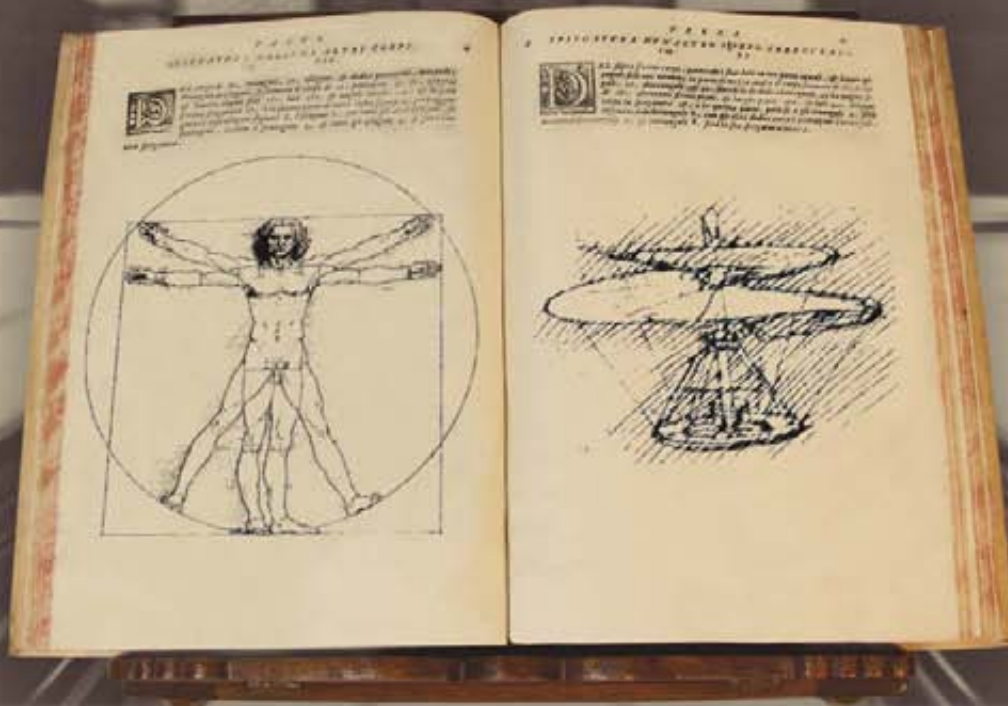


Environmental monitoring solutions for Pharmaceutical, Healthcare & Food Industries, Hospitals and Indoor Air Quality



**The “Atlantic Codex” by Leonardo da Vinci is preserved in the
Ambrosiana Library in Milan. The environment is
microbiologically monitored using a “SAS” sampler to protect the
famous book**

SAS

• SAS SUPER ISO

YOUR PARTNER IN ENVIRONMENTAL MICROBIOLOGY



The very familiar “yellow SAS (Surface Air System)” is considered the international standard for portable air microbiological samplers.

Over 25 years experience has been gained in five continents helping microbiologists in the pharmaceutical and food industry, hospital sector and indoor air quality fields. Experience has also been gained from space exploration as the SAS (Surface Air System) was used on board the International Space station. This knowledge has resulted in the development of the new “SAS-ISO 100” and “SAS-ISO 180”.



SAS (Surface Air System) IN SPACE

References of SAS - Surface Air System

FDA - 1987 Guideline on Sterile Drug Products by Aseptic Processing
ACGIH - Guideline for the Assessment of Bioaerosols in the indoor Environment

ASTM - Draft Protocol - Committee D22.05.06

USP (United State Pharmacopeia) - chapter <1116> - Microbiological Evaluation of Clean Rooms and other Controlled Environments

EU Guide for GMP - Manufacture of Sterile Medicinal Products Control of Medicines and Inspection
ISO 14698-1

THE BASIC IDEA

- To use a simple plate for air and surface sampling
- To have the additional flexibility of choice, either Contact plates or Petri dishes
- To apply cGLP and cGMP to air sampling operations
- To establish data on the microbial level in selected environments
- To organise sequential sampling to obtain a more representative air sample under actual operating conditions

The “SAS – ISO” has the following new features:

- Performance in compliance with ISO 14698-1
- Large LCD with illuminated touch panel
- All operator commands via touch keypad for easier cleaning
- Over 70.000 litres of air / 8 hours autonomy
- Infrared transfer of sampling data to PC or printer
- Up to 300 sampling cycles memorised
- USP chapter <1116> and 21-CFR 11 Compliance
- Sampling rate accurately maintained by speed sensor-incorrect aspiration aborts cycle
- Design avoids turbulence in unidirectional air flow and re-aspiration of tested air in accordance with ISO specifications
- Total traceability
- Bi-directional port to input and output data to a central unit from 1 to 24 samplers
- Automatic time calibration reminder
- Easy calibration monitoring with additional anemometer system
- Sampler can be operated whilst attached to mains

Established «yellow SAS (Surface Air System)» features and performances are maintained:

- Possibility to use 55 mm, 84 mm Contact plates (RODAC) or standard disposable 90 mm Petri dishes
- Interval sampling with fully programmable parameters for “in operation” monitoring
- Delay Start of up to 60 minutes
- Infrared remote control (optional extra)
- Certified aspirating head in aluminium or stainless steel
- Multiple language choice
- Reduced sampling time (six or ten minutes for 1000 litres of air)
- Suitability in isolator

Plus a worldwide service and support network which includes:

- International PBI is the only company with its own microbiological wind tunnel to test the air samplers from a microbial point of view
- Complete validation documentation available to help the local validation process
- Product specialists provide on-site training and certification of personnel for the proper usage of the air samplers
- Official factory calibration in Milan performed in 48 hours
- Over 100 Application Notes
- Standard Operating Procedures (SOP)
- I.Q., O.Q., P.Q. documentation or on-site activation

WHAT TO ORDER

CODE	DESCRIPTION
86279	SAS SUPER ISO 100 with air flow of 100 l/min (without head and battery charger)
86834	SAS SUPER ISO 180 with air flow of 180 l/min (without head and battery charger)
89131	battery charger 220V for SAS SUPER ISO 100 and 180
89130	battery charger 110V for SAS SUPER ISO 100 and 180

SAS • **DUO SAS SUPER 360**

DUAL HEAD PORTABLE MICROBIOLOGICAL AIR SAMPLER

Single body with two aspirating heads: two separate plates may be used for simultaneous sampling to differentiate micro-organisms (onto two different media) or onto the same media to calculate an average value and to obtain a more representative result



DUO SAS SUPER 360:
24584

The DUO-SAS-SUPER-360 features:

- The technical performances are the same as SAS Super 180
- The high flow rate of 360 litres per minute (180+180 litres) is ideal for low contamination environments, for example Clean Rooms where it is necessary to test a large volume of air
 - Two different media types (e.g.: Total Bacterial Count and mould / yeast media) may be used for simultaneous samples
- Up to ten sequential sampling cycles for “in operation” monitoring according to USP recommendations
- High speed sampling: 1000 litres in less than 3 minutes (500 per head)
- Potentially up to 18 cubic meters of air / hour may be monitored
- It can be used either with 55 mm Contact plates (U.S., or European made) , 84 mm Maxi Contact plates or 90 mm Standard Petri dishes

WHAT TO ORDER

CODE	DESCRIPTION
24584	DUO SAS SUPER 360 air sampler with air flow of 180 l/min per head (without head and battery charger)
86603	battery charger “Revit” 220V for DUO SAS SUPER 360
86604	battery charger “Revit” 110V for DUO SAS SUPER 360

SAS ISOLATOR

CRITICAL AIR MONITORING IN ISOLATOR AND BARRIER ENVIRONMENTS

It consists of a programmable unit which remains outside the controlled area and an independent sampling head which uses RODAC Contact plates or Standard 90 mm Petri dishes

- Any type of RODAC Contact plates or Standard 90 mm Petri dishes may be used

The SAS Isolator features:

- The technical performances are the same as the SAS Super ISO 100 or SAS Super ISO 180
- The sampling head may be positioned anywhere within the isolator
- Minimal disturbance of the unidirectional air flow
- Fast sampling (up to 1000 litres = 1 cubic metre - of air in six minutes)
- Fully programmable from outside
- Compatible with the most commonly used sanitizing and sterilizing agents
- Printed documentation (sampling location, operator name, etc.)



WHAT TO ORDER

CODE	DESCRIPTION
43216	SAS ISOLATOR air sampler for contact plates with air flow of 100 l/min (without head and battery charger)
43217	SAS ISOLATOR air sampler for contact plates with air flow of 180 l/min (without head and battery charger)
43218	SAS ISOLATOR air sampler for Petri dishes with air flow of 100 l/min (without head and battery charger)
43219	SAS ISOLATOR air sampler for Petri dishes with air flow of 180 l/min (without head and battery charger)
89131	battery charger 220V for SAS ISOLATOR
89130	battery charger 110V for SAS ISOLATOR

Choose your favorite head by consulting the wide range of "ACCESSORIES" page 14

• **SAS PCR** • **SAS IAQ**

A simple well known air sampler to be used by Industrial Hygienists for "SBS" (Sick Building Syndrome) and "HVAC" (Heating Ventilation Air Conditioning) studies and by Agro – Food – Dairy technologists for "HACCP" (Hazard Analysis Critical Control Point) applications



SAS IAQ: 37565

The SAS IAQ features:

- Volume of aspirated air programmable from 1 to over 1000 litres
- Air flow rate 100 litres per minute
- It uses RODAC Contact plates or Standard 90 mm Petri dishes
- Can accommodate any type of Contact plate (US or European shape)
- Reduced weight: only 1,400 grams
- Robust construction for use in industrial environments
- Autonomy over 70,000 litres (8 hours)

The SAS-PCR air sampler has been specifically developed, patented and built to collect pathogenic micro-organisms dispersed in the bioaerosol for "almost in real time" detection by molecular biology tests or traditional microbiological culture tests.

The SAS PCR features:

Air and sterile collecting fluid flow together through a nozzle and are poured into a vessel with a coil. The liquid is circulated continuously to prolong the contact time between bioaerosol and collecting liquid.



SAS PCR: 29498

WHAT TO ORDER

CODE	DESCRIPTION
37565	SAS IAQ air sampler with air flow of 100 l/min (without head and battery charger)
29498	SAS PCR pathogenic micro-organisms air sampler complete with one SPIRANTRA device
86459	battery charger for SAS PCR
86603	battery charger "Revit" 220V for DUO SAS SUPER 360
86604	battery charger "Revit" 110V for DUO SAS SUPER 360

SOS • PINOCCHIO SUPER II

“Pinocchio Super II” is a microbial impaction sampler to test the microbiological quality of compressed air and gases used in Clean Room.

A compressed air source is connected to the “Pinocchio Super II” system and the flow meter regulated to achieve the required flow rate, e.g.: 100 litres of air / minute. The sampling period is timed to obtain the required total sample volume, e.g. 1000 litres.

The “Pinocchio Super” characteristics and features:

- Self contained unit consisting of connections, air flow meter, pressure gauge, tap, funnel head complete with plate housing
- Unit requires no power and is fully transportable
- It can collect air samples either on RODAC plates or Standard 90 mm Petri dishes
- It is sterilisable
- It is calibrated according to International Standard

- I.Q., O.Q., P.Q. documentation available
- Standard Operating Procedure (SOP) available
- Application Notes available
- No electric or electronic parts



CARRYING CASE:
34538



PINOCCHIO SUPER II:
39089 - 35026

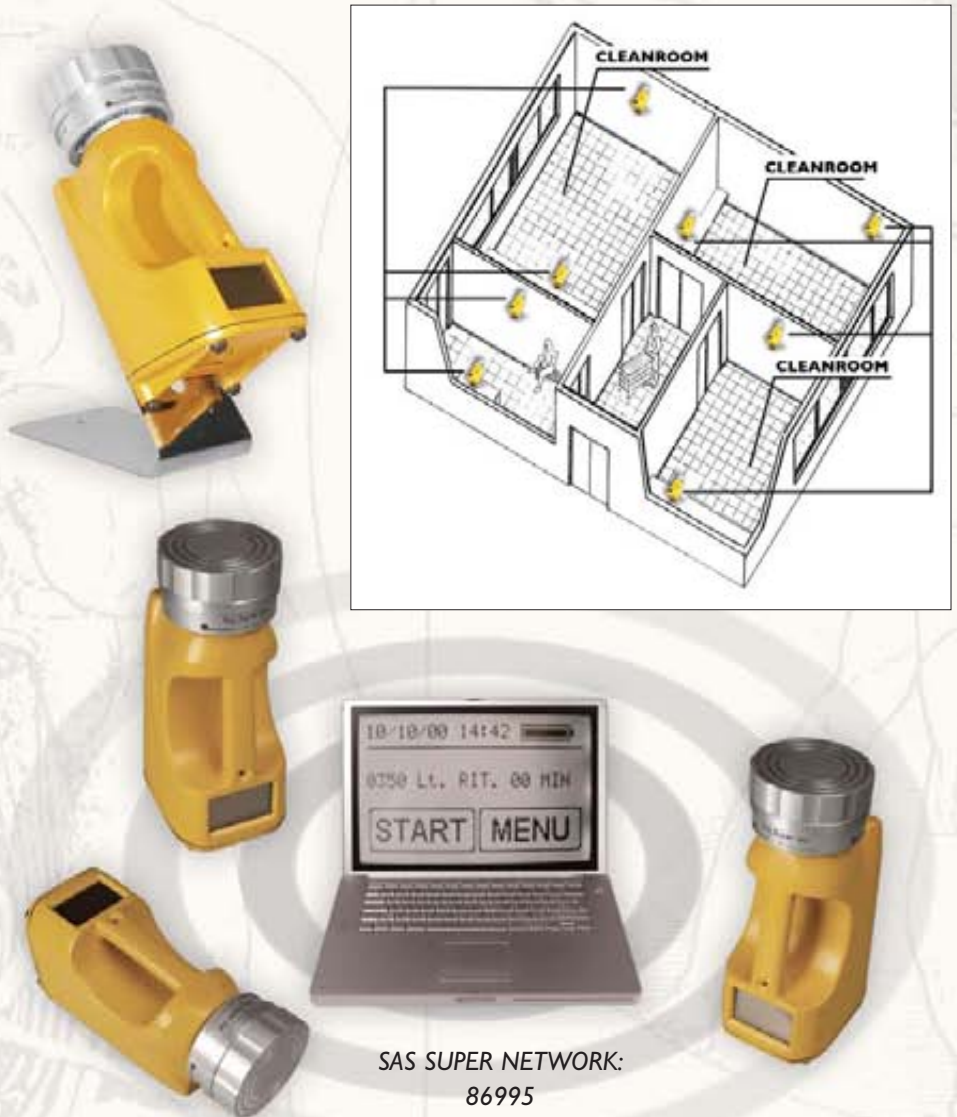
WHAT TO ORDER

CODE	DESCRIPTION
39089	PINOCCHIO SUPER II for contact plates Compressed gas and air microbial sampler
35026	PINOCCHIO SUPER II for Petri plates Compressed gas and air microbial sampling
89218	PINOCCHIO SUPER II for contact plates Compressed gas and air microbial sampler with calibration certificate
89219	PINOCCHIO SUPER II for Petri plates Compressed gas and air microbial sampling with calibration certificate
34538	Carrying case for PINOCCHIO SUPER II

SAS SUPER NETWORK

The “SAS Super Network” is a complete system for performing sequential and/or simultaneous microbiological air sampling with multiple “SAS Super ISO” and “SAS ISOLATOR” units positioned at different locations within a clean room.

All the air samplers (up to 24 units) are independently programmed and controlled by an external PC. Vacuum line connections to each sampler is not necessary as control is via infrared communications.



SAS SUPER NETWORK:
86995

WHAT TO ORDER

CODE	DESCRIPTION
86995	SAS SUPER NETWORK SOFTWARE - Software for connecting up to 24 SAS SUPER ISO or SAS ISOLATOR at different locations with a PC
86279	SAS SUPER ISO 100 with air flow of 100 l/min (without head and battery charger)
86834	SAS SUPER ISO 180 with air flow of 180 l/min (without head and battery charger)
43216	SAS ISOLATOR air sampler for contact plates with air flow of 100 l/min (without head and battery charger)
43217	SAS ISOLATOR air sampler for contact plates with air flow of 180 l/min (without head and battery charger)
43218	SAS ISOLATOR air sampler for Petri dishes with air flow of 100 l/min (without head and battery charger)
43219	SAS ISOLATOR air sampler for Petri dishes with air flow of 180 l/min (without head and battery charger)
89131	battery charger 220V for SAS SUPER ISO 100 and 180
89130	battery charger 110V for SAS SUPER ISO 100 and 180

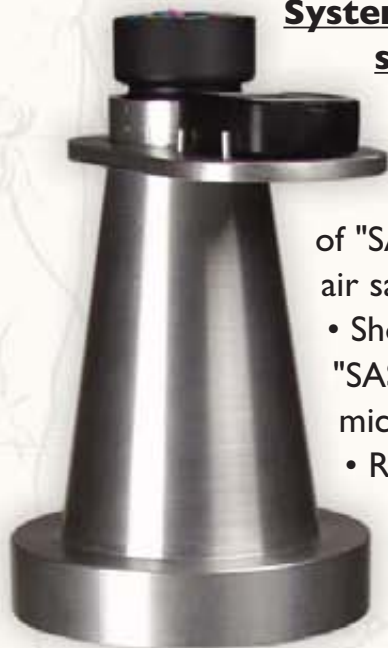
CALIBRATION / VALIDATION

The flow rate of any air sampler should be periodically checked to evaluate that the volume of aspirated air is consistent.

There are two types of check to adopt:

- an “on site” monthly or quarterly quality control check to confirm continued performance and identify any irregularity, possibly caused by damage
- bi-annual or annual “official” calibration to re-validate the sampling rate and satisfy regulatory bodies that the instrument is operating correctly.

The “on site” Quality Control monitoring of the SAS (Surface Air System) Family of air samplers:



Impeller anemometer with LCD display for the routine evaluation of "SAS (Surface Air System)" air sampler performance

- Shows the air flow of any "SAS (Surface Air System)" microbiological air samplers
- Readings in either litres per minute (l/min) or cubic feet per minute (CFM)
- Just position it on top of the aspirating head of

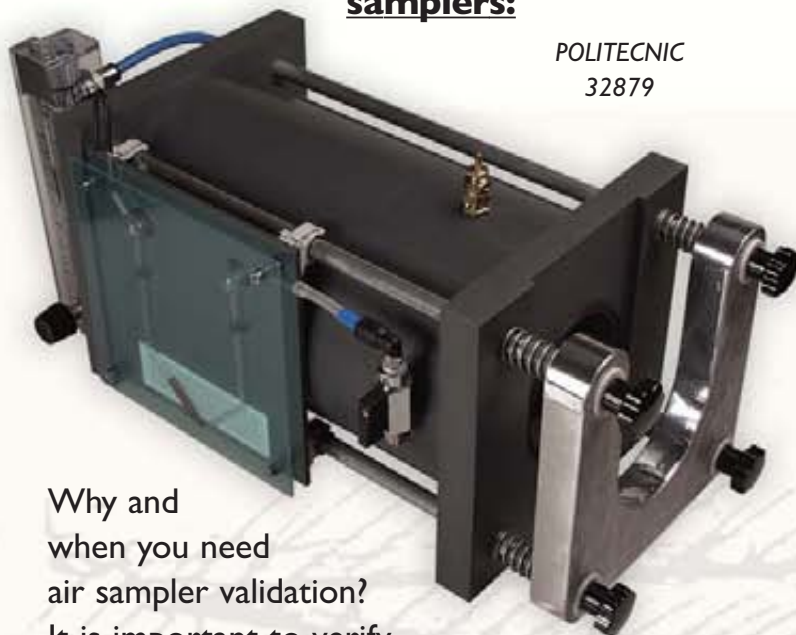
PYRAMID - 86666 the air sampler and switch on

- Measuring time 30 seconds
- According to Good Laboratory Practice and Good Manufacturing Practice
- Standard Operating Procedure



The official calibration of the SAS (Surface Air System) family of air samplers:

POLITECNIC
32879



Why and when you need air sampler validation?

It is important to verify that the volume of air you are sampling with your air sampler is correct to avoid errors in monitoring the contamination of an environment. Validation is an important step to assure that the final calculation is based on an accurately sampled volume of air. Validation of the aspirated volume should be performed every 6 months or 12 months. Re-validation is also recommended if the air sampler has potentially been damaged or the flow rate has been compromised.

SERVICING

International PBI guarantees a comprehensive calibration and service program in its Milan (Italy) premises or through local authorized distributors.

The list of distributors trained for calibration and servicing is listed on the web **www.internationalpbi.it** (English Version) at calibration-validation chapter.



• **AGAR CONTACT**

READY TO USE CONTACT PLATES FOR THE CONTROL OF THE MICROBIOLOGICAL CONTAMINATION OF THE SURFACE AND OF THE AIR.

Certificates:

Agar Contact plates are always delivered with a Certificate of Fertility of the medium (made after irradiation) and Certificate of Sterility made after manufacture.

Long Life:

Vacuum package guarantees the best storage for long periods and at environment temperatures (10 to 25 °C) up to 7 months.

Traceability:

Shelf life, batch and media type are listed to the bottom of every plate.



Use:

Suitable for Air and Surface monitoring.

Packaging:

Every box of 20 pcs with 4 vacuum bags containing 5 plate each.

Clean-rooms:

TSA and SDA plates are provided with triple packaging fully compliant to clean-rooms normatives.



“AGAR-CONTACT” can be used for:

- The microbiological control of the environment (air, surfaces and personnel staff).
- To define the degree of microbiological contamination of clean room
- To confirm the effectiveness of the operations of sanitization
- To apply the norms of good manufacturing practice “GMP”
- To apply the HACCP method
- To train the staff as regards the right sanitary procedures

Microbiological recommend limits for “Clean Areas”

Grade	Air Samples (CFU/m ³)	Contact Plate (CFU/plate)	Gloves imprint (CFU/glove)
A	<1	<1	<1
B	10	5	5
C	100	25	-
D	200	50	-

EU for GMP guide.

WHAT TO ORDER

CODICE	CONTACT PLATE DESCRIPTION	EXPIRY FROM THE DATE OF MANUFACTURE	PLATES PER PACK
“AGAR-CONTACT” STERILE CONTACT PLATES READY TO USE IN IRRADIATED STERILE VACUUM PACKAGING*			
17572.B	Agar-Contact TSA (Tryptic Soy Agar) for total count	9 months	20
17354.B	Agar-Contact TSA with agents for neutralizing disinfectants for total count	9 months	20
5210.B	Agar-Contact PCA (Plate count Agar) for total count	9 months	20
7426.B	Agar-Contact PCA with agents for neutralizing disinfectants for total count	9 months	20
7429.B	Agar-Contact SDA (Sabouraud Dextrose Agar) for count of moulds and yeasts	9 months	20
17573.B	Agar-Contact SDA with agents for neutralizing disinfectants for count of moulds and yeasts	9 months	20

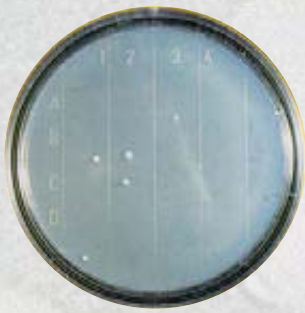
The plates with agents for neutralizing disinfectants are suggested for the control of the surfaces to avoid inhibition due to the presence of residual of disinfectants

“AGAR-CONTACT” STERILE CONTACT PLATES READY TO USE IN DOUBLE VACUUM PACKAGING*

7427.B	Agar-Contact VRBA for count of Gram -/ Coliform bacteria	6 months	20
29788.B	Agar-Contact VRBG for count of Enterobacteria	6 months	20
17574.B	Agar-Contact MSA (Mannitol Salt Agar) for count of Staphylococci bacteria	6 months	20
19927.B	Agar-Contact Mac Conkey for count of Coliform bacteria	6 months	20
17575.B	Agar-Contact Pseudomonas for count of Pseudomonas bacteria	6 months	20
18625.B	Agar-Contact Legionella for count of Legionella bacteria	6 months	20

* all the AGAR-CONTACT are sterile; irradiation of the packs is necessary when it is important to have, in addition to the sterility of the plates, also the sterility of the cardboard box and of the external plastic bag (usually for the use inside clean rooms)

Environmental Monitoring



1. Total viable count of a clean surface on Plate Count Agar



2. Total viable count of a questionable surface on Plate Count Agar



3. Total viable count of an unacceptable surface on Plate Count Agar



4. Normal resident microbial population of hands



5. Black colonies with halo of *Staphylococcus aureus* and black colonies of harmless *Staphylococci* on tellurite Pyruvate Glicine Egg Yolk medium



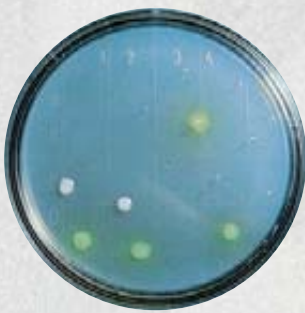
6. Few pink colonies of *Salmonella* spp surrounded by many white-yellowish colonies of coliform on Brilliant Green Agar



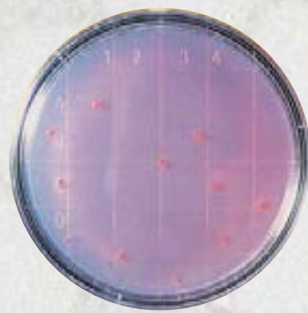
7. Typical bright red colonies of *Escherichia coli* on Violet Red Bile Agar



8. Reddish, mucoid colonies of *Enterobacter* and light, small pink colonies of *Serratia* on McConkey agar



9. Green pigmented colonies of *Pseudomonas aeruginosa* on Cetrinide agar



10. Colonies with dark pink center of *Yersinia* spp on Cefsulodin Irgasan Novobiocin Agar



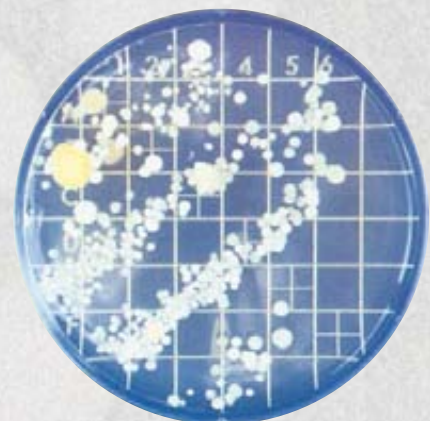
11. Blue background around colonies of *Bacillus cereus* on Holbrook and Anderson media (with polymyxin)



12. Large and creamy colonies of yeast on Oxytetracycline Glucose Yeast Extract Agar



Irradiated triple-wrapped bag for clean room



Printing of fingers on "Maxi-contact" plates

SAS • **DISPO-HEAD**

DISPOSABLE ASPIRATING HEAD FOR SAS AIR MONITORING

- All analytical material that are used for microbiological testing should be sterile and, according to the cGLP, a document of certification should prove that it has been correctly sterilized.
- This rule is also valid for the aspiration head that is used with microbiological air samplers. Each cycle of air sampling should use a documented sterile aspirating head.
- The "Dispo-Head", is a disposable aspirating head for microbiological air monitoring, which has been developed and produced by international pbi to simplify the workload of the microbiologist.
- The "Dispo Head", made in antistatic resin plastic, is triple packed, irradiated and comes with certification of sterilisation, conformity and endotoxin level (LAL test)
- It has a shelf-life of five years and it is suitable for any type of SAS Super air sampler that uses diameter 55 mm Contact Plates (RODAC).



WHAT TO ORDER

CODE	DESCRIPTION
86996	Dispo-Head" for 55 mm Contact Plates Certified sterile



86682



86996



32879



5215



89131 - 86603



5214



20914



86666



71360001



86279 - 43216

15931 - 15503



22536



86279 - 43216

19123



20153



18143

SAS ACCESSORIES

WHAT TO ORDER

CODE DESCRIPTION

HEAD FOR YOUR SAS

15931	"DRILLED" aluminium head for 55 mm contact plates, certified
15503	"INOX DRILLED" stainless steel head for 55 mm contact plates, certified
19117	"PETRI-SYSTEM" aluminium head + adaptor for standard 90 mm Petri dishes, certified
19119	"PETRI-SYSTEM" stainless steel head + adaptor for standard 90 mm Petri dishes, certified
19123	"MAXI CONTACT SYSTEM" aluminium head + adaptor for 84 mm contact plates, certified
18148	"MAXI CONTACT SYSTEM" stainless steel head + adaptor for 84 mm contact plates, certified
19115	"ATRIUM" autoclavable chamber for contact plates (without head)
23236	"DRILLED" stainless steel head (without adaptor) for standard 90 mm Petri dishes
34494	"DRILLED" aluminium head (without adaptor) for standard 90 mm Petri dishes
21160500	"STRAIGHT" autoclavable container for transferring SAS head into CR
86996	"DISPO HEAD" disposable drilled head for contact plates - 50 each/box

CARRYING CASES

18143	"PRATICA" soft carrying case for SAS SUPER ISO and SAS IAQ, SAS SUPER 100-180
20153	"LIGHT-CASE" aluminium carrying case with special impact-proof inner lining for SAS SUPER 100-180
25094	Soft carrying case for DUO SAS SUPER 360
86751	"TRANS CASE" aluminium carrying case for DUO SUPER SAS
71350001	"BIO SAFE CARRIER" clean room polycarbonate transfer case for SAS SUPER ISO and SAS IAQ
71360001	Handle for "BIO SAFE CARRIER" case
86475	Carrying case for SAS PCR
88713	Carrying case for SAS ISOLATOR
34538	Carrying case for PINOCCHIO SUPER II

TRIPODS

5215	"TELESCO" tripod - floor model
5214	"TELESCO" tripod - table model
20914	"SAS HOLDER" table and wall holder
89229	Stainless steel holder for "SAS NETWORK" interface

CALIBRATION

32879	"Politecnic" SAS calibration system with calibration certificate
42767	"Politecnic" SAS calibration system without calibration certificate
86666	"Pyramid" SAS calibration system
32949	Calibration certificate for "Politecnic"

OTHER ACCESSORIES

87085	"PIER" Aspiration Chamber for SAS Isolator without head (contact plates 55 mm)
88826	"PIER" Aspiration Chamber for SAS Isolator without head (Petri dishes 90 mm)
18950	"TELECON" infrared remote control for DUO SAS SUPER 360; SAS SUPER 100-180
89170	Infrared remote control for SAS SUPER ISO
22536	SAS Software for downloading the data from DUO SAS SUPER 360; SAS SUPER 100-180
26025	Cable for SAS software code 22536
86726	Sterile head disinfectant - 4 each/box
89320	SAS Software for downloading data from SAS ISO
89321	Cable for SAS Software code 89320
29499	SPIRANTRA device for SAS PCR

