$VIDII\Delta$

Vidiia Hunter Rapid Extraction Device (VH-RED)/Snap collect ReadyGo[™] Instructions for Use (IFU)

For in-vitro diagnostic use

This product uses proprietary IP which is owned by ReadyGo Diagnostics Ltd., UK.

This product uses proprietary IP which is owned by ReadyGo Diagnostics Ltd., UK.

$VIDII\Delta$

Please read these instructions thoroughly before you use the device.

INTENDED USE

The Vidiia Hunter rapid extraction device (VH-RED) standardises sample collection and processing prior to conducting molecular tests and analysis.

It is intended to be used for the collection and processing of saliva, sputum and swab samples for subsequent analysis via molecular techniques such as Loop-mediated isothermal amplification (LAMP), Polymerase Chain Reaction (PCR) or Next Generation Sequencing (NGS). Other biological samples may be collected and processed using the VH-RED, but the process and validity of alternate sample types would require local validation.

SUMMARY AND EXPLANATION OF THE DEVICE

The VH-RED is designed to allow simple collection and processing of a saliva, sputum and swab samples prior to conducting a molecular assay. The device consists of a tip that will draw up a known volume of sample (65µL). This tip is pretreated with a chemistry that breaks open microorganisms on contact releasing nucleic acids (DNA or RNA).

Sample collection method will depend on the sample type:

- Saliva and sputum: the tip of the device is dipped in the sample for 30 seconds.

- Swab: the swab is placed in liquid (molecular water) and rotated 4 times, before the device is dipped in this liquid for 30 seconds.

- Other: follow local guidelines for collection of sample type of choice

After collection the sample is deposited into the test or collection tube by breaking the 'snap-valve' and squeezing through the liquid buffer.

CONTENTS

VH-RED devices as described below. Single use devices only.

COLLECTION INSTRUCTIONS

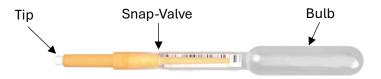
Wear lab coat and gloves before opening the sampler package.

Use immediately upon removal from the package.

Make sure the device and any components do not touch any foreign object or surface before or after collection.

$VIDII\Delta$

Remove the collection device from its packaging and check its integrity.



- 1. Dip the tip of the sampler in the sample for 30 seconds.
- 2. Break the Snap-Valve by bending the neck of the tube until you hear it snap.



Make sure that the valve is

properly broken by bending the neck backward and forward 2 more times and by checking that the bulb of the sampler is inflating.

3. Gently squeeze the bulb to push through the extracted material from the wick and deposit the contents drop-wise into a RNAse/DNAse and DNAfree collection tube.



4. Proceed with your assay immediately or store the sample at -20 or -70°C until required.

STORAGE

The VH-RED are to be stored at room temperature, between 15°C and 25 °C.

The sample should be processed immediately after extraction, however once it is dispensed into a collection tube, it can be stored at either -20°C or -70°C for longer term storage. Avoid repeated freeze-thaw steps as this will lead to precipitates.

DISPOSAL

$VIDII\Delta$

Dispose according to local guidelines dependent on sample type. Collected specimen is potentially infectious and should be handled with appropriate biosafety practices.



Single Use



Temperature range



Consult instructions before use



Manufactured by ReadyGo Diagnostics Ltd