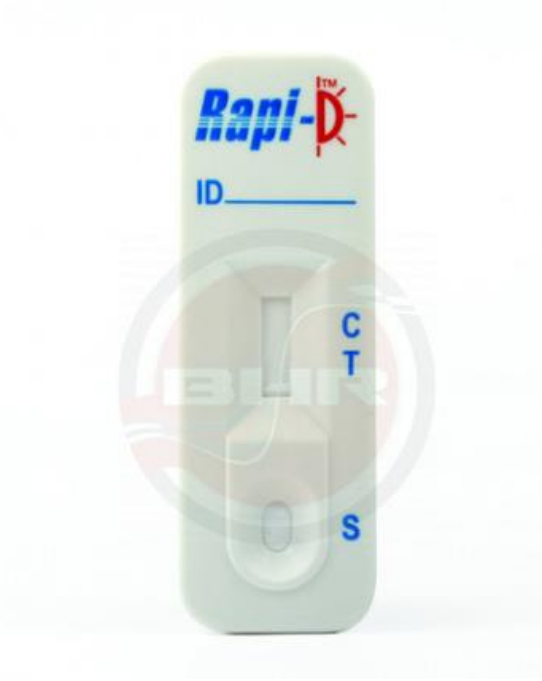
Rapi-D One-Step Whole Blood Vitamin D Test

The Rapid-D "Sandwich" Immunochromatographic Test is for the Semi-Quantitative, (or Quantitative with the aid of the Rapi-D Reader) detection of total 25-OH Vitamin D in human whole blood (finger-prick sample). This assay provides a preliminary diagnostic test result in the screening for Vitamin D deficiency.



Vitamin D – why is the test needed?

1. Millions of people in the UK are Vitamin D deficient as shown by the Molloy study attached to this mail, and by the SACN (Scientific Advisory Committee on Nutrition) report referenced below. Many health risks are exacerbated by low vitamin D levels in the body – mainly issues related to musculoskeletal health - bone strength. Among these conditions are:
    a. Rickets
    b. Osteoporosis
    c. Osteomalacia

2. Some 3 million people in the UK have osteoporosis, according to the National Osteoporosis Society.

3. Every year, the population experiences more than 300,000 fragility fractures, often after a minor bump or fall – so, ensuring optimal bone health is important throughout life.

4. According to NICE, 8-24 per cent of children have low levels of vitamin D. In addition to helping the skeleton resist the rough-and-tumble of childhood, vitamin D also helps to reduce the risk of serious diseases.

5. A study done in Ireland shows that greater than 70% of the population tested in Galway showed deficiency in vitamin D levels at the height of the summer months! Please find the study done by Molloys Lifestyle Group in Ireland attached for your review.

6. **SACN – The Scientific Advisory omission on Nutrition -** is now recommending everyone in the general UK population aged 4y and above an RNI (Reference Nutrient Intake) vitamin D supplement of 10 µg/day (400 IU/day), throughout the year. The RNI of 10 µg/d (400 IU/d) for the general UK population includes pregnant and lactating women and population groups at increased risk of vitamin D deficiency. Since there was insufficient data to set RNIs for children aged under 4y, the recommended intake for this age group is 8.5-10 µg (340-400 IU) per day for all infants aged under 1y, and 10 µg for ages between 1 and up to 4y. The RNI/Safe Intakes have been developed to ensure that the majority of the UK population has a satisfactory vitamin D status (as measured in the blood) throughout the year, in order to protect musculoskeletal health.

7. The proportion of the population (by age) with a plasma 25(OH) D concentration < 25 nmol/L was: 2-8%, 5m-3y; 12-16%, 4-10y; 20-24%, 11-18y; **22-24%, 19-64y**; 17-24%, ≥ 65y and above. Nearly **40% of institutionalised adults** had a plasma 25(OH) D concentration < 25 nmol/L.

8. PHE advises that in spring and summer, the majority of the population get enough vitamin D through sunlight on the skin and a healthy, balanced diet. During autumn and winter, everyone will need to rely on dietary sources of vitamin D. Since it is **difficult for people** to meet the 10 µg recommendation from consuming foods naturally containing or fortified with vitamin D, people should consider taking a daily supplement containing 10 µg of vitamin D in autumn and winter.

9. People whose skin has little or no exposure to the sun, like those in institutions such as care homes, or who always cover their skin when outside, risk vitamin D deficiency and need to take a supplement throughout the year. Ethnic minority groups with dark skin, **from African, Afro-Caribbean and South Asian** backgrounds, may not get enough vitamin D from sunlight in the summer and therefore should consider taking a supplement all year round.

How good is the Rapi-D One-Step Vitamin D Test?

1. Please find the study attached comparing the Rapi-D test against a gold standard (reference test)– the Siemens Advia Laboratory system. The results from this point of care test compare very well against the lab standards. Please see attached document.

2. **DEQAS** – Vitamin **D** **E**xternal **Q**uality **A**ssessment **S**cheme based in UK (www.deqas.org) was established in 1989 with the objective of ensuring the analytical reliability of Vitamin D Assays globally (1200 Participants in 54 countries). DEQAS works in collaboration with NIST (US National Institute of Standards & Technology) and CDC's VDSCP (Vitamin D Standardization-Certification Program). Today, all

major Vitamin D Assay manufacturers participate in this program. DEQAS Certificate is accepted by the College of American Pathologists (CAP) as a Proficiency Testing scheme for 25OHD assays