

Drawings, Design, Product-Specifications

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

Prepared by / date	Reviewed by / date	Approved by / date
Researcher	R&D Director	QMR
Seo seul ki	Jedae Moon	Jung Young Choi
2020-06-02	2020-06-02	2020-06-02



Technical File

0. Revision history

Revision History		
Rev O	2020. 06. 02	Release of the product specification for the GenBody COVID-19 Ag

1. Design information

Refer to Design history file (GDHF-COVIDAG)

1.1. Total Design Process**Section 1. Target Gene Template**

1. Target gene selection
2. Target gene-specific region selection
3. Gene synthesis of target gene-specific region
4. Conjugation
5. Serial dilution
6. Use for RDT

Section 2. RDT experiment

1. Target Analysis
2. Optimization of RDT
3. RDT experiment

Section 3. RDT

1. RDT with plasmid template
2. Optimization with IPC(Internal Positive Contol)
3. Optimization of RDT condition
4. RDT condition test
5. Evaluation based on Ag/Ab guideline by MFDS or CE (if required)

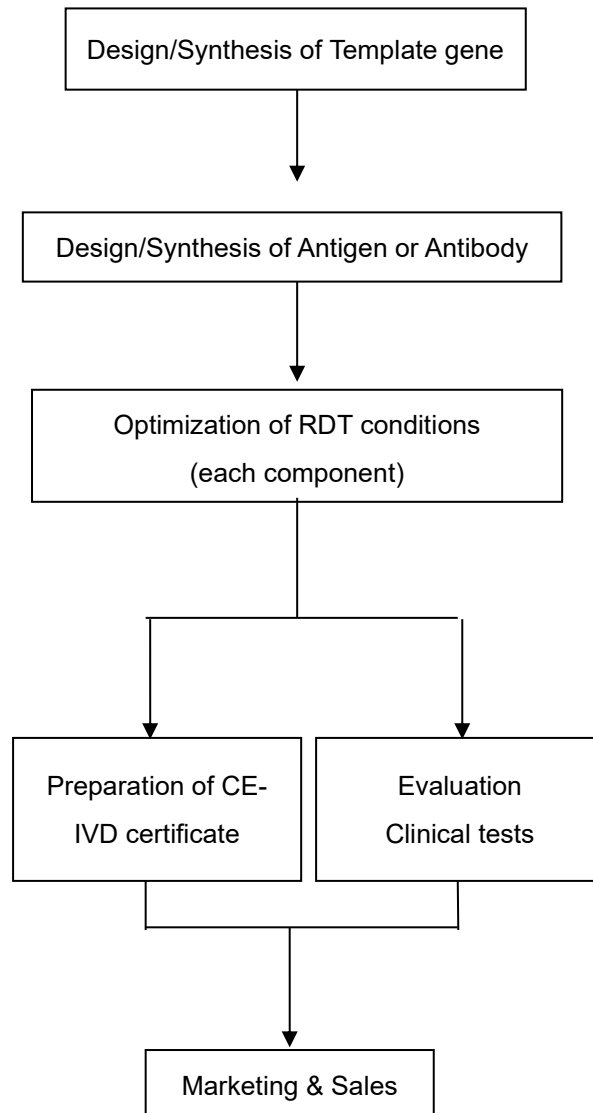
Section 4. CE certification preparation and Clinical Test

1. Preparation of CE-IVD certificate aquisition
2. Preparation of Mass clinical tests

Section 5. Marketing

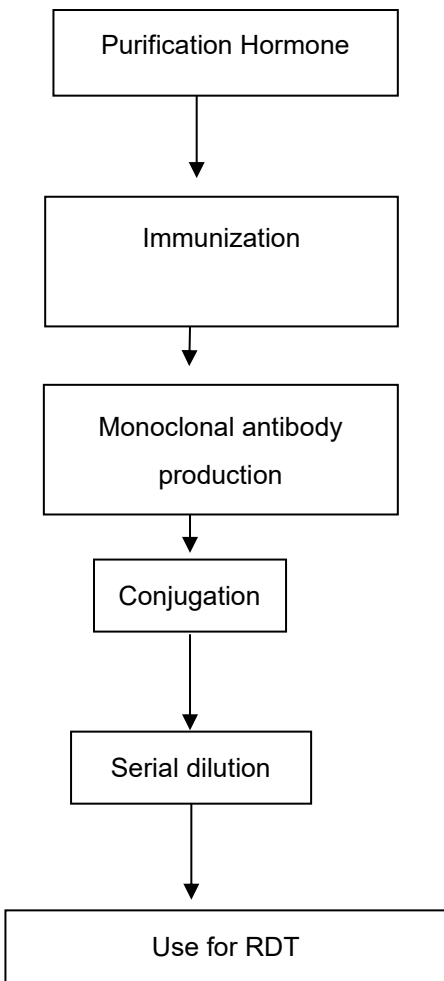
1. Survey/Analysis of marketing documents
2. Strategic marketing planning
3. Preparation of marketing material such as Catalog
4. Advertisement & sales

1.2. Total Design Process Flow Diagram



1.3. Detailed Design Process Flow Diagram

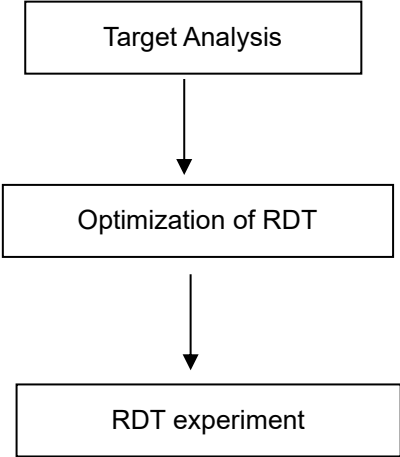
Section 1. Target Gene Template



Time table	1	2	3	4
Hormone selection				
Immunization				
Monoclonal antibody production				
Conjuation				
Serial dilution				

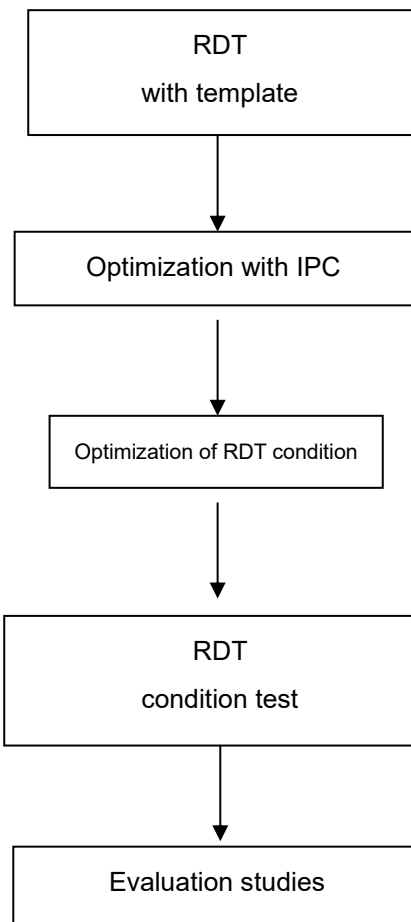
Time table	5	6	7	8
Immunization				
Monoclonal antibody production				
Conjuation				
Serial dilution				
Serial dilution				

Section 2. RDT experiment



Time table	1	2	3	4
Target Analysis				
Optimization of RDT				

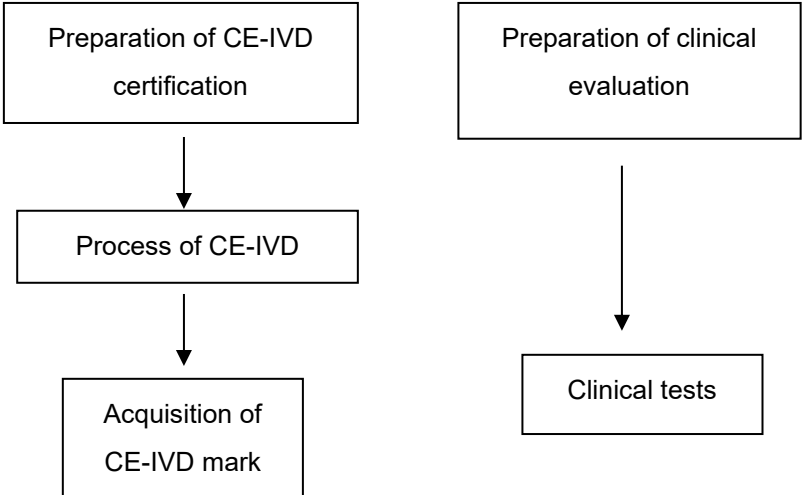
Section 3. RDT



Time table	1	2	3	4
RDT with template				
Optimization with IPC				
Optimization of RDT				
Evaluation studies				

Time table	5	6	7	8
RDT condition test				
Evaluation studies				

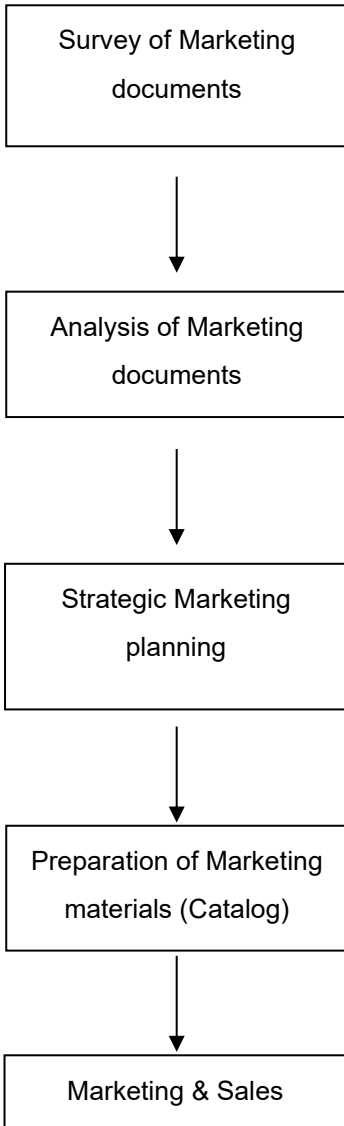
Section 4. CE certification preparation and Clinical Test



Time table	1	2	3	4
Preparation of CE-IVD certification				
Preparation of clinical evaluation				
Process of CE-IVD				
Time table	5	6	7	8
Preparation of CE-IVD certification				
Preparation of clinical evaluation				
Process of CE-IVD				

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Section 5. Marketing & Sales



Time table	1	2	3	4
Survey of Marketing documents				
Analysis of Marketing documents				
Strategic Marketing planning				
Preparation of Marketing materials (Catalog)				
Marketing & Sales				

Time table	5	6	7	8
Survey of Marketing documents				
Analysis of Marketing documents				
Strategic Marketing planning				
Preparation of Marketing materials (Catalog)				
Marketing & Sales				

Time table	9	10	11	12
Survey of Marketing documents				
Analysis of Marketing documents				
Strategic Marketing planning				
Preparation of Marketing materials (Catalog)				
Marketing & Sales				

2. Result of design calculations

Refer to Design history file (GDHF-COVIDAG)

3. Design drawings, diagrams of components, sub-assemblies, circuits etc. in case of Instruments

Refer to chapter 4, Raw material QC document, Final product/Packaging QC and Design history file

4. Documentation on design, verification and validation

Refer to chapter 7, 8, 9, Final product/Packaging QC document and Design history file

5. Documentation on validation of the packaging

Refer to chapter 4, Final product/Packaging QC document and Design history file

6. Comprehensive description of the product

Refer to chapter 1, 4, Kit manuals and Design history file

7. (Sample of Product or empty set to get an impression): N/A

8. Photographs or Blueprints

Refer to chapter 4

9. QS (ISO 13485, ISO 9001 and KGMP) Certificate of design facility

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

*KGMP: Good Manufacturing Practices of Korea

10. Final product release criteria

Refer to Final product/Packaging QC document