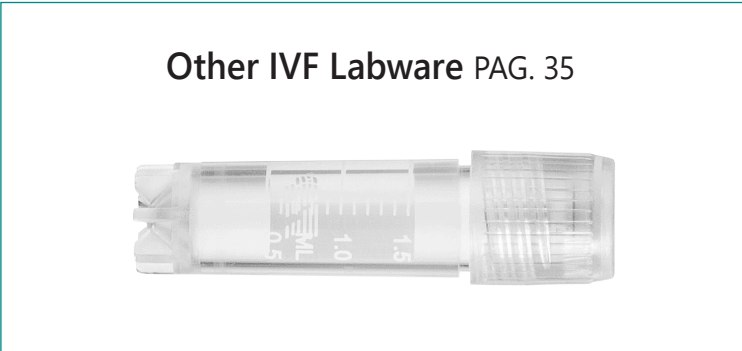
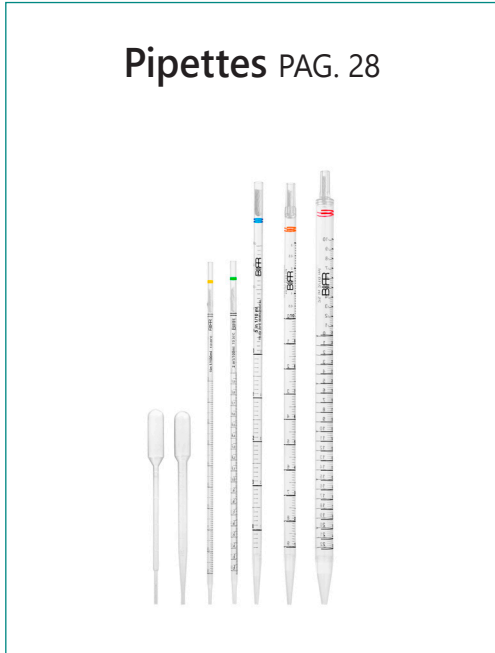
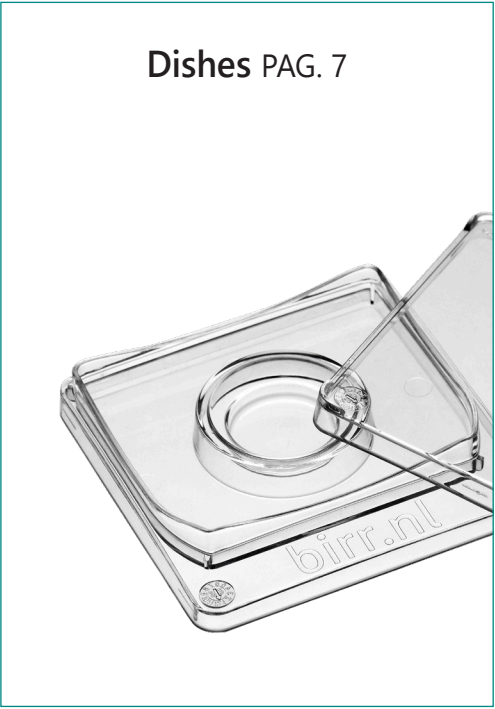


BIRR Interactive IVF Labware Catalog



IVF Labware portfolio
Table of content PAG. 3

BIRR's IVF Labware
quality standards PAG. 4



About
BIRR
PAG. 37

BIRR and IVF Labware: it's embryologic! Why?

BIRR has fertility expertise since 1971

All BIRR's IVF Labware has been designed in close collaboration with embryologists

BIRR's IVF labware portfolio is developed and produced in the EU, according to the highest quality standards

All BIRR's IVF Labware is CE Class IIa MDD certified

BIRR offers a complete IVF labware portfolio

BIRR commits to a reliable delivery process

If there's a customer/patient need for new products, BIRR designs it

Table of content

BIRRs IVF Labware quality standards

4

Dishes 7



7

5-Well Dish Round Edges



8

Square ICSI Dish



9

Square Center-Well Dish



10

6-Well Dish



11

4+8-Well Dish



13

Culture Dish 35 mm Time Lapse



14

Culture Dish 35 mm



15

Culture Dish 60 mm



16

Culture Dish 90 mm



17

Center-Well Dish 60 mm



18

ICSI Dish 60 mm



19

Nominal and Working Volume of BIRR's dishes portfolio

20

Tubes 21

Tubes portfolio



21

Round Bottom Tube 5 mL



22

Round Bottom Tube 14 mL



23

Conical Tube 11 mL



24

Conical Tube 15 mL



25

Conical Tube 15 mL



26

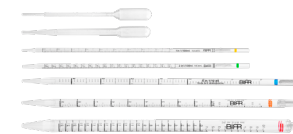
Conical Tube 50 mL



27

Pipettes 28

Pipettes portfolio



28

Dropping Pipette 1/3 mL



29

Serological Pipette 1/2/5/10/25 mL



30

Containers 31

Semen Collection Container 100 mL



32

Semen Collection Container 125 mL



33

other labware 34

Microvial 1.5 mL



35

Flask 40/270 mL



36

About BIRR

37

BIRR IVF Labware quality testing and certification standards

BIRR IVF Labware is developed and produced according to the highest quality standards. All our qualitative tests are performed in a state-of-the-art laboratory, which strives for continuous improvement on testing reliability and accuracy. This enables BIRR to ensure that labware products are safe and performant.

BIRR IVF labware certification and testing standards	Dishes	Tubes	Containers	Pipettes	Other labware
CE IIa medical device	✓	✓	✓	✓	✓
FDA clearance	✓	✓	✓	✓	✓
ISO 13485:2016 certified	✓	✓	✓	✓	✓
MEA (+) test	✓+	✓	✓	✓	✓
LAL test	✓	✓	✓	✓	✓
SMA test	✓	✓	✓	✓	
Produced in EU	✓	✓	✓	✓	✓

BIRR IVF labware is registered in several countries in Europe, North-America, South-America and Asia. When required, local regulatory registration will be established. For information about specific geographies, please reach out to us.

BIRR introduces its smART Labware label:

BIRR IVF labware with innovative feature and added value on ease of use or safety versus conventional labware



BIRR IVF Labware certification standards

BIRR IVF Labware is also certified according to the highest standards.

All BIRR IVF labware products are Medical Devices: they are certified CE Class IIa sterile Medical Devices in accordance with 93/42 EEC Directive. Medical devices (MD) are intended and tested for direct or indirect use with a human body (e.g., in vivo and in vitro).

CE IIa marking indicates that the product meets the high safety, health and environmental requirements set by the European Union. In Europe and other geographies, CE IIa marking is compulsory for products used in IVF treatments.

Different from Medical Devices, in Vitro Diagnostics Devices (IVD) are intended and approved for use in testing of human samples, where the results can assist in clinical diagnosis. Thus IVD-products are for diagnostic purposes only, NOT for clinical use.

BIRR IVF Labware testing standards

Why does BIRR have a robust testing program of its IVF labware portfolio? MEA, LAL and SMA tests are performed to detect whether the materials and processes employed in labware manufacturing affect gametes viability or embryo development. Successful testing ensures undeviating labware performance that doesn't interfere with specimens' biological processes. Lack of product quality assurance through each of these tests may compromise labware consistency, ultimately affecting laboratory and clinical outcomes. BIRR's robust quality assurance program ensures that labware standards are persistently maintained, providing laboratories the stability required for reliable gamete and embryo culture performance.

Test carried out on each product LOT:

Mouse Embryo Assay (MEA): Across the labware portfolio, two different type of MEA tests are performed, the Standard MEA or Extended MEA

- **The Standard MEA** is performed on the labware that has contact time <24 hours with gametes or embryos (e.g., tubes, pipettes). This approach involves the exposure of culture media to the tested labware for 2 hours. This media is then used for incubation of 1-cell mouse embryos (n=21, Test group) until Day 5 of development in a reference dish. In parallel, 1-cell mouse embryos (n=15, Control group) are cultured in the same type of reference culture dish using media that was not exposed to the testing labware. For each group, embryo cleavage is assessed at 24hrs and blastocyst formation is assessed at 96hrs (Day 5 development). A product lot is accepted when testing outcomes show blastocyst formation rate >80% in the Test group.
- **The Extended MEA (MEA+)** is performed on labware that has a contact time >24 hours, done for all dishes. This approach involves continued exposure of 1-cell mouse embryos (n=21, Test group) to the tested labware throughout a 96hrs culture period (Day 5 of development). In parallel, 1-cell mouse embryos (n=15, Control group) are cultured in the same type of reference culture dish using media that was not exposed to the testing labware. For each group, embryo cleavage is assessed at 24hrs and blastocyst formation is assessed at 96hrs (Day 5 development). A product lot is accepted when testing outcomes show blastocyst formation rate >80% in the Test group.

Sperm Motility Assay (SMA) test: Good quality post-preparation sperm samples are exposed to the testing labware (Experimental group) or left in the reference labware (Control group) for 8 hours. The ratio between sperm motility rate from the Experimental and Control groups determines sperm motility index (SMI). Product lot acceptance threshold is set at SMI >0.75.

Limulus Amebocyte Lysate (LAL) test: Presence of bacterial endotoxin lipopolysaccharide (LPS) is tested through LAL test on all labware. Acceptance detection threshold <0.03EU/device.

Results of quality test are available upon request for each LOT number.

IVF Dishes

Why our IVF Dishes

Quality

- Class IIa sterile Medical Device in accordance with the 93/42 EEC Directive
- Manufactured by BIRR in EU
- Specifically designed for IVF
- Non-pyrogenic
- MEA+ tested
- Sterility assurance level 10^{-6} (by irradiation)
- IVF dishes are made of medical-grade Polystyrene (PS)

Benefits

- Raised bottoms (200 micron air layer) to avoid scratches, minimize overheating in case of temperature spikes in the heated stage and provide uniform adherence to the surface
- Scratch protection improves visibility and safety
- Temperature consistency across all dishware suite



IVF Dishes

5-Well Dish Round Edges

Article code & Packaging

1130056 packed by 6 / 180 per box

Testing

MEA+, LAL & SMA per LOT number

New, smART
and available

smART characteristics

- Sloped walls of the wells facilitate specimens identification and recall
- Wide well design improves accessibility to the specimen and its manipulation
- Large labelling area accommodating all types of handwriting, ID labels, barcodes and RFID tags
- Clear well identification provided by well numbering 1-5
- Round edges

Intended use

- Multipurpose dish
- Cell culture (gametes or embryos)
- Oocyte insemination (IVF) and denudation

smART

LABWARE



IVF Dishes

Square ICSI Dish

Article code & Packaging

1130116 packed by 6 / 180 per box

Testing

MEA+, LAL & SMA per LOT number

New, smART
and available

smART characteristics

- The wide square area increases useable surface and improves access for micromanipulation
- The large surface allows extended customisation of media drops placement within the dish
- Slanted walls and rounded internal corners for improved recall and visualisation of specimens
- Large labelling area accommodating all types of handwriting, ID labels, barcodes and RFID tags

Intended use

- Multipurpose dish
- Intracytoplasmic Sperm Injection (ICSI)
- Cell culture (gametes or embryos)

smART

LABWARE



IVF Dishes

Square Center-Well Dish

Article code & Packaging

1130106 packed by 6 / 30x6 per box

Testing

MEA+, LAL & SMA per LOT number

smART characteristics

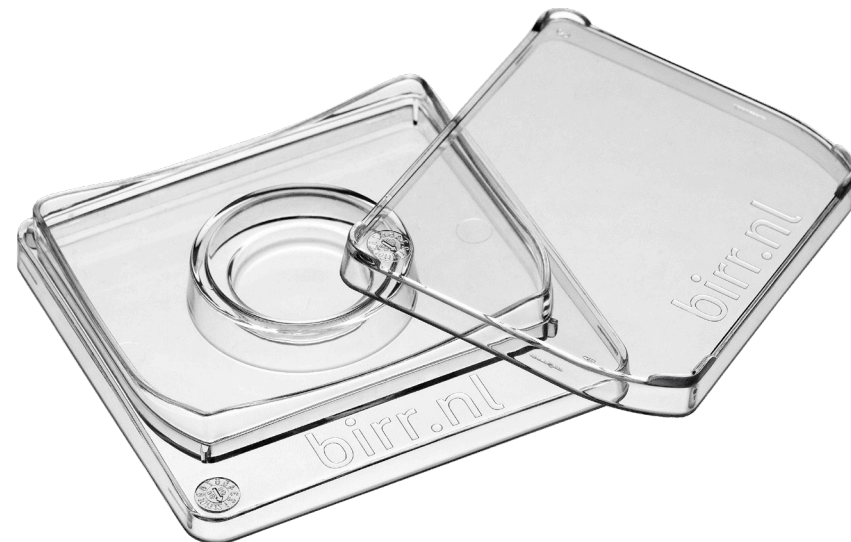
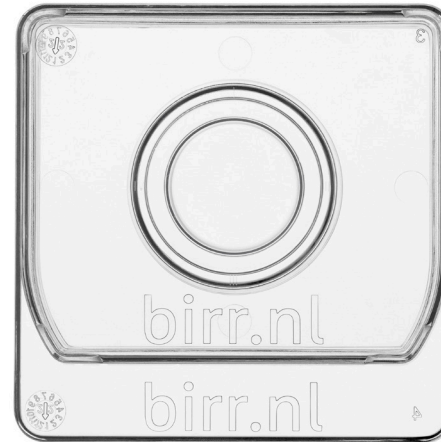
- Raised bottom and flat construction avoid undesired spinning of the dish
- Sloped walls of the well facilitate specimens identification and recall
- Large labelling area accommodating all types of handwriting, ID labels, barcodes and RFID tags

Intended use

- Multipurpose dish
- Embryo transfer
- Cell culture (gametes or embryos)
- Oocyte insemination (IVF) and denudation

smART

LABWARE



IVF Dishes

6-Well Dish

Article code & Packaging

113006 packed by 6 / 180 units per box

Testing

MEA+, LAL & SMA per LOT number

smART characteristics

- Large labelling area
- Clear embryo identification provided by well-numbering 1-6
- Indents on the outer rim of the dish allow for horizontal stabilisation of the vitrification carrier while loading it

Intended use

- Gamete and embryo cryopreservation
- Cell culture (oocytes or embryos)
- Oocyte insemination (IVF) and denudation

smART

LABWARE



IVF Dishes

16-Well Dish

Article code & Packaging

113016 packed by 6 / 180 units per box

Testing

MEA+, LAL & SMA per LOT number

smART characteristics

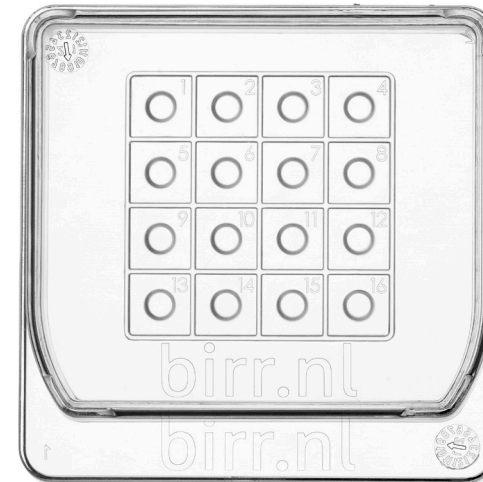
- Large labelling area
- Clear embryo identification provided by well-numbering 1-16
- Large working area for better access
- 16 wells increase embryo culture positions and/or number of available wash drops
- Reduced number of dishes per IVF procedure

Intended use

- Cell culture (gametes or embryos)

smART

LABWARE



IVF Dishes

4+8-Well Dish

Article code & Packaging

1134+8 packed by 10 / 240 units per box

Testing

MEA+, LAL & SMA per LOT number

smART characteristics

- Clear embryo/position identification due to well-numbering 1-8 (8 x 100 μ L wells), 9-12 (4 x 150 μ L wells)
- Compatible with either individual or group embryo culture
 - Small wells to store embryos after washes in the bigger wells (individual culture)
 - Big wells to store multiple embryos after serial washes in the smaller wells (group culture)
- No droplet mixing

Intended use

- Cell culture (gametes or embryos)
- Oocyte insemination (IVF) and denudation
- Handling or manipulation of embryos or gametes

smART

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IVF Dishes

Culture Dish 35 mm Time Lapse

Article code & Packaging

113030TL single packed / 200 units per box

113031TL packed by 10 / 480 units per box

Testing

MEA+, LAL & SMA per LOT number

smART characteristics

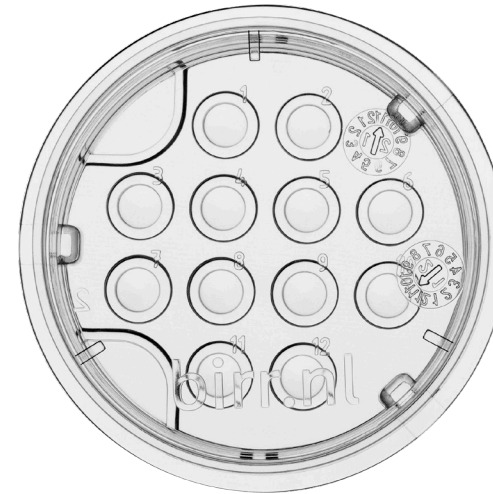
- 360° rim confers increased hand grip during operations
- Clear embryo identification provided by well-numbering 1-12
- Fits ASTEC timelapse
- Additional non-numbered side wells for washing embryos and flushing the pipette

Intended use

- Cell culture (gametes or embryos)

smART

LABWARE



IVF Dishes

Culture Dish 35 mm

Article code & Packaging

113030 single packed / 200 units per box

113031 packed by 10 / 480 units per box

Testing

MEA+, LAL & SMA per LOT number

Characteristics

- 360° rim confers increased hand grip during operations

Intended use

- Cell culture (gametes or embryos)
- Oocyte insemination (IVF)



IVF Dishes

Culture Dish 60 mm

Article code & Packaging

113060 single packed / 100 units per box

113061 packed by 4 / 192 units per box

Testing

MEA+, LAL & SMA per LOT number

Characteristics

- Rugged 360° rim confers increased hand grip during operations

Intended use

- Cell culture (gametes or embryos)
- Follicular fluid inspection (oocyte collection)
- Oocyte insemination (IVF) and denudation



IVF Dishes

Culture Dish 90 mm

Article code & Packaging

113090 single packed / 48 units per box

113098 packed by 8 / 96 units per box

Testing

MEA+, LAL & SMA per LOT number

Intended use

- Cell culture (gametes or embryos)
- Follicular fluid inspection (oocyte collection)
- Oocyte insemination (IVF) and denudation



IVF Dishes

Center-Well Dish 60 mm

Upgraded
& smART

Article code & Packaging

1130-CW single packed / 100 units per box

(upgrade in later stage info will follow)

1131-CW packed by 10 / 240 units per box

(UPGRADED version)

Testing

MEA+, LAL & SMA per LOT number

smART characteristics

- The dish now features room for labelling on the side wall (this was not possible due to the 360° grid of the previous version)
- The new design improves handling of both the dish and its lid, making the product more user friendly

Intended use

- Embryo transfer
- Cell culture (gametes or embryos)
- Oocyte insemination (IVF) and denudation

smART

LABWARE



Image current 1130-CW version left, upgraded 1131-CW version right

IVF Dishes

ICSI Dish 60 mm

Article code & Packaging

1130-ICSI single packed / 100 units per box

1131-ICSI packed by 10 / 240 units per box

Testing

MEA+, LAL & SMA per LOT number

Characteristics

- Low walled dish allows better access of micromanipulation pipettes to specimens
- The lid features a tight fit to the dish preventing gas exchange
- Rugged 360° rim confers increased hand grip during operations

Intended use

- Intracytoplasmic Sperm Injection (ICSI)



Nominal and Working Volume of BIRR's dishes portfolio

BIRR Dishes portfolio	Item	Nominal Volume	Working volume (working range)
5-Well Dish Round Edges	Well	1.87 mL	1.3 mL (1.0 mL - 1.4 mL)
Square ICSI Dish	Dish	18 mL	7 mL (6 mL - 8 mL)
Square Center-Well Dish	Inner	2.2 mL	1.5 mL (1.0 mL - 2.0 mL)
	Outer		4.0 mL (3.5 mL - 4.5 mL)
6-Well Dish	Well	480 µL	300 µL (200 µL - 400 µL)
16-Well Dish	Drop	9 µL	25 µL (20 µL - 25 µL)
	Dish	22.8 mL	7 mL (5 mL - 9 mL)
4+8-Well Dish	Large Drop	91 µL	150 µL (130 µL - 170 µL)
	Small Drop	62 µL	100 µL (90 µL - 120 µL)
	Dish	21.2 mL	8 mL (7 mL - 10 mL)
Culture Dish 35 mm Time Lapse	Drop		20 µL
	Dish	8.8 mL	
Culture Dish 35 mm	Dish	9.3 mL	5 mL (4 mL - 6 mL)
Culture Dish 60 mm	Dish	28 mL	7 mL - 14 mL
Culture Dish 90 mm	Dish		
Center-Well Dish 60 mm	Inner	2.2 mL	1.5 mL (1.0 mL - 2.0 mL)
	Outer		2.5 mL (2.0 mL - 3.5 mL)
ICSI Dish 60 mm	Dish	16.2 mL	8 mL (6 mL - 10 mL)

Disclaimer: these values are indicative and depending on use (e.g., embryo transfer, oocyte culture), each laboratory must validate solutions volumes prior to clinical use.

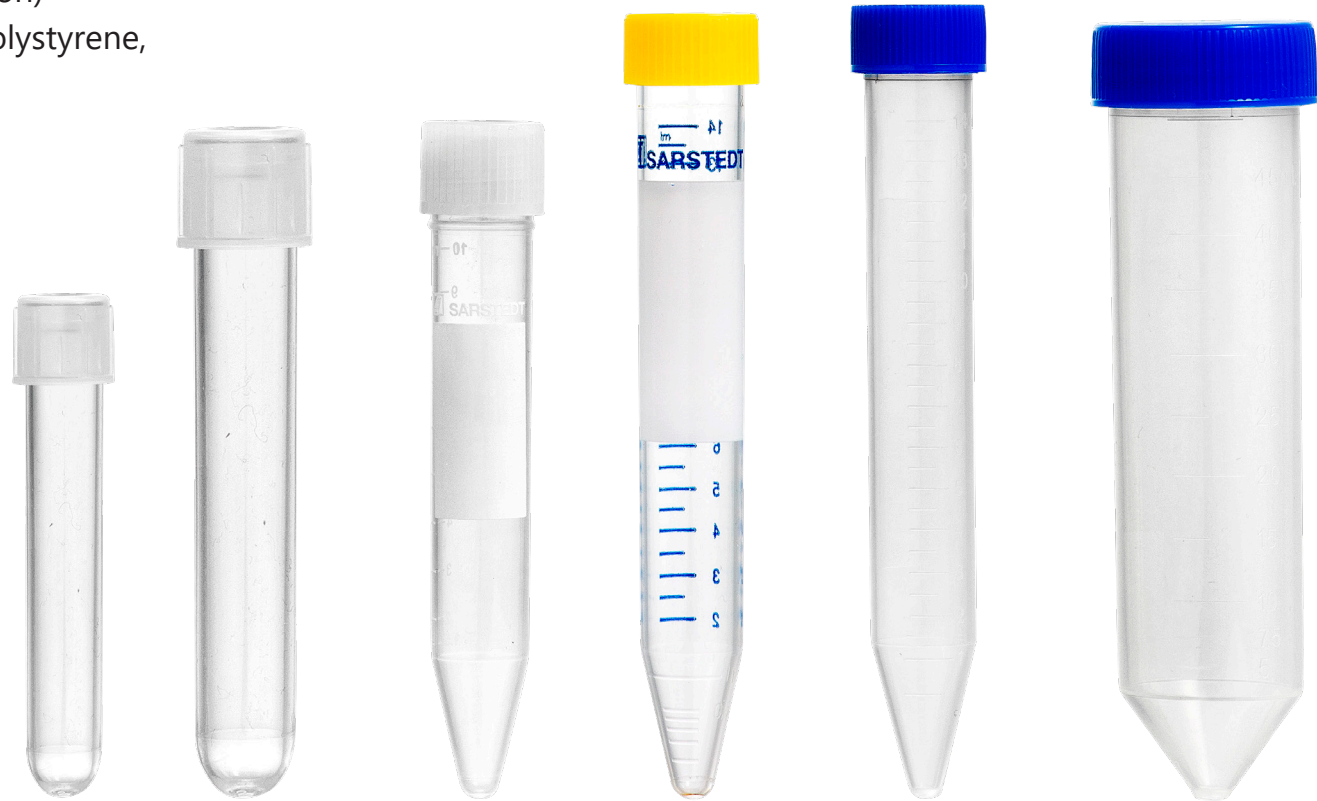
Nominal volume: the total capacity of the well, microwell or dish calculated as length x width x height of its walls.

Working volume: the amount of liquid required to operate the well, microwell or dish in a way that maximises performance and minimizes nuisance (e.g., spillage).

IVF Tubes

Why our Tubes

- Class IIa sterile Medical Device according 93/42 EEC Directive
- Manufactured by BIRR in EU
- IVF specific design
- Non-pyrogenic
- Sterility assurance level 10^{-6} (by irradiation)
- IVF tubes are made of medical-grade Polystyrene, Polypropylene and Polyethylene.



IVF Tubes

Round Bottom Tube 5 mL (polystyrene, polyethylene cap)

Article code & Packaging

113515 single packed / 800 units per box

113516 packed by 10 / 1800 units per box

Testing

MEA, LAL & SMA per LOT number

smART characteristics

- Dual position of the cap (sealed and venting)
- Unique cap design prevents accidental sealing
- Simple one-handed cap operability
- Moulded measuring scale (standard)

Intended use

- Short storage of culture media, density gradients or cell culture oil (days) (4-40 °C)
- Processing of semen samples (e.g., swim-up technique)
- Short storage of processed sperm cells

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IVF Tubes

Round Bottom Tube 14 mL (polystyrene, polyethylene cap)

Article code & Packaging

113520 single packed / 600 units per box

113521 packed by 10 / 1000 units per box

Testing

MEA, LAL & SMA per LOT number

smART characteristics

- Dual position of the cap (sealed and venting)
- Unique cap design prevents accidental sealing
- Simple one-handed cap operability
- Moulded measuring scale (standard)

Intended use

- Short storage of culture media, density gradients or cell culture oil (days) (4-40 °C)
- Collection of follicular fluid (e.g., oocyte collection procedure)

smART

LABWARE



IVF Tubes

Conical Tube 11 mL (polypropylene, polyethylene cap)

Article code & Packaging

113511 packed by 10 / 1000 units per box

Testing

MEA, LAL & SMA per LOT number

smART characteristics

- Moulded measuring scale
- Frosted labelling area

Intended use

- Preparation, centrifugation and storage of culture solutions (e.g., culture media, density gradients) or biological specimens used in ART procedures



IVF Tubes

Conical Tube 15 mL (polypropylene, polyethylene cap)

Article code & Packaging

113501 packed by 10 / 1000 units per box

Testing

MEA, LAL & SMA per LOT number

smART characteristics

- Moulded measuring scale
- Frosted labelling area

Intended use

- Preparation, centrifugation and storage of culture solutions (e.g., culture media, density gradients) or biological specimens used in ART procedures



IVF Tubes

Conical Tube 15 mL (polystyrene, polyethylene cap))

Article code & Packaging

113506 packed by 10 / 1000 units per box

Testing

MEA, LAL & SMA per LOT number

smART characteristics

- Moulded measuring scale
- Frosted labelling area
- Clear see-through plastic

Intended use

- Preparation, centrifugation and storage of culture solutions (e.g., culture media, density gradients) or biological specimens used in ART procedures



IVF Tubes

Conical Tube 50 mL (polypropylene, polyethylene cap)

Article code & Packaging

113510 single packed / 200 units per box

Testing

MEA, LAL & SMA per LOT number

smART characteristics

- Moulded measuring scale
- Frosted labelling area

Intended use

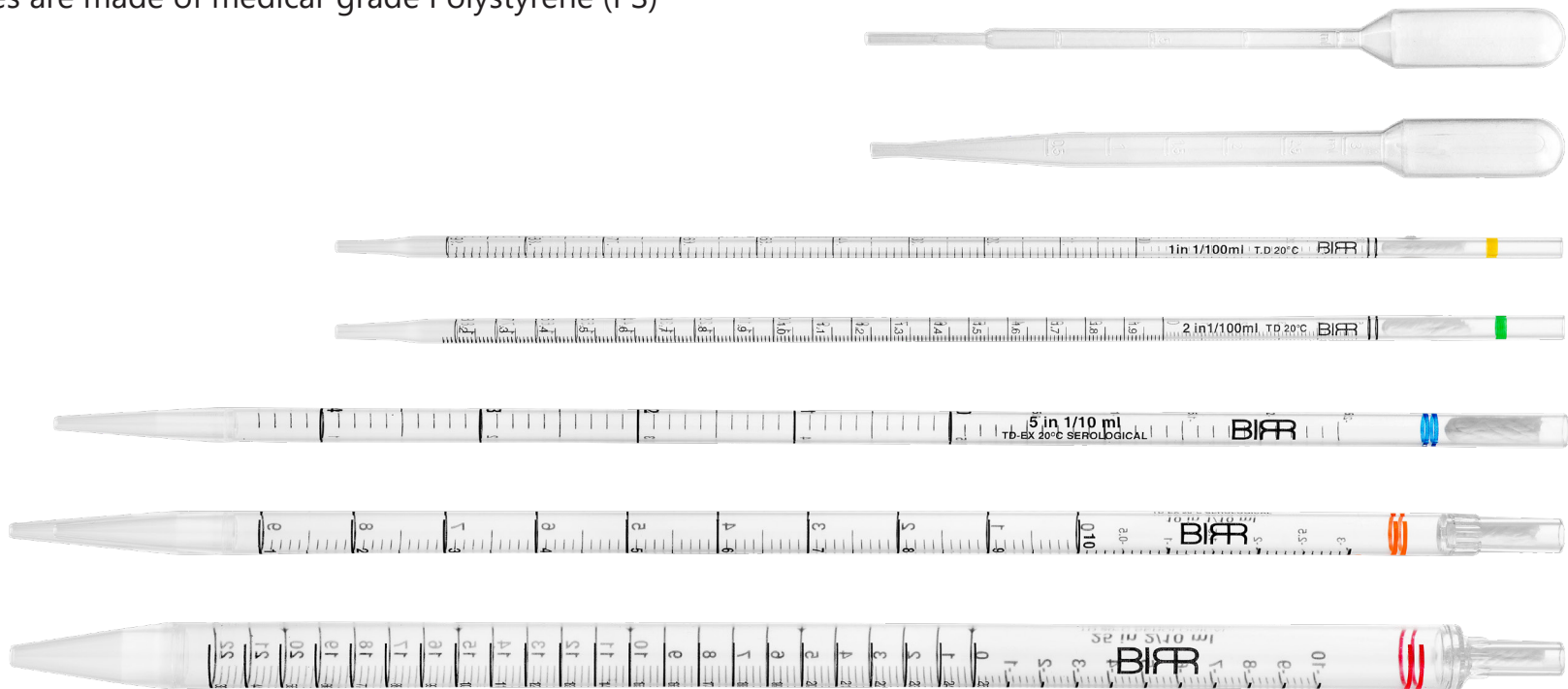
- Preparation, centrifugation and storage of culture solutions (e.g., culture media, density gradients) or biological specimens used in ART procedures



IVF Pipettes

Why our Pipettes

- Class IIa sterile Medical Device according 93/42 EEC Directive
- Manufactured by BIRR in EU
- Non-pyrogenic
- Sterility assurance level 10⁻⁶ (by irradiation)
- Dropping pipettes are made of medical-grade Polyethylene (PE)
- Serological pipettes are made of medical-grade Polystyrene (PS)



IVF Pipettes

Dropping Pipette 1 mL

Article code & Packaging

113410 single packed / 800 units per box
113411 packed by 10 / 1500 units per box

Testing

MEA, LAL & SMA per LOT number

Dropping Pipette 3 mL

Article code & Packaging

113420 single packed / 800 units per box
113421 packed by 10 / 1500 units per box

Testing

MEA, LAL & SMA per LOT number

Intended use

- Transfer of semen sample from the collection container to density gradients or other devices used for semen processing or storage
- Aliquoting of culture media and density gradients

1 ml



3 ml



IVF Pipettes

Serological Pipette 1 ml

Article code & Packaging

113701 single packed / 1000 units per box

Testing

MEA & LAL per LOT number



Serological Pipette 2 ml

Article code & Packaging

113702 single packed / 1000 units per box

Testing

MEA & LAL per LOT number



Serological Pipette 5 ml

Article code & Packaging

113705 single packed / 500 units per box

Testing

MEA & LAL per LOT number



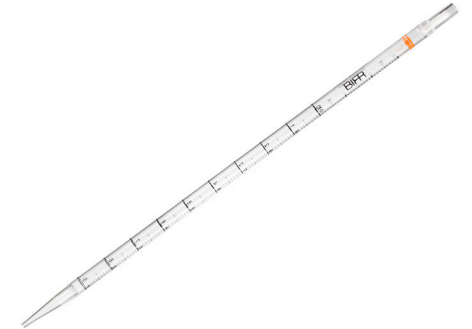
Serological Pipette 10 ml

Article code & Packaging

113710 single packed / 500 units per box

Testing

MEA & LAL per LOT number



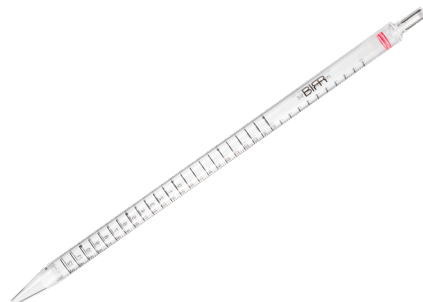
Serological Pipette 25 ml

Article code & Packaging

113725 single packed / 200 units per box

Testing

MEA & LAL per LOT number



Characteristics

- Portfolio of 5 pipettes including unique 25 mL

Intended use

- Accurate measuring of semen samples volume
- Aliquoting of culture media and density gradients

IVF Containers

Why our Containers

- Class IIa sterile Medical Device according 93/42 EEC Directive
- Manufactured by BIRR in EU
- IVF specific design
- Non-pyrogenic
- Sterility assurance level 10^{-6} (by irradiation)
- IVF containers and their caps are made of medical-grade Polypropylene (PP) and Polyethylene (PE), respectively.



IVF Containers

Semen collection Container 100 mL

Article code & Packaging

113102 packed by 5 / individually sealed / 200 units per box

Testing

MEA, LAL & SMA per LOT number

Characteristics

- Individually wrapped and labelled with LOT number and expiration date
- Seal of sterility
- Label for patients and samples identification

Intended use

- Collect semen for ART procedures and diagnostics



IVF Containers

Semen collection Container 125 mL

Article code & Packaging

113101 single packed / 100 units per box

Testing

MEA, LAL & SMA per LOT number

Characteristics

- Individually wrapped and labelled with LOT number and expiration date (bottom)

Intended use

- Collect semen for ART procedures and diagnostics



Other IVF Labware

Why our Microvials

- CClass IIa sterile Medical Device according 93/42 EEC Directive
- Manufactured by BIRR in EU
- IVF specific design
- Non-pyrogenic
- Sterility assurance level 10^{-6} (by irradiation)
- Microvials are made of medical-grade Polypropylene

Why our Flasks

- Class IIa sterile Medical Device according 93/42 EEC Directive
- Manufactured by BIRR in EU
- IVF specific design
- Non-pyrogenic
- Sterility assurance level 10^{-6} (by irradiation)
- Flasks and their caps are made of medical-grade
- Polystyrene and Polyethylene, respectively.



Other IVF Labware

Microvial 1.5 mL

Article code & Packaging

113301 packed by 10 / 1000 units per box

Testing

MEA & LAL per LOT number

Characteristics

- Printed measuring scale
- Frosted labelling area

Intended use

- Multipurpose microvial for ART specimens



Other IVF Labware

Flask 40 mL

Article code & Packaging

113601 packed by 5 / 200 units per box

Testing

MEA & LAL per LOT number

Flask 270 mL

Article code & Packaging

113650 single packed / 50 units per box

Testing

MEA & LAL per LOT number

Characteristics

- Moulded measuring scale
- Vertical or horizontal resting position

Intended use

- Storing of media



About BIRR

BIRR specialises in the supply of products for use in Assisted Reproductive Technologies (ART).

Our products are designed in close cooperation with our customers. As a result, our products are innovative and intuitive to help healthcare professionals provide better, more efficient patient treatment, ensuring the very best of care.

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Date:

DOC-ID: M0001 rev:03