

HLL LIFECARE LIMITED, MANESAR FACTORY, GURGAON**PROCUREMENT PLAN FOR FY:2013-14****MATERIAL REQUIREMENTS**

Sl. No	Item	Projected Quantities in Nos. for Manufacturing in FY:2013-14
1	RAPID PREGNANCY TEST DEVICE (IN ASSEMBLED CASSETTE MODE)	4,000,000
2	PLASTIC DROPPER (MEDICAL GRADE)	2,00,00000
3	SILICA GEL POUCHES	2,00,00000
4	LAMINATED & PRINTED ALUMINIUM POUCHES	1,24,00000
5	INNER CARTONS	1,25,000
6	INSTRUCTION LEAFLETS	1,25,000
7	CORRUGATED BOX	12,500
8	EMPTY CASSETTE (TOP & BOTTOM) MADE IN ABS	2,00,00000
9	UNCUT SHEETS OF URINE hCG PREGNANCY RAPID TEST CARDS	2,00,00000

**Sl. No-1: TECHNICAL SPECIFICATIONS OF RAPID PREGNANCY TEST DEVICE
(IN ASSEMBLED CASSETTE MODE)**

UN-POUCHED CASSETTES / CARD HAVING NITROCELLULOSE STRIP COATED WITH REAGENTS FOR DETECTION OF HUMAN CHORIONIC GONADOTROPIN IN URINE TO BE USED IN PRODUCTION OF DIAGNOSTIC KIT FOR DETECTION OF PREGNANCY OF WOMAN

1.	Test Specimen	:	URINE
2.	Test Principle	:	Single Step, Self performing sandwiched immunoassay using colloidal gold & anti hCG antibodies.
3.	Sensitivity	:	The test should show positive result at the minimum concentration of 15 to 20 mili IU per ml of hCG in the stipulated test time. However it should not give positive line at 5 mili IU per ml of hCG within 5 minutes of addition of the standard solution.
4.	Specificity	:	100% (No cross reactivity with other gonadotropin hormones like LH, FSH etc
5.	Background	:	Background of the device at the end of 5 minutes after addition of samples should be clear & matching with colour of the nitrocellulose paper of the untested device.
6.	Built in control	:	Should have built in control for correctness of the testing procedure.
7.	Nitrocellulose Strip	:	Width of strip 3.0mm \pm 0.01mm. Nitrocellulose paper coated with anti hCG antibodies for test band and appropriate reagent coating for control band and it should be masked with clear tape to avoid evaporation.
8.	Cassette	:	Cassette made of ABS and it should be provided with sample window & test window with marking for sample test & control. It should also have perforation above the test window for evaporation of liquid.
9.	Cassette size	:	Length: 65 to 75 mm; Width: 15 to 25 mm; Thickness: 4 to 6 mm

10.	Shelf life	:	Not less than 24 months from the date of manufacturing
11.	Storage condition	:	The kit should be stable at room temperature.
12.	Packing	:	Cassettes should be packed in air tight / moisture proof pouches with silica gel in minimum packs size of 400-1000 test & then packed in seven ply corrugated shipper box. All packages should be uniform quantity. The maximum qty.per box should not exceed 4000 Nos.

Sl. No-2: TECHNICAL SPECIFICATIONS OF PLASTIC DROPPER (MEDICAL GRADE)

PLASTIC DROPPER (MEDICAL GRADE)

(a)	Colour	:	Clear
(b)	Total Length	:	6-8 cm
(c)	Bulb Length	:	1-2 cm
(d)	Bulb diameter	:	4 -6mm
(e)	Capacity	:	NLT 0.20 ml
(f)	Body Length	:	3-4 cm
(g)	Tip Length	:	1-2 cm
(h)	Material	:	LDPE, 22 FA 002 Grade.
(i)	Weight	:	0.25 ± 0.03 gm
(j)	Drop size	:	35 ± 5 μ l

Sl. No-3: TECHNICAL SPECIFICATIONS OF SILICA GEL POUCHES

SILICA GEL Pouch (Indicating type blue colours)

- (a) 0.8 gm +/-0.1gm packed in a non woven fabric of 45 (+/-5) GSM.
- (b) Size of the sachet shall be 40 (+/-5)mm X 18 (+/-2)mm (L x W)
- (c) Adsorption Capacity: NLT 30% W by W at RT and 100% RH.
- (d) Should be rechargeable at 75 +/-10 degree Celsius.

Sl. No-4: TECHNICAL SPECIFICATIONS OF LAMINATED & PRINTED ALUMINIUM POUCHES FOR NISHCHAY BRAND

LAMINATED & PRINTED POUCHES

- (a) Three layer laminated pouch having total thickness Not Less Than 90 micron, with the individual layers of:
 - i) Top layer of fresh polyester of thickness Not Less Than 12 micron.
Polyester layer should not react with Ethyl Methyl Ketone.
 - ii) Middle layer of aluminum soft foil of thickness Not Less Than 9 micron.
 - iii) Inner layer of co-extruded dolex LDPE of thickness Not Less Than 70Micron.
- (b) Size: Length: 110 +/- 2 mm and Width: 65 +/- 1 mm.
- (c) Sealing: Three sides sealing (One at width & two length sides).
- (d) Printing: As per the approved art work, having 8 colours on both side of the pouch.
- (e) Sealing width: 6 to 9mm.
- (f) V- notch should be provided on any side of pouch 12-15mm below the opening
- (g) V - Notch depth: 1 -3 mm.
- (h) Performance: Opening end of the pouches should be able to open freely and easily with single hand for manual pouch filling operation.
- (i) Solvent free adhesive should be used for lamination.
- (j) Sealing integrity: 100% Leak-proof.

Sl. No-5: TECHNICAL SPECIFICATIONS OF INNER CARTONS FOR NISHCHAY BRAND

INNER CARTON

- (a) Made out of 350 GSM. ITC cyber excel board with lamination on top. The lamination should not react with the Methyl Ethyl Ketone solution.**
- (b) Printed in 8 colours.**
- (c) Seem Glued & supplied flat.**
- (d) Size: Internal dimension: 115 (L) x 65 (W) x 70 (H) mm**
- (e) Mode of Packing: 50 Nos. in one small bundle. 20 such bundles should be packed in a sturdy corrugated box. The maximum quantity per corrugated box should not exceed 1000 Nos.**
- (f) Proper identification label bearing name of material, quantity per box, name of supplier and date of dispatch is to be pasted on each box.**
- (g) Inner side of the carton should be white in colour.**

Sl. No-6: TECHNICAL SPECIFICATIONS OF INSTRUCTION LEAFLETS FOR NISHCHAY BRAND

INSTRUCTION LEAFLETS

- (a) Instruction Leaflets with 4 folds.**
- (b) Size 190 mm x 280mm made from 80 GSM maplitho white paper.**
- (c) Printed in 02 colours.**

Sl. No-7: TECHNICAL SPECIFICATIONS OF CORRUGATED BOX FOR NISHCHAY BRAND

CORRUGATED BOX

- (a) **Narrow flute 7 ply corrugated Card Board Box.**
- (b) **Internal Dimensions.**
485 (L) X 340 (W) X 380 (H) mm
- (c) **Printing: 2 colours (Red & Black)**
- (d) **Inner & outer ply to be virgin Kraft paper. The box shall be single piece with double stapling using flat wire of MS or GI materials, as per ISI - 10086-1981.**
- (e) **Total GSM comprising of**

Outer Lining	}	> 1100.
Lining: 160 x 3		
Fluting: 150 x 3		
- (f) **Direction of flute - vertical.**
- (g) **Puncture resistant: not less than 45 coz inch per tear inch.**
- (h) **Nature of gum: starch based.**
- (i) **Bursting strength: 15 kg/sq.cm. (min)**
- (j) **Style: Universal.**
- (k) **Burst factor: NLT 20**
- (l) **Stapling: NLT 20.**

**Sl. No-8: TECHNICAL SPECIFICATIONS OF EMPTY CASSETTE (TOP & BOTTOM)
MADE IN ABS**

EMPTY CASSETTE (TOP & BOTTOM) MADE IN ABS

Product : Empty cassettes (Top & Bottom) in ABS material

Cassettes top and bottom (in ABS material): As per standard sample available with us for reference purpose. The top part will have sample window & test window with marking for Sample (S), Test (T) and Control (C). It will also have perforation above the test window for evaporation of liquid. HLL logo and HLL will be embossed over the cassette.

S.No.	Parameters	Standards (Limits)
1.	Material :	ABS (Medical grade & non recycled)
*2.	Length (mm) :	70.00 ± 1.0
*3.	Width (mm) :	18.00 ± 0.5
*4.	Thickness (mm) :	5.00 ± 0.5
*5.	Average Weight (g) :	3.5 ± 0.1
6.	Color :	2 colours, Top and Bottom of different colours
7.	Evaporation window :	should be match with HLL cassette design
8.	Result window upper Dimension (mm) :	15.0 x 7.0 mm
9.	Result window lower Dimension (mm) :	9.0 x 2.70 mm
10.	Sample well inner Dimension (mm) :	3.7 x 2.1 mm (in oval shape)
11.	Locking of top & bottom :	There are 8 pins for locking ; Locking position should not be interchangeable;
12.	Locking & its strength :	Locking should be proper & it should not be open after falling from 3 feet height.
13.	Finishing :	Cassettes top and bottom should be smooth and free from cracks & scratches.
14.	Strips groove Dimension :	58.88 x 3.13 mm (one end of the groove should be closed.)

*** NB: These are indicative measurement for the purpose of price quotation. However, the exact measurement will be finalized during sample development by the tenderer in consultation with HLL re Limited.**

Sl. No-9: TECHNICAL SPECIFICATIONS OF UNCUT SHEETS OF URINE hCG PREGNANCY RAPID TEST CARDS

UNCUT SHEETS OF URINE hCG PREGNANCY RAPID TEST CARDS

1. Test Principle:

Single Step, Self performing sandwiched immunoassay using colloidal gold & anti hCG antibodies.

2. Sensitivity:

The test should show positive result at the minimum concentration of 15 - 20 milli IU per ml of hCG in 05 minutes time. However, it should not give positive line at 5 milli IU per ml of hCG within 05 minutes of addition of the standard solution. And simultaneously, the positive test line should not diminished in intensity when test is performed with standard up to 100 IU per ml.

3. Specificity:

100% (No cross reactivity with other Gonadotropin hormones like LH, FSH etc at physiological concentrations)

4. Background:

Background of the test at the end of 5 minutes after addition of samples should be clear and matching with colour of the nitrocellulose paper of the untested device.

5. Built in control:

Should have built in control for correctness of the testing procedure.

6. Nitrocellulose:

Nitrocellulose paper coated with anti hCG paper antibodies for test band and appropriate reagent coating for control band and it should be masked with clear tape to avoid evaporation.

(NOTE: the sample and absorbent pad shall not be masked.)

7. Shelf Life:

30 months from the date of manufacturing

8. Storage:

The Sheet should be stable at room temperature Condition (4 to 30 degree centigrade)

9. Packing:

Uncut sheets (for test strip) should be packed in air tight / moisture proof aluminium pouches with desiccant silica gel. Each Aluminum pouch should not contain more than 50 uncut sheets.

10. Size of uncut Sheet :

Width: 300 ± 0.5 mm

Length: 57.75 ± 0.25 mm

Note:

The dimensions of uncut sheet are indicative. However, the actual dimensions (specially the length and thickness etc.) should be tailored as per HLL's empty cassette design. The required nos. of empty cassettes will be provided for product optimization.