

## COVID-19 Antigen Test Stability testing

**Product name:** COVID-19 Antigen Test . **Product No:** RCCOVAG

**Test parameter:** COVID-19 Antigen rapid test reagents were performed for stability testing

**Kit lot number and expiry date:** Lot No: COVAG0921    Production date: 30.09.2020

Expiry date: 30.09.2021

**Performed by;** Ali İhsan Manav

**Test Method:** Accelerated Stability Testing

**Responsible person:** Dr Erdal Ataç

**Issue Date:** 30.12.2020

To determine the shelf life of the manufactured product the aging method was based on EP25A; Approved Guideline, Evaluation of Stability of In Vitro Diagnostic Reagent.

Accelerated stability studies were run at four different elevated temperatures. The results were analyzed by Arrhenius equation approach and used to predict shelf life for the product at its normal storage temperature condition at 25°C.

REDCELL COVID-19 Antigen Test kit stability studies are performed according to EN ISO 23640:

1. Accelerated Stability Study
2. Transport Simulation Stability Study
3. In use Stability Study

### 1. Accelerated Stability Study

Accelerated aging test was performed according to ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.

COVID-19 Ag Rapid Test and diluents are placed in an incubator with the temperature 58°C for 54 days with a safely margin. After completing the accelerated aging period, tests' performances are controlled; there is no loss in test performances.

Tests and diluents are stable at 58°C for 54 days. These data are plotted on an Arrhenius Plot and the shelf life of this product is determined to be at least 24 months from the date of manufacture.

The stability of the test is determined and validated to be 24 months.

### 2. Transport Simulation Stability Study

Transport simulation stability study is performed to control the effects of changes in transport conditions.

For upper limit, tests are exposed to 40-45°C for 3 days and for lower limit, tests are exposed to 2-30°C for 3 days. Exposures are done discontinuously to simulate worst case as well as determination of exposure time.

After completing period, tests' performances are controlled; there is no stability loss in test performances for both cases. Changes in transport conditions don't affect test performance with short time exposure.

### **3. In use Stability Study**

In use stability study is performed in order to control the effects of high humidity levels during use of the tests.

Environmental conditions are selected as follows: temperature of 20°C to 30°C, relative humidity of 30% to 70%. COVID-19 Ag Test Kits are stored for 1 hour after opening the inner package. After completing period, tests' performances are controlled; there is no loss in test performances.

In response to this study, related warning is added to Instruction for Use. Test should not be exposed to high humidity except for the test application period. Test should be used as soon as inner package is opened.

**Performed by**

**Responsible person**

Ali İhsan MANAV

Dr Erdal ATAÇ