

RFE MEMO

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Product Description(s): Vascular Injury Control Pack 1

Catalog Number(s) / Size(s): C4198-1

Lot Number: CP000036

Based on additional testing, the original date of expiration for this Control Pack been extended by 12 months. The expiration date of CP000036 has been extended to 30 JUN 2019.

The expiration dates for the following kit components have also been extended:

Description	Lot Number	Original Expiration Date	New Expiration Date
Vascular Injury Control 1	A00C0381	30 JUN 2018	30 JUN 2019
Vascular Injury Control 2	A00C0382	30 JUN 2018	30 JUN 2019
Vascular Injury Control 3	A00C0383	30 JUN 2018	30 JUN 2019

Function	Name	Signature	Date
Quality Assurance	Dawn Stollar	Dawn Stollar	12 MAR 2018

This memo supersedes all other statements regarding date of expiration for this product.

Memo Rev. A CM-00289-B



CERTIFICATE OF ANALYSIS

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Product Description: Vascular Injury Control Pack 1

Catalog Number: C4198-1 Lot Number: CP000036

Expiration Date: 30 JUN 2018

Concentration of Materials Tested:

Units = pg/mL	Assay			
	hu SAA	hu CRP	hu VCAM-1	hu ICAM-1
Vascular Injury Control 1 (A00C0381)	70 500	24 300	13 900	16 300
Vascular Injury Control 2 (A00C0382)	6620	4900	1331	1720
Vascular Injury Control 3 (A00C0383)	833	604	165	209

Control concentrations were assigned across 3 kit lots.

Vascular Injury Control Pack Component	S		
Description	Lot Number	Storage Temperature	Expiration Date
Vascular Injury Control 1	A00C0381	≤ -70° C	30 JUN 2018
Vascular Injury Control 2	A00C0382	≤ -70° C	30 JUN 2018
Vascular Injury Control 3	A00C0383	≤ -70° C	30 JUN 2018

Statement: The above product was manufactured and tested using MSD procedures and it conforms to MSD's specifications. This product is intended for Research Use Only. Not for use in Diagnostic Procedures.

	Name	Function	Signature	Date
Review/Approval	Dawn Stollar	Quality Assurance	Dawn Stollar	08 MAR 2017