single use extraction solution Stability Research Protocol

1. Purpose

This study is intended to verify validate the real-time stability of single use extraction solution in order to make sure that it meets the requirements of clinical testing.

Moreover, transport simulation was carried out before accelerated aging, thus the results demonstrate transport stability as well.

2. Material

S.N.	Name	Lot	Code
1	Positive control	FDS01	/
2	negative control	FDN01	/
3	Single use extraction solution	XY2020090801	P1
4	Single use extraction solution	XY2020090802	P2
5	Single use extraction solution	XY2020090803	P3
6	SARS-CoV-2 Antigen Rapid Qualitative Cartridge	X2009052	/

3. Design

3.1 Take three lots of single use extraction solution, and carry out accelerated aging, transportation mode,

3.2 and then use negative control and positive control to test three times for each lot, analyze and summarize the test results.

3.3 Accelerate the aging of 3 lots of single use extraction solution, 10 vials each buffer, and conduct transportation simulation. Drop them from a height over one meter and 3 times to check if there is any damage to the packaging, liquid leakage, appearance changes and precipitation.

4. Method

4.1 Analysis of estimated real time (t_e)

(1) single use extraction solutions from three continuous lots were subjected to transport simulation by vibrating at 45℃ for 7 days , and stored at 45℃,55℃ and 65℃ respectively afterwards for accelerated aging.

(2) Test all performance items listed in table 4 after storing for 0, 14, 28, 42, 56,70 and 84days under each accelerated aging temperature respectively. Record the accelerated aging time duration(AATD) by which all results meet the acceptance criteria for each performance items.

(3) Find out the shortest accelerated aging time duration(AATD) under each accelerated aging temperature by which acceptance criteria were met for all stability performance items.

(4) Check if the AATD of 45℃ is 70 days. If it is 84 day, move to the next step. Otherwise jump

to step (7) and use the AATD of 45 ℃ to calculate estimated real time (t_e) .

(5) Check if the AATD of 55℃ is 70 days. If it is84 day, move to the next step. Otherwise jump to step (7) and use the AATD of 55 ℃ to calculate estimated real time (t_e) .

(6) Use the AATD of 65 ℃ to calculate estimated real time (t_e).

(7) Calculate the estimated real time (t_e)of stability according to Arrhenius reaction rate theory with formula (1) and (2) below:

t_e=AATD*AAR (1)

t_e: Estimated real time

AATD: Accelerated aging time duration

AAR: Accelerated aging rate

$AAR=Q10^{((Te-Ta)/10)}$ (2)

Ta: Ambient temperature

Te: Elevated temperature

Q10:Reaction Rate

Note 1: Q10 =2 is the most commonly used according to Arrhenius reaction rate theory and was what we used in our study.

Note 2: Since the shelf life storage temperature of single use extraction solution is 2~30 ℃, we used 22 ℃ (~75% of the upper limit) as ambient temperature (Ta)

(8) Check if the estimated real time (t_e) is no less than 730 days (24 months)

4.12 Physical examination

(1) Visually inspect the appearance of the extraction solution, if the appearance was transparent; and if materials were attached firmly; an if contents of the reagent kit were complete and there was no liquid leakage and extractables and leachable? The results that meet all the index record as "Yes", otherwise the result was record as "No".

(3) Record the up-mentioned results as **Physical Examination.**

4.1.3 analytical performance

(1) The study was performed testing devices in triplicate using single use extraction solution of 3 replicates by positive control and negative control respectively. At each test, 1 drop control was added to single use extraction solution and then tested as per IFU.

(2) Record the results of T lines and C lines respectively.

(3) Positive signals are recorded as "+M" and negative signals are recorded as "-" .

Note: For positive signals: F indicates a faint line and M indicate a moderate or strong line

(4) Check if there were "-" for C line, which indicates invalid test results(Ri). Count and record the total number of Ri.

(5) For results which are not invalid, check the “+” for T line of each test. If a “+” is observed on T line of a test, this test should be regard as a positive result (Rp), If a “-” is observed on T line of a test, this test should be regard as a negative result (Rn).

6) While testing the positive control, calculate the percentage of positive results (Rp) of testing each specimen versus the test number of Rt with following formula: Rp/ Rt, +/ +. Record the calculating result as the **Positive Confidence.**

(7) While testing the negative control, calculate the percentage of negative results (Rn) versus the total test number (Rt) with following formula: Rn/Rt, -/-. Record the calculating result as the **Negative Confidence.**

4.2 The determination of the result.

Record the longest accelerated time of the kits by which all test results meet the performance acceptance criteria as the accelerated time of the kits .