

# CLINICAL RESULTS 2015





Success rates verified by an independent third-party entity.

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VERIFICATION REPORT			
Organization:	Instituto Valenciano de Infertilidad (IVI)		
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Organization Representative:	José Gregorio Niecha Mª José de los Santos		
Verification dates:	22-23/03/2016	Verification locations:	C/ Luis Buñuel director de cine 1, puerta 5 C/ Plaza Párcela Local 3 46015 Valencia
Head Verifier:	Reyes Salinas	Other members of the verifying team:	-

Version 001 in verifiers and operators version 000

**SCOPE**

SGS Tecnos, S.A. (hereinafter SGS) has performed, at request of the Instituto Valenciano de Infertilidad (hereinafter IVI), the independent verification of the document named "Clinical results 2015 ppt"

The verification's scope includes the text and data contained in the above mentioned reference document.

Said data matches the results of all the clinics from the IVI group, both national and international (in Europe, Latin America and Abu Dhabi) and refer to treatments performed during the time period comprised between 01/01/2015 and 31/12/2015.

For those results presented in the document "Clinical results 2015.ppt" in which the study includes an historical period of data outside 2015 or refers only to data from some of the clinics, the considered period will be specifically detailed as well as the clinics where the study was performed.

**INDEPENDENCE**

The information contained in the verified document and its elaboration is the responsibility of IVI.

SGS has not participated nor counselled in the elaboration of the verified document, restricting itself to act as an independent verifier by checking the validity of its contents.

The contents of this Verification Report and the opinions therein contained are the sole responsibility of SGS.

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**VERIFICATION**

**Methodology and verification team**

The verification methodology applied, established by SGS, is based on verification procedures according to the ISO 19011 norm and on verification mechanisms according to assurance guides and based in relevance, exhaustiveness and response capability principles. Among the methodology used to verify the information and data are:

- Interviews with the personnel responsible for the gathering and preparation and the data.
- The revision of documents and records (both internal and public).
- The checking of data and the validation of the same directly at the sources.
- The verification of the corrections and modifications proposed that were added to the final document.

In particular, for the verification of clinical data, the information evaluated originated from the specific databases that store the clinical results from protocols and patients.

These are:

- Servoy: used in national clinics, Lisbon, Buenos Aires, Chile, Panama and Abu Dhabi (SVIS).
- Filemaker: used in some clinics in Latin America (Mexico, Salvador and Sao Paulo).

The data verification was performed by means of visits to IVI Valencia on 22 and 23/03/2016 (Systems Department and IV3 Clinic).

The verification team was formed by personnel from SGS

- Ms Reyes Salinas González (Verifier)

and was set up according to her knowledge, experience and qualifications for the performance of this independent verification.

**Verification development**

Using the document "Clinical results 2015.ppt" as base, the origin of the data was verified, as well as the extraction, transformation, loading and calculation of all the values presented in the report.

The clinical results from the 2015 memory correspond to the loading of data performed on 02/03/2016.

The systematics followed by the IVI personnel for the inclusion of the data in Servoy has been verified, including:

- Data registry in paper form in the laboratories of different clinics (Valencia, Bilbao, Sevilla, Alicante).
- The uploading of said data into the SVIS database.

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- Verification on the embryologists part of the data included in the database before the definitive filing of the paper forms containing the original registry.

During the visit to the Valencia IVI clinic, the team verified the correct storage of data in SVIS, checking several clinical chart numbers (NHC) and protocols in paper forms corresponding to several treatments (ICSI, FIV, Egg Donation, Verification, PGC FISH, PCR, IAD, IAH, etc.) both in patients from the Valencia clinic and in patients from other IVI clinics (through the consultation of paper forms duly scanned and encrypted).

The corroborated data for each protocol correspond to the variables necessary for the retrieval of the different indicators in the clinical results (number of embryos transferred, BhCG test results, ultrasound scan results, number of sacs seen in scan, chemical miscarriages, clinical miscarriages... as well as the clinical gynecological history of the patients that include the specialists' comments).

The use given to all data was also verified, as well as the consultations defined with Data Transformation Services (DTS), the use of SQL to obtain the results presented in the 2015 memory and the definition and execution of cubes (through SQL repository tools), from which the several variables that are part of the clinical results were obtained.

Throughout the visit the calculation formulae from the different indicators presented as graphics were also verified.

**CONCLUSIONS**

Based on the executed verification, the verifying team of SGS considers that:

- The document named "Clinical results 2015.ppt" from IVI contains trustworthy data and information and has been elaborated according to the relevance, exhaustiveness and response capability principles.
- These results represent in a coherent way the clinical results of the organization for the aforementioned period.

Valencia, March 31<sup>st</sup> 2016

Signed  
Head Verifier Jefe



Reyes Salinas González

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RESULTS OF ASSISTED REPRODUCTIVE TREATMENTS CARRIED OUT  
AT THE IVI GROUP DURING 2015.

In Vitro Fertilisation (FIV-ICSI)	11,890 cycles
Ovum donation (OVODON)	6,661 cycles
Frozen Embryo Transfer	10,184 cycles
Preimplantation Genetic Diagnosis (PGD)	3,175 cycles
Vitrification of ova	3,979 cycles
Artificial insemination (AI)	4,048 cycles

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**Total** **39,937 cycles**

NB: Number of procedures from our clinics in Spain + Lisbon + Latin America + Rome + Abu Dhabi.



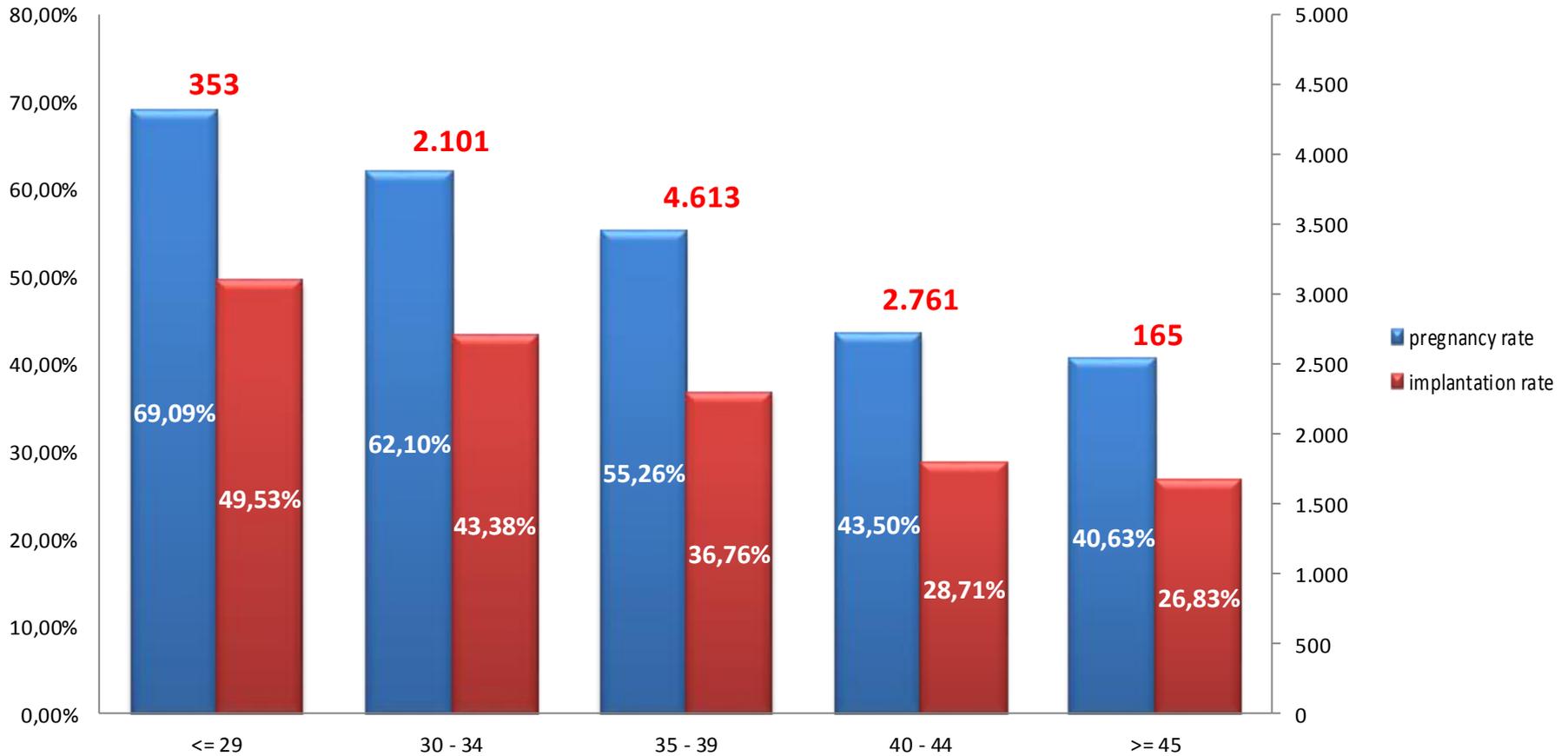
## 2015 RESULTS FOR IVF-ICSI AND OVODON (OVUM DONATION).

	FIV - ICSI	OVUM DONATION
Cycles carried out (transfers)	11,890 (6,135)	6,661(5,807)
No. of pregnancies	3,295	3,976
% pregnancy following transfer	53.7	68.5
% implantation following embryo transfer	36.1	49.4
% twin pregnancy	23.9	27.0

NB: Number of procedures from our clinics in Spain + Lisbon + Latin America + Rome + Abu Dhabi.



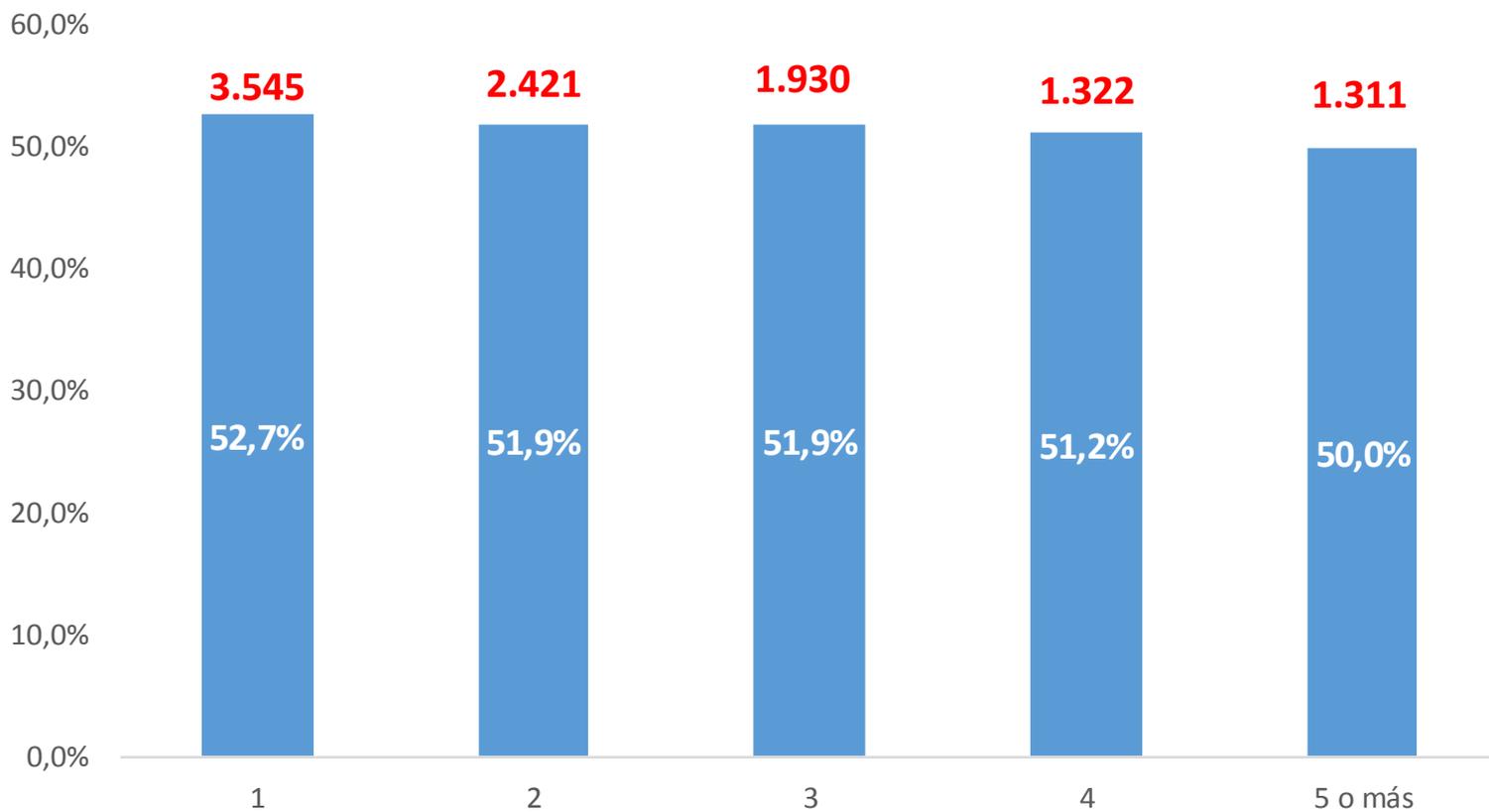
# PREGNANCY AND IMPLANTATION RATES WITH IVF AND ICSI BY AGE GROUPS 2015.



NB: These rates include fresh cycles and its deferred transfers (transfers of cryopreserved embryos from the fresh cycles). They apply to our clinics in Spain + Lisbon + Chile + Panama + Rome.



## PREGNANCY RATES FOR A FIRST FIV-ICSI ATTEMPT IN AN IVI CLINIC COMPARED TO PREVIOUS ATTEMPTS IN OTHER CLINICS.



NB: The chart shows treatment data for patients who have undergone previous cycles, including frozen cycles, between 2007 and 2015 at our clinics in Spain and Lisbon.



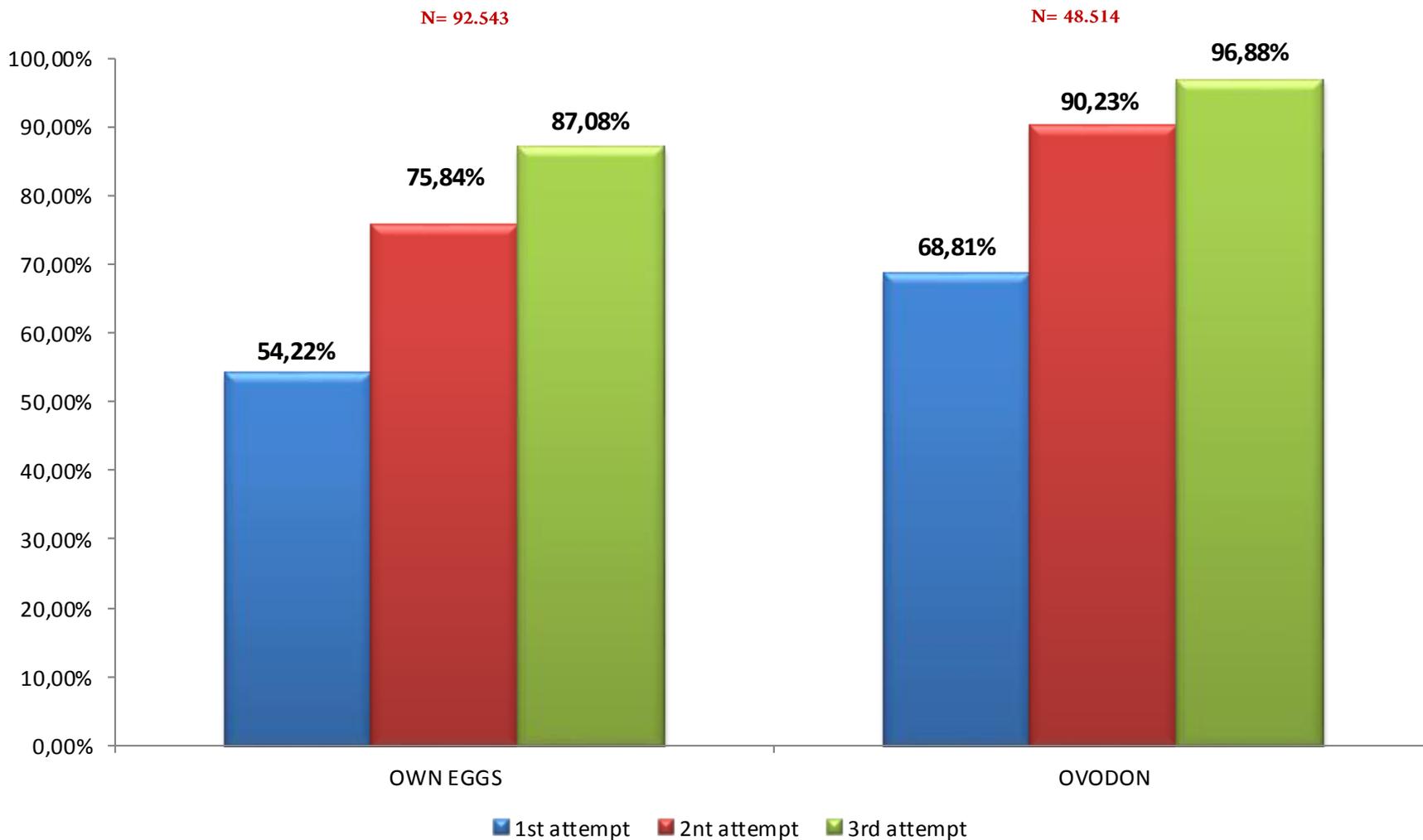
## 2015 RESULTS FOR FROZEN EMBRYO TRANSFERS

	TOTAL
Embryos thawed (frozen embryo transfers)	10.184(9.377)
Rate of embryo transfer %	92,1
No. of pregnancies	4.806
% pregnancy following transfer	51,3
% embryo implantation	36,3

NB: Number of procedures at our clinics in Spain + Lisbon + Latin America + Rome.



# TASA CUMULATIVE CLINICAL PREGNANCY RATE ON THE THIRD ATTEMPT (including frozen embryo transfer).



NB: The chart shows data for patients who were discharged from our clinics in Spain and Lisbon between 2005 and 2015.



2015 RESULTS FOR PGD. Chromosomal abnormality study: FISH and CGH Arrays methods combined.

	TOTAL
Cycles carried out (transfers)	2,394 (946)
% abnormal embryos	80.0
No. of pregnancies	569
% pregnancy following transfer	60.1
% Implantation	47.0

NB: The chart shows data for patients who were discharged from our clinics in Spain + Lisbon in 2015.



Myotonic dystrophy, fragile X syndrome, cystic fibrosis, spinal muscular atrophy...	
Cycles carried out (transfers)	146(90)
No. of pregnancies	54
% pregnancy following transfer	60.0
% Implantation	43.2

NB: The chart shows data for patients treated in 2015 at our clinics in Spain + Lisbon.



Treatment	Artificial insemination (using donor sperm)	Artificial Insemination
No. of cycles	1.831	2.217
Pregnancies	447	358
Pregnancy rate / Cycle	24,4	16,2
Twin pregnancy rate	10,1	12,5

NB: Number of procedures at our clinics in Spain + Lisbon + Latin America + Rome + Abu Dhabi.



# LIVE BIRTH RATES (LB)

## OWN EGGS

	AGE	FRESH & FROZEN EMBRYOS FROM OWN EGGS
LIVE BIRTH PER TREATMENT CYCLE	<35	41,9%
	35-37	31,9%
	38-39	23,1%
	40-42	13,2%
	43-44	4,9%
	>44	2,7%
LIVE BIRTH PER EMBRYO TRANSFERRED	<35	27,1%
	35-37	21,9%
	38-39	17,3%
	40-42	13,7%
	43-44	9,5%
	>44	8,7%
PROPORTION OF SINGLE BIRTHS	<35	72,3%
	35-37	78,5%
	38-39	84,3%
	40-42	88,9%
	43-44	89,0%
	>44	85,2%

## DONOR EGGS

	FRESH & FROZEN EMBRYOS FROM DONOR EGGS
LIVE BIRTH PER TREATMENT CYCLE	41,5%
LIVE BIRTH PER EMBRYO TRANSFERRED	25,9%
PROPORTION OF SINGLE BIRTHS	73,6%

NB: The information shows the live birth rates from treatments at our clinics in Spain + Lisbon between 2003 and 2014.



- **Pregnancy rate:** the percentage of positive results from biochemical pregnancy tests in relation to the number of embryo transfers.
- **Clinical pregnancy rate:** the percentage of pregnancies with a gestational sac observed by ultrasound in relation to the number of embryo transfers.
- **Implantation rate:** the percentage of gestational sacs observed by ultrasound in relation to the number of embryos transferred.
- **Twin pregnancy rate:** the percentage of pregnancies with 2 gestational sacs in relation to the total number of pregnancies.
- **Deferred Embryo Transfer:** embryo transfers that are not performed during the same stimulation cycle, where it is necessary to defer the transfer to a subsequent cycle using cryopreserved embryos.
- **Rate of abnormal embryos:** the percentage of abnormal embryos among the biopsied embryos.
- **Live birth per cycle:** the percentage of procedures with LB in regards to the total number of procedures.
- **Live birth per embryo transferred:** the percentage of LB in regards to the total number of transferred embryos.
- **Proportion of singleton LB:** the percentage of births with a singleton LB in regards to the total number of births.



[www.ivi-fertility.com](http://www.ivi-fertility.com)