




# CERTIFICADO DE ANÁLISE

<b>Produto</b>	Micropipeta Denudação 300 µm	<b>Código</b>	50090021
<b>Apresentação</b>	20 unidades	<b>Lote</b>	Ingámed 21010044 Fornecedor 44200403
<b>Fabricação</b>	10/2020	<b>Validade</b>	10/2023

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

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

\*Vide Certificado de Análise do Fornecedor em Anexo

  
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## 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)	<b>passed*</b>
Soft Denudation Tip (LOT: 44200403)	21	21(100)	17 (80,95)	9(52,94)	<b>passed*</b>

### 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 %CO<sub>2</sub> and %O<sub>2</sub>. 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

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