



## **VBL IgE Whole Blood/Serum Cassette Test**

### **Name and Intended Use**

The VBL IgE Whole Blood/Serum Cassette Test qualitatively detects elevated human immunoglobulin E (IgE) levels in human whole blood, serum and plasma. The results obtained are of a preliminary nature.

### **Summary of Test**

Immunoglobulin E is an antibody isotype associated with allergies. Through an interaction with mast cells and basophils, it causes the release of histamine. Histamine is the causative agent of allergic reactions such as sneezing, skin hypersensitivity (rash), vomiting and diarrhea. While all adults have a basal level of less than 150 IU/ml IgE present in their whole blood or serum, those who display frequent allergies have an elevated concentration of IgE. The VBL IgE Whole Blood/Serum Cassette Test identifies elevated levels of IgE in whole blood or serum samples.

### **Principle of Procedure**

The VBL IgE test is a colloidal gold/antibody complex based immunoassay designed for the qualitative determination of IgE in serum or blood samples.

To perform the VBL IgE test, whole blood, plasma or serum is dispensed into the sample well of the cassette. IgE that is present in the serum is bound by antibody-gold conjugate forming an antibody-antigen complex. This complex migrates to the test zone (T) of the window where it is captured by another anti-IgE antibody immobilized on the membrane, forming a pink-coloured line. The rest of the particles migrate to the control zone (C) of the window, where gold conjugate is captured by an immobilized antibody, producing a pink-coloured control line even in the absence of IgE.

At basal levels (normally below 150 IU/ml in adults), a faint signal appears at the test zone. When elevated levels of IgE are present, a much darker signal will appear at the test zone (see Figure 2a).

### **Precautions**

1. For in-vitro diagnostic use only.
2. Do not use beyond the expiry date indicated on packaging.
3. Dispose of all used test devices in proper container.

## Storage and Handling

- \* store the VBL IgE Test at room temperature
- \* the shelf life of the test is indicated on the test pouch
- \* wear disposable glove while handling specimens and thoroughly wash hands afterwards. All patient samples should be handled as if they are potentially infectious.
- \* if serum or plasma samples have been stored in the refrigerator, allow them to return to room temperature before testing

## Test Procedure

The use of a 150 IU/ml IgE standard is recommended to verify correct positive result. Use the standard in the same manner as a specimen by following the test procedure.

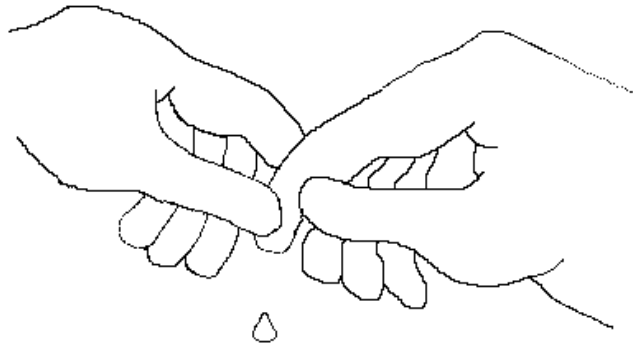
### 1) Whole Blood Sample

*a) from Vein:*

1. Collect blood in tubes containing an anticoagulant such as EDTA or Heparin and mix well. Use only fresh blood.
2. Bring both the test device and whole blood sample to room temperature.
3. Remove the test device from the pouch.
4. Dispense 160 uL (or 4 drops) of whole blood into the sample well.
5. At 10 minutes, read the results. Do not interpret the results after this time.

*b) from Finger Prick:*

1. Bring the test device to room temperature.
2. Remove the test device from the pouch.
3. Obtain the whole blood sample by pricking the finger with a lancet. Squeeze the finger to force fresh blood out, allowing one hanging drop of blood to *fall freely* on to the sample well. *Hold the finger above the cassette, do not let it touch the sample well.* (see Figure 1).
5. Wait one minute, add 80 uL (or two drops) of chaser buffer.
6. At 10 minutes, read the results. Do not interpret the results after this time.



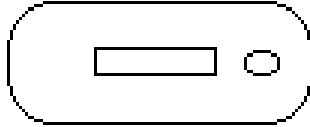


Figure 1

2) Serum or Plasma Sample

1. Bring both the test device and sample to room temperature.
  2. Remove the test device from the pouch.
  3. Dispense 120 uL (or three drops) of the serum into the sample well.
  4. At 10 minutes, read the results. Do not interpret the results after this time.
- Note: No chaser buffer is required.

**Interpretation of Results**

A positive or negative result is determined by comparing the color intensity of the test line with that of the cassette run in the 150 IU/mL IgE standard.

Refer to *Figure 2*:

- a. POSITIVE:** The test band's color intensity is equal to or darker than that of the cassette run in the 150 IU/ml IgE standard. The color intensity of the test band reflects the concentration level of IgE
- b. NEGATIVE:** The test band's color intensity is lighter than that that of the cassette run in the 150 IU/mL IgE standard, meaning that the IgE level is below the 150 IU/ml cutoff.
- c. INVALID:** If there is no rose-color band visible in the control window, then the test result is invalid. It is recommended that the specimen be retested.

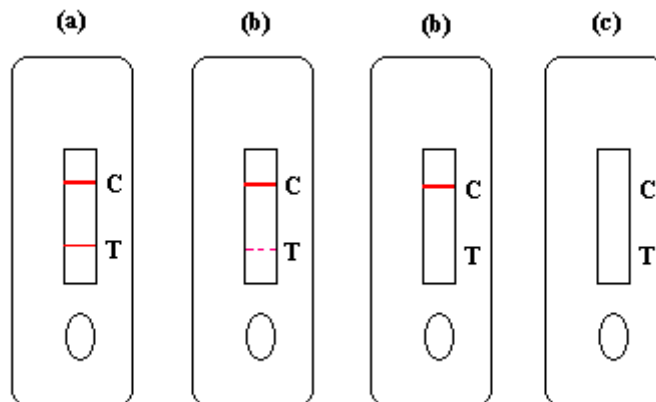


Figure 2 – Test Results

## **Test Limitations**

1. A positive result indicates elevated levels of IgE. It does not determine the absolute concentration of IgE
2. A basal level in adults is normally below 150 IU/ml and level at 100 IU/ml will show a very faint signal at the test zone.