



RAPID TEST VITAMIN-D IN WHOLE BLOOD

Within 10 minutes, Test4DTM lets you know if you are vitamin D deficient or not, with a simple “yes or no” response.

INTENDED USE

Test4DTM is a rapid chromatographic immunoassay for the detection of vitamin D levels in human blood at a cut-off concentration of $32\text{ng/mL} \pm 6\text{ng/mL}$ ($80\text{nmol/L} \pm 15\text{nmol/L}$). This assay is designed for qualitative determination of Vitamin D and may be used in the point of care setting.

This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. The performance characteristics of this assay have not been established in a pediatric population.



Test4DTM will show 2 dark lines (as pictured) if you are vitamin D deficient. Only 1 line (control line) will appear if your levels are sufficient

PERFORMANCE CHARACTERISTICS

• Specificity

No interference and cross reactivity was observed with human serum albumin, cholesterol and vitamin A.

• Sensitivity

The sensitivity level of Test4D is $80\text{nmol/L} \pm 15\text{nmol/L}$ ($32\text{ng/mL} \pm 6\text{ng/mL}$)

• Accuracy

The accuracy of the “Test4D” test was evaluated in comparison to Diasorin Liason Assay (FDA Approved) at a cut off concentration of $80\text{nmol/L} \pm 15\text{nmol/L}$. Twenty five human blood samples were tested and results from “Test4D” were found to be in agreement with Diasorin Liason Assay.

MATERIALS PROVIDED

Each kit contains:

1. Test4D test device
2. Disposable transfer pipette
3. Lancet
4. Buffer Vial
5. Desiccant
6. Package Insert

AKSA MEDICAL, SPOORAKKERWEG 11, 5071 NC, UDENHOUT, THE NETHERLANDS

TEL: +31 (0) 13 590 58 00, FAX: +31 (0) 13 590 57 44,

E-MAIL: INFO@AKSAMEDICAL.COM WWW.AKSAMEDICAL.COM