

## **Uncut Sheet For Rapid Test Kit Manufacturing**

Feb. 2021

Company: XXX
Location: India
Contact: -

Attention: -

**Project:** HCG Rapid Test Kit Manufacturing Unit Set Up **Method:** Immunochromatography (Colloidal Gold)

**Production capacity:** - **Schedule:** March 2021

**Future Products:** Drugs, Hiv, HbsAg, HbsAb, HCG, LH, Covid 19, ... etc.

Cleanroom requirement: Relative humidity <30%, 100,000 class, room temperature control,

build by XXX

Initial stage: HCG Test Kit

Next stage: HIV, HBsAg, Covid-19

## Background:

A new factory set up with technique transfer request. The first proposal with simple description in technique and equipment requirement.

#### **PART ONE**

Technique manufacturing flow chart

#### **PART TWO**

Materials and accessories

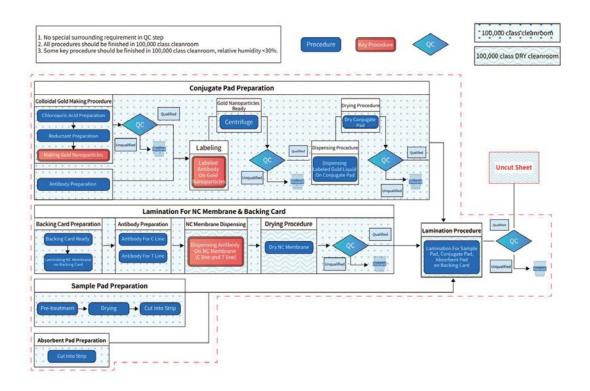
#### **PART THREE**

Equipment and flow chart



## PART ONE

## Manufacturing flow chart



## Description as below:

- 1. Colloidal gold manufacturing
- 2. Antibody/antigen labeling on colloidal gold
- 3. Conjugate pad preparation
- 4. NC membrane laminating on backing card
- 5. Sample pad preparation
- 6. Absorbent pad preparation
- 7. The pads laminating on backing card
- 8. Uncut sheet finish



## **PART TWO**

## **Materials list**

No.	Material	Description	QTY
1	Antibody	Antibodies for hcg and Control line	-
2	Antigen	Antigen for hcg	-
3	BSA	Bovine Serum Albumin	-
4	Other reagents	Chemical reagents	-
5	NC membrane	Nitrocellulose membrane	-
6	Lateral flow backing card	PVC based backing card	-
7	Lateral flow sample pad	glass fibre based materials for lateral flow assay test kit	-
8	Lateral flow absorbent pad	glass fibre based materials for lateral flow assay test kit	-
9	Lateral flow conjugate pad	glass fibre based materials for lateral flow assay test kit	-
10	Colloidal gold nanoparticles	Usually made by CITRIC ACID TRISODIUM	-
11	Other materials	MAX arrow label, label	-
12	Lab consumable items	Various tubes, tips, micropipettor, glassware, etc.	-

Remark: the list can be changed according to different product

## PART THREE

# **Main Equipment list**

No.	Equipment	Description	QTY	EXW Price
1	Lateral flow dispenser	2 reagent nozzle and 1 colloidal	1	
		gold nozzle, dispensing reagents		_
		on NC membrane or conjugate		-
		pad		
2	Blast drier	Reduce water from materials	3	-
3	Centrifuge	Isolation component from	3	
		materials		_
4	Micropipette	Measure micro low	10	-
5	Balance High precision balance		3	-
6	Other devices	PH measuring instrument,	10	
		oscillator, mixer, etc.	10	

Remark: The above list only show the partial equipments, full list according to different product or project will be different.



## **Price list**

No.	Project	EXW Price	
1	Supply main equipment (refer equipment list)	-	
2	Transfer technique	-	