Title:

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

Prepared by:

G FLOOD

Approved by: J BRADBURY

Document:

wi/qcrs/0.30a

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20.10.2021

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V:41 -4 N					
Kit Lot Number:	KMK216		Kit Expiry Date: 04 APRIL 2022		
<sup>125</sup> I-labelled MuSK:	MK216		Expiry Date: 04 APRIL 2022		
Reconstitution Buffer:	165B		Expiry Date: 01 SEPTEMBER 2022		
Anti Human IgG:	179Gv		Expiry Date: 23 OCTOBER 2022		
Precipitation Enhancer:	PE181		Expiry Date: 27 OCTOBER 2022		
Wash Solution:	406W		Expiry Date: 12 MAY 2022		
Negative Control:	MKN38e		Expiry Date: 13 AUGUST 2022		
Positive Control:	MKP38e		Expiry Date: 13 AUGUST 2022		
Specific activity of <sup>125</sup> I-labelled MuSK:1986		1986	Ci/mmol ( 36.1 μCi/μg)		
Total cpm in 50 μL of labelled MuSK:49618					
MuSK labelling date: <u>07 February</u>					
% 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	297	-	-
Positive Controll	11567	0.7072	0.66 ± 0.33

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:	10 February 2022	
Performed by: _	Jonathon Davies	
Signature:		

Position: Scientist

Authorised by: DR G FLOOD
Signature: 4

Position: Head of Quality Control

Date: 11TH FEB 2022