




CERTIFICADO DE ANÁLISE

Produto	Micropipeta Denudação 275 µm	Código	50090020
Apresentação	20 unidades	Lote	Ingámed 20120803 Fornecedor 44200403
Fabricação	10/2020	Validade	10/2023

Indicação de Uso	Indicado para procedimento de Fertilização in Vitro. Manipulação e denudação de oócitos e embriões humanos.
Material	Polycarbonato transparente, flexível e reto.
Armazenamento	Armazenar em temperatura ambiente, em local livre de umidade e fontes de calor para garantir a integridade do produto.
Não utilizar o produto caso a embalagem esteja danificada, aberta ou úmida.	

Análises e Ensaios		Resultado
Análises Microbiológicas	Endotoxina	Conforme*
Análise Biológica	Bioensaio com embriões de camundongo	Conforme*

*Vide Certificado de Análise do Fornecedor em anexo.



Laís Yamada
Bióloga RT – CRBio 108303/07-D



to order of BRAZIL

Certificate of Sterilization

relating the products manufactured by us and sold mentioned in
INVOICE No. 402011188 dated December 18th, 2020

REF 711724LF-100
REF 447300/20
REF 447135/20
REF 447275/20

LOT 71200401, 71210101
LOT 44200403
LOT 44200403
LOT 44200403

All raw materials were adapted optimally to the validated sterilization by gamma irradiation during the developmental phase.

We guarantee the sterility of our products according to DIN EN 11137

Rheinbach/Germany
December 18th, 2020

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Sparkasse KölnBonn / Swift-Code COLSDE33XXX
IBAN DE56 3705 0198 0005 4049 26
Raiffeisenbank Voreifel / Swift-Code GENODED1RBC
IBAN DE96 3706 9627 0035 4330 15

Volksbank Bonn Rhein-Sieg / Swift-Code GENODED1BRS
IBAN DE38 3806 0186 0706 9230 12
Kreissparkasse Köln / Swift-Code COKSDE33XXX
IBAN DE38 3705 0299 0045 8438 69

CERTIFICATE OF ANALYSIS

ASSAY: MEA – Standard Mouse embryo assay
DESCRIPTION OF TEST PRODUCT: Soft Denudation Tip
REF: 447XXX/20
LOT – NUMBER: 44200403
EXPIRE DATE: 10-2023

PROTOCOL

Three samples were incubated at 37°C for 10 min with previously tested culture medium. Culture dishes were prepared with the extracted 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, washed thoroughly and cultured in the extracted medium up to Day 5. Control group was prepared following the same set-up and conditions, and embryos cultured in parallel using tested medium not exposed to test samples. Embryo development of test and control group was followed every 24 h and photos were taken and included in this report.

CONTROL AND TEST ASSAY RESULTS

Embryo developmental rates of control and tested group

	n	Day 2 Two-cell stage n(%)	Day 5 blastocyst stage n(%)	Good Quality (morph) Blastocysts n (%)	Result
Control	15	15(100)	15(100)	15(100)	passed*
Soft Denudation Tip (LOT: 44200403)	21	21(100)	17 (80,95)	9(52,94)	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. The 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.

* More than 80% of the test group embryos developed to the expanded blastocyst stage within 5 days, fulfilling acceptance criteria for this test.

** The endotoxin concentration amounted to < 0.1250 IU/ml and < 1.2500 IU / sample