Quality Control Record Sheet Title: 125 I-labelled MuSK QC Data

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

wi/qcrs/0.30a

Revision: Issue date:

20.10.2021

Page 1 of 1

Kit Lot Number:	KMK214	V
<sup>125</sup> I-labelled MuSK:	MK214	Kit Expiry Date: 07 MARCH 2022
Reconstitution Buffer:	165B	Expiry Date: 07 MARCH 2022
Anti Human IgG:	179Gu	Expiry Date: 01 SEPTEMBER 2022
Precipitation Enhancer:	PE181	Expiry Date: <u>02 OCTOBER 2022</u>
Wash Solution:		Expiry Date: 27 OCTOBER 2022
Negative Control:	406W	Expiry Date: <u>12 MAY 2022</u>
Positive Control:	MKN38d	Expiry Date: <u>16 JULY 2022</u>
TOSILIVE CONTROL:	MKP38d	Expiry Date: <u>16 JULY 2022</u>

Specific activity of <sup>125</sup>I-labelled MuSK: \_ 2185 Ci/mmol ( 39.7 μCi/μg)

Total cpm in 50 μL of labelled MuSK: \_\_\_\_\_

MuSK labelling date: 10 January 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	187	-	-
Positive Controll	11894	0.6677	0.66 ± 0.33

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

Assay Date:	13 January 2022	
Performed by:	Janet Bradbury	
Signature:	Bradbury	
Position:	Head of Operations	

Authorised by: \_\_\_\_\_\_\_ Signature:

Position: **Head of Quality Control** Date: 14 Th JAN