

5

The following charts, one for each of the formulations, illustrates the result of the tests.

CHART II

| RESULTS OF TEST WITH FORMULATION I |                        |   |                        |   |
|------------------------------------|------------------------|---|------------------------|---|
| Room Temp.                         | 92% Rel. Humidity      |   | 56° C.                 |   |
| 15 hrs. and 33 hrs. differentiates | 15 hrs. differentiates | 33 hrs. slight discoloration but differentiates | 15 hrs. differentiates | 48 hrs. slight discoloration but differentiates |

Conclusion: Chart No. II demonstrates that Formulation I was temperature stable, humidity stable, and properly differentiated among the various levels or amounts of ketones.

CHART III

| RESULTS OF TEST WITH FORMULATION II (NO TRIS) |                                |                        |                                |   |
|---|--------------------------------|------------------------|--------------------------------|---|
| Room Temp.                                    | 92% Rel. Humidity              |                        | 56° C.                         |   |
| 15 hrs. differentiates                        | 33 hrs. will not differentiate | 15 hrs. differentiates | 33 hrs. will not differentiate | 15 hrs. and 48 hrs. no differentiation at lower ketone levels |

Conclusion: Chart III demonstrates that Formulation II provides satisfactory results only if used promptly and at room temperature. Both the room temperature and the high humidity strips lost the ability to differentiate among various levels of ketones after 33 hours and the test strips subjected to elevated temperature lost the ability to differentiate among the lower levels of ketones.

CHART IV

| RESULTS OF TEST WITH FORMULATION III (NO TAPS) |                           |                         |                        |                            |
|--|---------------------------|-------------------------|------------------------|----------------------------|
| Room Temp.                                     | 92% Rel. Humidity         |                         | 56° C.                 |                            |
| 15 hrs. and 33 hrs. differentiates             | 15 hrs. not differentiate | 33 hrs. lost reactivity | 15 hrs. differentiates | 48 hrs. not differentiates |

Conclusion: Chart IV demonstrates that Formulation II provides satisfactory results only at room temperature, or at elevated temperature if used promptly. In the absence of TAPS, all of the test strips exhibited a green discoloration. Furthermore, the results of the humidity tests indicated that the absence of TAPS might have some bearing on humidity stability. But Formulation II (Chart III) which substituted TAPS for TRIS did not exhibit long term humidity stability. Surprisingly, however, the presence of both TAPS and TRIS (Chart II) was humidity stable. Similarly, while TAPS alone was not temperature stable and while TRIS alone was not temperature stable (long term), the combination of TRIS and TAPS exhibited both short term and long term temperature stability.

CHART V

| RESULTS OF TEST WITH FORMULATION IV (NO TRIS - pH ADJUSTED) |                            |                            |                            |                                 |  |
|---|----------------------------|----------------------------|----------------------------|---------------------------------|--|
| Room Temp.  | 92% Rel. Humidity          |                            | 56° C.                     |                                 |  |
| 15 hrs. no differentiation                                  | 33 hrs. no differentiation | 15 hrs. no differentiation | 33 hrs. no differentiation | 15 hrs. reduced differentiation | 48 hrs. no differentiation at lower ketone levels. |

6

Conclusion: Chart V demonstrates that after adjusting the pH of Formulation II, the test strips were essentially of no value. That is, neither the room temperature test strips nor the elevated humidity test strips were able to differentiate among various levels of ketones, the test strips which were subject to an elevated temperature for 15 hours had a reduced ability to resolve the various levels of ketone and the test strips subjected to an elevated temperature for 48 hours were not able to differentiate among the various levels of ketone.

CHART VI

| RESULTS OF TEST WITH FORMULATION V (NO TAPS - pH ADJUSTED) |                         |  |   |                              |                            |
|--|-------------------------|--|---|------------------------------|----------------------------|
| Room Temp.   |                         | 92% Rel. Humidity                          |   | 56° C.                       |                            |
| 15 hrs. differentiation                                    | 33 hrs. differentiation | 15 hrs. no differentiation at lower levels | 33 hrs. no differentiation at higher levels | 15 hrs. poor differentiation | 48 hrs. no differentiation |
|  |                         |  | erroneous differentiation at lower levels   |                              |                            |

Conclusion: The results of Formulation V, demonstrates that, after adjusting the pH of Formulation III the test strips provide satisfactory results only if used promptly. Again there is neither temperature nor humidity stability.

From the above test results we conclude that the combined presence of TAPS and TRIS is critical to providing a system which is stable in response to temperature variations and humidity variations, and which maintains the ability to resolve or differentiate among various levels of ketones.

The foregoing is a complete description of the preferred embodiment of the present invention. It may be appreciated, however, that the composition of the present invention may be embodied in the form of a pressed or molded tablet containing conventional carrier material. To accomplish, this, rather than using water to form the first and second solutions, the ingredients are all in the dry state. Specifically, sodium nitroprusside, nickel chloride, TAPS and TRIS are mixed together in the aforementioned proportions and thereafter mixed with a conventional tablet carrier material and thereafter pressed or molded into a plurality of tablets.

What is claimed is:

1. A method for the preparation of a test device for the detection of ketone bodies in body fluids comprising the steps of:

impregnating a carrier with an aqueous solution of a soluble nitroprusside chromogen;

drying the impregnated carrier;

further impregnating the carrier in the area previously impregnated with an aqueous solution including a metal salt, TAPS and TRIS; and drying the carrier;

the pH of the finished test device being no greater than 7.0.

2. The invention as defined in claim 1 wherein said carrier is bibulous.

3. A test device for the detection of ketone bodies in body fluid prepared by the process comprising; impregnating a carrier with an aqueous solution of soluble nitroprusside; drying the impregnated carrier;