TEST FOR VITAMIN A

Test 4A

RAPID ONE STEP DETECTION OF VITAMIN A

PACKAGE INSERT – READ BEFORE USE

IVD | 8 °C – 30 °C | Σ 25

REF | Cat # NSA – QN - 25

INTENDED USE:

Test4A is a rapid chromatographic immunoassay for the quantitative detection of Vitamin A levels in human blood/serum.

This product is meant for professional use only. This assay provides a preliminary screening result. The performance characteristics have not been established in a pediatric population.

PRINCIPLE:

Test4A is based on the principle of a competitive enzyme immunoassay. The assay is based on the competition of Vitamin A present in blood/serum sample and Vitamin A present on the test line for fixed number of antibody-gold conjugate. Depending upon the concentration of Vitamin A in blood/serum, there will be free antibody-gold conjugate molecule that will bind to Vitamin A on the test strip and will show a colored line in test line zone. A control line is present in the test window to work as procedural control.

MATERIALS PROVIDED:

Each package contains:
1. 25 Test4A individually packed test devices
2. 25 blood lancets
3. 25 transfer pipettes
4. 1 Buffer Vial containing Chase Buffer (5.0 mL)
5. 1 Package Insert and 1 RFID card

MATERIALS REQUIRED BUT NOT PROVIDED:

□ Timer or clock
□ Cube reader

PROCEDURE:

1. Remove the cassette from the sealed pouch and place it on a hard flat surface with the view window facing up. Ensure cassette and kit components are at room temperature before using.

2. Twist the lancet cap off and press into tip of finger until an audible click is heard. Gently squeeze the bulb of the pipette and then touch the blood drop with the tip until blood reaches the black mark (10 µL). Place sample directly into the sample well by releasing pressure from bulb and careful not push the tip in membrane with force.

3. Add 2 full drops of Chase Buffer into the buffer well (Do not move the cassette after addition of buffer).

4. Let the cassette sit for 10 minutes and immediately read your results by cube reader as shown below.

TEST RESULTS AND REPORT:

1. After 10 minutes, place the adapter on top of the test cassette with the ridge on bottom right as shown with arrow.

Place the cube reader on top of the adapter correctly. Press the black button on reader, it will display "ON".

2. Press the button again and display will read "RFID."

3. Place the Lot Specific RFID card on the cube reader.

4. Following a beep signal, "TEST" is displayed.

5. Press the black button, it will display "RUN."

6. The results will scroll horizontally on the display screen in µmol/L. Note the results.

7. The reader will switch off automatically after 50 seconds.

PERFORMANCE CHARACTERISTICS:

Detection Range: The Detection range of TestD™ is from 0.25 µmol/L to 4.0 µmol/L.
Accuracy: The accuracy of test was determined using 25 serum samples in comparison with HPLC on an Agilent system. The comparison result showed a correlation coefficient of 95%. The accuracy was also evaluated using blood samples in comparison with corresponding serum samples. The comparison result showed a correlation coefficient of 96%.
Precision: Precision measurements were performed to evaluate repeatability. Precision studies were conducted using the samples that had a wide range of the assay. Precision was found to be 10-12% CV at all levels tested
Specificity: No interference and cross reactivity was observed with added high concentrations of Vitamin D, bilirubin, triglycerides and cholesterol.

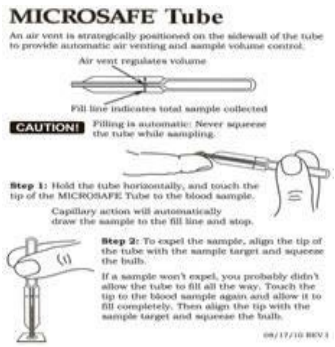
PRECAUTIONS:

For *in vitro* diagnostic use only.
1. Reagents and device must be at room temperature (8 ºC – 30 ºC).
2. Do not use if test device packaging is open or damaged.
3. Do not use the product beyond expiration date. Handle all specimens as potentially infectious.
4. Read test results at 10 minutes. Results may deteriorate and may not be consistent after 10 minutes.

STORAGE AND STABILITY:

The test device should be stored at 8 °C – 30 °C and will be stable until the expiration date. The product is humidity sensitive and should be used immediately after being open.

INSTRUCTIONS TO USE LANCET AND BLOOD TRANSFER PIPETTE:
Alternative lancet and pipette can be used



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