













## WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose. In the event of performance changes or product malfunction, please contact manufacturer.

## BIBLIOGRAPHY

1. Lips P. Vitamin D physiology. Prog Biophys MolBiol, 92(2006) 4-8.
2. Holick MF, C Hen TC. Vitamin D deficiency a worldwide problem with health consequences. Am J Clin Nutr, 87(2008)1080-1086.
3. Hollis Editorial: The Determination of circulating 25-Hydroxyvitamin D. No Easy Task BW J Clin Endocrinol Metab, 2004, 89(7): 3149-3151.
4. Yanji. Progress of vitamin D and cardiovascular diseases, journal of clinical drug therapy, 2012, vol. 10, No. 4.
5. Vitamin D and cancer: research status and prospects, vol. 25, no. 2, February 2013, life sciences.

## SYMBOL KEYS

 Temperature Limitation	 Consult Instructions for use	 Date of Manufacture	 Do not reuse
 Manufacturer	 IVD In vitro Diagnostic Medical Device	 This side up	 Use by
 Contains sufficient for <n> tests	 REF Catalogue Number	 LOT Batch Number / Lot Number	 DEVICE Device



Manufactured by:

**Zephyr Biomedicals**

A Division of Tulip Diagnostics (P) Ltd.

M 46-47, Phase III B, Verna Industrial Estate, Verna, Goa - 403 722, INDIA.

Regd. Office: Gitanjali, Tulip Block, Dr. Antonio Do Rego Bagh, Alto Santacruz, Bambolim Complex P.O., Goa - 403 202, INDIA.

# **FIAcheck™**

## **25-OH-Vitamin D**

Fluorescence Immunoassay for Quantitative determination of 25-OH-Vitamin D in Human Serum, Plasma and Whole blood

**DEVICE**

FOR IN VITRO DIAGNOSTIC USE ONLY  
Store at 4°C to 30°C

## INTENDED USE

**FIAcheck™ 25-OH-Vitamin D** Fluorescence Immunoassay is intended for the in-vitro quantitative measurement of 25-OH-Vitamin D in human serum, plasma and whole blood.

## INTRODUCTION

Vitamin D is a steroid hormone responsible for enhancing intestinal absorption of calcium and the regulation of its homeostasis. There are two common forms of Vitamin D: Vitamin D2 and D3. Vitamin D3 is naturally produced in the human skin through the exposure to ultraviolet light and Vitamin D2 is mainly obtained from plant foods. Vitamin D is transported to the liver where it is metabolized to 25-hydroxy Vitamin D. In medicine, a total 25-hydroxy Vitamin D test is used to determine Vitamin D concentration in the body. The blood concentration of 25-hydroxy Vitamin D (including D2 and D3) is considered the best indicator of Vitamin D status.

## PRINCIPLE OF THE TEST

**FIAcheck™ 25-OH-Vitamin D** is based on principle of agglutination of antibodies/anti-sera with respective antigen in immuno-chromatographic format using fluorophores as signal generators. The **FIAcheck™ 25-OH-Vitamin D** test device is coated with immobilized 25-OH-VD antigen on the test line, sheep anti chicken IgY in control line and a mixture of 25-OH-VD sheep monoclonal antibody and Chicken IgY labeled with fluorescent microspheres on the binding pad. 25-OH-VD in sample binds to the 25-OH-VD sheep monoclonal antibody labeled with fluorescent microspheres in the binding pad.

The fluorescent labeled Ag-Ab complex moves forward due to capillary action and is captured by the immobilized 25-OH-VD antigen forming a double antibody sandwich and produces the test line. Chicken IgY labelled with fluorescent microspheres binds with sheep anti chicken IgY to produce the control line. When the **FIAcheck™** test device is inserted in the **FIAcheck™** analyzer, it scans both the test line and control line. The ratio of the two fluorescence values is used to calculate the concentration of the analyte present in the sample.

## MATERIALS AND COMPONENTS

**Materials provided with the test kits:**

- **FIAcheck™ 25-OH-Vitamin D** test device in a sealed pouch with desiccant and special tip.
- QR Code card for calibration.
- Sample Diluent. Ready to use.
- Empty vials for sample dilution.

**Materials required but not provided**

- Precision pipettes: 5µl, 100-1000µl
- Disposable pipette tips
- Disposable Gloves
- **FIAcheck™** Analyzer (Time Resolved Fluorescence Immunoassay Analyzer)
- Digital Thermometer
- Stopwatch

## STORAGE AND STABILITY

1. **FIAcheck™ 25-OH-Vitamin D** kit is stable at 4°C to 30°C upto expiry date printed on the label. DO NOT FREEZE.
2. **FIAcheck™** Test device should be used within 30 minutes once the foil pouch is opened.
3. If the colour of the desiccant has changed from blue to pink or colourless at the time of opening the pouch, kindly discard the device and use another device.
4. Once opened, the sample diluent can be stored between 4°C to 30°C for remaining duration of shelf life.

## SAMPLE COLLECTION

1. Only human Serum/Plasma and whole blood sample should be used. Other bodily fluids and samples may not give accurate result.

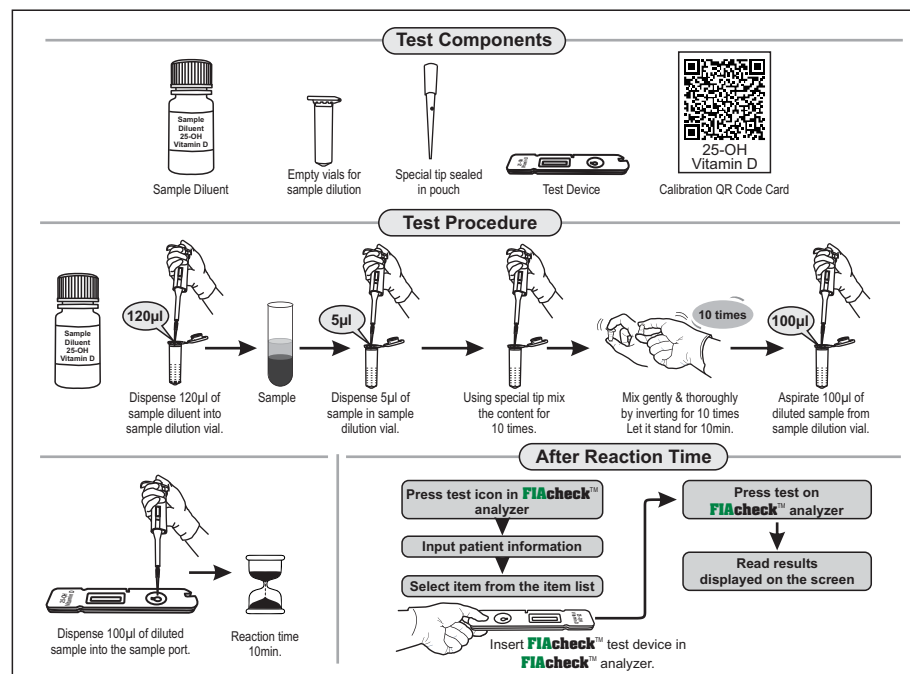
- Plasma can be anti-coagulated with Heparin and Sodium citrate or Tri sodium citrate under aseptic conditions.
- Whole blood can be anti-coagulated with EDTA under aseptic conditions.
- The test should be performed within 4 hours after the sample collection at room temperature.
- Avoid grossly hemolytic, lipemic or turbid serum/plasma samples. Do not use clotted or hemolysed whole blood samples.
- Preferably use fresh samples. Serum/Plasma samples can be stored for 3 days at 2°C to 8°C and if more than 3 days, they should be stored at -20°C. Whole Blood samples should be used immediately and should not be stored.
- The sample should be recovered to room temperature (18°C to 30°C) before testing. Avoid repeated freezing and thawing of samples as it can affect the test values.
- Samples containing precipitate or particulate matter should be clarified by centrifugation prior to use.
- Samples should be free from particulate matter and microbial contamination.

#### PRECAUTIONS

- Only for In vitro diagnostic use.
- Bring all reagents and samples to room temperature before use.
- After the test device is removed from the sealed pouch, it should be used immediately or within 30 minutes of opening the pouch.
- Do not reuse the tested **FIACheck™** device. Do not use sample dilution vial for more than one sample.
- Do not use damaged **FIACheck™** test device or pouch.
- All samples should be considered potentially infectious and discarded appropriately as per Standard Bio-Safety guidelines.
- Do not use kit after the expiry date.
- Do not mix components of one kit with another.
- Always use new tip for each sample and reagent.
- Scan QR code card specific to the lot you are using.
- Ambient temperature of testing environment directly impacts the accuracy of results. Ideal working temperature is 18°C to 30°C.
- It is highly recommended to mix the sample diluent and sample mixture thoroughly by gently inverting the vial 10 times. (Refer pictorial presentation.)
- It is not recommended to use the sample diluent and sample mixture beyond specified time.
- The **FIACheck™** test device should be read immediately after the specified reaction time. Delay in reading might affect the accuracy of results.
- The **FIACheck™** test device should be used only in conjunction with **FIACheck™** analyzer for accurate and reliable results.

#### TEST PROCEDURE

- To calibrate the **FIACheck™ 25-OH-Vitamin D** kit, scan the QR code card provided with the kit.
- Dispense **120 µl** of sample diluent into the empty sample dilution vial.
- Add **5 µl** of the test sample into the sample diluent, and mix thoroughly.
- Using the special tip mix the content for 10 times.  
Note: It is required to use the special tip which is sealed in the sealed pouch.
- Close the lid of the sample dilution vial, label with sample identity and mix the content of the vial by gently inverting it for 10 times, let it stand for 10 minutes.
- Remove **FIACheck™ 25-OH-Vitamin D** test device from sealed pouch and place it horizontally on a clean table, label the device with sample identity.
- Dispense 100 µl of the above mixture on the sample port in the **FIACheck™ 25-OH-Vitamin D** test device.
- Incubate at room temperature (18°C to 30°C) for **10 minutes**.
- After 10 minutes, insert the test device immediately into the **FIACheck™** analyzer and read results.



#### Expected Range

**Reference Range: >30ng/mL**

25-OH-Vitamin D concentration is determined using samples obtained from 200 apparently healthy individuals. It is recommended that each laboratory establish its own reference range for the population it serves.

#### PERFORMANCE CHARACTERISTICS

- Measuring Range: 5.0-70ng/mL.
- Lower Detection Limit: ≤5.0ng/mL.
- Upper Detection Limit: ≥70ng/mL.
- Accuracy: Based on comparison experiments, the relative standard deviation of ≤15%, and the correlation coefficient of  $r \geq 0.990$  was observed.
- Within-Run Precision: ≤15%.
- Between-Run Precision: ≤15%.
- Hook Test: No hook effect with high concentration sample. Hook test was conducted with reference material exceeding the upper limit of measuring range, and the detection result was greater than the upper limit of detection.
- In an internal Study, **FIACheck™ 25-OH-Vitamin D** was evaluated against commercially available licensed kit with 100 random clinical samples and **FIACheck™ 25-OH-Vitamin D** has demonstrated 100% clinical correlation with the commercially available licensed kit.

25-OH-Vitamin D Levels	No. of samples	<b>FIACheck™ 25-OH-Vitamin D</b>	EIA 25-OH-Vitamin D
Normal	80	80	80
Low	8	8	8
High	12	12	12

- In an external Study, **FIACheck™ 25-OH-Vitamin D** has been evaluated by a NABL accredited lab against their reference method. In this evaluation **FIACheck™ 25-OH-Vitamin D** has demonstrated 100% correlation with the reference method.

\*Data file: Zephyr Biomedicals (A Division of Tulip Diagnostics (P) Ltd).

#### LIMITATIONS OF THE ASSAY

- As with all diagnostic tests, a definite clinical diagnosis should not be based on the results of a single test but should only be made by the physician after all clinical and laboratory findings have been evaluated.
- This kit is only for human serum, plasma and whole blood.