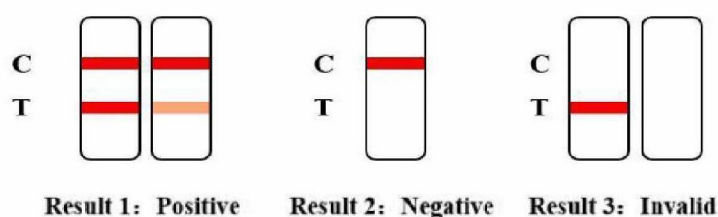


### Verification of testing procedures

#### 1. State whether the kit contains quality control products or quality control lines.

The kit does not contain quality control products, but contains quality control lines.

#### 2. If so, please explain how to determine and distinguish the test results of the quality control products/quality control lines, what are the reasons for the unqualified quality control? How to deal with unqualified quality control?



As shown in the Figure above, the quality control line is the C line. When there is C line, the test result will be normal, otherwise the test will be invalid.

#### Reasons for unqualified quality control

A. Mainly because the reagent is stored improperly or the tearing time is too long, and the humidity is too high, causing the reagent to become damp;

Solution: Test shall be performed as soon as possible after tearing.

B. The size of samples added is too small, resulting in incomplete chromatography;

Solution: Increase the sample size.

### 3. Inspection requirements for semi-finished and finished products.

#### 3.1 Inspection standards for semi-finished products

##### 3.1.1 Inspection standards:

(1) Appearance: Coated with the NC membrane, clean surface, no visible impurities or scratches; colloidal gold pad, no obvious stains or damage on the surface, and

uniform color.

(2)Compliance rate of positive references: The results shall be all positive.

(3)Minimum detection limit: The result L1 shall be positive, the result L2 shall be negative or positive, and the result L3 shall be negative.

(4)Compliance rate of negative references: The results shall be all negative.

(5)Fluidity: The flow velocity of fluid on the NC membrane shall be no less than 10mm/min.

### **3.1.2 Inspection methods:**

(1)Appearance: Visual inspection. The test result shall meet the requirements of 3.1.1.(1).

(2)Compliance rate of positive references: Test positive references (P1-P5) once respectively, and the results shall meet the requirements of 3.1.1.(2).

(3)Minimum detection limit: Test sensitivity references (L1, L2, L3) once respectively, and the results shall meet the requirements of 3.1.1.(3).

(4)Compliance rate of negative references: Test negative references (N1-N20) once respectively, and the results shall meet the requirements of 3.1.1.(4).

(5)Fluidity: Add 100µl of the sample diluent to the sample hole of the cassette. Start timing when the sample diluent flows through the lower end of the NC membrane, and stop timing when it flows to the upper end of the NC membrane; and calculate the flow velocity of the sample diluent. The test result shall meet the requirements of 3.1.1.(5).

## **3.2 Inspection standards for finished products**

### **3.2.1Inspection standards:**

#### **3.2.1.1Physical properties:**

(1)Appearance: All components of the kit shall be complete, and the outer packing box shall be intact; the label shall be clear and identifiable; the liquid component shall be clear and transparent, without precipitation or flocculation, and the aluminum foil bag shall be free from damage and air leakage.

(2)Flow velocity of liquid: The flow velocity of liquid shall be no less than 10mm/min.

(3)Width of the test strip: The width of the test strip shall be  $4.0\pm 0.1$ mm.

3.2.1.2Compliance rate of positive references: The results shall be all positive.

3.2.1.3Minimum detection limit: The result L1 shall be positive, the result L2 shall be negative or positive, and the result L3 shall be negative.

3.2.1.4Compliance rate of negative references: The results shall be all negative.

3.2.1.5Repeatability: The results J1 and J2 shall be positive, the result J3 shall be

negative, and the color rendering index of each reference shall be uniform.

3.2.1.6 Difference between lots: The results J1 and J2 shall be positive, the result J3 shall be negative, and the color rendering index of each reference shall be uniform.

### **3.2.2 Inspection methods:**

3.2.2.1 Physical properties:

(1) Appearance: Visual inspection, and the result shall meet the requirements of 3.2.1.1(1).

(2) Flow velocity of liquid: Add 100µl of purified water to the sample hole of the cassette. Start timing when the purified water flows through the lower end of the observation window, and stop timing when it flows to the upper end of the observation window; calculate the flow velocity of the purified water, and test it once. The test result shall meet the requirements of 3.2.1.1(2).

(3) Width of the test strip: Measure the width of the test strip once with a caliper, and the measurement result shall meet the requirements of 3.2.1.1(3).

3.2.2.2 Compliance rate of positive references: Test positive references (P1-P5) once respectively, and the results shall meet the requirements of 3.2.1.2.

3.2.2.3 Minimum detection limit: Test sensitivity references (L1, L2, L3) once respectively, and the results shall meet the requirements of 3.2.1.3.

3.2.2.4 Compliance rate of negative references: Test negative references (N1-N20) once respectively, and the results shall meet the requirements of 3.2.1.4.

3.2.2.5 Repeatability: Test precision references (J1, J2, J3) 20 times respectively, and the results shall meet the requirements of 3.2.1.5.

3.2.2.6 Difference between lots: Use 3 kits with different lot numbers to test precision references (J1, J2, J3) 20 times respectively, and the results shall meet the requirements of 3.2.1.6.