

Document name	QC-S008-001_cellasys-8_V3_0.odt			
Status	☐ x ☐ Released ☐ Draft ☐ Replaced			Controlled Document? ☐ x ☐ yes ☐ no
History	Author/Function	Description of change	Date	Version
	JWI/QR	Initial creation, release, chiptest added, cellasys know-how update	2020/11/12 - 2023/12/02	0.1 – 2.0
	JWI/TFM	GmbH update	2026/09/13	3.0

1 6XIMOLA-IVD

Used system: _____

Date: _____

Name of tester: _____

2 INSTALLATION QUALIFICATION

Chiptest before experiment for 6-IMOLAs ok? ☐ | ☐ yes ☐ | ☐ no

Chiptest after experiment for 6-IMOLAs ok? ☐ | ☐ yes ☐ | ☐ no

Remarks:

3 CELLS

Confluence _____

Cell type _____

Time _____

Seeded cells _____

Cell medium _____

4 BIOCHIP-NUMBERS

1 _____

2 _____

3 _____

4 _____

5 _____

6 _____

5 MEDIUM

Reference medium _____

Test medium _____

Toxic substances _____

Test substance _____

Test substance concentration _____

6 RESULTS

IMOLA 1:

pH values - negative control (0 h – 20 h) ok? | | yes | | no

pH values - positive control (20 h – 24 h) ok? | | yes | | no

IDES-values (0 h – 20 h) Re: _____ Im: _____

IDES-values (20 h – 24 h) Re: _____ Im: _____

Remarks:

IMOLA 2:

pH values - blank control (0 h – 20 h) ok? | | yes | | no

pH values - blank control (20 h – 24 h) ok? | | yes | | no

IDES-values (0 h – 20 h) Re: _____ Im: _____

IDES-values (20 h – 24 h) Re: _____ Im: _____

Remarks:

IMOLA 3:

pH values (0 h – 20 h) ok? | | yes | | no

pH values (20 h – 24 h) ok? | | yes | | no

IDES-values (0 h – 20 h) Re: _____ Im: _____

IDES-values (20 h – 24 h) Re: _____ Im: _____

Remarks:

IMOLA 4:

pH values - (0 h – 20 h) ok? | | yes | | no

pH values - (20 h – 24 h) ok? | | yes | | no

IDES-values (0 h – 20 h) Re: _____ Im: _____

IDES-values (20 h – 24 h) Re: _____ Im: _____

Remarks:

IMOLA 5:

pH values - (0 h – 20 h) ok? | | yes | | no

pH values - (20 h – 24 h) ok? | | yes | | no

IDES-values (0 h – 20 h) Re: _____ Im: _____

IDES-values (20 h – 24 h) Re: _____ Im: _____

Remarks:

IMOLA 6:

pH values (0 h – 20 h) ok? | | yes | | no

pH values (20 h – 24 h) ok? | | yes | | no

IDES-values (0 h – 20 h) Re: _____ Im: _____

IDES-values (20 h – 24 h) Re: _____ Im: _____

Remarks:
