GenBody Inc.
(주)젠바디

Technical File

Manufacturing

Product:	**GenBody COVID-19 Ag**
Date:	**2020-06-02**

Prepared by / date	Reviewed by / date	Approved by / date
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2020-06-02	**2020-06-02**	**2020-06-02**

0. Revision history

Revision History		
Rev.O	2020. 06. 02	Release of the GenBody COVID-19 Ag's Manufacturing information

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1. The documentation of the quality system

Refer to technical document as below

- Manufacturing Process document: GB-COVIDAG-01, -02, -03
- Final product/Packaging QC document: GB-COVIDAG-06
- Incoming QC (raw material QC) document: GB-COVIDAG-04
- Process QC document: GB-COVIDAG-05
- material QC document: GB-COVIDAG-06
- QC Process document: GB-COVIDAG-06

2. A description of the manufacturing process

Refer to technical document as below

- Manufacturing Process document: GB-COVIDAG-01, -02, -03
- Final product/Packaging QC document: GB-COVIDAG-06
- Incoming QC (raw material QC) document: GB-COVIDAG-04
- Process QC document: GB-COVIDAG-05
- material QC document: GB-COVIDAG-06
- QC Process document: GB-COVIDAG-06

3. QMS (ISO 13485, EN ISO 9001, MDSAP(for Brazil) and KGMP) certificate from a NB or other registrar for the manufacturing plant

Products are manufacturing according to certified ISO 13485, ISO 9001, KGMP and MDSAP(for Brazil) manufacturing processes.

*KGMP: Good Manufacturing Practices of Korea

4. The training of these procedures/work instructions

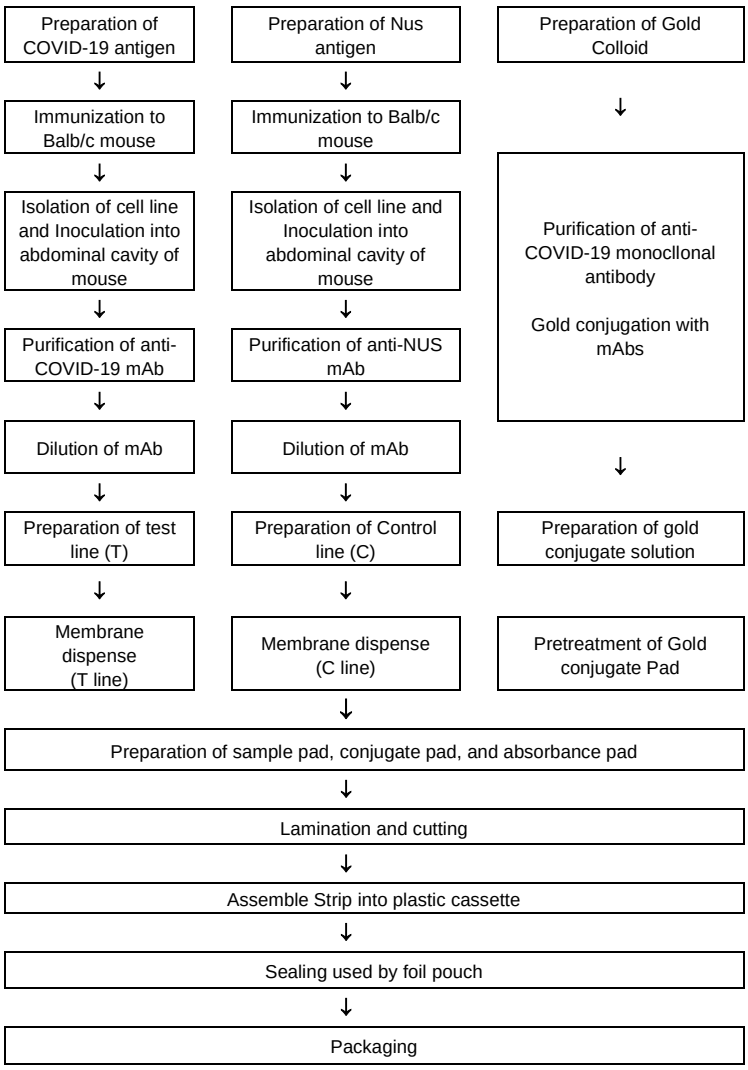
Training & work instruction are performed periodically based on the company's product quality management instruction.

5. Environmental conditions

Refer to manufacturing facility control document (Manufacturing room control/management document: GQP-704, -705, -706, GQI-705001, -705002)

6. "Special processes", e.g. sterilization, the results of which may affect the safety and performance of the finished device: N/A

7. Manufacturing flow chart

Manufacturing Process	Quality Control process
	1. Check the plastic device and sealing tape (SOP No: GB-COVI-01) 2. Check the reagent (SOP No: GB-COVI-02) 3. Check the volume of gel (SOP No: GB-COVI-03) 4. Check the rigisty of the gel (SOP No: GB-COVI-04) 6. Check the components (SOP No: GB-COVI-05) * QC of the final product