Title:

Quality Control Record Sheet 125I-labelled MuSK QC Data

Prepared by:

G FLOOD

Approved by: R STEPHENS

Document: Revision:

Issue date:

wi/qcrs/0.30

40.0,0.0

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QC Sheet no:	MK204	_		
<sup>125</sup> I-labelled MuSK lot no:	MK204	_		
Specific activity of 125 l-labelled MuSK: _	1904	_Ci/mmol (	34.6	μCi/μg)
Total cpm in 50 μL of labelled MuSK: _	44844			
MuSK labelling date: 01 June 2021	Expiry date: 27 July 2021	<b>-</b> j:		
% Counter Efficiency: 72.	3			

125 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	

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:	04 June 2021	Authorised by: DR & FLOOD
Performed by:	Jonathon Davies	_ Signature: _ < floor
Signature:		Position: Head of Quality Control
Position:	Scientist	Date: 4 T JUN 2021

When the	above tracer was tested	d with AChRAb IPA kit lot KRBAN <u>181</u> , 50 μl of	the negative control lot
MKN	37f gave a result of	240 cpm and 50 $\mu l$ of the positive control lot MK	(P37f gave a
result of	11690 cpm		

Methods for diagnosing myasthenia gravis by detecting autoantibodies to MuSK are the subject of patents EP327147 B1 and US7,267,820 B2.