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 32ng/mL±6ng/mL (80nmol/L±15nmol/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.

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 80nmol/L±15nmol/L
  (32ng/mL ± 6 ng/mL)

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

MATERIALS PROVIDED
Each kit contains:
1. Test4D test device
2. Disposable transfer pipette
3. Lancet
4. Buffer Vial
5. Desiccant
6. Package Insert

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