**Test Protocol for Accelerated Stability Test**

1. **Test Objective**

The accelerated stability test is performed to determine the valid period of the Advanced QualityTM One Step Ebola Test.

1. **Principle**

The test was based on the model Arrhenius Model of high temperature accelerated test. The acceleration factor is expressed as:

**AF=exp {(Ea/k)\* [(1/Tu)-(1/Ts)]+ (RHu^n-RHs^n)},**

where,

Ea: the start energy (eV),

K: the boltzmann's constant and k=8.6\*10E-5eV/K,

T: the absolute temperature,

RH: the relative humidity (in%) ,

The subscript u: the normal state,

The subscript s: was the acceleration state (e.g. Rhu ^ n referred to the n power of relative humidity under normal state),

n: generally n was 2.

Since the product is packed in aluminum foil bags, the humidity factor was not considered; the product is stored under 2-30℃, and the temperature of accelerated stability test is 50℃, then the acceleration factor AF = exp [(0.8 \* 10 ^ 5 / 8.6) \* (1 / (273 + 30) - 1 / (273 + 50))] = 6.69242, and it can be calculated that, for 24 months of valid period, the time for accelerated test at 50℃ is: 24 months/6.69242=3.586 months.

**3. Materials and Methods**

3.1 Materials

3.1.1 Advanced QualityTM One Step Ebola Test, lot number:

Lot #1: Lot #2: Lot #3:

3.1.2 LOD quality control 1, prepared by NP antigen 1 from Wuhan Institute of Virology, CAS;

LOD quality control2, prepared by NP antigen 2 (from Fitzgerald Industries):

3.2 Steps

3.2.1 Store the three batches of reagents at 50℃ for up to 4 months;

3.2.2 When stored at 50℃ for 0 months, 1 months, 2 months, 3 months, 4 months, the three batches of reagents were tested by the quality controls, to investigate products’ performance characteristics of quality controls.

3.2.3 Testing with quality controls:

The test result of LOD quality control 1 was positive;

The test result of LOD quality control 2 was positive;

**4. Test Results**

4.1 Test result of storage at 50℃

|  |  |  |  |
| --- | --- | --- | --- |
| Lot No.  Test result |  |  |  |
| 0 month storage |  |  |  |
| 1 months storage |  |  |  |
| 2 months storage |  |  |  |
| 3 months storage |  |  |  |
| 4 months storage |  |  |  |

**5. Conclusions**

