

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

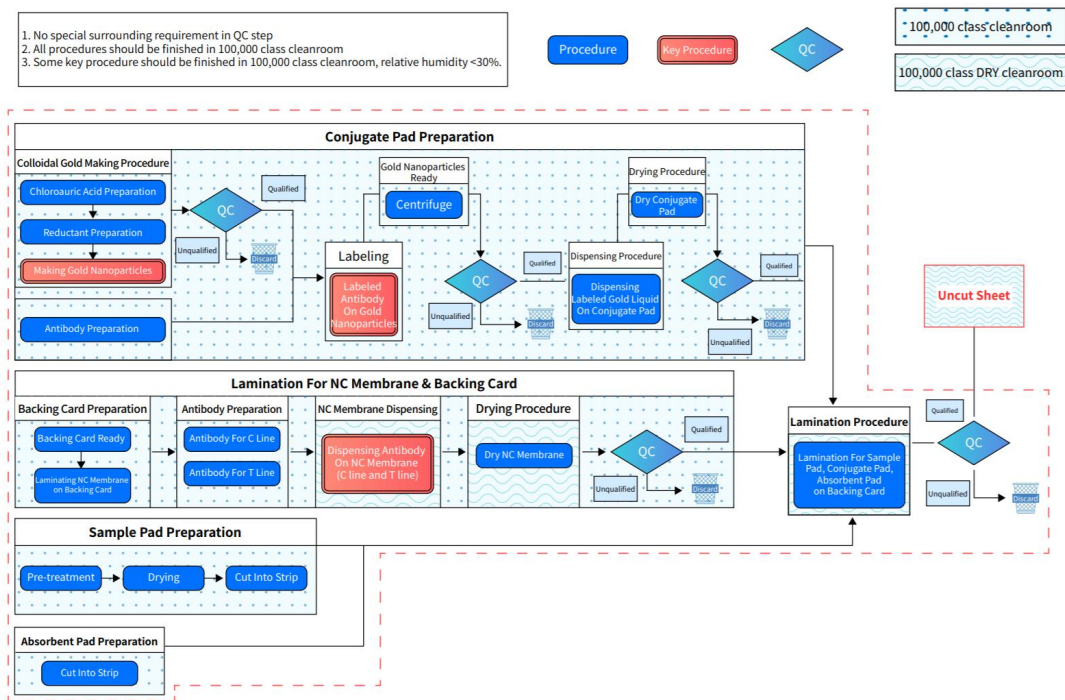
Materials and accessories

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 gold nozzle, dispensing reagents on NC membrane or conjugate pad	1	-
2	Blast drier	Reduce water from materials	3	-
3	Centrifuge	Isolation component from materials	3	-
4	Micropipette	Measure micro low	10	-
5	Balance	High precision balance	3	-
6	Other devices	PH measuring instrument, 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	-