

Pocket Matcher validation

REPORT REQUESTED BY IMT INTERNATIONAL



QC

Certificate of Analysis

REQUESTED BY: Embryotools, S.L. (Avda. Dr. Marañón, 8, Barcelona 08028 BARCELONA Spain)

ASSAY REQUESTED BY CUSTOMER: EXP - Experiment

OPERATION PROCEDURE: SOP-MEA-00/WI-MEA-05

TYPE OF ASSAY: Indirect

INTERNAL NUMBER: EXP.015.200.2020

DATE: 02/09/2020 - 07/09/2020

DESCRIPTION OF TEST PRODUCT: Pocket Matcher light R1 (IMT)

REF: N/A

LOT NUMBER: N/A

EXP. DATE: N/A

PROTOCOL:

Culture dishes were prepared with previously tested culture medium in triplicate and equilibrated overnight prior to use. Fresh 1-cell stage mouse embryos were collected from F1 hybrid females (B6/CBA) crossed with males from the same genetic background and washed thoroughly and cultured. Embryos were exposed to the Pocket Matcher light for 3 minutes every 24 hours (as explained in the project plan). Control group was prepared following the same set-up and conditions, and embryos cultured in parallel without the Pocket Matcher light exposure. Embryo development of test and control group was followed every 24 h up to day 6 and photos were taken and included in this report (annex I).

CONTROL AND TEST ASSAY RESULTS:

Embryo developmental rates of control and tested group.

Embryo development rates					
	n	Day 2 Two-cell stage n (%)	Day 6 Expanded blastocyst stage n (%)	Good Quality (morphology) Blastocysts n (%)	Result
Control	15	15 (100)	15 (100)	15 (100)	Passed*
Pocket Matcher light R1 (IMT) (Lot:N/A)	21	21 (100)	19 (90.48)	14 (73.68)	Passed*

SUMMARY OF OBSERVATIONS: All test and control embryos were selected randomly from a common pool and cultured at 37.3°C with a tri-gas atmosphere with optimal %CO₂ and %O₂. Embryotools acceptance criteria for this standard test is that more than 80% of mouse embryos develop to the expanded blastocyst stage and pass a visual morphological examination of the inner cell mass (ICM) and trophectoderm (TE) cells. The results of this assay refer to the items tested.

* More than 80% of the test group embryos developed to the expanded blastocyst stage within 6 days, fulfilling acceptance criteria for this test.

Nuno Costa-Borges, PhD



Scientific Director

Gloria Calderón, PhD



Quality Assurance

Annex I Control

#1, 07/09/2020 10:51:40



#2, 07/09/2020 10:51:46



#3, 07/09/2020 10:51:52



#4, 07/09/2020 10:52:09



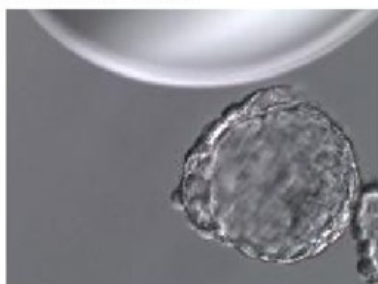
#5, 07/09/2020 10:52:16



#6, 07/09/2020 10:52:54



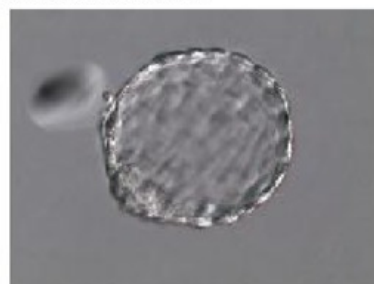
#7, 07/09/2020 10:53:05



#8, 07/09/2020 10:53:24



#9, 07/09/2020 10:53:29



#10, 07/09/2020 10:54:02



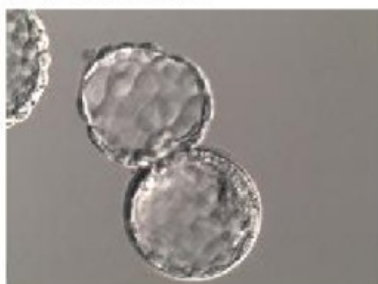
#11, 07/09/2020 10:54:07



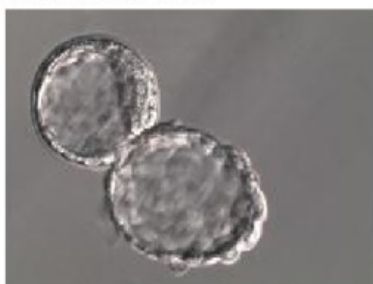
#12, 07/09/2020 10:54:26



#13, 07/09/2020 10:54:32



#14, 07/09/2020 10:55:14



#15, 07/09/2020 10:55:21



Pocket Matcher light R1 (IMT)
(REF: N/A ; Lot: N/A)

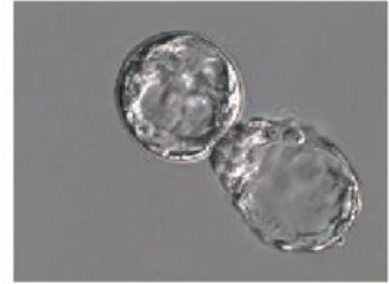
#1, 07/09/2020 11:49:09



#2, 07/09/2020 11:49:16



#3, 07/09/2020 11:49:25



#4, 07/09/2020 11:50:15



#5, 07/09/2020 11:50:22



#6, 07/09/2020 11:51:00



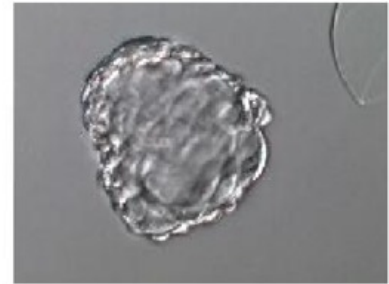
#7, 07/09/2020 11:51:05



#8, 07/09/2020 11:51:33



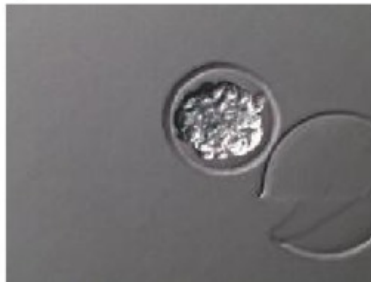
#9, 07/09/2020 11:52:09



#10, 07/09/2020 11:52:34



#11, 07/09/2020 11:52:42



#12, 07/09/2020 11:54:11

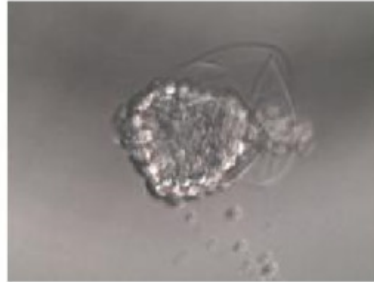


Pocket Matcher light R1 (IMT)
(REF: N/A ; Lot: N/A)

#13, 07/09/2020 11:54:16



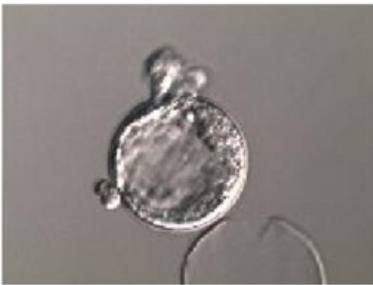
#14, 07/09/2020 11:55:45



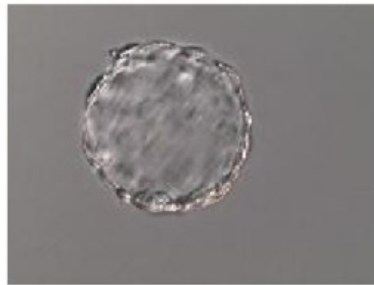
#15, 07/09/2020 11:55:51



#16, 07/09/2020 11:56:15



#17, 07/09/2020 11:56:30



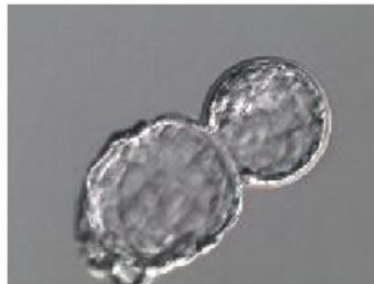
#18, 07/09/2020 11:57:28



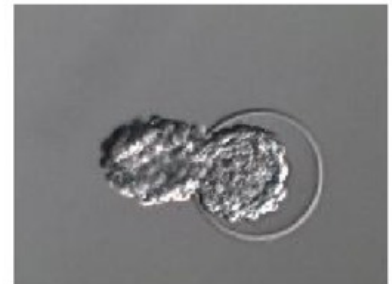
#19, 07/09/2020 11:57:33



#20, 07/09/2020 11:57:56



#21, 07/09/2020 11:58:01



Additional information on embryo development rates at different time points:

Control			
	Total	n	%
Early blastocysts at 78h	15	15	100
Early blastocysts at 78h from 2-cells	15	15	100
Expanded blastocysts at 96h	15	15	100
Expanded blastocysts at 96h from 2-cells	15	15	100

Pocket Matcher light R1 (IMT) (lot.:N/A)				
	Total	n	%	p-value*
Early blastocysts at 78h	21	16	76	0.062
Early blastocysts at 78h from 2-cells	21	16	76	0.062
Expanded blastocysts at 96h	21	19	90	0.5
Expanded blastocysts at 96h from 2-cells	21	19	90	0.5

*Fisher's exact test p-values: Comparison control vs test group

QC

Certificate of Analysis

REQUESTED BY: Embryotools, S.L. (Avda. Dr. Marañón, 8, Barcelona 08028 BARCELONA Spain)

ASSAY REQUESTED BY CUSTOMER: EXP - Experiment

OPERATION PROCEDURE: SOP-MEA-00/WI-MEA-05

TYPE OF ASSAY: Indirect

INTERNAL NUMBER: EXP.015.201.2020

DATE: 02/09/2020 - 07/09/2020

DESCRIPTION OF TEST PRODUCT: Culture labels R1 (IMT)

REF: N/A

LOT NUMBER: N/A

EXP. DATE: N/A

PROTOCOL:

One label was stuck on each culture dish. Culture dishes were prepared with previously tested culture medium in triplicate and equilibrated overnight prior to use. Fresh 1-cell stage mouse embryos were collected from F1 hybrid females (B6/CBA) crossed with males from the same genetic background and washed thoroughly and cultured in labelled dishes. Control group was prepared following the same set-up and conditions, and embryos cultured in parallel without the labels exposure. Embryo development of test and control group was followed every 24 h up to day 6 and photos were taken and included in this report (annex I).

CONTROL AND TEST ASSAY RESULTS:

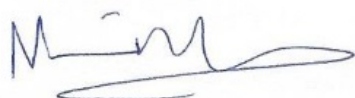
Embryo developmental rates of control and tested group.

Embryo development rates					
	n	Day 2 Two-cell stage n (%)	Day 6 Expanded blastocyst stage n (%)	Good Quality (morphology) Blastocysts n (%)	Result
Control	15	15 (100)	15 (100)	15 (100)	Passed*
Culture labels R1 (IMT) (Lot:N/A)	21	21 (100)	18 (85.71)	15 (83.33)	Passed*

SUMMARY OF OBSERVATIONS: All test and control embryos were selected randomly from a common pool and cultured at 37.3°C with a tri-gas atmosphere with optimal %CO₂ and %O₂. Embryotools acceptance criteria for this standard test is that more than 80% of mouse embryos develop to the expanded blastocyst stage and pass a visual morphological examination of the inner cell mass (ICM) and trophectoderm (TE) cells. The results of this assay refer to the items tested.

* More than 80% of the test group embryos developed to the expanded blastocyst stage within 6 days, fulfilling acceptance criteria for this test.

Nuno Costa-Borges, PhD



Scientific Director

Gloria Calderón, PhD



Quality Assurance

Annex I Control

#1, 07/09/2020 10:51:40



#2, 07/09/2020 10:51:46



#3, 07/09/2020 10:51:52



#4, 07/09/2020 10:52:09



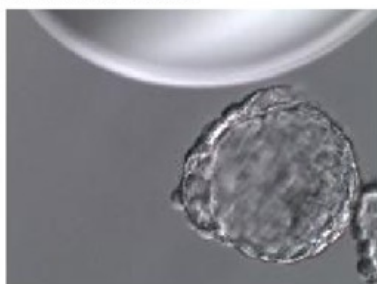
#5, 07/09/2020 10:52:16



#6, 07/09/2020 10:52:54



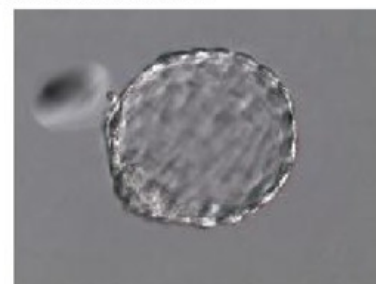
#7, 07/09/2020 10:53:05



#8, 07/09/2020 10:53:24



#9, 07/09/2020 10:53:29



#10, 07/09/2020 10:54:02



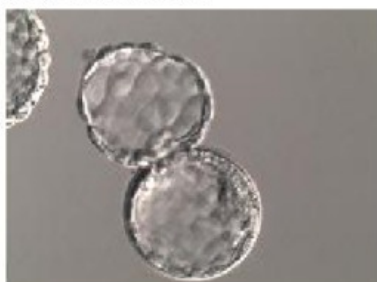
#11, 07/09/2020 10:54:07



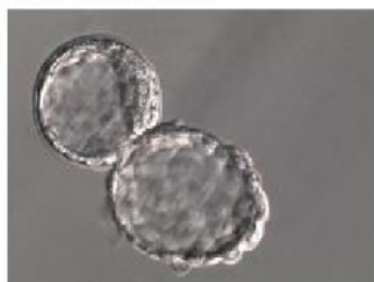
#12, 07/09/2020 10:54:26



#13, 07/09/2020 10:54:32



#14, 07/09/2020 10:55:14



#15, 07/09/2020 10:55:21



Culture labels R1 (IMT)
(REF: N/A ; Lot: N/A)

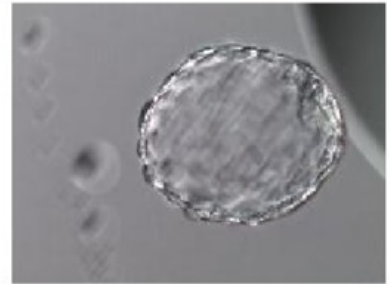
#1, 07/09/2020 12:02:21



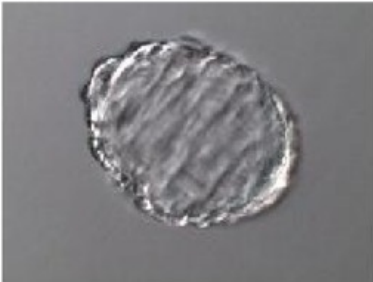
#2, 07/09/2020 12:02:30



#3, 07/09/2020 12:02:35



#4, 07/09/2020 12:03:08



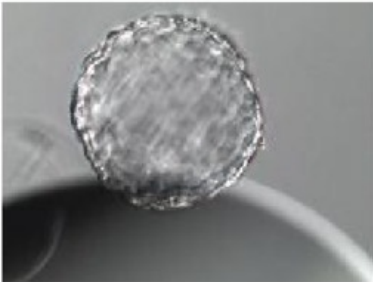
#5, 07/09/2020 12:03:16



#6, 07/09/2020 12:03:36



#7, 07/09/2020 12:03:41



#8, 07/09/2020 12:04:10



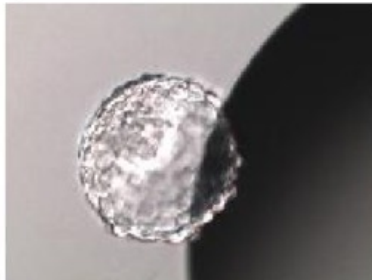
#9, 07/09/2020 12:04:20



#10, 07/09/2020 12:04:55



#11, 07/09/2020 12:05:00

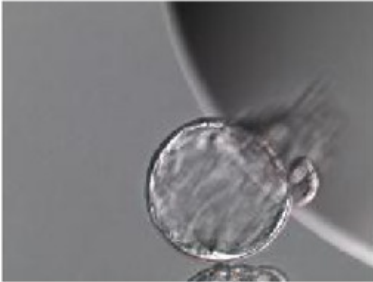


#12, 07/09/2020 12:05:47

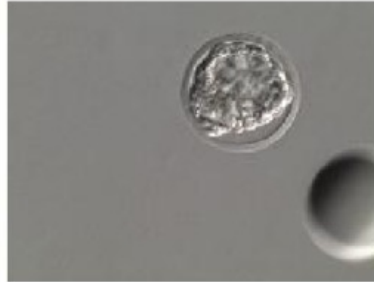


Culture labels R1 (IMT)
(REF: N/A ; Lot: N/A)

#13, 07/09/2020 12:05:52



#14, 07/09/2020 12:06:37



#15, 07/09/2020 12:06:42



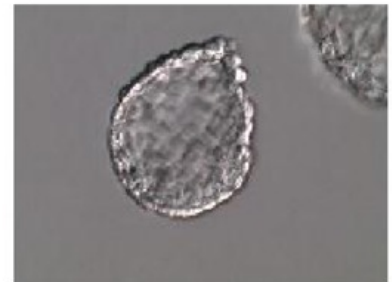
#16, 07/09/2020 12:07:06



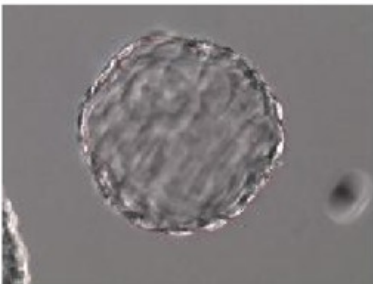
#17, 07/09/2020 12:07:15



#18, 07/09/2020 12:07:36



#19, 07/09/2020 12:07:40



#20, 07/09/2020 12:08:15



#21, 07/09/2020 12:08:20



Additional information on embryo development rates at different time points:

Control			
	Total	n	%
Early blastocysts at 78h	15	15	100
Early blastocysts at 78h from 2-cells	15	15	100
Expanded blastocysts at 96h	15	15	100
Expanded blastocysts at 96h from 2-cells	15	15	100

Culture labels R1 (IMT) (lot.:N/A)				
	Total	n	%	p-value*
Early blastocysts at 78h	21	18	86	0.25
Early blastocysts at 78h from 2-cells	21	18	86	0.25
Expanded blastocysts at 96h	21	18	86	0.25
Expanded blastocysts at 96h from 2-cells	21	18	86	0.25

*Fisher's exact test p-values: Comparison control vs test group

QC

Certificate of Analysis

REQUESTED BY: Embryotools, S.L. (Avda. Dr. Marañón, 8, Barcelona 08028 BARCELONA Spain)

ASSAY REQUESTED BY CUSTOMER: EXP - Experiment

OPERATION PROCEDURE: SOP-MEA-00/WI-MEA-05

TYPE OF ASSAY: Indirect

INTERNAL NUMBER: EXP.015.202.2020

DATE: 02/09/2020 - 07/09/2020

DESCRIPTION OF TEST PRODUCT: Pocket Matcher light + labels R1 (IMT)

REF: N/A

LOT NUMBER: N/A

EXP. DATE: N/A

PROTOCOL:

One label was stuck on each culture dish. Culture dishes were prepared with previously tested culture medium in triplicate and equilibrated overnight prior to use. Fresh 1-cell stage mouse embryos were collected from F1 hybrid females (B6/CBA) crossed with males from the same genetic background and washed thoroughly and cultured in labelled dishes. Embryos were exposed to the Pocket Matcher light for 3 minutes every 24 hours (as explained in the project plan). Control group was prepared following the same set-up and conditions, and embryos cultured in parallel without the imager light exposure. Embryo development of test and control group was followed every 24 h up to day 6 and photos were taken and included in this report (annex I).

CONTROL AND TEST ASSAY RESULTS:

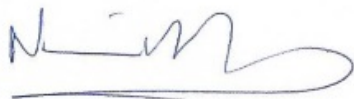
Embryo developmental rates of control and tested group.

Embryo development rates					
	n	Day 2 Two-cell stage n (%)	Day 6 Expanded blastocyst stage n (%)	Good Quality (morphology) Blastocysts n (%)	Result
Control	15	15 (100)	15 (100)	15 (100)	Passed*
Pocket Matcher light + labels R1 (IMT) (Lot:N/A)	21	21 (100)	18 (85.71)	16 (88.89)	Passed*

SUMMARY OF OBSERVATIONS: All test and control embryos were selected randomly from a common pool and cultured at 37.3°C with a tri-gas atmosphere with optimal %CO₂ and %O₂. Embryotools acceptance criteria for this standard test is that more than 80% of mouse embryos develop to the expanded blastocyst stage and pass a visual morphological examination of the inner cell mass (ICM) and trophectoderm (TE) cells. The results of this assay refer to the items tested.

* More than 80% of the test group embryos developed to the expanded blastocyst stage within 6 days, fulfilling acceptance criteria for this test.

Nuno Costa-Borges, PhD



Scientific Director

Gloria Calderón, PhD



Quality Assurance

Annex I Control

#1, 07/09/2020 10:51:40



#2, 07/09/2020 10:51:46



#3, 07/09/2020 10:51:52



#4, 07/09/2020 10:52:09



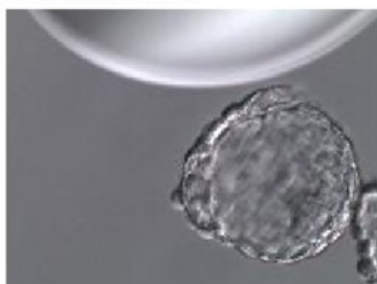
#5, 07/09/2020 10:52:16



#6, 07/09/2020 10:52:54



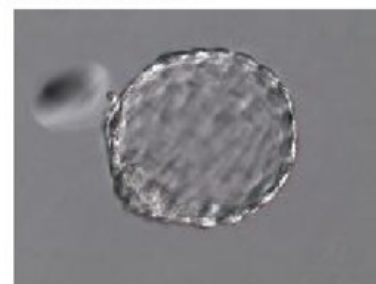
#7, 07/09/2020 10:53:05



#8, 07/09/2020 10:53:24



#9, 07/09/2020 10:53:29



#10, 07/09/2020 10:54:02



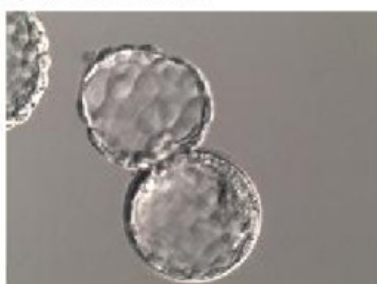
#11, 07/09/2020 10:54:07



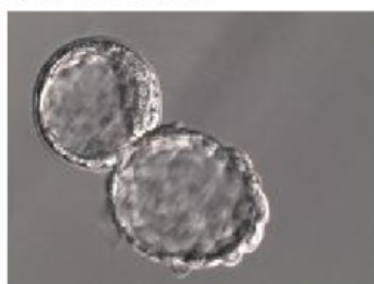
#12, 07/09/2020 10:54:26



#13, 07/09/2020 10:54:32



#14, 07/09/2020 10:55:14



#15, 07/09/2020 10:55:21

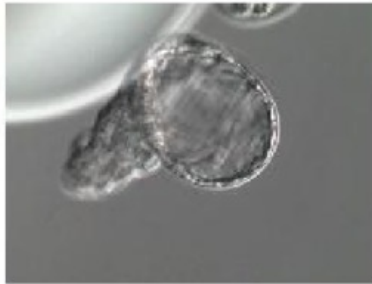


Pocket Matcher light + labels R1 (IMT)
(REF: N/A ; Lot: N/A)

#1, 07/09/2020 12:12:59



#2, 07/09/2020 12:13:15



#3, 07/09/2020 12:13:20



#4, 07/09/2020 12:13:44



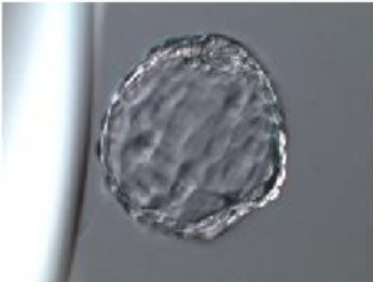
#5, 07/09/2020 12:13:50



#6, 07/09/2020 12:14:17



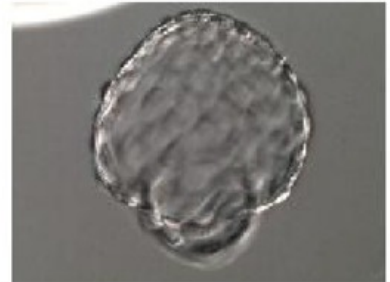
#7, 07/09/2020 12:14:21



#8, 07/09/2020 12:14:53



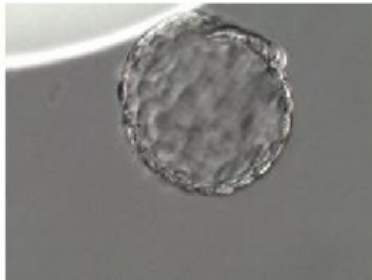
#9, 07/09/2020 12:15:01



#10, 07/09/2020 12:15:38



#11, 07/09/2020 12:15:49



#12, 07/09/2020 12:16:16

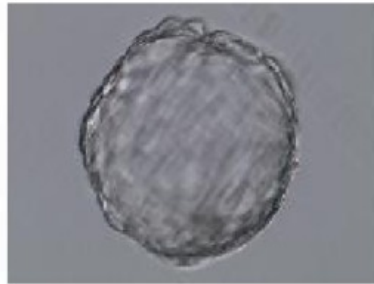


Pocket Matcher light + labels R1 (IMT)
(REF: N/A ; Lot: N/A)

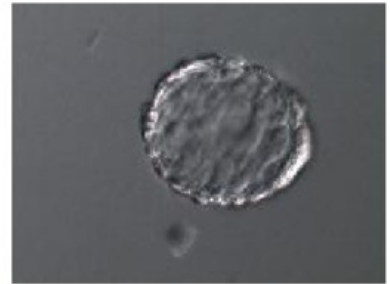
#13, 07/09/2020 12:16:20



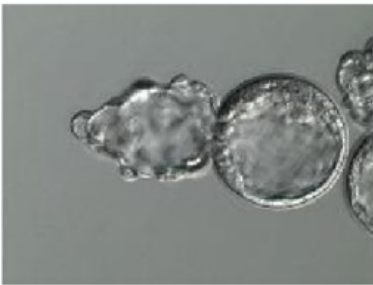
#14, 07/09/2020 12:16:49



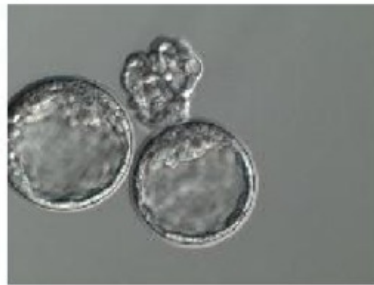
#15, 07/09/2020 12:17:26



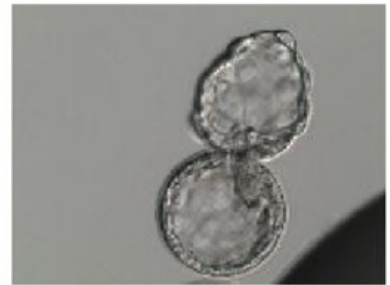
#16, 07/09/2020 12:17:44



#17, 07/09/2020 12:17:46



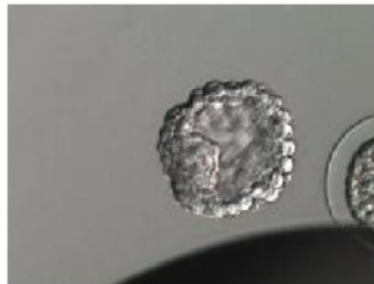
#18, 07/09/2020 12:18:21



#19, 07/09/2020 12:18:25



#20, 07/09/2020 12:18:48



#21, 07/09/2020 12:18:55



Additional information on embryo development rates at different time points:

Control			
	Total	n	%
Early blastocysts at 78h	15	15	100
Early blastocysts at 78h from 2-cells	15	15	100
Expanded blastocysts at 96h	15	15	100
Expanded blastocysts at 96h from 2-cells	15	15	100

Pocket Matcher light + labels R1 (IMT) (lot.:N/A)				
	Total	n	%	p-value*
Early blastocysts at 78h	21	19	90	0.5
Early blastocysts at 78h from 2-cells	21	19	90	0.5
Expanded blastocysts at 96h	21	18	86	0.25
Expanded blastocysts at 96h from 2-cells	21	18	86	0.25

*Fisher's exact test p-values: Comparison control vs test group

QC

Certificate of Analysis

REQUESTED BY: Embryotools, S.L. (Avda. Dr. Marañón, 8, Barcelona 08028 BARCELONA Spain)

ASSAY REQUESTED BY CUSTOMER: EXP - Experiment

OPERATION PROCEDURE: SOP-MEA-00/WI-MEA-05

TYPE OF ASSAY: Indirect

INTERNAL NUMBER: EXP.015.236.2020

DATE: 09/09/2020 - 14/09/2020

DESCRIPTION OF TEST PRODUCT: Pocket Matcher light R2 (IMT)

REF: N/A

LOT NUMBER: N/A

EXP. DATE: N/A

PROTOCOL:

Culture dishes were prepared with previously tested culture medium in triplicate and equilibrated overnight prior to use. Fresh 1-cell stage mouse embryos were collected from F1 hybrid females (B6/CBA) crossed with males from the same genetic background and washed thoroughly and cultured. Embryos were exposed to the Pocket Matcher light for 3 minutes every 24 hours (as explained in the project plan). Control group was prepared following the same set-up and conditions, and embryos cultured in parallel without the Pocket Matcher light exposure. Embryo development of test and control group was followed every 24 h up to day 6 and photos were taken and included in this report (annex I).

CONTROL AND TEST ASSAY RESULTS:

Embryo developmental rates of control and tested group.

Embryo development rates					
	n	Day 2 Two-cell stage n (%)	Day 6 Expanded blastocyst stage n (%)	Good Quality (morphology) Blastocysts n (%)	Result
Control	15	15 (100)	15 (100)	12 (80)	Passed*
Pocket Matcher light R2 (IMT) (Lot:N/A)	21	20 (95.24)	20 (95.24)	18 (90)	Passed*

SUMMARY OF OBSERVATIONS: All test and control embryos were selected randomly from a common pool and cultured at 37.3°C with a tri-gas atmosphere with optimal %CO₂ and %O₂. Embryotools acceptance criteria for this standard test is that more than 80% of mouse embryos develop to the expanded blastocyst stage and pass a visual morphological examination of the inner cell mass (ICM) and trophectoderm (TE) cells. The results of this assay refer to the items tested.

* More than 80% of the test group embryos developed to the expanded blastocyst stage within 6 days, fulfilling acceptance criteria for this test.

Nuno Costa-Borges, PhD



Scientific Director

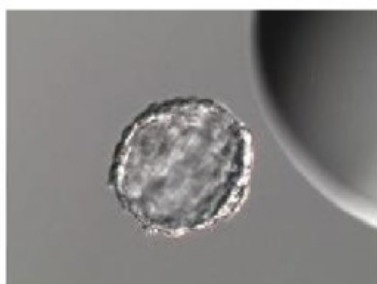
Gloria Calderón, PhD



Quality Assurance

Annex I Control

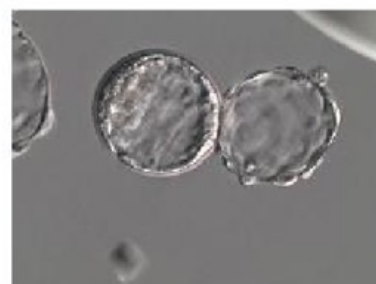
#1, 14/09/2020 10:25:34



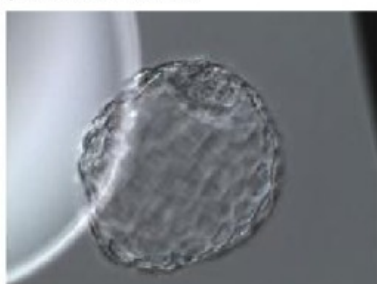
#2, 14/09/2020 10:25:47



#3, 14/09/2020 10:25:54



#4, 14/09/2020 10:26:20



#5, 14/09/2020 10:26:29



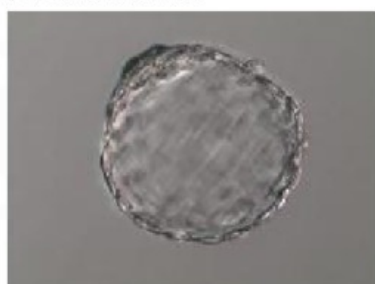
#6, 14/09/2020 10:26:56



#7, 14/09/2020 10:27:02



#8, 14/09/2020 10:27:31



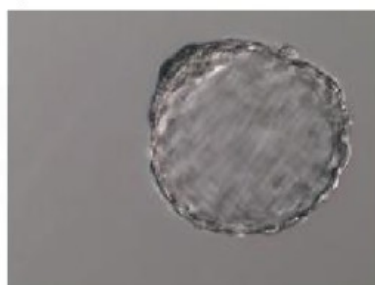
#9, 14/09/2020 10:27:37



#10, 14/09/2020 10:28:59



#11, 14/09/2020 10:29:05



#12, 14/09/2020 10:29:59



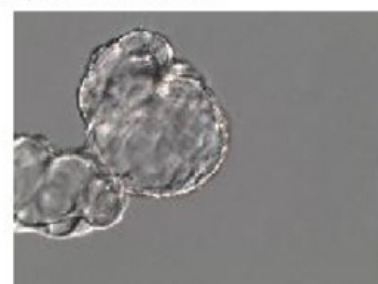
#13, 14/09/2020 10:30:06



#14, 14/09/2020 10:30:33



#15, 14/09/2020 10:30:36



Pocket Matcher light R2 (IMT)
(REF: N/A ; Lot: N/A)

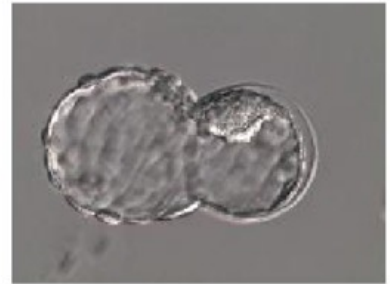
#1, 14/09/2020 10:38:23



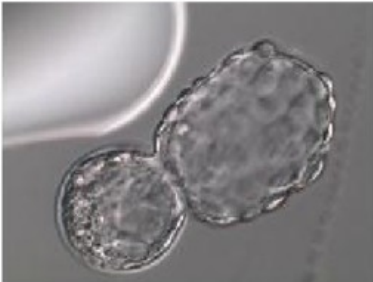
#2, 14/09/2020 10:38:30



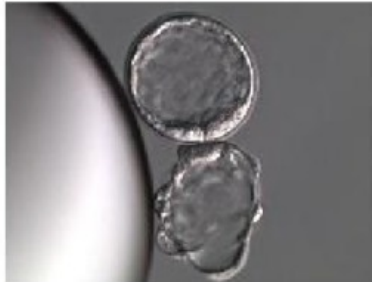
#3, 14/09/2020 10:38:35



#4, 14/09/2020 10:39:04



#5, 14/09/2020 10:39:13



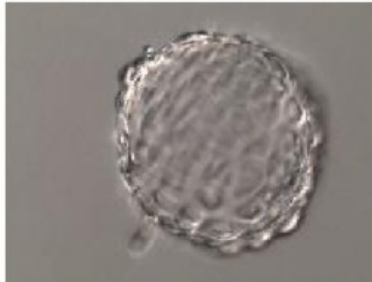
#6, 14/09/2020 10:39:37



#7, 14/09/2020 10:39:41



#8, 14/09/2020 10:39:57



#9, 14/09/2020 10:40:13



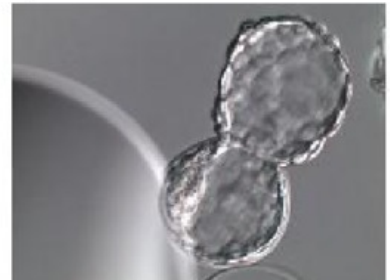
#10, 14/09/2020 10:40:29



#11, 14/09/2020 10:40:36



#12, 14/09/2020 10:41:51



Pocket Matcher light R2 (IMT)
(REF: N/A ; Lot: N/A)

#13, 14/09/2020 10:41:55



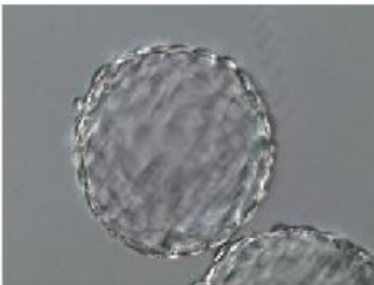
#14, 14/09/2020 10:42:11



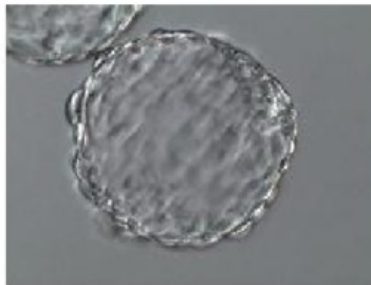
#15, 14/09/2020 10:42:26



#16, 14/09/2020 10:42:54



#17, 14/09/2020 10:42:59



#18, 14/09/2020 10:43:20



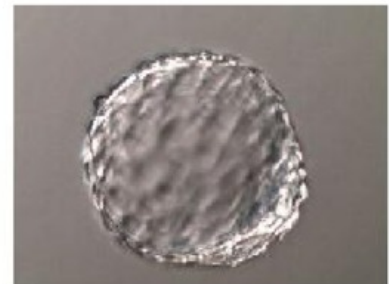
#19, 14/09/2020 10:43:26



#20, 14/09/2020 10:43:51



#21, 14/09/2020 10:43:58



Additional information on embryo development rates at different time points:

Control			
	Total	n	%
Early blastocysts at 78h	15	14	93
Early blastocysts at 78h from 2-cells	15	14	93
Expanded blastocysts at 96h	15	15	100
Expanded blastocysts at 96h from 2-cells	15	15	100

Pocket Matcher light R2 (IMT) (lot.:N/A)				
	Total	n	%	p-value*
Early blastocysts at 78h	21	19	90	1
Early blastocysts at 78h from 2-cells	20	19	95	1
Expanded blastocysts at 96h	21	20	95	1
Expanded blastocysts at 96h from 2-cells	20	20	100	1

*Fisher's exact test p-values: Comparison control vs test group

QC

Certificate of Analysis

REQUESTED BY: Embryotools, S.L. (Avda. Dr. Marañón, 8, Barcelona 08028 BARCELONA Spain)

ASSAY REQUESTED BY CUSTOMER: EXP - Experiment

OPERATION PROCEDURE: SOP-MEA-00/WI-MEA-05

TYPE OF ASSAY: Indirect

INTERNAL NUMBER: EXP.015.237.2020

DATE: 09/09/2020 - 14/09/2020

DESCRIPTION OF TEST PRODUCT: Culture labels R2 (IMT)

REF: N/A

LOT NUMBER: N/A

EXP. DATE: N/A

PROTOCOL:

One label was stuck on each culture dish. Culture dishes were prepared with previously tested culture medium in triplicate and equilibrated overnight prior to use. Fresh 1-cell stage mouse embryos were collected from F1 hybrid females (B6/CBA) crossed with males from the same genetic background and washed thoroughly and cultured in labelled dishes. Control group was prepared following the same set-up and conditions, and embryos cultured in parallel without the labels exposure. Embryo development of test and control group was followed every 24 h up to day 6 and photos were taken and included in this report (annex I).

CONTROL AND TEST ASSAY RESULTS:

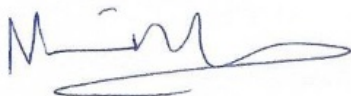
Embryo developmental rates of control and tested group.

Embryo development rates					
	n	Day 2 Two-cell stage n (%)	Day 6 Expanded blastocyst stage n (%)	Good Quality (morphology) Blastocysts n (%)	Result
Control	15	15 (100)	15 (100)	12 (80)	Passed*
Culture labels R2 (IMT) (Lot:N/A)	21	21 (100)	20 (95.24)	12 (60)	Passed*

SUMMARY OF OBSERVATIONS: All test and control embryos were selected randomly from a common pool and cultured at 37.3°C with a tri-gas atmosphere with optimal %CO₂ and %O₂. Embryotools acceptance criteria for this standard test is that more than 80% of mouse embryos develop to the expanded blastocyst stage and pass a visual morphological examination of the inner cell mass (ICM) and trophectoderm (TE) cells. The results of this assay refer to the items tested.

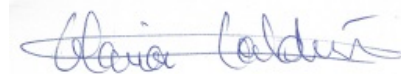
* More than 80% of the test group embryos developed to the expanded blastocyst stage within 6 days, fulfilling acceptance criteria for this test.

Nuno Costa-Borges, PhD



Scientific Director

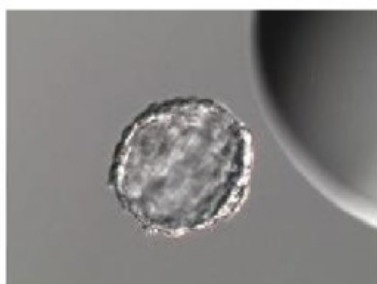
Gloria Calderón, PhD



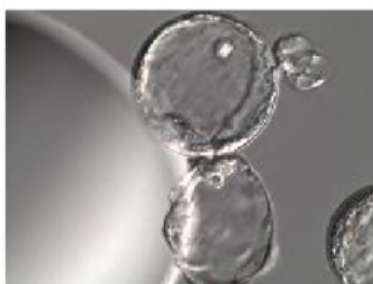
Quality Assurance

Annex I Control

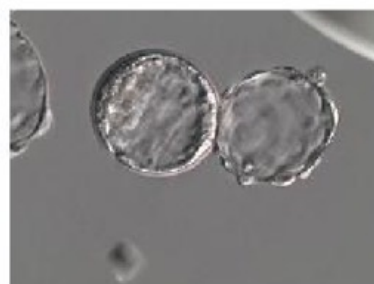
#1, 14/09/2020 10:25:34



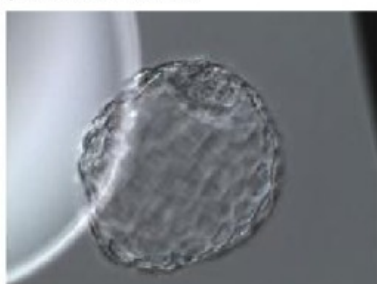
#2, 14/09/2020 10:25:47



#3, 14/09/2020 10:25:54



#4, 14/09/2020 10:26:20



#5, 14/09/2020 10:26:29



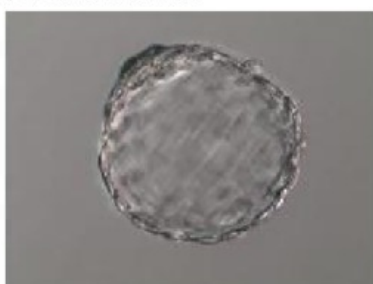
#6, 14/09/2020 10:26:56



#7, 14/09/2020 10:27:02



#8, 14/09/2020 10:27:31



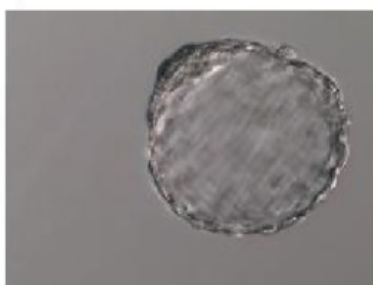
#9, 14/09/2020 10:27:37



#10, 14/09/2020 10:28:59



#11, 14/09/2020 10:29:05



#12, 14/09/2020 10:29:59



#13, 14/09/2020 10:30:06



#14, 14/09/2020 10:30:33

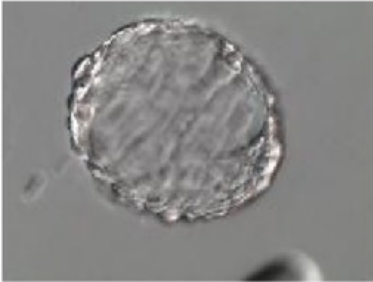


#15, 14/09/2020 10:30:36

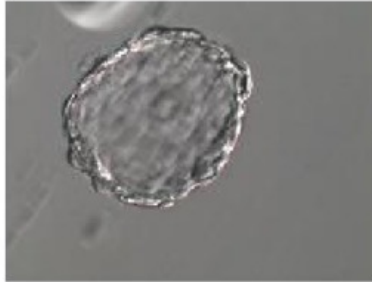


Culture labels R2 (IMT)
(REF: N/A ; Lot: N/A)

#1, 14/09/2020 10:47:13



#2, 14/09/2020 10:47:18



#3, 14/09/2020 10:47:23



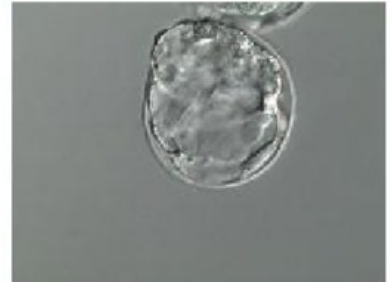
#4, 14/09/2020 10:47:51



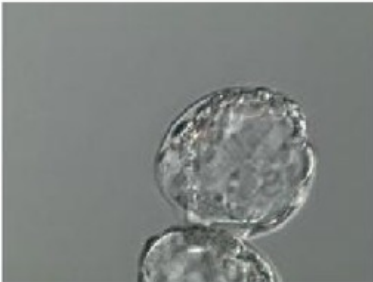
#5, 14/09/2020 10:47:55



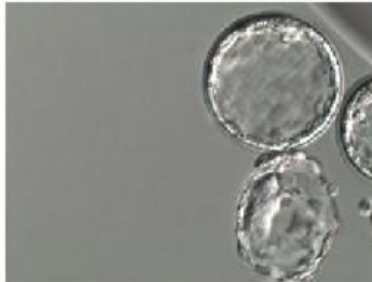
#6, 14/09/2020 10:48:25



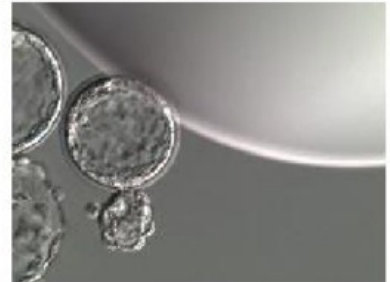
#7, 14/09/2020 10:48:30



#8, 14/09/2020 10:48:54



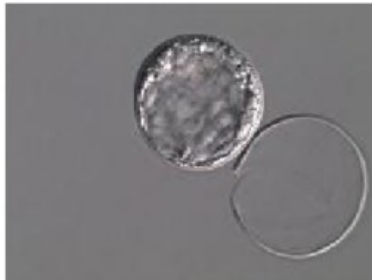
#9, 14/09/2020 10:48:57



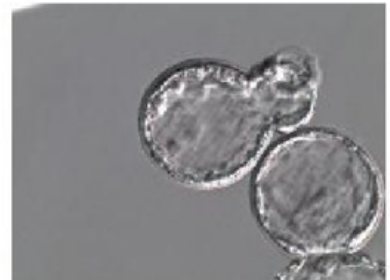
#10, 14/09/2020 10:49:21



#11, 14/09/2020 10:49:27

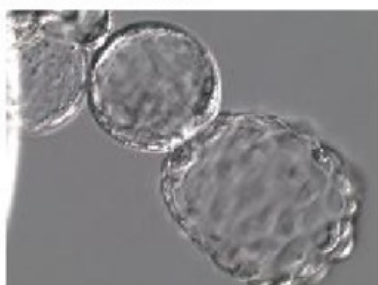


#12, 14/09/2020 10:49:46

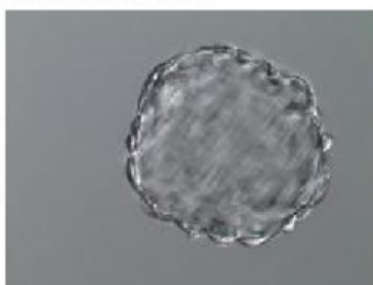


Culture labels R2 (IMT)
(REF: N/A ; Lot: N/A)

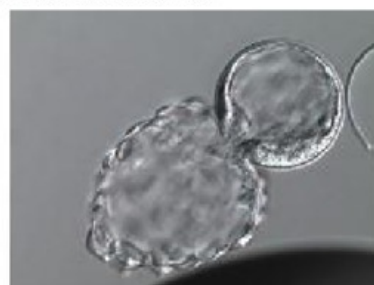
#13, 14/09/2020 10:50:03



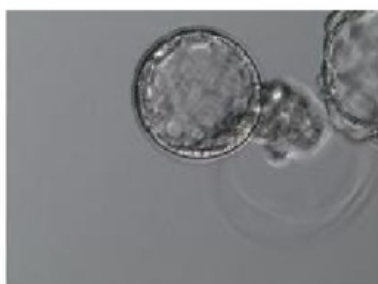
#14, 14/09/2020 10:50:35



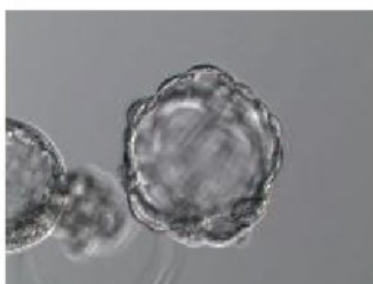
#15, 14/09/2020 10:50:41



#16, 14/09/2020 10:51:02



#17, 14/09/2020 10:51:08



#18, 14/09/2020 10:52:34



#19, 14/09/2020 10:52:43



#20, 14/09/2020 10:53:09



#21, 14/09/2020 10:53:12



Additional information on embryo development rates at different time points:

Control			
	Total	n	%
Early blastocysts at 78h	15	14	93
Early blastocysts at 78h from 2-cells	15	14	93
Expanded blastocysts at 96h	15	15	100
Expanded blastocysts at 96h from 2-cells	15	15	100

Culture labels R2 (IMT) (lot.:N/A)				
	Total	n	%	p-value*
Early blastocysts at 78h	21	20	95	1
Early blastocysts at 78h from 2-cells	21	20	95	1
Expanded blastocysts at 96h	21	20	95	1
Expanded blastocysts at 96h from 2-cells	21	20	95	1

*Fisher's exact test p-values: Comparison control vs test group

QC

Certificate of Analysis

REQUESTED BY: Embryotools, S.L. (Avda. Dr. Marañón, 8, Barcelona 08028 BARCELONA Spain)

ASSAY REQUESTED BY CUSTOMER: EXP - Experiment

OPERATION PROCEDURE: SOP-MEA-00/WI-MEA-05

TYPE OF ASSAY: Indirect

INTERNAL NUMBER: EXP.015.238.2020

DATE: 09/09/2020 - 14/09/2020

DESCRIPTION OF TEST PRODUCT: Pocket Matcher light + labels R2 (IMT)

REF: N/A

LOT NUMBER: N/A

EXP. DATE: N/A

PROTOCOL:

One label was stuck on each culture dish. Culture dishes were prepared with previously tested culture medium in triplicate and equilibrated overnight prior to use. Fresh 1-cell stage mouse embryos were collected from F1 hybrid females (B6/CBA) crossed with males from the same genetic background and washed thoroughly and cultured in labelled dishes. Embryos were exposed to the Pocket Matcher light for 3 minutes every 24 hours (as explained in the project plan). Control group was prepared following the same set-up and conditions, and embryos cultured in parallel without the imager light exposure. Embryo development of test and control group was followed every 24 h up to day 6 and photos were taken and included in this report (annex I).

CONTROL AND TEST ASSAY RESULTS:

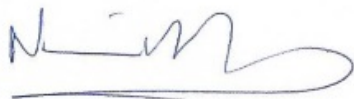
Embryo developmental rates of control and tested group.

Embryo development rates					
	n	Day 2 Two-cell stage n (%)	Day 6 Expanded blastocyst stage n (%)	Good Quality (morphology) Blastocysts n (%)	Result
Control	15	15 (100)	15 (100)	12 (80)	Passed*
Pocket Matcher light + labels R2 (IMT) (Lot:N/A)	21	21 (100)	20 (95.24)	15 (75)	Passed*

SUMMARY OF OBSERVATIONS: All test and control embryos were selected randomly from a common pool and cultured at 37.3°C with a tri-gas atmosphere with optimal %CO₂ and %O₂. Embryotools acceptance criteria for this standard test is that more than 80% of mouse embryos develop to the expanded blastocyst stage and pass a visual morphological examination of the inner cell mass (ICM) and trophectoderm (TE) cells. The results of this assay refer to the items tested.

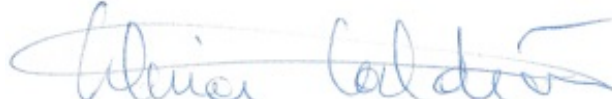
* More than 80% of the test group embryos developed to the expanded blastocyst stage within 6 days, fulfilling acceptance criteria for this test.

Nuno Costa-Borges, PhD



Scientific Director

Gloria Calderón, PhD



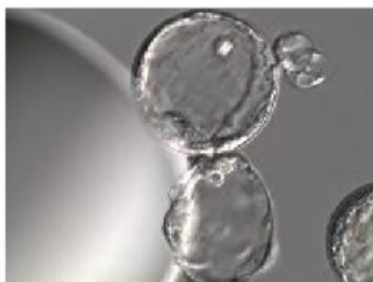
Quality Assurance

Annex I Control

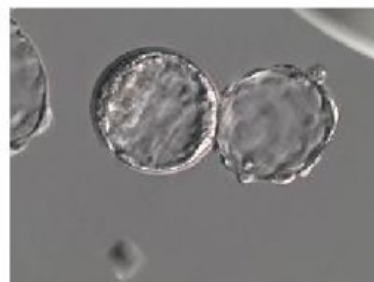
#1, 14/09/2020 10:25:34



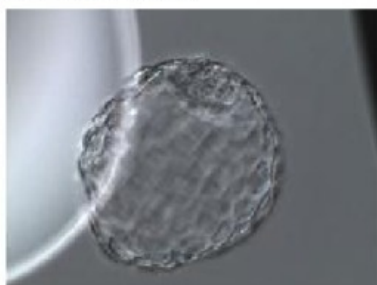
#2, 14/09/2020 10:25:47



#3, 14/09/2020 10:25:54



#4, 14/09/2020 10:26:20



#5, 14/09/2020 10:26:29



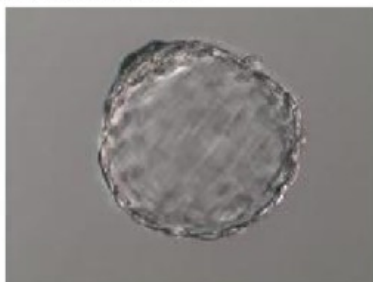
#6, 14/09/2020 10:26:56



#7, 14/09/2020 10:27:02



#8, 14/09/2020 10:27:31



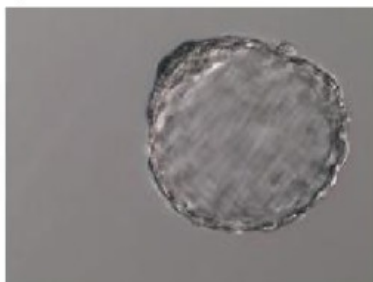
#9, 14/09/2020 10:27:37



#10, 14/09/2020 10:28:59



#11, 14/09/2020 10:29:05



#12, 14/09/2020 10:29:59



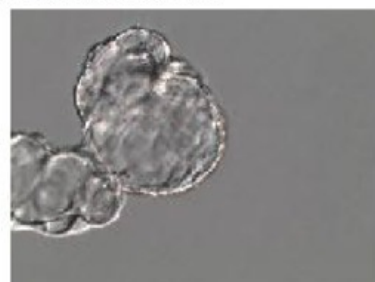
#13, 14/09/2020 10:30:06



#14, 14/09/2020 10:30:33



#15, 14/09/2020 10:30:36

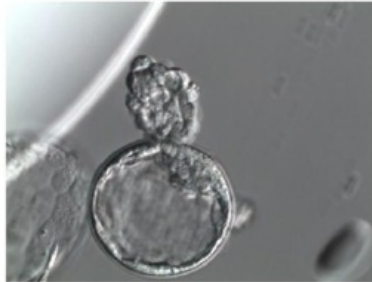


Pocket Matcher light + labels R2 (IMT)
(REF: N/A ; Lot: N/A)

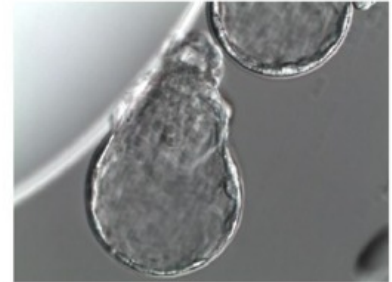
#1, 14/09/2020 11:01:02



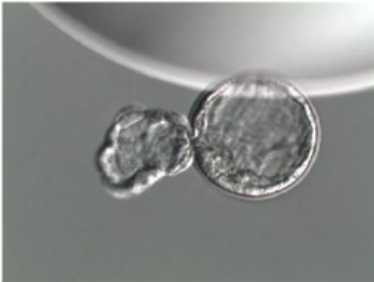
#2, 14/09/2020 11:01:09



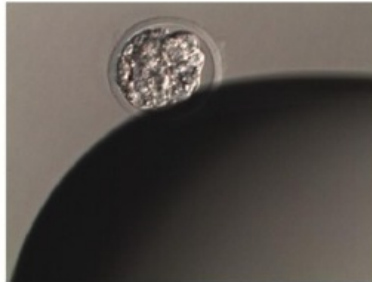
#3, 14/09/2020 11:01:44



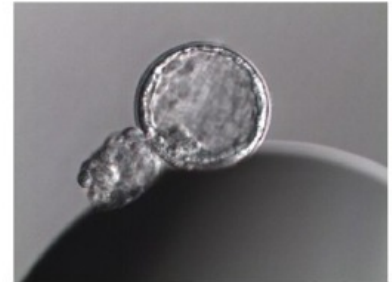
#4, 14/09/2020 11:02:34



#5, 14/09/2020 11:02:44



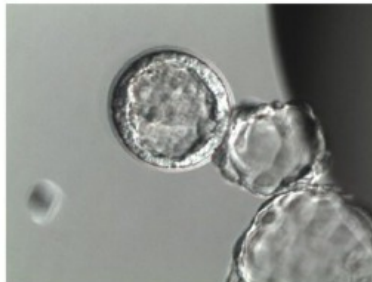
#6, 14/09/2020 11:03:05



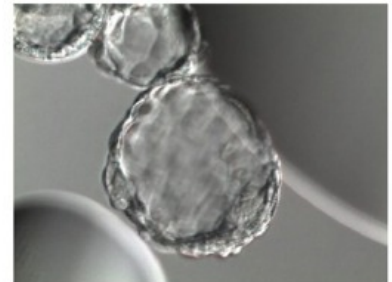
#7, 14/09/2020 11:03:10



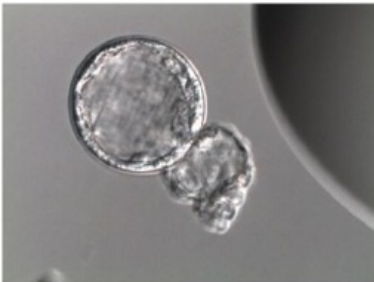
#8, 14/09/2020 11:03:30



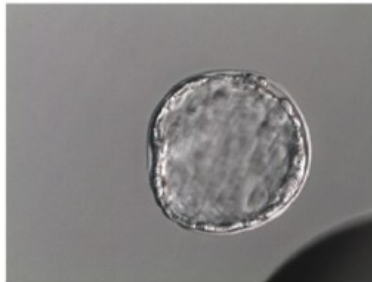
#9, 14/09/2020 11:03:34



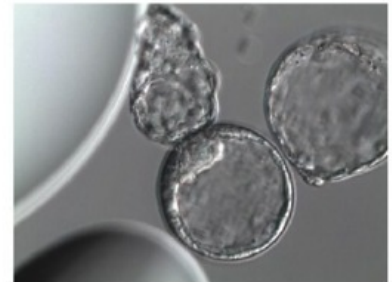
#10, 14/09/2020 11:03:57



#11, 14/09/2020 11:04:02



#12, 14/09/2020 11:08:12

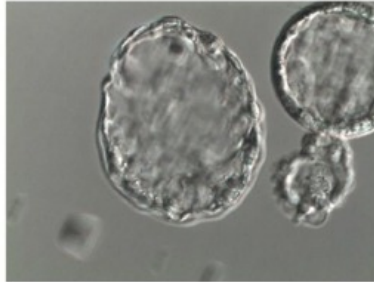


Pocket Matcher light + labels R2 (IMT)
(REF: N/A ; Lot: N/A)

#13, 14/09/2020 11:08:15



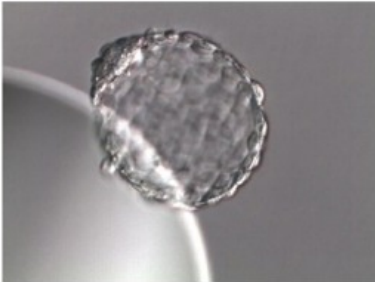
#14, 14/09/2020 11:08:39



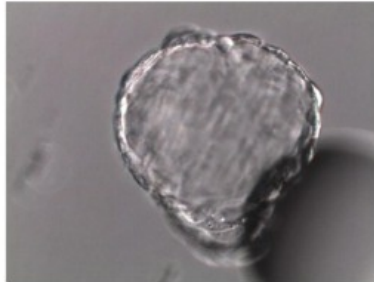
#15, 14/09/2020 11:08:43



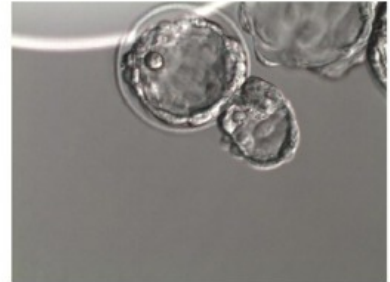
#16, 14/09/2020 11:09:04



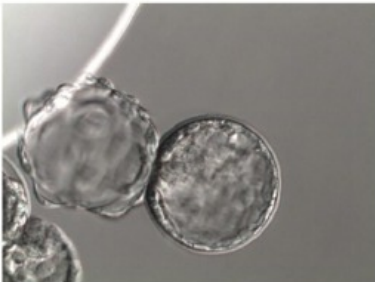
#17, 14/09/2020 11:09:10



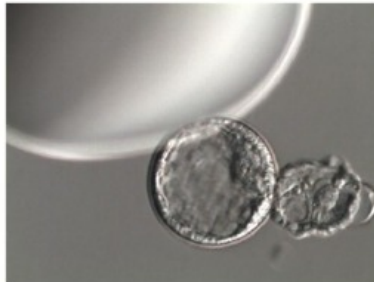
#18, 14/09/2020 11:09:41



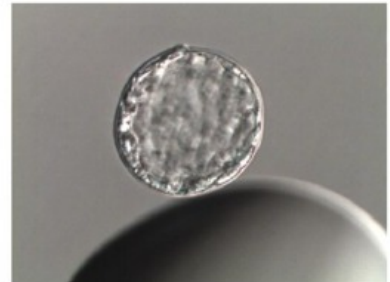
#19, 14/09/2020 11:09:46



#20, 14/09/2020 11:10:18



#21, 14/09/2020 11:10:31



Additional information on embryo development rates at different time points:

Control			
	Total	n	%
Early blastocysts at 78h	15	14	93
Early blastocysts at 78h from 2-cells	15	14	93
Expanded blastocysts at 96h	15	15	100
Expanded blastocysts at 96h from 2-cells	15	15	100

Pocket Matcher light + labels R2 (IMT) (lot.:N/A)				
	Total	n	%	p-value*
Early blastocysts at 78h	21	20	95	1
Early blastocysts at 78h from 2-cells	21	20	95	1
Expanded blastocysts at 96h	21	20	95	1
Expanded blastocysts at 96h from 2-cells	21	20	95	1

*Fisher's exact test p-values: Comparison control vs test group