

Ortho Clinical Diagnostics

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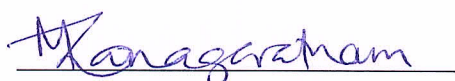
Statement of Copy

To whom it may concern:

We, Ortho-Clinical Diagnostics, located at
Felindre Meadows, Pencoed, Bridgend,
CF35 5PZ, United Kingdom

As a responsible official of Ortho-Clinical Diagnostics, I the undersigned hereby certify that the enclosed document copies of Product **Labelling** are true and accurate, for the following products:

Product Code	Product Name	Packaging Label Level	Label Version
707155	Blood Grouping Reagents Anti-A (Monoclonal) Anti-B (Monoclonal) Anti-D (Anti-D RH1)(Monoclonal) Control Reverse Diluent Ortho BioVue System (ABO-Rh Reverse Grouping Cassette)	1 x cassette front label 1 x cassette back label 1 x sleeve 1 x shipper label 1 x corrugated shipper Generic Insert	606-30-158-1 606-30-002-1 IJ5004-2 604-30-002-3 IJ5006-2 631-99-122-1
707250	Blood Grouping Reagents Anti-C (Anti-RH2) (Monoclonal) Anti-E (Anti-RH3) (Monoclonal) Anti-c (Anti-RH4) (Monoclonal) Anti-e (Anti- RH5) (Monoclonal) Anti-K (Anti-K1) (Monoclonal) Ortho BioVue System (Rh/K Cassette)	1 x cassette front label 1 x cassette back label 1 x sleeve 1 x shipper label 1 x corrugated shipper Generic Insert	606-30-161-1 606-30-014-1 IJ5004-2 604-30-007-2 IJ5006-2 631-99-122-1



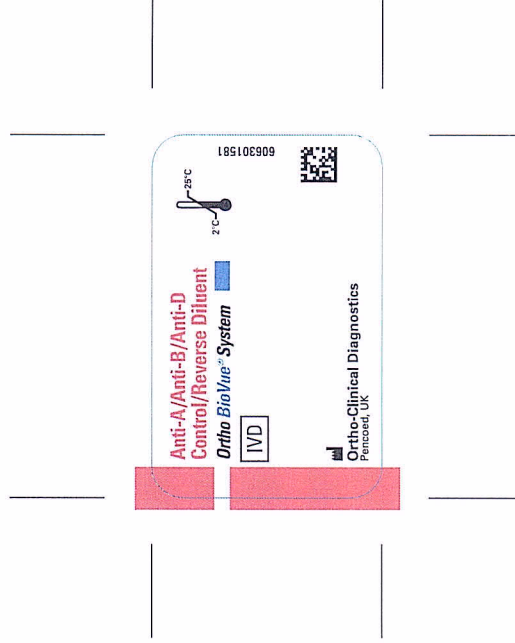
date: 17 May 2017

Michelle Tara Kanagaratnam
Regulatory Affairs, UK

OCD Mechanical Info. – FOR INTERNAL USE ONLY

Designer Who Last Modified File:	<i>Kim DePaola</i>	SPC Number in OTIS:	<i>SPC54715</i>	<i>01-27-16: KD used approved 606-30-001-2CRMU, added new component number, added new datamatrix code and made revs per marked up PDF for Crimson PH2 project. 01-29-16 KT signed.</i>
Date File Was Last Modified:	<i>01-27-16</i>	Dimension on SPC:	<i>1-15/16" x 1-7/32"</i>	
2nd Designer review: (layout and requested changes only)	<i>01-29-16 KT</i>	Line Screen:	<i>None</i>	
PMS Colors Used in File:	 Black   PMS 298			

606-30-158-1
BioVue Cassette Label Front



Kenagazham 17 May 2017

OCD Mechanical Info. FOR OCD USE ONLY - REFER TO SPECIFICATION

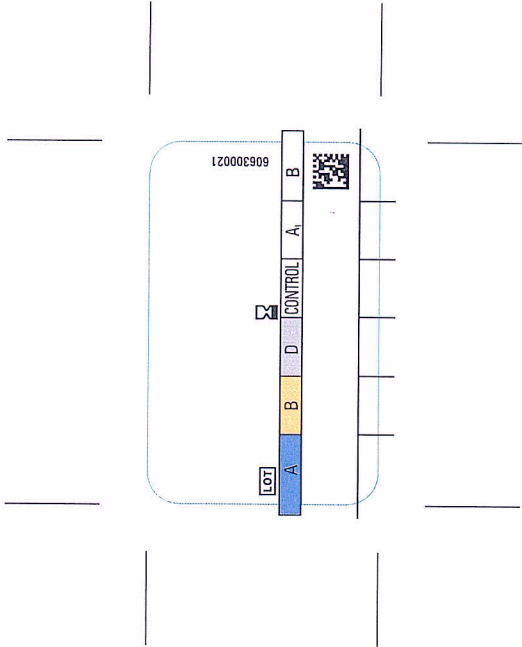
Date Copy Control Approved File:	7/17/02 gw	Designer Who First Created File:	Kim DePaola
Date Pkg. Engineering Approved File:	7/15/02 ro	Date File Was Last Modified:	4/15/02
PMS Colors Used in File:	PMS 298, 123, 429, & BLACK	Designer Who Last Modified File:	
Line Screen:	None	Dimension on Specification:	1 15/16" x 1 7/32"
Mechanical Modification Information: Additional modifications were made and are highlighted below:		YES ☐	NO ☐
		NEW ☒	



OTHER: 4/15/02—KD only replaced data matrix code in file to ensure correct size of code

5/9/02—KD replaced data matrix code with correct code

7/18: CM entered approval dates/Changed Default 133 line to None in slug area

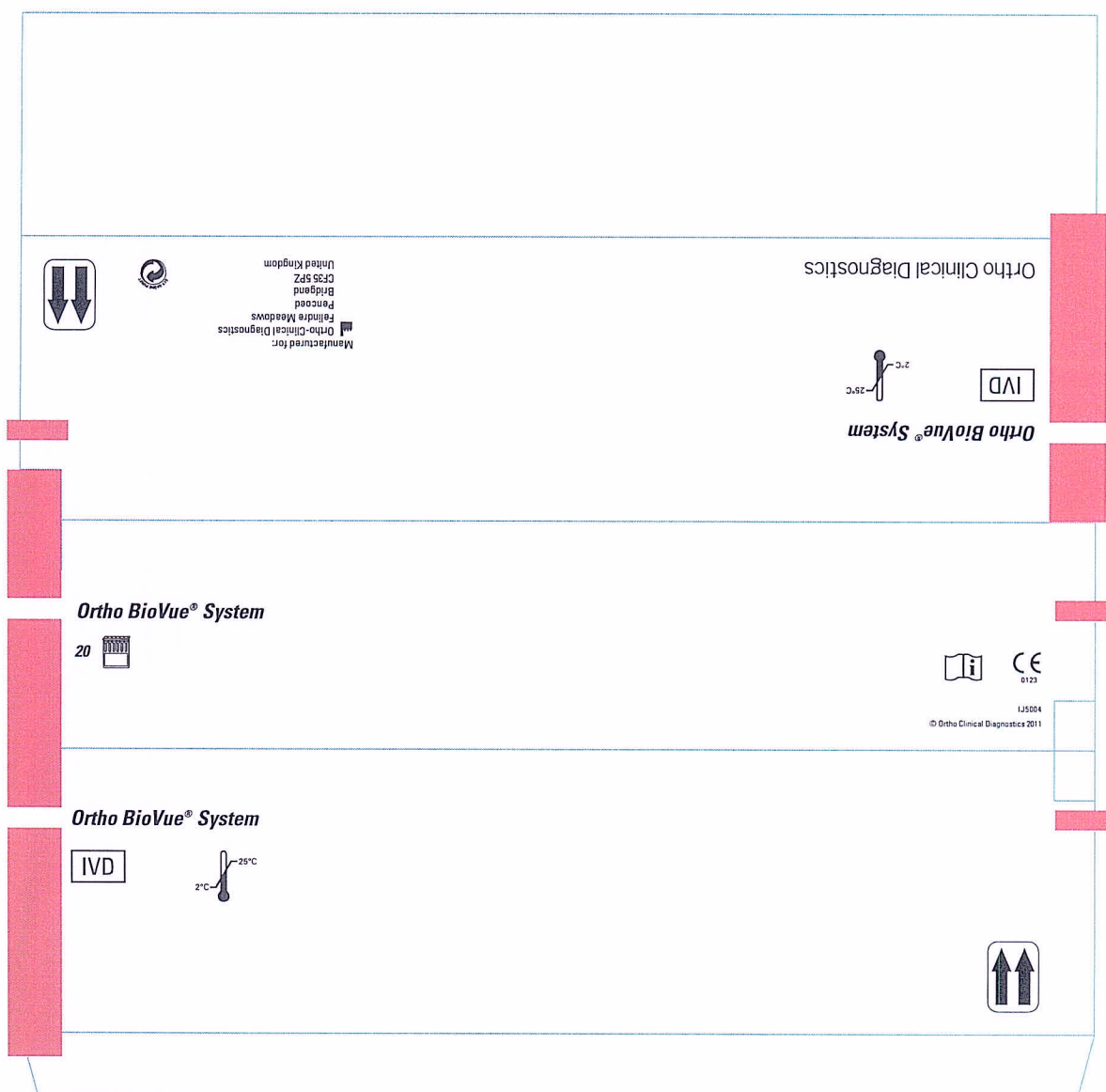


Ortho Clinical Diagnostics
Pencoed, UK
Handwritten signature
17 May 2017

OCD Mechanical Info. – FOR INTERNAL USE ONLY

Designer Who Last Modified File:	Kyle Tevlin	SPC Number in OTIS:	SPC54071 / LBL51220	01-22-16: KD used approved IJ5004CRMU, rolled tailcode, made file 100% per vendor request and made revs per marked up PDF for Crimson PH2 project. 01-22-16 CR signed 02-12-15 KT deleted tail code from artwork component # and rolled it to a -2 on upper left file name per LM email and new markup. 2-12-16: KD signed.
Date File Was Last Modified:	02-12-16	Dimension on SPC:	2 9/32" x 2 27/32" x 10 11/16" ± 1/64"	
2nd Designer review: (layout and requested changes only)	2-12-16.KD	Line Screen:	None	
PMS Colors Used in File:  Black  PMS 185				

IJ5004-2 **BioVue Sleeve** **for Pencoed**

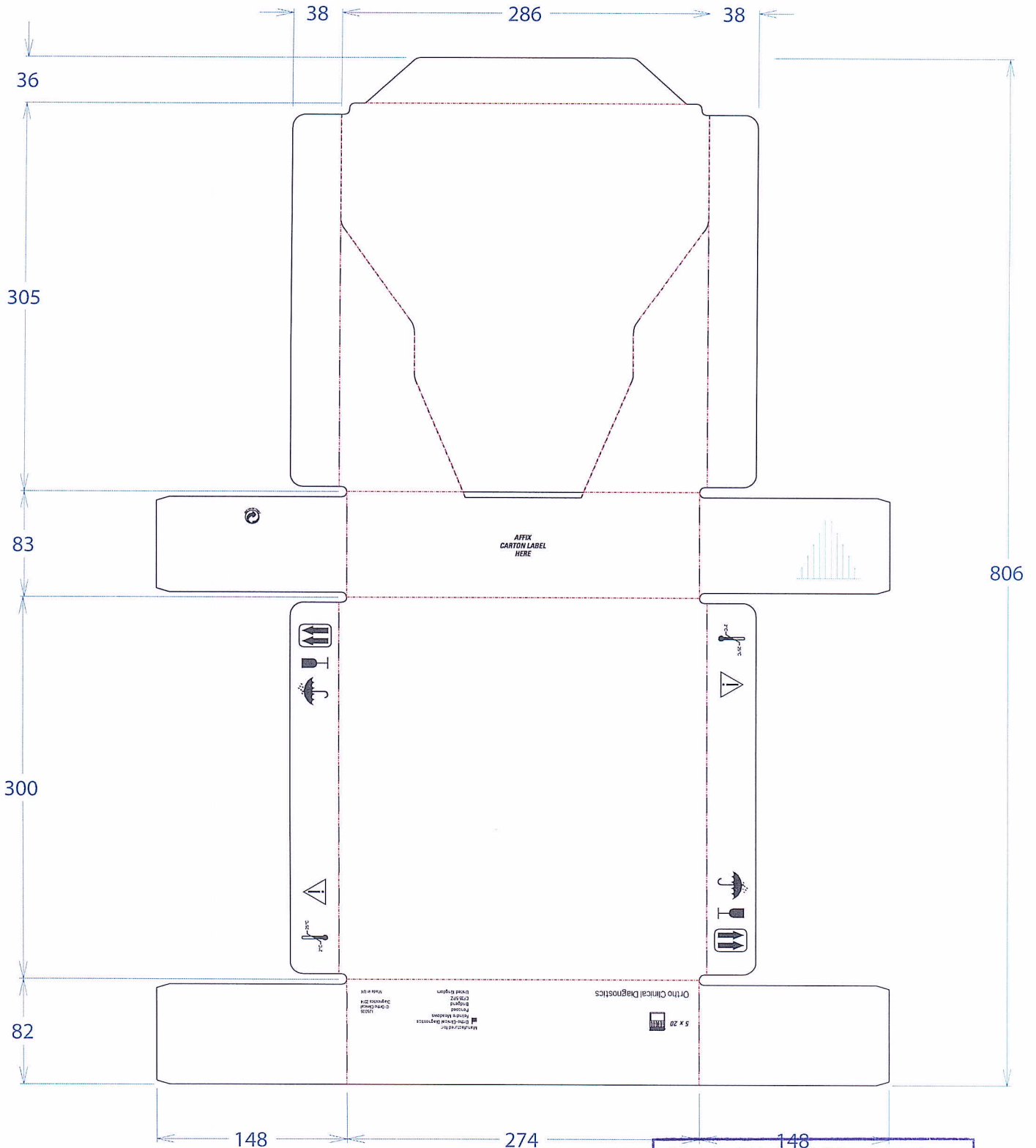


Ortho Clinical Diagnostics
Pencoed, UK
Kanagratnam
17 May 17

OCD Mechanical Info. - FOR INTERNAL USE ONLY

Designer Who Last Modified File: Kyle Tevlin	SPC Number in OTIS: SPC34056 LBL 31221	01-22-16 CR used IJ5006-1C1EMU and made revisions per marked up PDF for Crisman PHZ project.
Date File Was Last Modified: 02-12-16	Dimension on SPC: 305mm x 33mm x 266mm	01-25-16 KT aligned.
2nd Designer review. (Applied and requested changes only): 02-12-16 KD	Drawing #: UK006283	02-12-16 KT deleted tail code from network component # per LM email and new markup.
PMS Colors Used in File: DCM P50		02-12-16 KD aligned.

IJ5006-2
BioVue Pencoed 100 Count
Corrugated Shipper



Ortho Clinical Diagnostics
Pencoed, UK

Managaram
17 May 17

OCD Mechanical Info. FOR OCD USE ONLY - REFER TO SPECIFICATION

Date Copy Control Approved File:	2/6/12 CC	Designer Who First Created File:	Kim DuPaola
Date Pkg. Engineering Approved File:	2/6/12 MS, RZ	Date File Was Last Modified:	01/20/12
Line Screen:	NONE	Designer Who Last Modified File:	Kyle Tevlin
PMS Colors Used in File:	Dimension on Specification:		
	Drawing # N/A		
	Dimension on Specification: 8" x 3"		
Black		LBL 50386	
			

OTHER: 12/14/10 CR rolled tailcode to -2 Added text per marked up copy. Need decision on Chinese and (RH1) copy.
Added (Anti-RH1) and Anti- Infront of others in parenthesis per Nancy Geer email. Chinese needs nothing.
12/21/11 CR added copy per marked up PDF from CC
01/16/12 CR made revs per marked up PDF for GS1. Adjusted icons on bottom right. Rewrapped text, needed space for GS1 labeling
1/19/12 KT adjusted spacing between @ and System per CC phone conversation.
01/20/12 CR added space before and after backslash to be consistent with other labels per JL email response.
2/7/12 KT entered approval dates and locked file.

604-30-002-3
Shipper Label

Anti-A (Anti-AB01) / Anti-B (Anti-AB02) / Anti-D (Anti-RH1) /
Control / Reverse Diluent
抗 A / 抗 B / 抗 D / 质控 / 反定型稀释液
Ortho BioVue® System

IVD



Blue box does not print.
← Indicates GS1 area.

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Diagnostics, Inc. 2002
604300023

FOR EXPORT ONLY



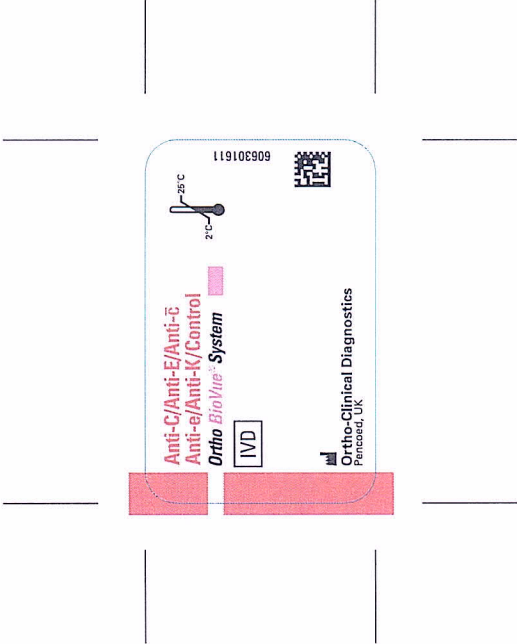
REF
707155

Ortho Clinical Diagnostics
Pencoed, UK
Ranganathan 17 May 17

OCD Mechanical Info. – FOR INTERNAL USE ONLY

Designer Who Last Modified File:	Kim DePaola	SPC Number in OTIS:	SPC54718	01-29-16: IVD used approved 606-30-013-2CRMU, updated to new component number and made revs per marked up PDF for Crimson PH2 project. 01-29-16 KT signed.
Date File Was Last Modified:	01-29-16	Dimension on SPC:	1-15/16" x 1-7/32"	
2nd Designer review: (layout and requested changes only)	01-29-16 KT	Line Screen:	None	
PMS Colors Used in File:	Black PMS 185 PMS 224			

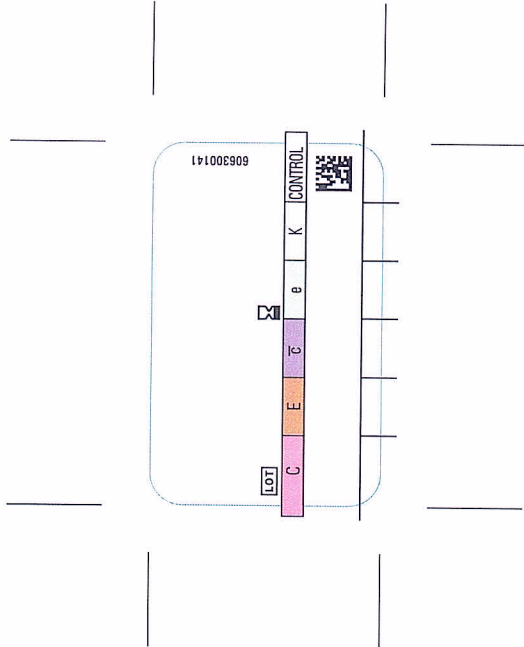
606-30-161-1
BioVue Cassette Label Front



Ortho Clinical Diagnostics
Pencoed, UK
K. Nagarajan 17/04/17

OCD Mechanical Info. FOR OCD USE ONLY - REFER TO SPECIFICATION

Date Copy Control Approved File:	7/15/02 gw	Designer Who First Created File:	Kim DePaola	
Date Pkg. Engineering Approved File:	7/12/02 ra 7/15/02 sd	Date File Was Last Modified:	4/25/02	
PMS Colors Used in File:	PMS 224, 153, 2572, 352 & BLACK	Designer Who Last Modified File:		
Line Screen:	none	Dimension on Specification:	1 15/16" x 1 7/32"	
Mechanical Modification Information: Additional modifications were made and are highlighted below:		YES ☐ NO ☐ NEW ☒	OTHER: 7/9/02—KD only changed line screen to "none" in slug 7/15/02—cf entered CC and Eng approval dates and locked file.	



Ortho Clinical Diagnostics
Pencoed. UK
Thomasa
17 May 17

Designer Who Last Modified File: <i>Kyle Tevlin</i>	SPC Number in OTIS: <i>SPC54071 / LBL51220</i>	<i>01-22-16: KD used approved IJ5004CRMU, rolled tailcode, made file 100% per vendor request and made revs per marked up PDF for Crimson PH2 project. 01-22-16 CR signed 02-12-15 KT deleted tail code from artwork component # and rolled it to a -2 on upper left file name per LM email and new markup. 2-12-16: KD signed.</i>
Date File Was Last Modified: <i>02-12-16</i>	Dimension on SPC: <i>2 3/32" x 2 27/32" x 10 11/16" ± 1/64"</i>	
2nd Designer review: (layout and requested changes only) <i>2-12-16.KD</i>	Line Screen: <i>None</i>	
PMS Colors Used in File: Black PMS 185		

[illegible]

Managerial
17 May 17

Designer Who Last Modified File: Kyle Twitlin	SFC Number in DTIS: SPCS4056 LBL: 31221	01-25-16 CR used L5006+1CRMU and made revisions per marked up PDF for Crimson PMS project.
Date File Was Last Modified: 02-12-16	Dimension on SFC: 305mm x38mm x 250mm	01-25-16 KT signed.
2nd Designer Review (checked and initiated changes only): 02-12-16 KD	Drawing #: UK000283	01-22-16 KT deleted tail code from artwork component # per LRM email and new marks.
PMS Colors Used in File:		02-12-16 KD signed.

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Ortho Clinical Diagnostics
Pencoed, UK

Thonagaram 17 May 17

OCD Mechanical Info. FOR OCD USE ONLY - REFER TO SPECIFICATION

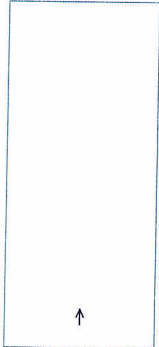
Date Copy Control Approved File:	1/20/12 CC	Designer Who First Created File:	Kim DePaola	OTHER: 01/10/12 CR made changes per marked up PDF for CSI Adjusted icons on bottom right. 1/19/12 KT adjusted spacing between @ and System per CC phone conversation. 2/1/12 KT entered approval dates and locked file.
Date Pkg. Engineering Approved File:	2/1/12 RS, RZ	Date File Was Last Modified:	01/19/12	
Line Screen:	NONE	Designer Who Last Modified File:	Kyle Twinn	
PMS Colors Used in File:				
		Dimension on Specification:	8" x 3"	
		Drawing #	N/A	
		LBL 50031		
				



604-30-007-2
Shipper Label

Anti-C / Anti-E / Anti-Ċ / Anti-e / Anti-K / Control
Ortho BioVue® System

IVD



Blue box does not print.
Indicates CSI area.

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Diagnostics, Inc. 2002
604300072
FOR EXPORT ONLY
0123
CE
REF 707250

Ortho Clinical Diagnostics
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17 May 17