

Affected Site(s):
US: MA: Tewksbury; US:
NC: Durham

Document Number:

LSR00216

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FALCON® Serological Pipettes 1mL-100mL

FALCON® Serological Pipets

FEATURES:

Easy-to-read high contrast graduations help you accurately measure and dispense culture media and reagents.

Color-coded pipets facilitate correct size selection.

Negative graduations provide extra capacity reducing the number of pipets required when adding media to culture dishes and flasks.

Reverse graduations (except 1 mL) are convenient for delivering repetitive volumes of liquid.

Polyester fiber plug protects your solution and pipettors from contamination from overfilling.

Flexible packaging options provide ability to simplify your aseptic work flow with color coding and ease of opening and removal using Falcon pipets. The individual packaging for pipets provide you superior ease-of-use and sterility assurance. A variety of packaging options including paper-plastic, all-plastic ADVANTAGE™ and bulk packages are available to meet your lab needs. The all-plastic packaging provides lower particulate shredding required for clean room environments and is fully recyclable.

CLAIMS:

Volumetric Accuracy – Serological pipets are accurate to \pm 2% at full volume in compliance with ASTM E394, "Standard Specification for Serological Pipet, Disposable Plastic" and ISO 12771, "Plastics Laboratory Ware – Disposable Serological Pipettes".

Sterility – Product has been sterilized and dosimetrically released per the requirements of ANSI/AAMI/ISO 11137, "Sterilization of Health Care Products – Radiation". Product meet a minimum Sterility Assurance Level (SAL) of 10^{-6} .

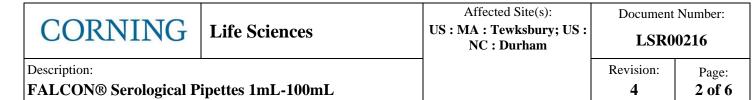
USP Class VI Testing – All material resin is tested, qualified and shown to be non-toxic as established in the Standards USP Class VI Chapter<87>, "Biological Reactivity Tests, in vitro" and Chapter<88>, "Biological Reactivity Tests, in vivo".

Non-Pyrogenic – Tested and met the criteria established in the current version of United States Pharmacopeia (USP) Chapter<85>, "Bacterial Endotoxins Test". The acceptance level for product is \leq 0.125 EU/ml or \leq 5 EU/device.

DNase / RNase Free – Tested by nuclease assay method and found to be free of detectable DNase/RNase contamination. The assay detection limit is 10^{-7} Kunitz units/ μ L for DNase and 10^{-9} Kunitz units/ μ L for RNase.

Human DNA Free – Tested by PCR method and found to be free of detectable human DNA contamination.

BSE / TSE – Product complies with the latest revision of EMA/410/01 "Note for guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products" by



virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMA/410/01.

Extractables – Data is available upon request (with an active NDA in place).

Quality Control Testing – Representative product samples are collected and inspected in accordance with current applicable product specifications. Inspection records are reviewed and approved by qualified personnel for product release.

LOT NUMBER DESIGNATION (7-DIGITS):

First digit – Last number of year of manufacture; next 3 digits – Julian date, start of manufacturing; last 3 digits – batch identification

SHELF LIFE:

5-years from date of manufacture

REGULATORY COMPLIANCE:

Falcon® serological pipets are manufactured under the current ISO 13485 Standards, and the current FDA Quality System Regulation 21 CFR Section 820.

TABLE I: MATERIALS

COMPONENT		MATERIAL
PIPET		POLYSTYRENE (PS)
PLUG		POLYESTER FIBER



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TABLE II: PRODUCT AND PACKAGING CONFIGURATION

FALCON® Serological Pipettes 1mL-100mL

SIZE (mL)	INCREMENTS	OVERFILL CAPACITY	REVERSE GRAD	COLOR	CAT. NO.	PACKAGING	CASE QTY	PACK QTY
					357506	BULK	1000	25
1	1/100 mL	.4 mL		YELLOW	356521	ADVANTAGE™	1000	100
					357521	PAPER-PLASTIC	1000	100
					357508	BULK	1000	25
2	1/100 mL	.8 mL	٧	GREEN	356507	ADVANTAGE™	1000	100
					357507	PAPER-PLASTIC	1000	100
	1/10 mL	2.5 mL	٧		357529	BULK	500	25
5				BLUE	356543	ADVANTAGE™	200	50
					357543	PAPER-PLASTIC	200	50
	1/10 mL	3 mL	٧	RED	357530	BULK	500	25
10					356551	ADVANTAGE™	200	50
					357551	PAPER-PLASTIC	200	50
25			٧	MAGENTA	357515	BULK	200	20
SPACE	1/4 mL	7 mL			356525	ADVANTAGE™	200	50
SAVER					357525	PAPER-PLASTIC	200	50
25	1/2 ml	11 mL	٧	MAGENTA	356535	ADVANTAGE™	200	50
EXTENDED	1/2 mL	11 ML			357535	PAPER-PLASTIC	200	50
50	1 mL	10 mL	٧	BLACK	356550	ADVANTAGE™	100	25
50	1 IIIL	10 IIIL	V	BLACK	357550	PAPER-PLASTIC	100	25
100	1mL: 3-30 mL 5mL: 30-110 mL	10 mL	٧	BLACK	357600	ADVANTAGE™	50	5

- ADVANTAGE™ is an all-plastic banana peel style wrapper
- For 100mL, to achieve total capacity of 125mL use the top bolded TD blow-out ring



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TABLE III: PRODUCT DIMENSIONS

FALCON® Serological Pipettes 1mL-100mL

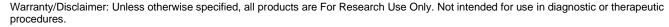
SIZE	0\	/ERALL DI	MENSION	NS .	TIP			MOUTHPIECE			EXTRUSION		
(mL)	Α	В	С	D	L	ID	OD	L	ID	OD	L	ID	OD
1	279.40 11.00"	3.35 .132"	4.65 .183"	4.65 .183"	N/A	1.67 .066"	3.35 .132"	N/A	2.96 .117"	4.65 .183"	N/A	N/A	N/A
2	282.58 11.13"	3.73 .147"	6.27 .247"	6.27 .247"	N/A	1.63 .064"	3.73 .147"	N/A	4.17 .164"	6.27 .247"	N/A	N/A	N/A
5	348.51 13.72"	3.35 .132"	8.03 .316"	8.03 .316"	37.36 1.471"	1.57 .062"	3.35 .132"	N/A	6.01 .236"	8.03 .316"	311.15 12.25"	6.01 .236"	8.03 >.316"
10	346.81 13.65"	3.30 .130"	8.05 .317"	9.61 .370"	37.36 1.471"	1.57 .062"	3.35 .132"	22.23 .875"	5.72 .225"	7.62 .300"	285.75 11.25"	7.95 .313"	9.60 .378"
25	310.90	4.78	7.62	15.16	39.24	2.36	4.78	25.91	5.08	7.62	249.35	13.43	15.16
S.S.	12.24"	.188"	.300"	.597"	1.545"	.093"	.188"	1.02"	.200"	.300"	9.82"	.529"	.597"
25	336.29	4.78	7.62	15.16	39.24	2.36	4.78	25.91	5.08	7.62	274.75	13.43	15.16
EXT.	13.24"	.188"	.300"	.597	1.545"	.093"	.188"	1.02"	.200"	.300"	10.82"	.529"	.597"
50	368.17	5.49	7.62	17.78	39.24	3.18	5.49	27.94	5.59	7.62	301.12	16.00	17.78
	14.50"	.216"	.300"	.700"	1.545"	.125"	.216"	1.10"	.220"	.300"	11.86"	.630"	.700"

TABLE IV: 100mL PRODUCT DIMENSIONS

Size			TIP		MOUTHPIECE						
(mL)	Α	В	С	D	Е	L	D	OD	L	ID	OD
100	370.26	6.20	6.32	36.58	20.27	235.97	3.81	6.20	133.73	4.19	6.32
100	14.58"	.244"	.249"	1.440"	.798"	9.290"	.150"	.244"	5.265"	.165"	.249"

L = length ID = interior diameter OD = outside diameter N/A = Not Available

Top/bottom dimensions = millimeters/inches





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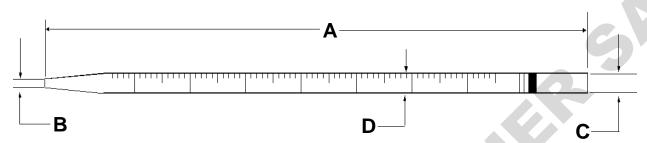
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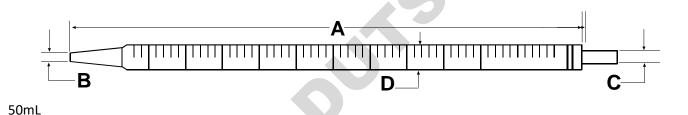
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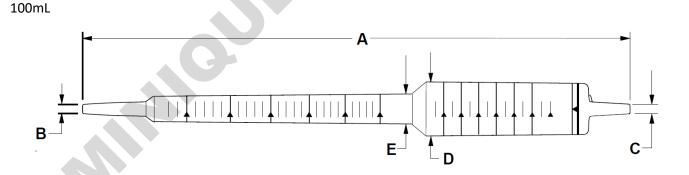
REPRESENTATIVE DIAGRAMS:

1mL, 2mL and 5mL



10mL, 25mL and





CORNING

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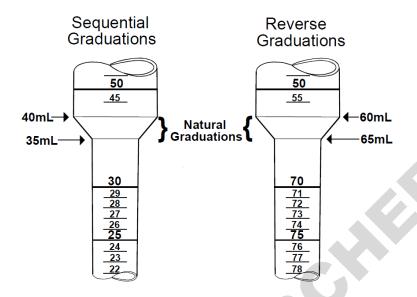
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RESTRICTIONS:

Refer to "Thermoplastics Properties Chart," (CLS-DL-AN-226) available at www.corning.com/lifesciences:

https://www.corning.com/catalog/cls/documents/compatibility-guides/CLS-DL-AN-226.pdf

Warranty/Disclaimer: Unless otherwise specified, all products are for research use only. Not intended for use in diagnostic or therapeutic procedures.