File Name Master File Qc R Test Prepared by

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1.Rapid test material specification

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R-Test raw material (Uncut sheet)

Specification: Supplier Name:

Performance Test

Test description Acceptance Level Criteria Protocol

1 Positivity Blood/Serum/Urine/Fluid Positive   
 Positive 1-2 Drop of Sample, 2 Drops of Buffer

2 Negativity 50 Negative Samples Negative 1-2 Drops of Sample, 2 Drops of Buffer

3 LOD L1  
L2  
L3  
L4  
L5  
L6  
L7  
L8  
L9  
L10 Positive (1/2) Serial Dilution

Positive (1/4) Serial Dilution

Positive (1/8) Serial Dilution

Positive (1/16) Serial Dilution

Positive (1/32) Serial Dilution

Positive (1/64) Serial Dilution

Positive (1/128) Serial Dilution

Positive (1/256) Serial Dilution

Positive (1/512) Serial Dilution

Positive (1/1024) Serial Dilution

4 Precision Uniform result 10 Replicates 1-2 drops of sample, 2 drops of buffer

5 Buffer Uniform Negative result 10 Replicates 2 drops of buffer

6 Flow time Within 2 Minutes 10 Replicates 1-2 drops of sample or 2 drops of buffer

7 Serum Uniform Negative Result 10 Replicates 1-2 drops of sample, 2 drops of buffer

Sr. #   
Parameters Specifications

1 Physical Appearance The shape of the uncut sheet shall be smooth & uniform. No dislocation of pads.

2 Dimensions 300 mm \* 60 mm ± 5

R-Test raw material (Diluent/ Buffer)

Specification:

QC Inspection Parameters for Buffer

1 Parameter Specification/Method

2 Appearance Visual Inspection

3 Color Visual Observation

4 Odor Sensory check

5 pH 7.9 ±0.3

6 Volume 1 liter

7 Shaking/ Mixing Min 1 hour

8 Sterility (if required) TSB/FTM incubation at 20–35°C

9 Conductivity (optional) Conductivity meter

10 Osmolality   
(optional) Osmometer

11 Sensitivity & specificity No false positive or negative

12 Documentation Review COA, MSDS, etc.

R-Test raw material (Plastic cassette) Type D

Sr. #   
Parameters Specifications

1 Physical Appearance No damage, clean, no discoloration

2 Cassette Size 20mm\*70mm with 17mm reading window.

3   
Coordinate Coordination Top & Bottom

4 Window Size 17mm × 5mm ± 0.2mm

5 Fitment Check/Tightness  
 Cassette pinching/ Strip fitment

6 Falling Test  
 Cassette should be tightly fit

7 Printing  
 Observe the logo on cassette

8 Weight  
  
 3.5g ± 0.2g

9 Flow Observation  
 Uniform flow, no leaks or blockages

10 Packaging Intact, clean, correctly labeled

Specification:

R-Test raw material (Plastic cassette) Type A

Sr. #   
Parameters Specifications

1 Physical Appearance No damage, clean, no discoloration

2 Cassette Size 28mm\*70mm with 17mm reading window

3   
Coordinate Coordination Top & Bottom

4 Window Size 17mm × 5mm ± 0.2mm

5 Fitment Check/Tightness  
 Cassette pinching/ Strip fitment

6 Falling Test  
 Cassette should be tightly fit

7 Printing  
 Observe the logo on cassette

8 Weight  
  
 3.5g ± 0.2g

9 Flow Observation  
 Uniform flow, no leaks or blockages

10 Packaging Intact, clean, correctly labeled

Specification:

R-Test raw material (Plastic cassette) Type M

Sr. #   
Parameters Specifications

1 Physical Appearance No damage, clean, no discoloration

2 Cassette Size 21.6mm\*69.6mm with 2.8\*16.6 mm reading window.

3   
Coordinate Coordination Top & Bottom

4 Window Size 16mm × 5mm ± 3mm

5 Fitment Check/Tightness  
 Cassette pinching/ Strip fitment

6 Falling Test  
 Cassette should be tightly fit

7 Printing  
 Observe the logo on cassette

8 Weight  
  
 3.5g ± 0.2g

9 Flow Observation  
 Uniform flow, no leaks or blockages

10 Packaging Intact, clean, correctly labeled

Specification:

R-Test raw material (Alu- pouch)

Specification:

Sr. #   
Parameters Specifications

2 Physical Characteristics Clean, Smooth, laminated with fine color quality

Quality Pouch have ALU and looks hard Havey from normal pouch.

3 Dimensions & Specifications Length: 120mm; Width = 65mm & Weight = 1.48g

4 Flame Resistance Test The pouch must be resisting 2-3 sec not catch fire/Sustainable for sometime

5 Sealing Integrity Test/Leak test No leakage and no air release found under high pressure in Leak tester (BK-134).

6 Color Fastness Test Acidic water and sodium hypochlorite is used to check the color; no discoloration and fadedness found

7 Humidity & Temperature Effect Alu foil pouches were subjected to high humidity (60%-70%) and high temperature (50 C) independently with indicator desiccants inside.

R-Test raw material (Desiccant)

Specification:

Test No. Test Description Test Condition Duration Measurements

1 Initial Moisture Content Room Temperature (25°C) and 50% RH 24 hrs. Weight of desiccant before and after conditioning

2 Adsorption Isotherm Various RH levels (e.g., 10%, 30%, 50%, 70%, 90%) Equilibrium Moisture adsorption at each RH level

Inspection and Observation

Test no. Temperature (˚C) Humidity (%) Duration (hours) Remarks Observation

1 25 40 24 Weight gain of 0.03 g No Color changed

2 30 53 24 Weight gain of 0.15 g No Color changed

3 48 68 24 Weight gain of 0.35 g No Color changed

Sr. No Test Parameter Specification

1 Physical Appearance White/Blue/Orange beads,  
 free from dust and damage

2 Packing integrity Sachets sealed properly, no leakage or tearing

3 Sachet Weight   
(e.g., 1g, 2g, 5g) 10% of label claim

4 Moisture Indicator Color  
 (if any) Blue → Pink (moist), Orange → Green (moist)

5 Adsorption Efficiency   
(optional) Meets internal test for water vapor absorption

6 Label/Printing Clear, legible, includes batch & expiry (if any)

Performance Test

Sr. #   
Parameters Specifications

1 Physical Appearance Clean & Smooth laminated with fine color quality.

2 Dimensions & specifications Width: 120 mm; Length: 195mm; Height: 9.5 mm  
Weight: 48 g; Thickness: 0.4mm

3 Grammage  
GSM 0.91 kg/m2 Approx  
910 gms

4 Surface area 52765 mm2 square mm

5 Volume 221400 mm3 cubic mm

6 Packing Capacity 50 pouches

7 Color testing No discoloration

8 Printing Quality Clear logo, correct color & alignment

9 Moisture Resistance (if laminated) Box should not absorb moisture or deform under normal humidity

10 Packaging Integrity  
  
 Should remain intact after simulated transport handling

R-Test Small box

R-Test Large box

Specification:

Performance Test

Sr. #   
Parameters Specifications

1 Physical Appearance Clean & Smooth laminated with fine color quality.

2 Dimensions & specifications Width: 125 mm; Length: 230mm; Height: 9.5 mm  
Weight: 48 g; Thickness: 0.4mm

3 Grammage  
GSM 1669.57 g/m²

4 Surface area 287.5 cm²

5 Volume 221400 mm3 cubic mm

6 Packing Capacity 150 pouches

7 Color testing No discoloration

8 Printing Quality Clear logo, correct color & alignment

9 Moisture Resistance (if laminated) Box should not absorb moisture or deform under normal humidity

10 Packaging Integrity Should remain intact after simulated transport handling

R-Test raw material (Dropper) 35ul

Specification:

Performance Test

Sr. #   
Parameters Specifications

1 Physical Appearance foreign particles, molding defects, black spots, cracks, deformation.

2 Dropper Functionality Test   
Test the number of drops per mL and uniformity of drops.

3 Volume Test Fill with water up to brim and measure actual capacity (e.g., 5 mL, 10 mL, etc.).

4 Dimensions Check Measure height, diameter, neck size, wall thickness (use Vernier caliper).

5 Color Transparent bottle body with white screw cap

6 Bottle Size 21.8 mm \* 66.7mm

7 Drop Size 35µl drop size

8 Total Capacity 10 ml

9 Coordinate Complete overall coordination, flexible and suitable tightness of cap

10   
  
Heat Resistance test 10 plastic droppers were placed in thermal incubator under 50ºC temperature to check the heat resistance capacity; there shall be no damage or wrinkles due to heat effect on bottles.

11   
  
Leak test  
 5 buffer filled plastic dropper bottles were placed under high pressure and temperature; result reveal there is no leakage and volume reduction found.

R-Test raw material (Dropper) 5ul

Specification:

Performance Test

Sr. #   
Parameters Specifications

1 Physical Appearance foreign particles, molding defects, black spots, cracks, deformation.

2 Dropper Functionality Test   
Test the number of drops per mL and uniformity of drops.

3 Volume Test Fill with water up to brim and measure actual capacity (e.g., 5 mL, 10 mL, etc.).

4 Dimensions Check Measure height, diameter, neck size, wall thickness (use Vernier caliper).

5 Color Transparent bottle body with white screw cap

6 Bottle Size 21.8 mm \* 66.7mm

7 Drop Size 5µl drop size

8 Total Capacity 3 ml

9 Coordinate Complete overall coordination, flexible and suitable tightness of cap

10   
  
Heat Resistance test 10 plastic droppers were placed in thermal incubator under 50ºC temperature to check the heat resistance capacity; there shall be no damage or wrinkles due to heat effect on bottles.

11   
  
Leak test  
 5 buffer filled plastic dropper bottles were placed under high pressure and temperature; result reveal there is no leakage and volume reduction found.

R-Test raw material (Box Seal)

Specification:

Performance Test

Sr. #   
Parameters Normal Ranges

1 Visual Inspection No defects, or Damage

2 Seal Strength   
≥1.5 kgf

3 Printing No Mistake

4   
Leak Test  
  
  
 No leak

5 Dye Test No dye leakage

Sr. #   
Parameters Specifications

1 Physical Appearance Clean & Smooth laminated with fine color quality.

2 Dimensions & specifications Width: 63.5mm; Length: 63.5 mm; Weight: 0.592 g  
Thickness: 0.1 mm  
Surface area: 80 Sq cm

3 GSM  
Grammage 733.5 g/m2  
1.47 g/cm3

4 Stickiness Stick to r test Box

5 Color testing No discoloration

R-Test raw material (sticker) Box

Specification:

R-Test raw material (sticker) Master Carton

Specification:

Sr. #   
Parameters Specifications

1 Physical Appearance Clean & Smooth laminated with fine color quality.

2 Dimensions & specifications Width: 100 mm; Length: 100 mm;   
Weight: 0.592 g  
Thickness: 0.1 mm

3 GSM  
Grammage 59.2 g/m²

4 Surface Area 0.01 m² (or 100 cm × 100 cm = 10000 mm²)

5 Stickiness Stick to r test Box

6 Color testing No discoloration

R-Test raw material (Sterile Swab)

Specification:

Performance Test

Sr. #   
Parameters Normal Ranges

1 Visual Inspection No defects, or Damage

2 Swab shaft and tip clean, smooth, and free from fibers/debris.

3 Packaging Intact, properly sealed, and labeled

4 Sterility Test No growth

5 Absorption Capacity 100–200 µL

6 Break Strength Breaks cleanly at breakpoint

7 Edges No sharp edges or splinters after breaking.

R-Test raw material (Master Carton)

Specification:

Performance Test

Sr. #   
Parameters Specifications

1 Physical Appearance Clean & Smooth / No damage

2 Ply/ Thickness 6.3mm

3 Dimensions & specifications Length: 46cm  
Width: 40 Cm  
Height: 45 Cm  
Weight: 1.40 kg

4 Quality of Cotton Corrugated, strong, moisture-resistant

5 Water Resistance Sustainability No delamination or swelling 60 sec soaks

6 Surface Area 1.21 m²

7 Grammage 1157.02 g/m²

8 Fiber Integrity Should not disintegrate under light mechanical stress

9 Packing Capacity 40 R test boxes

R-Test raw material (Stool collection device)

Specification:

Sr. No Performance Test Specification

1 Visual Inspection No damage/cracks

2 Dimension device Length: 75.5  
Width: 13.5

3 Volume 5 ml

4 Leakage test No leakage

5 Cap Functionality Easy open/close

6 Label Adhesion Firmly attached

R-Test raw material (Alcohol Swab)

Specification:

Sr. No Performance Test Specification

1 Outer Packaging Intact, labeled

2 Sachet Seal No leakage, sealed properly

3 Label Info Batch, MFG, EXP present

4 Alcohol Content 70% IPA

5 Swab Size/Material 3x3 cm, lint-free, soft

6 Saturation Level Adequately moist, not dry/drip

7 Odor/Contamination Sharp alcohol odor, clean swab

Role Name Designation Signature Date

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