INTRODUCTION
Carcinoembryonic Antigen (CEA) is a tumour-associated antigen characterised as an oncofetal glycoprotein. CEA is expressed in a variety of malignancies, particularly pulmonary or gastrointestinal tumours (e.g. colon cancer, liver cancer and lung cancer). CEA normally occurs in foetal gut tissue with detectable serum levels essentially disappearing after birth. Therefore, elevated levels of CEA can be of significant value in the diagnosis of primary carcinomas. In addition to qualitative assessment, CEA testing plays an important role in the monitoring of cancer patients. Clinical evidence indicates that CEA levels can serve as predictive markers in both pre- and post-treatment cancer. Progressive elevation of CEA may signal tumour recurrence 3-36 months before clinical evidence of metastasis. Persistently elevated circulating CEA following treatment is strongly indicative of occult metastatic and residual diseases and deficient therapeutic response.

INTENDED USE
The ulti med CEA test is a chromatographic immunoassay for the rapid qualitative determination of CEA in whole blood, serum or plasma. The sensitivity of this test is 5 ng/ml. For professional use.

MATERIALS PROVIDED
- CEA test cassette (20 per kit box)
- Pipettes (20 per kit box)
- 1 Instruction per kit box

MATERIALS REQUIRED, BUT NOT PROVIDED
- Stop watch
- Alcohol pads
- Lancets

PRECAUTIONS
The ulti med CEA test kit must be stored at 4-30°C. The test device is sensitive to humidity as well as to heat. Perform the test immediately after removing the test device from the foil pouch. Do not use it beyond the expiration date.

PROCEDURE OF THE TEST
1. Remove the test cassette from the foil pouch, and place it on a flat, dry and clean surface.
   Note: Once the test cassette is removed from the pouch, it should be used as soon as possible.
2. Clean the second or third finger by rubbing it with an alcohol pad.
3. Collect blood from the patient’s finger. Massage near the puncture site to obtain blood flow.
4. Add 100 µl of blood (6 drops) into the Sample Well (S). Before adding the next drop, the previous one should be fully absorbed.
5. As the test begins to work, you will see a purple coloured front move across the Result Window in the centre of the test cassette.
6. Interpret test results at 15 minutes. Do not interpret test results after more than 20 minutes.
Caution: The above interpretation time is based on reading the test results at room temperature of 15 to 30°C. If your room temperature is significantly lower than 15°C, then the interpretation time should be properly increased.

INTERPRETATION OF THE TEST
- A coloured line will appear in the section of the Result Window marked with “C” to show that the test is working properly. This is the Control Line.
- The section of the Result Window marked with “T” indicates the test results. If another coloured line appears in this section, it is the Test Line.
Positive Result: The presence of two coloured lines ("T" and "C") in the result window regardless of which line appears first indicates a positive result (Figure 1).

Note: Generally, the higher the CEA level in the specimen, the darker the "T" line colour will be. When the AFP level is close to but still within the sensitivity limit of the test, the colour of the "T" line will be very faint.

Negative Result: The presence of only one purple coloured line ("C"), in the Result Window, indicates a negative result (Figure 2).

Invalid Result: If after performing the test, no coloured line or only a "T"-line is visible in the Result Window, the result is considered invalid. Some causes of invalid results are not following the directions correctly or usage of an expired test (Figure 3 and 4).

Note: A positive result will not change once it has been established at 20 minutes. However, in order to prevent any incorrect results, the test result should not be interpreted after more than 20 minutes. When interpreting test results after more than 20 minutes, the sensitivity of the test will be higher than 5 ng/ml. Some specimens with a high rheumatoid factor concentration may yield a non-specific positive result.

LIMITATIONS OF THE TEST
Although the Finger Stick CEA Test is very accurate in detecting CEA, a low incidence of false results can occur. Other clinically available tests are required if questionable results are obtained. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

WARNINGS
- The same lancet needle should be used for one person only and should not be shared with another person, because the used needle is a biohazard.
- Decontaminate and dispose of all specimens, reaction kits, lancet needle and potentially contaminated materials, as if they were infectious wastes, in a biohazard container.
- Do not use the kit after the expiration date.
- Do not use test if pouch is torn or damaged.
- For in vitro diagnostic use only.

REFERENCES

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Contents sufficient for &lt;n&gt; tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>IVD</td>
<td>For in vitro diagnostic use only</td>
</tr>
<tr>
<td></td>
<td>Lot no.</td>
</tr>
<tr>
<td>2</td>
<td>For single use only</td>
</tr>
<tr>
<td></td>
<td>Use by</td>
</tr>
<tr>
<td>3</td>
<td>Read instructions for use</td>
</tr>
<tr>
<td></td>
<td>Store at</td>
</tr>
</tbody>
</table>