: 11 SEPTEMBER 2023		
Precipitation Enhancer:	PE187		Expiry Date: 09 OCTOBER 2023		
Wash Solution:			Expiry Date: 25 MAY 2023		
Negative Control:	MKN40h		Expiry Date: 11 JUNE 2023		
Positive Control:			Expiry Date: 11 JUNE 2023		
Specific activity of <sup>125</sup> I-labelled MuSK:		1635	Ci/mmol ( 29.7 μCi/μg)		
Total cpm in 50 μL of labelled MuSK:		43799			
MuSK labelling date: <u>09 DEC</u>	EMBER 2022				
% Counter Efficiency:	72.3				

<sup>125</sup>I Decay Table:

QC date (weeks after labelling date)	Decay factor		
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	258	<u>-</u>	-
Positive Control	9893	0.7234	0.63 ± 0.31

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: 13 DECEMBER 2022
Performed by: Jonathon Davies

Position: Scientist

Signature:

Authorised by: OR G FLOOD

Signature: \_\_\_

Position: Head of Quality Control

Date: 13 TO DEC 2022