Title: Quality Control Record Sheet

125 I-labelled MuSK QC Data

Prepared by: G FLOOD Approved by: J BRADBURY Document: Revision:

wi/qcrs/0.30a

Issue date:

20.10.2021

1 of 1

Page

Kit Lot Number:	KMK236	Kit Expiry Date: 29 MAY 2023			
<sup>125</sup> I-labelled MuSK:	MK236	Expiry Date: 29 MAY 2023			
Reconstitution Buffer:	168B	Expiry Date: 01 SEPTEMBER 2023			
Anti Human IgG:	181Ga	Expiry Date: 09 JANUARY 2024			
Precipitation Enhancer:	PE188	Expiry Date: 03 JANUARY 2024			
Wash Solution:	431W	Expiry Date: 02 JANUARY 2024			
Negative Control:	MKN40p	Expiry Date: <u>09 OCTOBER 2023</u>			
Positive Control:	MKP41e	Expiry Date: <u>09 OCTOBER 2023</u>			
Specific activity of <sup>125</sup> I-labelled M	Ci/mmol ( 30.2 μCi/μg)				
Total cpm in 50 μL of labelled MuSK:46135					
MuSK labelling date: 03 APRIL 2023					

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

% Counter Efficiency: 72.3

1 Decay Table.		
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	296	-	-
Positive Control	11717	0.844	$0.77 \pm 0.38$

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:	06 APRIL 2023	Authorised by: DR G
Performed by:	Jonathon Davies	Signature:
Signature:		Position: Head of Qua
Position:	Senior Scientist	Date: 6TH APR