

## Drawings, Design, Product-Specifications

Product:	<b>GenBody COVID-19 Ag</b>
Date:	<b>2020-06-02</b>

Prepared by / date	Reviewed by / date	Approved by / date
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<b>2020-06-02</b>	<b>2020-06-02</b>	<b>2020-06-02</b>



**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)

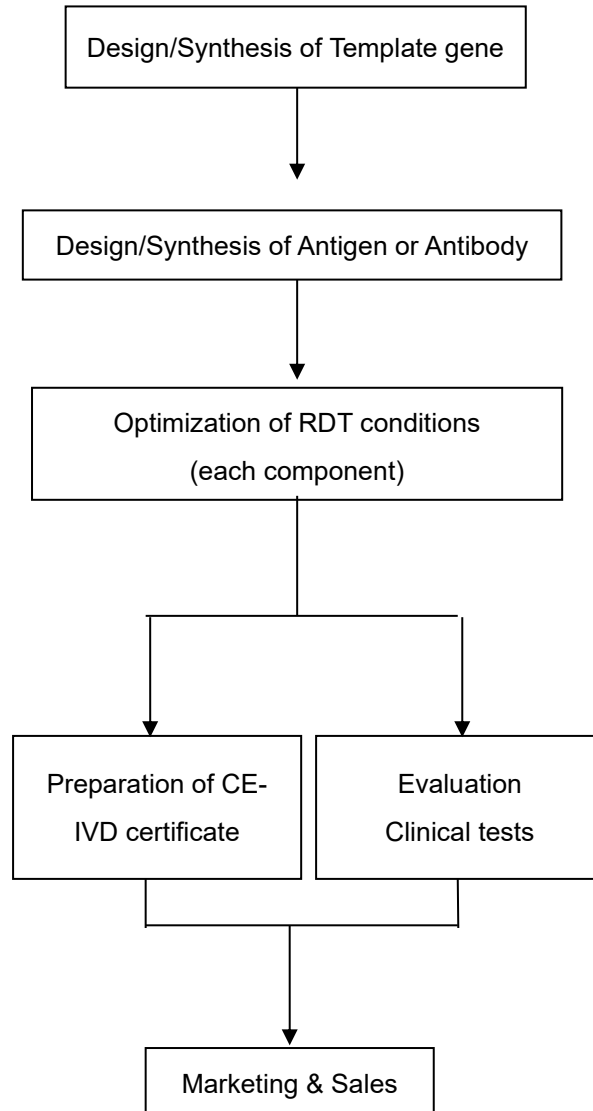
#### Section 4. CE certification preparation and Clinical Test

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

#### Section 5. Marketing

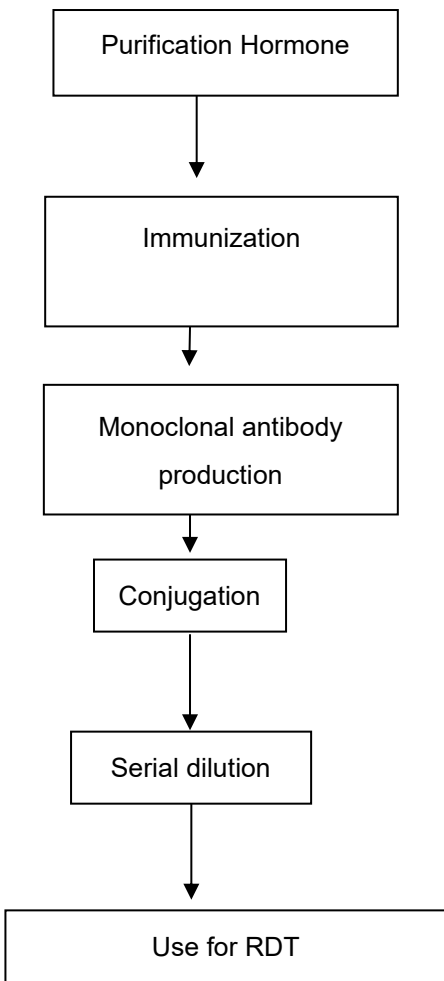
1. Survey/Analysis of marketing documents
2. Strategic marketing planning
3. Preparation of marketing material such as Catalog
4. Advertisement & sales

1.2. Total Design Process Flow Diagram



1.3. Detailed Design Process Flow Diagram

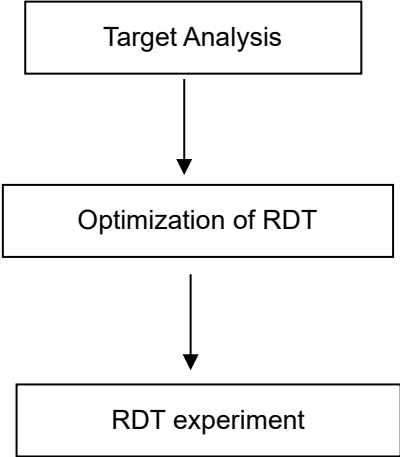
Section 1. Target Gene Template



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

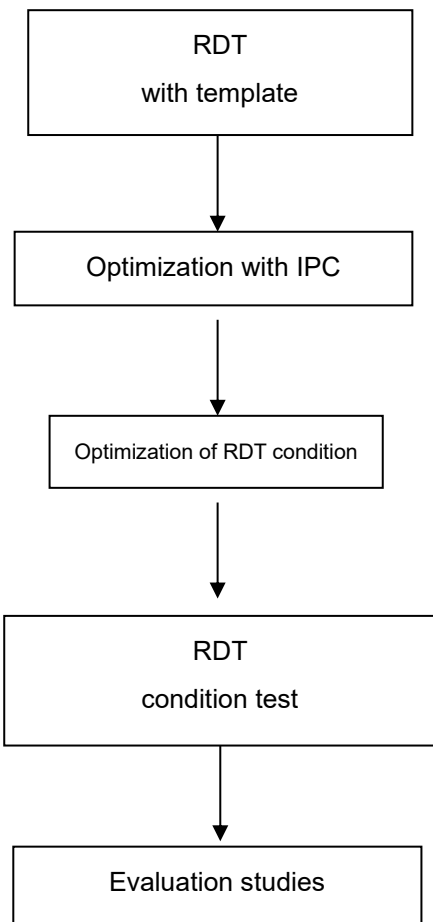
Time table	5	6	7	8
Immunization				
Monoclonal antibody production				
Conjuation				
Serial dilution				
Serial dilution				

Section 2. RDT experiment



Time table	1	2	3	4
Target Analysis				
Optimization of RDT				

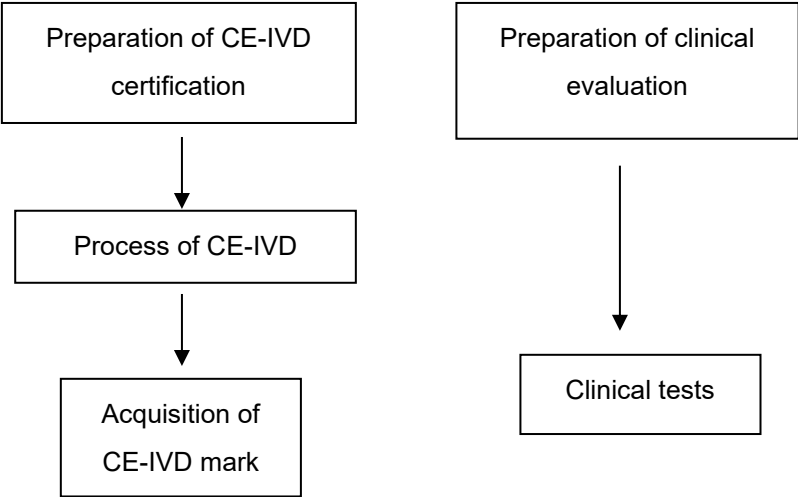
Section 3. RDT



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

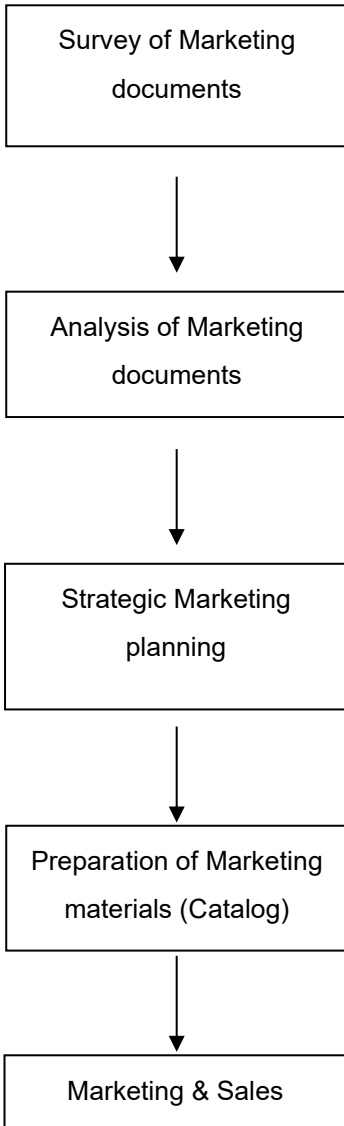


Time table	1	2	3	4
Preparation of CE-IVD certification				
Preparation of clinical evaluation				
Process of CE-IVD				
Time table	5	6	7	8
Preparation of CE-IVD certification				
Preparation of clinical evaluation				
Process of CE-IVD				



**Technical File**

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