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DIAGNOSTIC COMPOSITION

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9 Claims. (Cl. 252—408)

1

The present invention relates to new and improved diagnostic compositions useful for the qualitative detection and quantitative estimation of ketone bodies in body fluids, particularly acetone bodies in the urine.

More specifically, the invention relates to diagnostic compositions in solid dry form, preferably tableted in suitable sized tablets, which composition can readily be used, even by unskilled persons, rapidly to detect the presence of acetone in urine without evolvement of ammonia, with ready distinction between positive and negative tests, and without the use of equipment or apparatus other than some means of obtaining a drop of test fluid.

In the metabolism of fat, acetone bodies or ketone bodies are regarded as normal intermediate compounds which are subsequently oxidized to carbon dioxide and water. The ketone bodies include acetone, acetoacetic acid (beta-ketobutyric acid or diacetic acid) and beta-hydroxybutyric acid. Under normal circumstances, no significant quantity of these ketone substances appears in the urine. However, if there is an excessive metabolism of fat, the intermediate acetone bodies accumulate in the blood and are excreted in the urine in variable amounts. In diabetes mellitus such an excessive fat metabolism occurs and many of the symptoms of this disease can be ascribed to the toxic effects of the acetone bodies. The medical profession is well aware of the usefulness in diagnosis of tests for acetone bodies in the urine in diabetes mellitus cases. Acetone bodies also occur in the urine in other well recognized disturbances of the metabolism, and in such cases it is also important to carry out tests for detection of these substances.

A variety of reagents and techniques have been used or proposed in the past for the detection of acetone bodies in urine. A number of such reagents and techniques have involved the use of a water soluble nitroprusside as a reactive ingredient or agent. In one particular reagent formulation, the nitroprusside reaction is carried out in the presence of ammonia in order to develop particular colorations (see United States Patent No. 2,186,902 to Fortune). An improvement over the Fortune type formulation is disclosed in copending application Serial No. 12,699, filed March 2, 1948, now Patent No. 2,509,140 issued on May 23, 1950, by Alfred H. Free, assigned to the assignee of the present application. Application Serial No. 12,699 discloses formulations for detection of acetone bodies in the urine which contain water soluble nitroprusside, an aliphatic amino acid and an alkaline material.

2

It was found, according to application Serial No. 12,699, that when the soluble nitroprusside is present in alkaline solution with an aliphatic amino acid (e. g. glycine), a diagnostic composition is provided which is particularly adapted for the detection of acetone bodies in urine without evolvement of ammonia.

According to the present invention, it has been discovered that the addition of lactose to the diagnostic formulation set forth in application Serial No. 12,699 greatly enhances the usefulness and reliability of that type of diagnostic formulation.

The object of the present invention, generally stated, is the provision of improved diagnostic compositions in stable dry form, preferably as tablets, which can be used even by an unskilled person conveniently to give an accurate qualitative test for, and a quantitative estimation of, the presence of acetone bodies in urine, which test clearly distinguishes between positive and negative specimens, even when the quantity of acetone is small, so as to give only what is known as a "trace positive."

An important object of the invention is the provision of a stable dry diagnostic composition for the detection of acetone bodies in urine which contains a water-soluble nitroprusside, an aliphatic amino acid, and an alkaline material, as active ingredients, and in addition contains lactose which serves to prevent color change in the case of acetone-negatives and to keep the colors in the whole range of positives very truly and characteristically lavender, so that there will be no chance for confusion between positive and negative specimens, even where there are only trace amounts of acetone bodies in the positives.

Other objects of the invention will in part be obvious and will in part appear hereinafter.

The following example discloses a presently preferred embodiment of the invention.

Example I

The following formulation is uniformly composed by known blending and mixing techniques, and is then tableted in known manner:

	Parts by weight
Glycine	4.5
Sodium nitroprusside	0.5
Disodium phosphate (anhydrous)	47.0
Sodium borate	36.5
Lactose	10.0
Corn starch	1.25
Magnesium stearate	0.25
	100.00