SOLUTIONS FOR CONTROLLED ENVIRONMENTS & MANUFACTURING PROCESS



How can you protect against cleanroom contamination?

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Managing risk and minimizing the complexity of your global single-use supply chain



Little things that can help maintain a spore free cleanroom

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Minimizing the complexity of your supply chain

Avantor's quality programs were designed with a customer-centric approach that decreases the complexity our customers experience around their quality, regulatory and security requirements.

As Avantor's channel brand, VWR, part of Avantor offers an integrated, seamless purchasing experience that is optimized for the way you do business and follows Avantor's commitment to quality and supply chain security.

- Global network of cGMP and cGDP facilities
- Change notification to help you stay in control of changing situations and minimize risks associated with changes to products
- Risk-based audits for new and existing suppliers
- Collaborative forecasting, planning and replenishment (CPFR)
- Certificates of Conformance, quality, and analysis available with SDS documents

Our field-based technical experts are available to help you match your requirements to high-quality suppliers of bioprocessing materials. Contact your sales representative today to learn more.



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designed for protection

VWR® N95 DISPOSABLE RESPIRATORS

- Meet NIOSH requirements for minimum filter efficiency of 95% against 0.3µm particles
- Provide protection against solid and liquid particles that do not contain oil
- Lightweight construction allows for comfortable, extended use

VWR® N95 Disposable Respirators combine excellent safety and comfort features to ensure reliable protection and a lightweight, secure fit. An adjustable noseclip provides a secure seal against the user's face. Respirators are available plain or with an exhalation valve that reduces heat and humidity buildup within the mask.

Description	Cat. No.
N95 Respirator	89201-508
N95 Respirator with Valve	89201-510

designed for protection

VWR® MAXIMUM PROTECTION FACE MASKS

Masks feature three-ply construction for superior particle and bacterial filtration efficiency. Available with spandex ear loops or polypropylene ties that are ultrasonically welded to maintain softness and protect against particulates. A full-length arch within the mask's protective layers holds the fabric away from the wearer's mouth to allow cooler, more comfortable breathing without restricting downward vision.

- Superior protection against bacteria and particles
- Highly breathable and fluid resistant
- Soft and hypoallergenic
- Equipped with multiple comfort-enhancing features
- Latex-free

Description	Color	Cat. No.
Mask With Ear Loops	Pink	414004-672
Mask With Ear Loops	White	414004-673
Mask With Ear Loops	Blue	414004-670
Mask With Ties	Blue	414004-675





COLLECTION



designed for protection

VWR® DISPOSABLE GOGGLES, STERILE

Individually bagged to provide optimum comfort for extended wear times.

- Two types of ventilation
- Produced under stringent conditions
- Monitored closely to ensure high quality
- Anti-fog and anti-scratch
- Fits over prescription glasses

Goggles come in two types of ventilation: indirect and direct. Produced under stringent conditions and monitored closely to ensure high levels of quality for every pair. The goggles passed tests according to the American National Standard for Occupational and Educational Personal Eye and Face Protective devices. Ideal for use in controlled environments requiring sterile apparel.

Ventilation	Cat. No.
Direct	10770-146
Indirect	10770-152

designed for protection

VWR® STERILE SLEEVES

- Excellent breathability and water vapor transmission rate
- Superior fluid and particulate barrier
- Lowest level of particle shedding
- Durable yet soft, cloth-like fabric
- Gamma irradiated to SAL of 10⁻⁶
- Color: White

VWR® Sterile Sleeves are manufactured from a specially formulated breathable microporous fabric that provides significant fluid and barrier protection. Garments exhibit excellent water vapor transmission to optimize user comfort.

Sleeves feature elastic openings and sonically welded seams. They are available in two versions; with thumb loops or without.

Sleeves are rigorously tested and manufactured in an ISO Certified facility under stringent process controls to ensure that each product meets exacting quality standards and performs to specification. Products are validated through independent lab testing.

Size	Length, cm (in.)	Cat. No.
Sterile Sleeves without Thumb Loop) – El Carlo de Carlo	
Universal	49.5 (191⁄2)	414004-510
X-Large	54.6 (211/2)	414004-511
Sterile Sleeves with Thumb Loop		
Universal	49.5 (191⁄2)	76169-446
X-Large	54.6 (211/2)	76169-448







designed for protection

VWR® CERTICLEAN® CLASS 10 NITRILE GLOVES

Ambidextrous, powder-free gloves with beaded cuffs for strength and reduction of cuff roll down

- Long, tapered beaded cuff
- Superior strength and puncture resistance
- Textured fingertips for a reliable grip
- Film thickness designed for comfort and tactile sensitivity
- Color: White

designed for protection

VWR® PURETOUCH CUT-RESISTANT GLOVE LINERS

Cut-resistant glove liners provide a comfortable barrier that enhances safety, while reducing perspiration and wicking moisture during extended use. They prevent skin irritation without diminishing tactile sensitivity, and limit wear and tear.

- Compatible underglove for all cleanroom requirements
- 13-gauge white nylon with HPPE
- Ambidextrous
- Color-coded for visual size identification
- Sturdy, launderable, and reusable
- ANSI 2 cut resistant
- For use with latex, nitrile, PVC, and all exam gloves

Size	Cat. No.
X-Small	40101-353
Small	40101-352
Medium	40101-354
Large	40101-356
Large +	40101-357
X-Large	40101-358

Size	Glove Color	Cat. No.
Small	Green	76102-378
Medium	Orange	76102-380
Large	Blue	76102-382
X-Large	Red	76102-384







designed for protection

VWR® ADVANCED PROTECTION ANTI-SKID SHOE COVERS

Highly durable shoe covers ensure long-lasting abrasion and skid resistance.

- Specially formulated polypropylene/polyethylene microporous film
- Excellent fluid and barrier protection
- Standard or static-dissipative formats
- High coefficient of friction to provide excellent traction
- Non-linting
- Color: Blue

Size	Case of	Cat. No.
Standard		
Universal	300	414004-649
Universal	9000	414004-498
X-Large	300	414004-650
X-Large	9000	414004-499
2X-Large	300	414004-651
2X-Large	9000	414004-500
Static Dissipative		
Universal	300	414004-644
X-Large	300	414004-645

designed for protection

VWR® BASIC PROTECTION SPP SHOE COVERS

These spunbonded polypropylene (SPP) shoe covers protect against dirt, grime, and certain dry particulates in nonhazardous environments.

- Economical, disposable first-line barrier
- Maximum breathability
- Low-linting
- Available with rubber-coated soles for secure footing on wet or dry surfaces
- Elastic top and bottom
- Color: Blue

Description	Size	Cat. No.
Anti-Skid Shoe Covers	X-Large	414004-653
Anti-Skid Shoe Covers	Universal	97041-236
Heavy Weight Anti-Skid Shoe Covers	Universal	89233-794
Standard Shoe Covers	Universal	97041-234

How can you protect against cleanroom contamination?

By Damon Larkin, Senior Category Manager - Scientific Business, Kimberly-Clark Professional

To avoid contamination in the cleanroom, you have to look at its primary source: People. They are the largest contributor to contamination, accounting for 46 percent of all particle contamination.¹

Body regenerative processes, such as skin flakes, oils, perspiration and hair, can contribute to cleanroom contamination. And even the most carefully manicured person generates a shroud of particles from his or her skin, hair and clothing every day.² For example:

- People shed 1 million skin cells per day.³
- 5 million particles greater than 0.3 microns are generated by people when moving.⁴
- 1 mL of saliva contains 100 million microbes.⁵

When it comes to aseptic processing, the challenge is always personnel, because where there are people, there is a risk of microbial contamination. Microorganisms introduced into a cleanroom environment need only three things to grow: moisture, food and temperature – all of which exist in a cleanroom. Therefore, all incoming air, water, chemicals, and materials must be filtered or sterilized to meet high standards of purity and microbiological control, so as not to contaminate processes or products in production. The cleanroom operator also must be "filtered," in a sense, to protect the process.

This particular risk can be mitigated by using sterile cleanroom apparel that protects the environment from viable particles such as bacteria and yeast, and non-viable particles such as hair, dead skin cells, and dandruff. Be sure to choose apparel that provides the highest levels of contamination control because the right cleanroom garment can dramatically reduce the potential for contamination.

Before making your selection, it's important to understand that not all cleanroom garments are the same. And the impact of choosing the wrong solution can be steep:

- \$375 million to address one FDA contamination concern⁶
- \$1.1 billion in global sales losses due to shutdowns⁷
- \$3.1 million average annual cost to remediate contamination events⁸

TYPES OF APPAREL

Cleanroom apparel falls into two main categories: single-use apparel and reusable laundered apparel.

Single-use apparel

Sterile single-use garments, such as Kimtech[™] apparel, are engineered to reduce contamination risk and offer significantly higher Bacterial Filtration Efficiency (BFE) ratings than laundered reusable apparel. These non-woven garments provide a strong barrier against particles and liquids. And they're guaranteed to be sterile every time.

Laundered garments

Laundered garments may degrade after multiple laundering and sterilization cycles. Testing conducted by Kimberly-Clark Professional found BFE declines of more than 25 percent after an average of five washes⁹, equivalent to one out of four workers not wearing sterile garments at all. This presents a real, yet invisible contamination risk. The testing also found:

- 100 percent of the worn sterile reusable garments tested showed a decline in BFE after washing.
- The filtration efficiency of the reusable garments was typically less than 70 percent.
- Fabric degradation was visible at the sub-micron level enough to allow bacteria to penetrate the material.
- The product declined more rapidly than expected and that decline continued through multiple wash cycles.
- The total cost of ownership for reusable cleanroom apparel was much higher than projected.
- The average number of wash cycles was much lower than expected.

ADDITIONAL CONCERNS

The laundering process for reusable cleanroom garments involves multiple processing steps – such as sorting, multiple wash cycles, drying, cool-down and inspection – which all put the fabric under additional stress. This is repeated each time the gown is serviced. Therefore, the laundering process itself creates channels for bacteria to pass through.

RECYCLING SINGLE-USE GARMENTS

In addition to higher BFE ratings, Kimtech apparel is recyclable through The RightCycle Program, the first large-scale recycling

KIMTECH

Kimberly-Clark



program for non-hazardous lab, cleanroom, and industrial waste. The program mitigates waste and assures cleanrooms of a sustainable apparel solution. It makes it easy to collect previously hard-to-recycle items, such as Kimberly-Clark Professional singleuse apparel items, nitrile gloves, and safety eyewear, and have them turned into new consumer goods.

The garments offer a number of other benefits including:

- Features that lower the risk of contamination during the donning process.
- Built-in snaps that automatically release as the garment is put on – lowering the risk of it touching the floor.
- A visible blue line along the inside of the garment to signal the proper place to hold while gowning. This helps operators avoid touching the outside of the garment.
- Built-in thumb loops to keep garment sleeves from rolling back and exposing the arm or wrist.
- A sterility assurance level of level of 10⁻⁶.
- Breathable, cloth-like comfort.

CONCLUSION

Contamination is bad for business, especially for an industry where purity is paramount, and compromised lab and cleanroom garments can be a primary cause of alerts. To protect your scientific process, it's crucial to use the most reliable protective apparel available. The risks of cleanroom contamination are simply too great. Not all garments perform equally when it comes to holding in particles. That's why it's essential to choose a garment that controls contamination and gives workers the assurance to do their best work.

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Are you Dressed For Success™

Kimberly-Clark Professional is asking pharmaceutical manufacturing production managers to take a closer look at their existing reusable apparel. Is it protecting their process and their people? Or is it a potential cause of contamination?

Since people are the largest source of contamination, if their garments are compromised a manufacturer's process could be too. Selecting the right garment can dramatically reduce this risk. Kimtech" Brand single-use apparel can control this threat by simplifying the contamination control process. How? Contact your VWR representative to find out what it means to be Dressed For Success".

STERILE COVERALLS

Description	Cat. No.
Small	89092-898
Medium	89092-900
Large	89092-902
X-Large	89092-904
XX-Large	89092-906
3X-Large	89092-908
4X-Large	89092-910
5X-Large	89166-188
6X-Large - 8X-Large	89166-190

Kimtech™ apparel products are recyclable via The RightCycle Program.



To reuse or not to reuse:

A life cycle assessment of reusable garment properties

Jennifer Galvin, Ph.D., Principal Investigator, Dupont

Humans can be a source of contamination in cleanrooms and controlled environments. Cleanroom workers in aseptic environments are typically garbed head-to-toe in either sterile single-use or sterile reusable garments. The process of wearing, laundering and sterilizing reusable garments can impact their physical properties and change garment functionality. Laundering and wear abrade garment fibers. Simultaneously, changes to the polymers that make up the garments can occur at the molecular level. Although routine visual inspection is often part of garment quality evaluation programs, nonvisible properties also change with time. When selecting reusable garments for use in cleanroom environments, it is important to understand how they will perform over their intended life cycle. Consideration of these properties should be part of the decision process for when to take reusable garments out of service. Physical property data are often available for new cleanroom garments; however, there are less data available throughout the entire garment life cycle. To aid in garment choice, DuPont conducted a study of the physical properties of reusable cleanroom garments after a set number of laundering and gamma radiation exposure cycles. The results are summarized here.

Protection – The primary function of cleanroom garments is to protect a product or a process. To represent process protection, particle shedding was measured via the Helmke drum method and particle dispersion via the Body Box method. Both Helmke and Body Box data show an increase in both amount and variability of shedding after an increased number of laundering and gamma exposure cycles. **Durability** – Testing showed that garment durability decreases with increasing cycles of laundering and exposure to gamma radiation. Reducing potential impact from garment tearing is important, especially in cleanrooms and controlled environments where workers may have physical activities such as climbing stairs or bending to monitor or adjust equipment.

Comfort – Though assessment of garment comfort encompasses a wide variety of fabric test methods, air permeability provides information on air movement through a garment. The results show increasing air permeability with increasing exposure to laundering and gamma radiation. Worker comfort is an important feature in garment assessment; however, it is important to understand the trade-off between air permeability and barrier.

Key Takeaways – The data outlined here demonstrate that garment properties do change after a number of laundering and gamma exposure cycles. These changes are not always visible to the naked eye, so visual garment inspection alone may not be sufficient to understand garment performance. Based on these findings, the following guidelines are recommended:

- Consider performance data over the entire garment life cycle.
- Enact testing protocols to monitor the performance of garments as they age, based on the risk assessments and needs of each individual cleanroom.
- Establish criteria for taking garments out of service when they no longer meet functionality requirements.

Please visit vwr.com/dupontprotection for more information.



DuPont[™] Tvvek[®]



DUPONT[™] TYVEK[®] ISOCLEAN[®] COVERALLS

Coveralls are constructed of Tyvek[®] flash-spun polyolefin protective material that provides an effective barrier to dry particles, microorganisms, and nonhazardous liquids.

- Garments are gamma sterilized to SAL of 10⁻⁶
- Clean-processed garments offer lowest level of particle shedding within DuPont product portfolio
- Bound seams are covered with garment fabric to reinforce the seam and to reduce the potential for particle penetration
 Color: White
- Color: wr
- Sterile

Coveralls have elastic openings for tighter fit at wrist and ankle, bound neck for lower particle shedding, front zipper closure for easy donning and doffing, and dolman sleeve for greater range of motion and comfort.

Size	Chest Size	Inseam	Sleeve	Cat. No.
S	221/2"	291/4"	341⁄4"	89127-240
М	231/2"	301⁄2″	351⁄2″	89127-236
L	241/4"	321/4"	363/4"	89125-616
XL	261/2"	331/2"	381⁄4"	89127-246
2X	281/2"	34"	393/4"	89127-212
3X	301/2"	35″	403⁄4″	89127-218
4X	321/4"	38"	421/4"	89127-224
5X	341⁄4"	371/2"	421/2"	89127-226
6X	361/4"	37"	423/4"	76187-508
7X	381/4"	361⁄2″	43"	76187-510

DUPONT[™] TYVEK[®] ISOCLEAN[®] FROCKS

Frocks provide protection and durability while remaining comfortable.

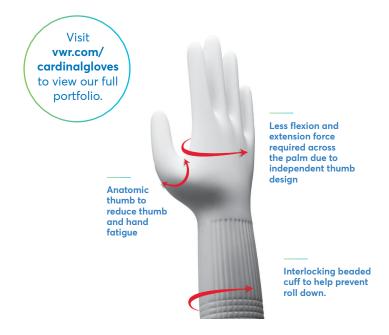
- Garments are gamma sterilized to SAL of 10⁻⁶
- Clean-processed garments offer lowest level of particle shedding within DuPont product portfolio
- Serged seams have multiple interlocking threads that are sewn around the raw edges of garment material to create a strong, stress-resistant seam
- Color: White

Frocks have elastic openings for tighter fit at wrist, bound neck for lower particle shedding, front zipper closure for easy donning and doffing, and raglan sleeve design for greater range of motion and comfort.

Size	Length	Chest Size	Cat. No.
S	41"	23"	10016-084
М	423/4"	24"	10016-082
L	45"	25"	10693-068
XL	47"	26"	10693-070
XXL	53"	303⁄4″	10693-072
3XL	55″	313/4"	10693-074
4XL	57"	32"	10693-076



A mold unlike any other



There are important differences in cleanroom glove manufacturing and technology that can impact the way a glove feels and performs. We believe that the glove mold used makes all the difference in the fit and feel of the glove.

The Cardinal Health[™] glove mold features an independent thumb design — meaning the finger placement replicates the anatomical position of a resting hand — allowing for natural, comfortable movement.

Glove Size	Cat. No.	Glove Size	Cat. No.
5.5	PH2Y72PL55	7.5	PH2Y72PL75
6	PH2Y72PL60	8	PH2Y72PL80
6.5	PH2Y72PL65	8.5	PH2Y72PL85
7	PH2Y72PL70	9	PH2Y72PL90

Visit vwr.com/cardinalgloves to view our full portfolio.

One study shows that gloves featuring an independent thumb require less force for similar displacements of the thumb than those gloves produced without an independent thumb feature.¹

¹ Bennet, M. A. & Tekamp, D. A. Surgical Glove Comparison Testing. Stress Engineering Services. February 2012.

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designed for protection

VWR® DISPOSABLE SCRUB SHIRTS

These garments feature high-quality sewn-seam construction and are made from SMS nonwoven fabric for comfort.

- Single-use
- Long sleeve
- No pocket
- Snap adjustable neck closure
- Perfect with VWR disposable scrub pants
- Case of 30
- Color: Blue

Size	Cat. No.
Small	10755-052
Medium	10754-966
Large	10754-968
X-Large	10754-970
XX-Large	10754-972
3X-Large	10754-974
4X-Large	10754-976
5X-Large	10754-978



designed for protection

VWR® DISPOSABLE SCRUB PANTS

VWR Disposable Scrub Pants are an ideal option for single-use needs.

- Elastic waist
- Single-use
- Hip pockets available
- Perfect with VWR disposable scrub shirts
- Comes in cases of 30
- Color: Blue

Size	Cat. No.	Siz
Scrub Pants with Pockets		Sci
X-Small	76006-546	X-Sr
Small	76006-548	Small
Medium	75832-236	Medium
Large	75832-238	Large
X-Large	75832-240	X-Large
XX-Large	75832-242	XX-Large

Visit **vwr.com** to see a full listing of sizes and styles.



WELLS LAMONT

Industrial



VWR® ESD MICRO DENIER SCRUB TOP WITH KNIT CUFF

- Pullover design with three-snap, Henley-style collar that provides added room for easy on/off
- Binding on collar helps maintain shape and uniformity
- Raglan-style sleeves provide increased mobility
- Sleeves include color-coordinated filament knit cuff for extra comfort
- 5" side slits at garment bottom for added comfort and longterm durability
- Color: Navy

Size	Cat. No.	Size	Cat. No.
XX-Small	76202-674	XX-Large	76202-666
X-Small	76202-676	3X-Large	76202-668
Small	76202-658	4X-Large	76202-670
Medium	76202-660	5X-Large	76202-672
Large	76202-662	6X-Large	76202-678
X-Larae	76202-664		

designed for protection

VWR® ESD MICRO DENIER SCRUB PANT

This style of scrub pant is widely used in pharmaceutical cleanroom operations.

- Combination elastic back and drawstring front for secure comfort
- Leg opening with elastic back and threeposition snaps for closure
- Double-needle felled outer seams for extra durability
- Garments include color-coded loops for easy size identification
- All edges are pre-serged or laser cut for lint limitation
- Color: Navy

Size	Cat. No.	Size	Cat. No.
X-Small	76202-680	XX-Large	76202-690
Small	76202-682	3X-Large	76202-692
Medium	76202-684	4X-Large	76202-696
Large	76202-686	5X-Large	76202-698
X-Large	76202-688	6X-Large	76202-700



These scrubs provide an excellent base-layer of protection for any cleanroom garment system. Made with Sandwash material, this lightweight micro-denier fabric is woven from 100% continuous-filament polyester to eliminate any source for lint.

Sterile glove liners

WELLS LAMONT GLOVE LINERS

If you're looking for sterile glove liners that offer cut resistance protection and comfort, look no further than these three options from Wells Lamont Industrial:

- All sterilized gloves are manufactured and sterilized in the USA
- They can be worn as a stand alone glove, or as a liner underneath another glove
- They help protect from allergic reactions to latex, while providing a high level of dexterity and tactile sensation Ambidextrous
- M102 Spec-Tec Liner offers ANSI Level 1 cut resistance
- M104- Spec-Tec Stretch liner offers ANSI Level A2 cut resistance
- M321- Scepter liner offers ANSI A4 cut resistance

SPEC-TEC SPECTRA® FIBER STERILE CRITICAL ENVIRONMENT GLOVE LINERS

Size	Glove Color	Cuff Color	Cat. No.
Small	White	Green	80091-126
Medium	White	Orange	80091-124
Large	White	Blue	80091-122



STERILE SPEC-TEC STRETCH GLOVE LINERS

SCEPTER[™] STERILE M321

White

White

White

Glove Color Cuff Color

Green

Blue

Red

GLOVE LINER

Small

Large

X-Large

Size	Glove Color	Cuff Color	Cat. No.
Small	White	Green	80091-132
Medium	White	Orange	80091-130
Large	White	Blue	80091-128
X-Large	White	Red	80091-134



Cat. No 52428-890 52428-894

52428-896



Not all water is created equal

AQUAPUR PURIFIED WATER

WATER, WATER EVERYWHERE...BUT DOES **IT REALLY MEET USP SPEC?**

Not all water is created equal! It's easy to make water that meets USP spec today! But, what about after it sits on a shelf for 2 weeks, 2 months or 12 months? Our testing of major brands of packaged purified water show a high amount of microbial growth which can affect TOC and other parameters. Decon's proprietary manufacturing process ensures that our AquaPur Purified Water meets spec when you use it.

Purified Water

- Meets USP/EP Specs
- Made in FDA-registered / cGMP facility
- Validated system incorporating deionization, UV and ultrafiltration
- Maintains microbial spec through expiration date

Sterile Purified Water

- Meets USP Specs
- Double-bagged, gamma-irradiated

designed for production

VWR LIFE SCIENCE SERADIGM

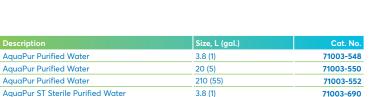
alternatives, including:

FBS alternative

- Meets USP WFI spec for sterility and endotoxin
- For applications in lab or production environments that require sterile purified water
- Lot Specific Document detailing testing shipped with each case

VWR Life Science Seradigm is a fully-integrated supplier of animal sera, providing the cell culture community with access to the most reliable supply of high performance, exceptional quality Fetal Bovine Serum (FBS) and FBS

Ultimate Grade FBS, Premium Grade FBS, Ultra Low IgG FBS, Iron Supplemented Bovine Calf Serum, and FB Essence, a cost-effective







Learn more today at vwr.com/seradigm

Description	Volume	Origin	Endotoxin	Hemoglobin	Cat. No.
VWR Life Science Seradigm Fetal Bovine Serum (FBS)					
Fetal Bovine Serum, Ultimate Grade	500 mL	U.S.A.	<10 EU/mL	<25 mg/dL	97068-101
Fetal Bovine Serum, Ultimate Grade, Heat Inactivated	500 mL	U.S.A.	<10 EU/mL	<25 mg/dL	97068-107
Fetal Bovine Serum, Premium Grade	500 mL	U.S.A.	<20 EU/mL	<25 mg/dL	97068-085
Fetal Bovine Serum, Premium Grade, Heat Inactivated	500 mL	U.S.A.	<20 EU/mL	<25 mg/dL	97068-091
Fetal Bovine Serum, Ultra Low IgG	500 mL	U.S.A.	≤20 EU/mL	≤25 mg/dL	10018-826
Fetal Bovine Serum, Ultra Low IgG, Heat Inactivated	500 mL	U.S.A.	≤20 EU/mL	≤25 mg/dL	10018-830
VWR Life Science Seradigm Bovine Calf Serum, Iron Supplemented					
Bovine Calf Serum, Iron Supplemented	500 mL	U.S.A	<20 EU/mL	<30 mg/dL	10158-358
Bovine Calf Serum, Iron Supplemented	1L	U.S.A	<20 EU/mL	<30 mg/dL	10153-134
Bovine Calf Serum, Iron Supplemented, Gamma Irradiated min 25 kGy	1L	U.S.A	<20 EU/mL	<30 mg/dL	10153-136
VWR Life Science Seradigm FB Essence					
FB Essence, FBS Alternative	500 mL	U.S.A.	<20 EU/mL	<25 mg/dL	10803-034
FB Essence, FBS Alternative, Heat Inactivated	500 mL	U.S.A.	<20 EU/mL	<25 mg/dL	10799-390



71003-690

Avantor J.T.Baker[®] brand: Trusted for the world's most demanding applications for over a century

The Avantor J.T.Baker® brand has stood for excellence along every step of our customers' processes—from the laboratory to full-scale production—for over a century. Choose from a range of high-purity acids, solvents and chromatography products that provide the quality you want for the results you need.

J.T.BAKER® HIGH-PURITY ACIDS

Offered in four distinct levels of purity from general use to trace-metal analysis

Description	Size	Packaging	Cat. No.
Acetic Acid, Glacial, BAKER ANALYZED® A.C.S. Reagent, (Aldehyde			
Free)	4 L	Poly Bottle	JT9508-6
Hydrochloric Acid, ULTREX® II Ultrapure Reagent	500 mL	Fluoropolymer Bottle	JT6900-5
Hydrochloric Acid, 36.5-38.0%, BAKER INSTRA-ANALYZED® Reagent	2.5 L	Clear PVC Coated Glass Bottle	JT9530-33
Hydrofluoric Acid, 48.0-51.0%, BAKER ANALYZED® A.C.S. Reagent	4 L	Poly Bottle, Bagged	JT9560-6
Nitric Acid, 69.0-70.0%, BAKER INSTRA-ANALYZED® Reagent	2.5 L	Clear PVC Coated Glass Bottle	JT9598-5
Nitric Acid, ULTREX [®] II Ultrapure Reagent	500 mL	Fluoropolymer Bottle	JT6901-5
Phosphoric Acid, BAKER ANALYZED® A.C.S. Reagent	2.5 L	Clear Glass Bottle	JT0260-5
Perchloric Acid, 70%, BAKER INSTRA-ANALYZED® Plus, for Trace			
Metal Analysis	500 mL	HDPE Bottle	JT9359-1
Sulfuric Acid, BAKER ANALYZED® A.C.S. Reagent	2.5 L	Clear PVC Coated Glass Bottle	JT9681-33
Sulfuric Acid, BAKER INSTRA-ANALYZED® Reagent, Low Selenium, for			
Trace Metal Analysis	2.5 L	Clear PVC Coated Glass Bottle	JT9673-33



J.T.BAKER[®] LC/MS SOLVENTS

High-purity to provide the performance needed with minimal risk of contaminants

Description	Size	Packaging	Cat. No.
Acetonitrile, BAKER ANALYZED® LC/MS	4 L	Narrow Mouth Amber Glass Bottle	JT9829-3
Acetonitrile, BAKER ANALYZED® ULTRA LC/MS	1 L	Narrow Mouth Flint Bottle	JT9853-2
Methanol, BAKER ANALYZED® LC/MS	4 L	Narrow Mouth Amber Glass Bottle	JT9830-3
Methanol, BAKER ANALYZED® ULTRA LC/MS	1 L	Narrow Mouth Flint Bottle	JT9863-2
Water, BAKER ANALYZED® LC/MS	4 L	Narrow Mouth Amber Glass Bottle	JT9831-3
Water, BAKER ANALYZED® ULTRA LC/MS	1 L	Narrow Mouth Flint Bottle	JT9823-2
Acetonitrile-0.1% Trifluoroacetic Acid LC/MS	4 L	Narrow Mouth Amber Glass Bottle	JT9835-3
Water-0.1% Trifluoroacetic Acid, LC/MS	4 L	Narrow Mouth Amber Glass Bottle	JT9836-3
Acetonitrile-0.1% Formic Acid LC/MS	4 L	Narrow Mouth Amber Glass Bottle	JT9832-3
Water-0.1% Formic Acid LC/MS	4 L	Narrow Mouth Amber Glass Bottle	JT9834-3

J.T.BAKER[®] CHROMATOGRAPHY PRODUCTS

High-performance solid phase extraction columns, media and other equipment

Description	Cat. No.
BAKERBOND® Wide-Pore WP Octyl (C8) Column, Analytical	JT7105-1
BAKERBOND® Narrow-Pore Prep Packings	JT7025-1
Baker-flex® Precoated Flexible TLC Sheets, 200µm Thickness, F254, 25 x 75mm Plate, Silica Gel Coating	JT4463-2
Baker-flex® Precoated Flexible TLC Sheets, 250µm Thickness, F254, 25 x 75mm Plate, Silica Gel Coating	JT4449-2
BAKERBOND® SPE Columns, Reversed Phase, Octadecyl, 6 mL	
Extraction Disks, 50 mm	
Normal Water Samples	JT8055-6
Water-Samples, Polar to Non-Polar Analytes	JT8055-7
Diquat/Paraquat Samples	JT8057-6
Hydrocarbons/Oil & Grease	JT8060-6

Managing risk and minimizing the complexity of your global single-use supply chain

By Timothy Korwan, Director of New Product Development and Commercialization, Avantor

With the rapid growth of single-use systems (SUS) for drug production, especially by drug manufacturers with multiple locations across the globe, there are many risks associated with underestimating the regulatory compliance, manufacturing and quality requirements of these systems. For example, using SUS introduces new logistics challenges that, if not properly understood and planned for, can leave biopharma manufacturers vulnerable to supply chain complexities.

To minimize these risks, biopharma manufacturers can benefit by adopting a global single-use supply chain strategy early in the drug development life cycle and carefully evaluating their chosen single-use equipment and materials suppliers. When reviewing a prospective supplier, there are two primary considerations for biopharma manufacturers to keep in mind: the regulatory and quality compliance and the supply chain operational excellence of the supplier.

REGULATORY AND QUALITY COMPLIANCE

There are four main categories to review when evaluating a singleuse provider's regulatory and quality compliance initiatives.

First, the environment where the single-use equipment and materials are being manufactured should be checked to ensure proper controls are in place to monitor and track environmental conditions where the materials are produced. The production facility should have documented evidence of annual cleanroom recertification and a validated process showing a rotational cleaning regimen, as well as air/surface viable and nonviable particulate testing being carried out on a scheduled basis. Cleanrooms should also be monitored for real-time temperature, humidity and differential pressure monitoring.

Second, product sterility validation that follows a well-defined, recognized reference standard identified by regulations such

as ANSI/AAMI/ISO 11137 should be investigated. There should be documented evidence this validation is performed on a routine basis. The single-use supplier's ability to perform lot release testing on finished products, to verify that the product meets certain requirements after sterilization, should be the third item reviewed. Most requests for this testing include USP <85> for bacterial endotoxins and USP <788> for particulate contamination.

The fourth and potentially most important item for reducing risk in the single-use supply chain is to fully understand a supplier's quality risk management (QRM) program. A key element of ISO 9001 and cGMP related to quality is risk-based decision-making, and a qualified single-use supplier will have developed quality metrics to control the risks associated with the manufacturing of their products.

Essential steps in risk management generally include risk assessment (identification, analysis and evaluation); risk control (mitigation, reduction and acceptance); and risk review. The QRM program should have a risk register to identify and review where the greatest risks may occur, and quality metrics and monitoring should be used. This will help track important quality indicators and improvement of those indicators, including: on-time delivery, turnaround time for engineer's drawings, turnaround time for quality documentation and tracking of manufacturing defects.

The single-use provider's QRM program should also include quality management for their suppliers, with risk-based audits of their raw material supply chain. Risk-based classifications for raw material suppliers should be included along with routine audits of high-risk suppliers, established quality agreements and performance reports from suppliers, and performance metrics that can be tracked and evaluated over time with suppliers.



Evidence of a business continuity plan should also be in place. This will ensure that the single-use supplier is ready to respond in case of a serious event that has the potential to disrupt operations.

SUPPLY CHAIN OPERATIONAL EXCELLENCE (OPEX)

Biopharma manufacturers should conduct an ongoing evaluation of a single-use supplier's supply chain OpEx capabilities. Aligning these capabilities with the manufacturer's own quality practices is important as biopharma manufacturers design their facilities entirely with SUS and expand globally.

These supply chain OpEx capabilities should be built around a collaborative planning, forecasting and replenishment (CPFR) program that includes:

- Understanding customer requirements, such as important product/order attributes of dating, documentation, order frequency, lot control and storage-material handling requirements.
- Effectively transferring documented requirements to internal systems to "operationalize" things such as customer-care instructions, warehouse instructions, and setup of customerspecific inventory reserves.
- Regularly engaging in customer-planning meetings to obtain updated forecasts.
- Engaging with customers and suppliers to manage changes in key factors such as required components and lead times.

Supply chain assurance can also be achieved through a customer-centric approach with flexibility and solutions that decrease complexity around storage and delivery. Integrated sales and operations planning (S&OP) is an integrated business management process that helps ensure the executive or leadership team of an organization is continually focused and

aligned across all functions. The S&OP process includes an updated forecast that leads to a sales plan, production plan, inventory plan, customer lead time (backlog) plan, new product development plan, strategic initiative plan and resulting financial plan. Done well, the S&OP process enables effective supply chain management.

One of the more challenging supply chain issues is faster lead times for finished goods. Stocking more finished goods has inherent risks related to proper warehousing and storage. Many biopharma manufacturers lack adequate warehousing infrastructure to store large volumes of single-use products. For this reason, it's beneficial to work with single-use equipment and materials suppliers that can provide local storage and quick delivery.

READY TO MANAGE AND MITIGATE RISK

Biopharma manufacturers can help ensure their single-use production operations remain secure by working with single-use suppliers who combine ingenuity and product leadership with powerful channel and supply chain operations. Ultimately, this should include superior single-use expertise with a collaborative approach in designing solutions; access to a broad product portfolio with components sourced from multiple suppliers; unique capabilities, such as expedited system design and delivery of drawings; and, ultimately, supply chain OpEx capabilities that are fully supported by regulatory and quality compliance.

Bioprocessing chemicals. More product solutions.

designed for production

VWR BIOPROCESSING CHEMICALS AND EXCIPIENTS

Avantor manufactures cGMP biological buffers, chemicals and biochemicals that are suitable for bioprocessing and excipient use. Available in convenient standard pack sizes as well as custom packaging, VWR Bioprocessing Chemicals and Excipients are backed by our analytical laboratory and regulatory support, and change management processes.

Additionally, our diverse sourcing capabilities, dedicated manufacturing and service teams, and audit support of raw materials manufacturers help to provide our customers with the resources they need and a transparent, robust supply chain to help meet the needs of highly regulated markets.

Other features:

- BSE-/TSE-free
- Custom testing available on select products
- Three-lot sample availability



Description	CAS No.	Formula	Molecular Weight	Grade	Available Sizes	Cat. No.
Amino Acid Derivatives						
Asparagine, Anhydrous	70-47-3	C4H8N2O3	132.12	Bioreagent	100g, 1kg, 5kg, 25kg	VWRB15005
L-Cystine Dihydrochloride	30925-07-6	C8H12N2O4S2+2HCI	313.23	Bioreagent	100g, 1kg, 5kg, 25kg	VWRB21502
Hypoxanthine Disodium Salt	102-32-9	C5H2N4O+2Na	180.11	Bioreagent	100g, 1kg, 5kg, 25kg	VWRB31608
Hypoxanthine Sodium Salt	45738-97-4	C5H3N4O•Na	158.11	Bioreagent	100g, 1kg, 5kg, 25kg	VWRB31752
L-Lysine Anhydrous	56-87-1	C6H14N2O2	146.19	Bioreagent	100g, 1kg, 5kg, 25kg	VWRB42307
L-Tyrosine Disodium, Dihydrate	122666-87-9	C9H9NO3Na2+2H2O	261.19	Bioreagent	1kg, 5kg, 25kg	VWRB87058
Biological Buffers						
HEPES Free Acid	7365-45-9	C8H18N2O4S	238.3	Bioreagent	1kg, 5kg, 25kg	VWRB30487
HEPES Sodium Salt	75277-39-3	C8H17N2O4SNa	260.3	Bioreagent	1kg, 5kg, 25kg	VWRB30567
PIPES Free Acid	5625-37-6	C8H18N2O6S2	302.37	Bioreagent	1kg, 5kg, 25kg	VWRB73007
PIPES Disodium Salt	76836-02-7	C8H16N2O6S2Na2	346.33	Bioreagent	1kg, 5kg, 25kg	VWRB73305
PIPES Sequisodium Salt	100037-69-2	C16H33N4O12S4+3Na	670.69	Bioreagent	1kg, 5kg, 25kg	VWRB73257
TRIS Hydrochloride	1185-53-1	C4H11NO3HCI	157.6	Bioreagent	1kg, 5kg, 25kg	VWRB85827
Tromethamine (TRIS)	77-86-1	C4H11NO3	121.14	USP, EP, BP, JPC, Endotoxin Tested	500g, 2.5kg, 12kg, 50kg	VWRB497
Carbohydrates						
					1kg, 2.5kg, 12kg,	
Dextrose, Anhydrous	50-99-7	C6H12O6	180.16	USP, EP, BP, JP, Endotoxin Tested	100lb, 200lb	VWRBK876
Chaotic Agents						
Urea	57-13-6	CH4N2O	60.06	USP, EP, BP, JP, Endotoxin Tested	500g*, 12kg, 50kg	VWRB568
Inorganic Salts						
Ammonium Sulfate	7783-20-2	H8N2O4S	132.14	ACS, NF, Endotoxin Tested	500g, 2.5kg, 12kg, 100kg	VWRB191
Calcium Chloride, Dihydrate	10035-04-8	CaCl2•2H2O	147.02	USP, EP, BP, JP, Endotoxin Tested	1kg, 12kg	VWRB556
Potassium Phosphate Monobasic,						
Anhydrous	7778-77-0	KH2PO4	136.09	NF, EP, BP, Endotoxin Tested	1kg, 12kg	VWRB0781
Sodium Chloride	7647-14-5	NaCl	58.44	USP. EP. BP. JP. Endotoxin Tested	1kg, 2.5kg, 12kg, 50kg, 350lb	VWRB241
Sodium Phosphate Dibasic,	7047-14-5	Nucl		OSF, EF, BF, SF, Endotoxin rested		V W KD241
Anhydrous	7558-79-4	Na2HPO4	141.96	USP, EP, Endotoxin Tested	1kg, 12kg	VWRB0404
, Sodium Phosphate Dibasic,						
Heptahydrate	7782-85-6	Na2HPO4•7H2O	268.07	ACS, USP, Endotoxin Tested	1kg, 12kg	VWRB0348
Sodium Phosphate Monobasic,						
Monohydrate	10049-21-5	Na2HPO4•H2O	137.99	ACS, USP, BP, Endotoxin Tested	1kg, 12kg	VWRB0823
Sodium Sulfate, Anhydrous	7757-82-6	Na2SO4	142.04	USP, EP, Endotoxin Tested	500g, 2.5kg, 12kg, 100kg	VWRB836

*This specific product is not available in Canada. Please contact your VWR Sales Representative to learn about easy access to similar options available in your region.

For complete listing, go to **vwr.com/bioprocesschemicals**

OMNITOP ASSEMBLIES, PRE-STERILIZED SINGLE-USE SAMPLE TUBES®

OmniTop Sample Tubes are a convenient device that can be used to obtain fluid samples. Each OmniTop tube comes with a pre-attached 0.2µm vent filter and 18" of tubing (C-Flex[®], TYGON[®], silicone or PharMed[®]).

- Customizable cap system
- Ability to use different ID and OD tubing diameters
- Easily configured with virtually any type of tubing
- Eliminate cleaning validation
- Flexible manufacturing
- Design permits quick delivery on small lots
- Available individually packaged or configured in manifold

Application(s):

- Transfer of biopharmaceutical products and reagents in a closed system
- Gas exchange transfer
- Sampling of biopharmaceutical products and reagents in a closed system
- Storage of biopharmaceutical products and reagents
- Use with bench top, pilot plant, and production bioreactors
- Use with sterile connecting devices and thermal or RF tubing sealers

These tubes are available with or without internal dip-tubes to facilitate removal of the fluid inside. OmniTop Sample Tubes are available in a wide variety of standard configurations or they can be customized to suit your specific applications.



Description	Cat. No.
15mL OmniTop Standard, PP	75840-758
50mL OmniTop Standard, PP	75840-774
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designed for production

VWR® STERILE SINGLE-USE BOTTLE ASSEMBLIES

Sterile containers with weldable tubing provide the maximum amount of flexibility and reliability.

- Sterile bottles come individually bagged and process ready
- Multiple bottle sizes allow for process-specific flexibility
- Gamma irradiated to Sterility Assurance Level (SAL) 10⁻⁶
- Tubing Material: C-Flex®
- Assembled in an ISO Class 7 cleanroom and manufactured from USP Class VI materials
- Offered in a comprehensive size selection with tubing that is completely weldable/ sealable



POLYCARBONATE

Capacity, mL (oz.)	Tubing Length	Cap Size	Tubing Connection	Tubing Size	Cat No.
	Port 1: 24"		Port 1: PP Tube Plug	Port 1: 1/8 x 1/4"	
125 (4)	Port 2: 3"	38-430	Port 2: 25mm Hydrophobic PE Vent Filter	Port 2: 1/8 x 1/4"	10830-302
	Port 1: 24"		Port 1: PP Tube Plug	Port 1: 1/8 x 1/4"	
250 (8)	Port 2: 3"	38-430	Port 2: 25mm Hydrophobic PE Vent Filter	Port 2: 1/8 x 1/4"	10830-304
	Port 1: 24"		Port 1: PP Tube Plug	Port 1: 1/8 x 1/4"	
500 (16)	Port 2: 3"	38-430	Port 2: 25mm Hydrophobic PE Vent Filter	Port 2: 1/8 x 1/4"	10830-306
	Port 1: 24"		Port 1: PP Tube Plug	Port 1: 1/8 x 1/4" P	
1000 (32)	Port 2: 3"	38-430	Port 2: 25mm Hydrophobic PE Vent Filter	ort 2: 1⁄8 x 1⁄4″	10830-696
	Port 1: 12"		Port 1: PP Tube Plug	Port 1: 3/8 x 1/2"	
	Port 2: 3"		Port 2: 50mm PTFE Vent Filter	Port 2: 1/4 x 3/8"	
2000 (64)	Port 3: 12"	53B	Port 3: PP Tube Plug	Port 3: 3/8 x 1/2"	10830-698

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Cat. No. 10806-005

Cat. No.

Cat. No

89133-808

82030-590



Puritan Medical Products Critical Cleaning Swabs



GLUE-FREE COTTON SWABS

- Special construction eliminates chemical migration

- Cleaning and removing residues

Description	
Regular Tip With No Glue, Wood Handle	

FOAM-OVER-COTTON SWABS

- Lint and residue free and extra absorbent
- Foam-over-cotton provides extra absorbency
- General cleaning

Description

Standard Foam-Over-Cotton Tip, Wood Handle

MICROFIBER SWABS

- Excellent wipe-dry characteristics and are safe to use on and around static-sensitive components
- Used for removing contaminants and excess materials

Des	cri	oti	on	
000		P		

Small Flexible Paddle Tip, Thermally Bonded to Polypropylene Handle

KNITTED POLYESTER SWABS

- Non-abrasive, lint-free, and non-absorbent
- Low particle generation, and low NVR's for good chemical resistance
- Can easily stand up to IPA, acetone and other solvents
- Ideal for cleaning electronic and communication devices and perfect for instrumentation and medical device manufacturing

Cat. No.
82030-704
89133-800
89133-802

Made in USA

Ideal for use with cleanroom wipers



designed for production

VWR® STERILE 70% ISOPROPANOL

- Filtered to 0.2µm and induction sealed to assure sterility
- Contains 70% USP grade isopropanol and 30% USP grade deionized water
- Double-bagged and gamma-irradiated to a Sterility Assurance Level of 10⁻⁶
- Ideal for use with sterile cleanroom wipers
- Excellent for wipedown of isolators, cabinets, and laminar flow hoods
- Each bottle is lot coded and has an expiration date
- Can be used on gloved hands in sterile environments

Description	Size	Cat. No.
Bottle	3.8 L (1 gal.)	89108-162
Trigger Spray Bottle	946 mL (32 oz.)	89499-420
Trigger Spray Bottle	473 mL (16 oz.)	89108-160



VERTIKLEAN[®] MAX[™] SEALED EDGE MOP

VertiKlean MAX Sealed Edge Mop was designed for applying disinfectants to both horizontal and vertical surfaces, and is ideal for general cleaning of ceilings, walls and floors in the most critical environments. This durable, lightweight mop features thermally sealed edges of a single layer hydrophilic polyurethane foam laminated to polyester microfiber fabric, backed by a semi-rigid thermoformed plate. The VertiKlean MAX Sealed Edge has a slim profile for cleaning in confined spaces. The ribbed microfiber material smoothly glides over floors and textured surfaces and provides superior contamination removal, while the pivoting mop head frame makes it easy to clean around doors, window and filter frames, light fixtures, and heavy equipment. NOW available in 18".

LARGE VERTIKLEAN MAX MOP HEAD, SEALED EDGE

Size, in. (cm)	Packaging	Cat. No.
18 x 5 x 0.375 (46 x 13 x 1)	4/Bag; 5 Bags/Case	76199-898
18 x 5 x 0.375 (46 x 13 x 1)	Individually Packaged, Sterile 1/Bag; 20 Bags/Case	76199-908
Description		Cat. No.
QuickConnect [™] 30.48 cm (12") Frame, for 32.4 cm (12¾") Mop Head, Autoclavable	10017-722
	12") Frame, for 32.4 cm (12¾") Mop Head, Autoclavable g Handle, Anodized Aluminum, Autoclavable,	10017-722

CONTEC® COMPACT BUCKET SYSTEM

Contec's autoclavable Compact Bucket System is an all-in-one solution to make cleaning and disinfecting easier and more efficient. The cart is designed for use with Contec mops such as the VertiKlean® MAX[™], VertiKlean® MAX[™] Sealed Edge, EasyCurve[™] and QuickTask[™] Mopping Systems.

Available with either two or three, autoclavable polypropylene buckets, or with three stainless steel buckets, and a choice of a standard or a utility cart handle. The utility handle allows two small buckets (6L) or one large bucket (15L) to be positioned on the handle providing additional storage for extra supplies such as clean mop heads, solution spray bottles, wipes, and other items as needed.

The stainless steel cart frame has a mop head removal tool on the front for easy, hands-free removal of a VertiKlean MAX or VertiKlean MAX Sealed Edge mop head. Two mop holders with handle clasps on either side of the cart allow for convenient mop storage during transport and storage. Case of 1.

Description	Capacity, L (gal.)	Cat. No.
Compact Bucket System, with Polypropylene Buckets, Standard		
Handle, and One Debris Screen	2 x 15 (3.9)	76199-900
Compact Bucket System, with Polypropylene Buckets, Utility		
Handle, and One Debris Screen	3 x 15 (3.9)	76199-902
Compact Bucket System, with Polypropylene Buckets, Standard		
Handle, and Two Debris Screens	3 x 15 (3.9)	76199-904
Compact Bucket System, with Polypropylene Buckets, Utility		
Handle With Two 6 L (1.6 Gal.) Buckets, and Two Debris Screens	3 x 15 (3.9)	76199-906
Compact Bucket System, with Stainless Steel Buckets and		
Standard Handle	3 x 10 (2.6)	76199-930

Little things that can help maintain a spore free cleanroom

By Karen Rossington, Global Cleanroom Market Manager, Contec Inc.

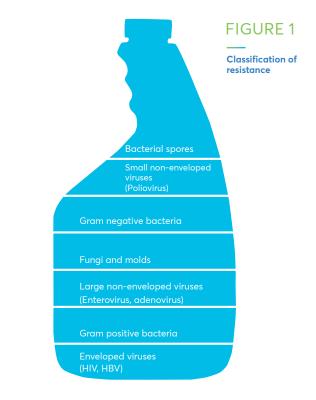
The control of microbial contamination, especially spores, is a regulatory requirement for life science cleanrooms. FDA 21 CFR 211 – cGMP for Finished Pharmaceuticals¹ states that there should be a written procedure assigning responsibility for sanitation which describes in detail the cleaning schedules, methods, equipment and materials used.

The FDA Guidance on Aseptic Processing² goes into further detail, stating that the suitability, efficacy and limitations of disinfecting agents and procedures used should also be assessed. It reminds us that procedures should be described in enough detail to enable reproducibility and that routine environmental monitoring should take place. The disinfectants used should be effective against inhouse isolates because 70% alcohol (amongst other disinfectants) is ineffective against spores, a sound disinfectant program will include a sporicidal agent. But are there other small areas of focus that could help in the war against spores in a cleanroom.

WHAT'S THE BIG DEAL WITH SPORES ANYWAY!

As defined by McDonell and Russell³, bacterial spores are one of the most resistant microorganisms to liquid disinfectants. It is not surprising that different microorganisms behave differently to disinfectants as they have different cellular structure, composition and physiology. Of the organisms which are likely to be found in a cleanroom, environment bacterial spores are the most difficult to kill with liquid disinfectants.

The creation of a spore (or endospore) is a survival mechanism which some bacterial species notably Bacillus spp. and Clostridium spp. are capable of when environmental conditions place them under stress. It allows the bacterium to produce a dormant and highly resistant structure which preserves the cell's genetic material in times of extreme stress. An outer proteinaceous coat surrounds the spore providing much of the chemical resistance. In some species, this is enclosed by the exosporium. Further layers including a thick cortex and germ cell



walls ensure the core is protected against destruction by most chemical biocides, heat, desiccation, UV and radiation. This allows the spore to remain dormant, in some cases, for many years, until conditions become favorable when the spore will germinate to become vegetative bacteria.

KEEPING CONTAMINATION OUT OF THE CLEANROOM Pharmaceutical cleanrooms are designed to prevent the ingress of contamination, including potential bacterial spores, using HEPA filters, pressure cascades, interlocked transfer hatches, change areas, etc. However due to the entry of materials and







particularly operators into the critical areas, contamination can still be a problem.

Contamination can find its way into a cleanroom from raw materials, including water, packaging, equipment, cleaning and disinfectant products themselves, and most significantly operators.

PEOPLE

People shed one outermost layer of skin cells every 24 hours that equates to 1 billion cells per day! Even sitting motionless will generate 100,000 particles per min — start moving your hands, and the rate increases to 500,000 particles per min. Simply standing up will generate 2,500,000 particles per min. Skin cells are approximately 5µm in size and make ideal carriers for microbes to adhere to and travel. Common organisms found on skin include S.epidermidis, S.hominis, and micrococcus spp. Not all skin cells carry microbes, but the higher the number of skin cells present, the higher the chance of contamination from microbecarrying-particles. Personnel need to be aware that sunbathing, ill health, smoking, even something as simple as taking antibiotics can increase the amount of skin cells that are shed. It has been suggested that 80% of particulate contamination in a cleanroom comes from personnel.

The contamination on people can be classified into two main groups, resident or colonising flora and transient flora. Resident flora are not easily removed by mechanical washing. Transient flora on the other hand are easily acquired and then transferred by direct contact. They are only loosely attached to the skin surface and can be easily removed by mechanical action, i.e. soap and water or destroyed by alcohol hand gels.

There are a variety of products designed to reduce the amount of contamination on personnel's hands. The use of a standard soap with a good handwashing technique will physically remove microorganisms and soil but will not kill any microorganisms. 70% alcohol; or hand rubs and gels based on 70% alcohol are used in many cleanrooms for hand disinfection. They are usually based on 70 -90% alcohol, the increased concentration giving better virucidal efficacy. However, no concentration of alcohol will kill bacterial spores. Simply using 70% alcohol, will be drying on hands, as alcohol acts to defat the skin. For this reason, alcohol sanitizers contain emollients for increased skin comfort. A hand gel will contain a thickening solution to make it easier to handle on the hands. Alternatively, alcohol-free hand gels are also available.

Best practice for hand hygiene follows the same theory as hard surface sanitation. Hands should be washed first to render them clean and then disinfected. A standard hand decontamination process would be to clean with soap, this would remove any transient microorganisms. This needs to be a documented process that covers all parts of both hands, there are many of these protocols publicized. A better result can be obtained by making sure hands are thoroughly wet first and this also minimizes the drying effect of the soap. It should take as long to dry the hands as to wash them, approx. 10-15 secs.

Hands can then be disinfected, but must be completely dry before exposure to a sanitizing agent. Enough alcohol or gel should be used to ensure the hands remain wet for the required contact time. A similar documented process for applying the hand sanitizer should be followed to hand washing, to ensure all areas of the hands contact the fluid. As alcohol doesn't kill spores, the physical removal of particle and micro-organisms is key.

When finger dabs are taken to check the effectiveness of operator's hand decontamination, the delay between activity and result doesn't always help when improvement is needed. This is especially problematic for new recruits who can't "see" the contamination. It is expensive to use microbial testing to reinforce

CONTEC

compliance. Consideration could be given to using fluorescent gels and powders, with a good UV light box which allows an operator to see visual and immediate results. They are easy and cost effective to use.

PROBLEMS WITH THE DISINFECTANTS THEMSELVES

All manufacturers will provide a facility with a validated shelf life for the un-opened bottle of disinfectant or pouch of wipes but an inspector will expect to see validation work to prove the shelf life of the disinfectant once it is in use. Disinfectants need to be sterile before they are used in the most critical areas of the cleanroom so not only do they need to be provided sterile but they need to maintain that sterility throughout use.

This will mean adding statements into the bio decontamination Standard Operating Procedure (SOP) which state how long a bottle or pouch of wipes can be used for before they are disposed of. The time point at which the bottle or pouch is opened needs to be clearly marked on the packaging in alcohol resistant ink. Consider unless other validation work has been carried out that sterile pre-saturated wipes are used for only one session. All non-sterile wipes need to be validated to ensure they don't dry out over the in-use shelf life period and provide insufficient disinfectant to a surface.

Concentrates should be diluted with water of suitable quality for the grade of room they are to be used in. This could be water for injection, purified water or deionized water. Highest grade areas may need sterile water to be used. All concentrates should be made up into clean containers. Again, unless validation work is carried out to prove otherwise, concentrates should be used immediately and not stored. If a ready- to-use solution is made up from a concentrate on a Monday, to be used all week, efficacy validation should be carried out on house isolates, on a solution that has been left to stand for 5 days. Care should also be taken when using hot loop WFI systems, as many concentrates will not tolerate dilution with hot water and efficacy could be immediately lost.

USE OF TRIGGER SPRAYS AND AEROSOL CANS

In mini-environments and critical areas, alcohol is very often applied to a surface or wipe, using a trigger spray or aerosol can. As alcohol doesn't kill spores, consideration should be given to protecting the sterile alcohol in-use from becoming contaminated itself. Aerosols work as a pressurized system, so the pressure differential prevents any ingress of contamination, trigger sprayers with a protected system are also available which provide the same result.

A trigger spray fitted with a protected system prevents any contaminated air being returned inside the bottle. The combination of a non-return trigger and two-part "bag in bottle" system means contaminated air cannot get into the sterile fluid. Two small holes in the base of the bottle allows air to enter between the bag containing the fluid and the bottle ensuring the bottle doesn't collapse. Using this simple trigger spray system means not having to take any small risk of contamination getting pulled back into the sterile fluid. The manufacturers will provide validation work to show how long the protected system can keep the product sterile for in use.

Trigger sprays are a very convenient method of dispensing a chemical in a cleanroom. There are significantly less disposal costs associated with trigger sprays versus aerosol cans. Usually aerosol cans only contain ¹/₃ to ¹/₂ of the volume of a trigger spray so more waste is created. Dependant on the mechanism used, the propellant can be used up, before all the fluid is dispensed, leaving waste fluid in the can. This causes more problems for disposal. Aerosol cans create a very fine mist, this generates more VOC's in the air (when used for alcohol) than a trigger spray, which can be designed to have a large droplet spray pattern. This has the advantage of not only reducing the amount of VOC's in the air, but also allows the surface or wipe to be covered faster.

Sometimes, it's the little things that can help to make a difference.

REFERENCES

- 1. Title 21: Food and Drugs Part 211—Current Good Manufacturing Practice for finished pharmaceuticals
- Guidance for Industry Sterile Drug Products Produced by Aseptic Processing Current Good Manufacturing Practice Sept 2004. U.S. Department of Health and Human Services - Food and Drug Administration
- 3. Clin Microbiol Rev. 1999 Jan; p 147–179. Antiseptics and Disinfectants: Activity, Action, and Resistance Gerald McDonnell and A. Denver Russell

Double-wall construction for fire protection

designed for protection

VWR[®] SAFETY CABINETS FOR FLAMMABLES AND CORROSIVES

VWR[®] Safety Cabinets are designed to protect both laboratory personnel and the cabinet contents.

- Fully welded, 18-gauge double-wall construction for fire protection
- Upper and lower diametrically opposed side vents
- All models fire tested and approved by FM Global



Depth (in.)	Height (in.)	Width (in.)	Color	Door Type	No. of Shelves	Cat. No.
30 Gallon Flammabl	e Storage					
18	44	43	Yellow	Bi-Fold	1	89522-618
18	44	43	Yellow	Manual	1	89522-620
18	44	43	Yellow	Self Close	1	89522-616
30 Gallon Corrosive	Storage					
18	44	43	Blue	Manual	1	89522-642
18	44	43	Blue	Self Close	1	89522-640

For a full listing of sizes and styles, visit **vwr.com**.

Designed with a broad spectrum of applications in mind

designed for production

VWR® SINGLE-USE C-FLEX ADAPTERS AND EXTENSIONS

Designed to facilitate and expedite the on-site construction of single-use fluid transfer assemblies. Applications include life sciences and general lab use, environmental assays, and production and cleanroom.

- Manufactured in ISO Class 7 Cleanroom
- Supplied Gamma Irradiated to Sterility Assurance Level (SAL) 10⁻⁶
- Tubing assemblies are offered with custom size and configuration capabilities
- Sterile C-Flex tubing is weldable/sealable

Description	I.D x O.D.	Cat. No.
Single-Use C-Flex Adapters		
24" of 374-125-2 Connected to 24" of 374-275-4; Both Ends Plugged	1/8 x 1/4" and 3/8 x 5/8"	76124-604
24" of 374-250-2 Connected to 24" of 374-250-3; Both Ends Plugged	1/4 x 3/8" and 1/4 x 7/16"	76124-606
24" of 374-250-2 Connected to 24" of 374-250-4; Both Ends Plugged	1/4 x 3/8" and 1/4 x 1/2"	76124-608
24" of 374-250-2 Connected to 24" of 374-375-4; Both Ends Plugged	1/4 x 3/8" and 3/8 x 5/8"	76124-610
Single-Use C-Flex Extensions		
1/8" I.D. C-Flex; 5' Length; Both Ends Plugged	1/8 x 1/4"	76124-616
¼" I.D. C-Flex; 5' Length; Both Ends Plugged	1/4 x ³ /8"	76124-618
¼" I.D. C-Flex; 5' Length; Both Ends Plugged	1/4 x ⁷ /16"	76124-620
1⁄4" I.D. C-Flex; 5' Length; Both Ends Plugged	1/4 x 1/2"	76124-622

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designed for production

VWR® SINGLE-USE TUBING ASSEMBLIES

Unique features make these tubing assemblies a superior alternative to others. Assemblies have been designed with a broad spectrum of applications in mind, including life sciences and general lab use, environmental assays, and production and cleanroom applications.

- Manufactured in ISO Class 7 Cleanroom
- Supplied Gamma Irradiated to Sterility Assurance Level (SAL) 10⁻⁶
- Offered with custom size and configuration capabilities
- Tubing is weldable/sealable
- Tubing Material: C-Flex

Description	Length	I.D x O.D	Cat. No.
Single Drop PP TEE with Clamps	12"	1/8 x 1/4"	10830-692
Two Drop Clamp PP TEE with Clamps	12"	1/8 x 1/4"	10830-694
50' Roll with Clamps	50″	1/8 x 1/4"	10830-258
Mini TC Jumper	36″	1/8 x 1/4"	10830-260
C-Flex MPC Body Jumper	36″	1/8 x 1/4"	10830-262
MPC Insert Jumper	36″	1/8 x 1/4"	10830-264
³ /4" TC Jumper	36″	1/8 x 1/4"	10830-266
1 ¹ / ₂ " TC Jumper	36″	³ /8 x ¹ /2"	10830-268
MPC Body Jumper	36″	3/8 x 1/2"	10830-270
MPC Insert Jumper	36″	³ /8 x ¹ /2"	10830-272
DAC Jumper	36″	³ /8 x ¹ /2"	10830-274
AQG Jumper	36″	³ /8 x ¹ /2"	10830-276

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MASTERFLEX® L/S BIOPHARM PLATINUM-CURED SILICONE TUBING

Ultra-smooth with low extractables make this tubing ideal for lab, biotech, and pharmaceutical applications.

- Formulation: Tygon 3350 silicone, platinum cured
- Ultra-smooth tubing minimizes bacterial growth
- Good for mild to medium concentration bases, salts, and alcohols
- Odorless, tasteless, and non-toxic
- Transparent finish
- Length: 7.6 m (25')

Description	I.D., mm	Cat. No.
For Use With All Masterflex® L/S® Thin Wall Pumps"		
Size 13; L/S [®] Pump Flow Range: 0.006 to 36 mL/min. (600 rpm),		
0.001 to 6 mL/min. (100 rpm)	0.08	76049-322
Size 16; L/S [®] Pump Flow Range: 0.08 to 480 mL/min. (600 rpm),		
0.016 to 80 mL/min. (100 rpm)	3.2	76049-328
Size 25; L/S [®] Pump Flow Range: 0.17 to 1000 mL/min. (600 rpm), 0.033 to 170 mL/min. (100 rpm)	4.8	76049-336
For Use With All Masterflex® L/S® Thick Wall Pumps		
Size 15; L/S [®] Pump Flow Range: 0.17 to 1000 mL/min. (600 rpm),		
0.033 to 170 mL/min. (100 rpm)	4.8	76049-326
Size 24; L/S® Pump Flow Range: 0.28 to 1700 mL/min. (600 rpm), 0.057 to 280 mL/min. (100 rpm)	6.4	76049-334
Size 35; L/S® Pump Flow Range: 0.38 to 2300 mL/min. (600 rpm), 0.077 to 380 mL/min. (100 rpm)	8	76049-342
For Use With All Masterflex® I/P® Pumps		
Size 26; I/P [®] Pump Flow Range: 1 to 4000 mL/min. (650 rpm)	6.4	76049-340
Size 73; I/P [®] Pump Flow Range: 1 to 8000 mL/min. (650 rpm)	9.5	76049-344
Size 82; I/P® Pump Flow Range: 2 to 13000 mL/min. (650 rpm)	12.7	76049-346

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PLAS LABS, INC.

Cleanliness, safety, portability, and a draft-free atmosphere

PLAS-LABS[™] COMPACT GLOVE BOXES

Designed specifically for use when weighing hazardous materials that must be contained, glove boxes provide cleanliness, safety, portability, and a draft-free atmosphere for the maximum effectiveness of your balance.

Top section is removable for easy installation of equipment, such as analytical balances, top loaders, bench scales, and moisture analyzers. Basic features include four purging gas valves (two on the transfer chamber and two on the main chamber), a white leveling tray for easy transferring of liquids, white ambidextrous Hypalon[®] gloves for superior chemical and UV resistance, a pressure relief valve that minimizes glove "fight back," and replaceable HEPA and organic vapor canister filters. All clamps are stainless steel and completely adjustable.

- Beneficial when working with toxic substances, asbestos fibers, sewage residue, and harmful liquid vapors
- Ideal for determining the dry weight or moisture content of aqueous solutions, adhesives, cereals, toxic chemicals, pharmaceuticals, paper, plastics, and light radioactive materials
- Minimize product degradation caused by moisture absorption



Volume, L (cu. ft.)	Exterior Dimensions W x D x H, cm (in.)	Shipping Weight, kg (lbs.)	Cat. No.
Glove Box with Acce	ss Door		
498 (17 ³ ⁄5)	125 x 77 x 79 (49 x 30 x 31)	97.5 (215)	97000-998
730 (254/5)	125 x 77 x 79 (49 x 30 x 31)	158.8 (350)	97001-002
317 (111⁄5)	125 x 77 x 79 (49 x 30 x 31)	77.1 (170)	97000-994
Glove Box with Acce	ss Door and Vent Outlet		
730 (254⁄5)	160 x 78 x 86 (63 x 31 x 34)	158.8 (350)	97001-004
498 (17 ³ / ₅)	160 x 78 x 86 (63 x 31 x 34)	97.5 (215)	97001-000
317 (111⁄5)	160 x 78 x 86 (63 x 31 x 34)	77.1 (170)	97000-996
Glove Box with Trans	sfer Chamber		
730 (254/5)	160 x 78 x 86 (63 x 31 x 34)	143 (315)	10718-114
498 (17 ³ / ₅)	125 x 77 x 79 (49 x 30 x 31)	95.3 (210)	10718-112
317 (11½)	110 x 61 x 79 (43 x 24 x 31)	90 (200)	32940-008

Durable for rigorous cleaning

designed for production

VWR® SPEC-WIPE® 7 WIPERS

- 100% interlock knit polyester
- Sealed edges
- No-run material
- Excellent for cleaning rough, abrasive or irregular surfaces, yet soft enough for delicate surfaces.

Use these 100% interlock knit polyester wipers where low particle and fiber contamination are most critical. Appropriate for use in electronic, semiconductor, aerospace, pharmaceutical, medical device, research, and education industries. No-run interlock knit provides durability for vigorous cleaning. Edges are sealed for reduced lint and fiber.

W x L, cm (in.)	Cat. No.
22.9 x 22.9 (9 x 9)	21913-214
30.5 x 30.5 (12 x 12)	21913-216









PERFEX TRUCLEAN® MOPPING SYSTEMS

TruCLEAN Mopping Systems work to capture and isolate contaminants, ensuring the delivery of unadulterated cleaning and sanitizing agents. TruCLEAN Disinfection systems are designed for fast, easy application of sterilants to floors, walls and ceilings. TruCLEAN components are constructed with highgrade stainless steel, entirely autoclavable, easy to maintain and guaranteed to deliver reliable cleaning results time after time.

- Compatible with gamma, ETO and autoclave sterilization
- Reduce the risk of cross-contamination
- Multiple color combinations available

TRUCLEAN® MOPS AND ACCESSORIES

Designed for cleanrooms or sterile environments where contamination control is extremely critical. Low profile, stainless steel mop frame compatible with all TruCLEAN mops. Easily change mop heads with our quick squeeze release and framelocking mechanism. Choose between our polymer adjustable handle and fixed length stainless steel handle. All TruCLEAN mops can be repeatedly laundered providing exceptional value.

- Excellent chemical and microbial resistance
- Low particle generation, excellent surface coherence
- Ideal for disinfection and sterilization procedures

Description	Cat. No.
TruCLEAN Clean Room Mop	89096-038
TruCLEAN Microfiber Mop	89096-040
TruCLEAN Anti-Microbial Mop	89096-036
TruCLEAN Sponge Mop	22940-023
TruCLEAN Mop Cover	22940-191

Color	Cat. No.
TruCLEAN Triple Bucket Mopping System*	
Red	22940-012
White	22940-015
Blue	22940-014
TruCLEAN II	
Red	89095-990
Blue	89095-992

*Also available in green and yellow

SUPPLIES

Dispensers for controlled environments



FOR USE IN CLEANROOMS. LABORATORIES. AND SAFETY APPLICATIONS

Organize and maintain your personal protection equipment and cleanroom supplies

- Designed to protect the cleanroom supplies from contamination
- Provide "ease-of-access" for the cleanroom workers
- Maximize space utilization for supplies in the production gowning room
- Products include easy to use wall mounting keyholes
- Multiple sizes and variations to cover every need
- All dispensers are also available in chemical resistant **PETG** material

To see our full line of products, visit vwr.com and enter 'S-Curve Technologies' in the search bar.

A. 98106-916 Four Compartment Dispenser

B. 98106-902 **Cleanroom Dispenser**

C. 89140-776





Wiper Dispenser

For use in critical environments

designed for production

VWR® SPEC-WIPE® 3 AND SPEC-WIPE® 3E WIPERS

- Low extractables
- Creped fabric

These nonwoven wipers are suitable for use in critical environments, for absorbing spills of water and most common solvents, and for tasks such as cleaning laminar flow benches. Low extractables and metallic ions make these wipers good for use where chemical purity is of prime importance. Spec-Wipe 3 wipers are made from a blend of 45% polyester and 55% cellulose fibers. Spec-Wipe 3e wipers are made from a creped fabric that is a blend of 46% polyester and 54% cellulose fibers. The creped fabric provides extra softness and bulk.

Cat. No.
21914-758
21912-042
89065-956
89065-958









Introducing the Micronova MegaWringer - a modular, lightweight and portable downward press wringer for consistent, flat head mop wringing with minimal effort



The unique design allows for an ergonomic, no operator bend, one-hand action, as the mop handle slides into the wringer grip and provides the leverage to create the wringing pressure.

Minimizes dripping and over-saturation of flat head style mops, removing much more liquid than a sieve-style wringer.

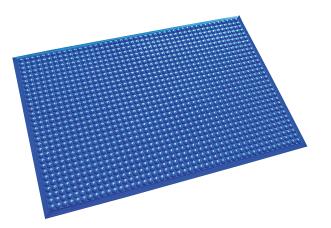
- Lightweight and durable the wringer is a combination of molded Polyketone and electropolished stainless steel
- Storage and cleaning are simple wringer easily removes from bucket(s)
- No cart is necessary to hold the wringer
- The MegaWringer easily clamps directly to the Micronova B-7 series bucket in a single, double, or triple bucket configuration
- Works with Micronova BucketBinder Multi Bucket System or Micronova SlimT Double Bucket System
- Autoclavable and compatible with strong disinfectants and cleaning solutions

Size, in.	Weight	Cat. No.
22L x 7D x 9H	5 Lbs.	76299-864











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VWR® ERGONOMIC BUBBLE MATS

The VWR[®] Bubble Mat is a true ergonomic mat. It has the comfort of a polyurethane mat and the added benefit of easy clean-ability due to its closed-cell/non-porous top surface.

- Stimulate the body to increase blood circulation and alertness
- Molded beveled edges eliminate tripping hazards
- Silcone-free, latex-free
- Antistatic and meets ISO Class 5 (Class 1000) compliance
- Easy-to-clean, closed-cell/nonporous top surface
- Highly resistant to chemicals and UV light
- Molded beveled edges that will never curl up, eliminating tripping hazards
- Thickness: 1.6 cm (5/8")

Length, m (ft.)	Width, m (ft.)	Cat. No.
0.9 (3)	0.6 (2)	89184-910
1.2 (4)	0.9 (3)	89184-948
1.5 (5)	0.6 (2)	89184-912
1.8 (6)	0.9 (3)	89184-952
2.1 (7)	0.6 (2)	89184-918
2.4 (8)	0.9 (3)	89184-956
2.7 (9)	0.6 (2)	89184-922
3.0 (10)	0.6 (2)	89184-924

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designed for every day use

VWR® STERILE BIN LINERS

STERILE LDPE LINER FOR USE IN CLEAN AND CONTROLLED ASEPTIC ENVIRONMENTS

Uses include transport of product and waste disposal. Liners are individually bagged and tagged in a double bagged pack.

Bin liners are gamma irradiated.

- Sterile
- LDPE construction
- Individually bagged

Description	Material	Dimensions	Thickness	Color	Cat. No.
Sterile Bin					
Liner	LDPE	40 x 48"	2 mil	Clear	89495-442

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