

Title	cellasys#8			
Doc.-#	SOP-S008-001			
Abstract	Instruction for cellasys#8 microphysiometric test			
Effective date				
Number of pages	7			
Document Status	x Released	Draft	Replaced	
Distribution				Number of copies
cellasys laboratories			1	
Document history	Author/Function	Description of change	Date	Version
	JWI / TFM	Initial creation	2019/08/10	0.1
	JWI / TFM	Update to SOP-S008-001	2019/10/11	0.2
	JWI / TFM	Media volume update	2019/11/15	0.3
	JWI / TFM	Update / release	2020/10/13	1.0
	JWI / TFM	Update / reference elec.	2020/10/14	1.1
	JWI / TFM	Dismounting updated	2020/10/22	1.2

Approval section:

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1 PURPOSE

Procedure for the evaluation of cellular response to a test medium.

This procedure describes the preparation, implementation and evaluation of a microphysiometric test using cellasys's IMOLA-IVD technology.

2 APPLICATION

6xIMOLA-IVD laboratories

3 DOCUMENTATION

Document the performance of the tests with the form QC S008-001_cellasys#8.

4 OVERVIEW

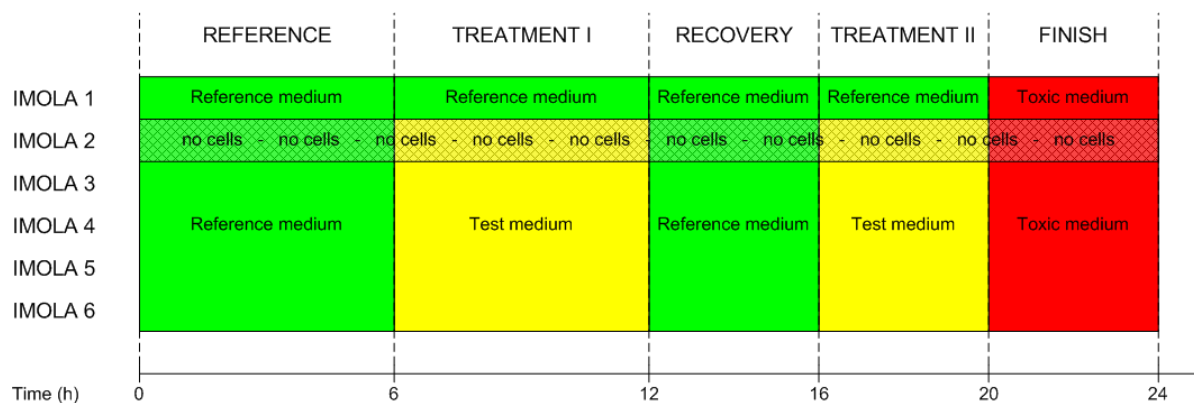


Figure 1: Experimental setup of the cellasys #8 test with the 6xIMOLA-IVD.

- IMOLA 1 serves as negative (0 h – 20 h) and positive (20 h – 24 h) control.
- IMOLA 2 serves as blank control without living cells.
- IMOLA 3 to IMOLA 6 are replicates for the evaluation of the cellular response to the test medium.

5 EQUIPMENT AND MATERIALS

5.1 TOOLS

Pos	Equipment
1	S1 laboratory
2	6xIMOLA-IVD
3	6x fluidic heads
4	12x O-Rings
5	18x 100 ml sterile bottles (GL45)
6	18x distribution caps with luer-steel needles
7	6x reference electrodes with barrels
8	6x flasks for sodium hypochlorite solution
9	6x flasks for ddH2O

5.2 CONSUMABLES & REAGENTS

Pos	Consumables
1	Cells under investigation (approx. 5x 100.000 in 300 µL reference medium)
2	6 x BioChips
3	Pipettes
4	Large petri dish (145x20)

Pos	Reagents
1	~ 2 % sodium hypochlorite solution
2	70 % denaturated ethanole solution
3	ddH2O
4	265 mL reference medium
5	325 mL test medium
6	Toxic substance (e.g. 3 ml 10% SDS solution)

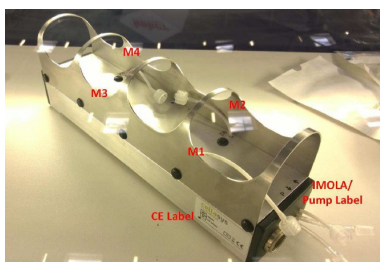
6 TIMETABLE

The SOP cellasys #8 can be performed within 2 days in a cell culture laboratory.

Day	Tasks
1 (afternoon)	1.1 Print and fill QC S001-002_cellasys_8 1.2 Setup 6xIMOLA-IVD 1.3 Sterilize 6xIMOLA-IVD 1.4 Prepare medium flasks 1.5 Setup 6xIMOLA-IVD with medium 1.6 1 st Prefill 6xIMOLA-IVD with medium (set temperature) 1.7 Seed cells onto BioChips
2 (morning)	2.1 2 nd Prefill 6xIMOLA-IVD with medium 2.2 Assemble BioChips with fluidic heads 2.3 Assemble BioChips into 6xIMOLA-IVD 2.4 Start experiment
3 (24 h's after start of experiment)	3.1 Stop experiment 3.2 Export data 3.3 Dismount 6xIMOLA-IVD

7 PROTOCOL

Task	Description
1.1 QC S001-002_cellasys_8	- Print and fill QC S001-002_cellasys_8
1.2 Setup 6xIMOLA-IVD	- Start IMOLA_IVD (laptop, power supply, IMOLAs) - Close pump cartridges - Assemble and mount reference electrodes (6x)
1.3 Sterilize 6xIMOLA-IVD	- Fill 6 flasks with sodium hypochlorite solution and put 4 (3) luer-steel connectors per IMOLA-IVD into it - Load application cellasys #8 prefi-steri - Press start and wait until time counts down from 86.000 seconds (it takes approx. 25 min)
1.4 Prepare medium flasks	With reference medium prepare 7x 40 mL 1x 25 mL (+ toxic substance, e.g. 500 µL 10% SDS solution) With test medium prepare: 5x 40mL 5x 25 mL (+ toxic substance, e.g. 500 µL 10% SDS solution) DALIA client: Press STOP
1.5 Setup 6xIMOLA-IVD with medium	Set 6x M2 flasks into 6xIMOLA-IVD: IMOLA 1: 25 mL reference medium + toxic substance IMOLA 2 – 6: 25 mL test medium + toxic substance Set 6x M3 flasks into 6xIMOLA-IVD: IMOLA 1: 40 mL reference medium IMOLA 2 – 6: 40 mL test medium Set 6x M4 flasks into 6xIMOLA-IVD: IMOLA 1 – 6: 40 mL reference medium - DALiA client: Press START - Switch on 6xIMOLA-IVD incubator



- | | |
|---|---|
| 1.7 Seed cells onto BioChips | <ul style="list-style-type: none"> - Seed cells in 300 µL medium onto BioChips for IMOLA 1,3,4,5,6 - Fill BioChips for IMOLA 2 with 300 µL medium (no cells) - Place 6 BioChips in large petridish and place in CO₂-incubator over night |
| 2.1 2 nd Prefill 6xIMOLA-IVD with medium | <ul style="list-style-type: none"> - DALiA client: Press STOP - DALiA client: Press START - after approx. 25 min press STOP |
| 2.2 Assemble BioChips with fluidic heads | <ul style="list-style-type: none"> - Make sure the luer connectors and clamps of the fluidic heads are open - Sterilize fluidic heads in sodium hypochlorite solution for 20 min - Flush fluidic heads and 6 O-Rings in ddH₂O - Gently press fluidic heads into BioChips - Close luer connectors of fluidic heads |
| 2.3 Assemble BioChips into 6xIMOLA-IVD | <ul style="list-style-type: none"> - Assemble BioChips into 6xIMOLA-IVD |
| 2.4 Start experiment | <ul style="list-style-type: none"> - Load application cellasys #8 run - DALiA client: Press START
 - Let the experiment run for 24 h |
| 3.1 Stop experiment / export data | <ul style="list-style-type: none"> - DALiA client: Press STOP - DALiA client → Database → Export format is start time of the experiment “yyyymmddhhmmss.exp” |
| 3.2 Dismount 6xIMOLA-IVD | <ul style="list-style-type: none"> - Prepare 6x flasks with ddH₂O - Dismount medium flasks with distribution caps (check remaining volume consistency); put Luer-steel tubes in flasks with ddH₂O - Flush distribution caps with ddH₂O and prepare for sterilization - Flush medium flasks with water and prepare for dishwasher - Disassemble BioChip / fluidic head / reference electrode setup - Separate BioChip / fluidic head / reference electrode / barrel - Flush BioChip, fluidic head and barrel with ddH₂O - Store barrels of reference electrodes in 3 mol KCl - Run steri-prefi protocol (wait until countdown from 20 min) - Release cartridges of 6xIMOLA-IVDs pump - Copy .exp file for data processing and documentation - Shut down IMOLA / PC - Empty waste flasks |

8 DOCUMENTATION

Fill in QC S008-001_cellasys#8.

9 ARCHIVAL STORAGE

The original paper version of this document in its approved and released status is stored in the cellasys laboratory's archive, located at:

cellasys laboratory
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D-85579 Neubiberg

10 RESPONSIBILITIES

Creation	Laboratory personnel
Approval	Testing Facility Manager
Archiving	Archiving Manager
Processing	Laboratory personnel

11 REFERENCES

IFU-49023 6xIMOLA-IVD User manual
IFU-49090 DALiA client 3.1
QC S008-001_cellasys#8

12 ANNEXES

None.