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METHOD AND COMPOSITION FOR BLOOD SUGAR TESTING

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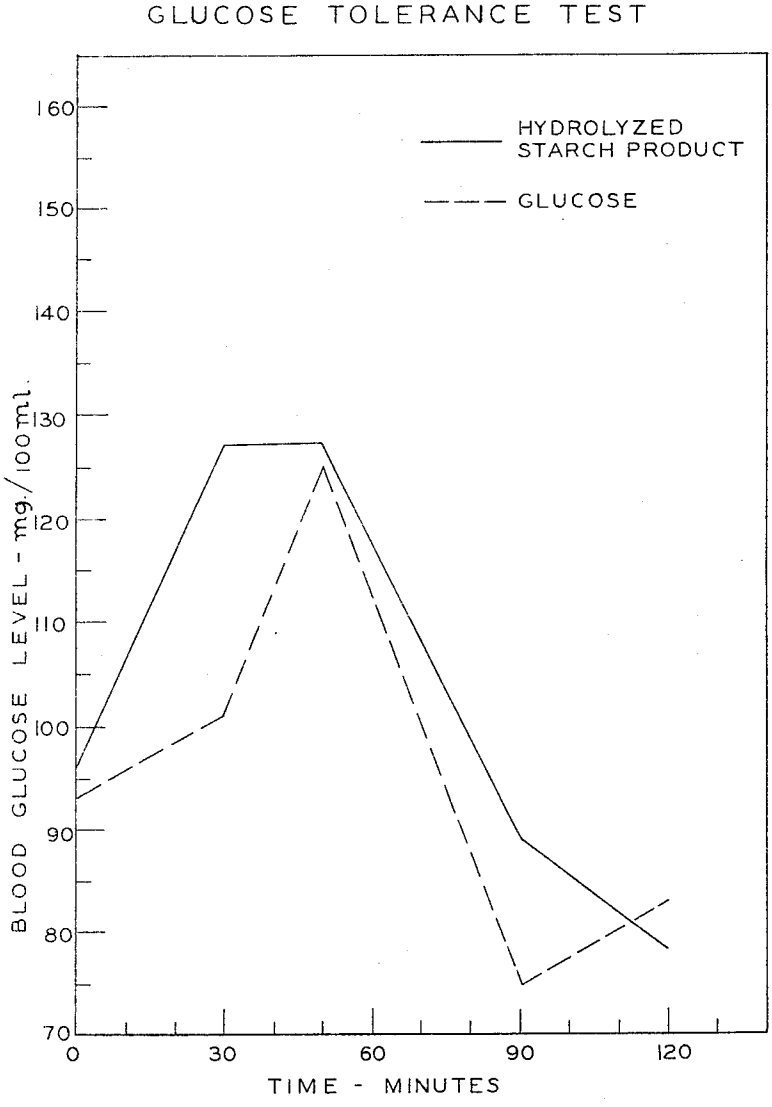

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METHOD AND COMPOSITION FOR BLOOD SUGAR TESTING

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This invention relates to a novel food product. In one of its more particular aspects it relates to a novel meal for use in glucose tolerance and post-prandial blood sugar testing. In another of its more particular aspects it relates to a meal or food suitable for use as a nutritional supplement.

One of the most valuable and commonly used tests for diagnosis of diabetes mellitus is the so called Glucose Tolerance Test. In essence, this test involves the oral administration of measured quantities of glucose and the subsequent determination of blood sugar concentration at timed intervals thereafter. A rise of blood sugar concentration stimulates the secretion of insulin and in the normal body, the metabolic mechanism comes into play with the result that much of the glucose is rapidly removed from the blood. In a normal person, that is, one free of a diabetic condition, this removal of glucose from the blood usually maintains the blood sugar concentration below the level at which glucose is excreted by the kidneys. In other words, the renal threshold is ordinarily not exceeded and glycosuria is absent. When a glucose tolerance test is performed on a diabetic person, the blood sugar concentration will rise excessively after glucose administration, and will not return to its original value for many hours.

One of the commonly used standard meals for the glucose tolerance test is 50–100 grams of glucose with or without a minute amount of flavoring.

Another of the commonly used glucose tolerance tests is the one hour, two-dose test devised by Exton and Rose, The One-Hour, Two-Dose Dextrose Tolerance Test, Am. J. Clin. Path., 4, 381 (1934). This test consists of administering orally two 50 gram doses of glucose thirty minutes apart and determining the blood sugar at 0, 30 and 60 minutes. The criteria of a normal response include a fasting blood sugar within the normal limits of the blood sugar method employed, a rise in blood sugar which does not exceed 75 mg. in the 30 minute sample, a blood sugar level in the 60 minute sample which does not exceed the 30 minute sample by more than 5 mg. and urine samples that are all negative to Benedict's Test.

Many studies have been made on the efficiency of the glucose tolerance test and in particular concerning the retention of glucose in the stomach, which retention, it will be apparent, may radically affect the results of the test and lead to erroneous results. These studies have, in general, indicated that it is doubtful whether or not a two dose glucose tolerance test offers any advantage over a one dose test.

It will be appreciated that early detection of a diabetic condition aids greatly in the treatment thereof and in most cases enables a more favorable prognosis for less rigid treating regimens. In the United States, substantially in excess of 300,000 glucose tolerance tests per year are conducted in hospitals alone. Because the glucose tolerance test is a much more definitive procedure than the known urine sugar tests or fasting blood sugar determinations, there is a growing trend to utilize a post-prandial blood sugar determination in mass screening for diabetes. In other words, the trend in the medical profession is to use a post-prandial blood sugar determination in the doctor's office and clinics as well as in hospitals for screening and diagnosis.

The use of glucose solutions as the standard test meal in post-prandial blood sugar determinations has several major disadvantages. One of the most important is the extreme sweetness of glucose which makes it difficult and sometimes impossible for patients to accept. Another major disadvantage is that ingestion of glucose often results in gastrointestinal distress or disturbance, for example, nausea, vomiting or diarrhea. It has been estimated that gastrointestinal distress or disturbance of one form or another occurs in about one-third of the patients ingesting standard test meals in the form of glucose solutions. Still another of the major disadvantages of glucose as the standard meal is that a glucose solution is retained in the stomach for varying periods of time before being absorbed into the blood stream. Thus, drawing blood and checking the blood sugar level at constant intervals after ingestion of a glucose solution will not accurately reflect the patient's glucose tolerance level. As may be readily observed, the ingestion of a glucose solution as a standard test meal is frequently unpleasant or impossible, depending upon the patient's reaction, and a blood sugar determination based thereon is of dubious value in estimating the patient's glucose tolerance.

In accordance with this invention, a test meal for use in glucose tolerance or post-prandial blood sugar testing is provided which does not suffer from any of the aforementioned disadvantages of the commonly used glucose solution and which is further characterized by numerous advantages. The test meal of this invention is not extremely sweet, does not cause gastro-intestinal distress or disturbance, and empties out of the stomach and intestines more rapidly than a pure glucose solution. It offers the advantage that the end product of intestinal digestion thereof, that is, pure glucos, is available in the blood stream at the required level much sooner than that of a test meal in the form of a pure glucose solution. This advantage greatly enhances the desirability of the novel test meal of this invention for use in physician's offices and clinics having limited waiting facilities.

Stll another advantage of the invention is the provision of a relatively economical and truly standardized meal as opposed to the numerous nonstandardized test meals heretofore utilized by physicians in screening for diabetes using post-prandial blood sugar determinations.

Broadly, the standard meal composition of this invention for use in determining glucose tolerance and in post-prandial blood sugar screening comprises a partially hydrolyzed starch product. More specifically, the composition comprises a starch partial hydrolysis product containing a mixture of glucose and polymers of glucose. For example, such mixture may contain varying proportions of glucose, maltose, maltotriose, maltotetrose, maltopentose and higher polysaccharides. Such mixtures are suitably used in the form of aqueous solutions which may also be carbonated and flavored to lend palatability to the solutions.

Partially hydrolyzed starch products suitable for use in the compositions of this invention may be prepared by acid or enzyme, for example, amylase, hydrolysis of starches, or a combination of acid and enzyme hydrolysis of starch may be used to provide a mixture of materials having molecular weights ranging between those of starch and glucose. Optimum results are obtained utilizing a starch hydrolysis product which contains a mixture of materials having from about two to eight glucose (dextrose) units per molecule. The starch hydrolysis product of the present invention may be prepared by any of the well known hydrolytic methods.

The starch hydrolysis product is dissolved in distilled water and bottled to provide in one bottle a standardized meal containing a predetermined equivalent of glucose.

In the usual case, the solutions are so made that one bottle contains an amount of hydrolyzed product equivalent to 50–100 grams of pure glucose, which amount of glucose is generally used as a standard meal for post-prandial blood sugar screening.

It is contemplated by this invention that the standard meal composition may be flavored by various flavoring agents as for example, cola, lemon-lime, cherry or other popular flavors. In addition, the composition may be carbonated to improve the palatability.

Various methods may be used for carbonating the standard meal composition when it is desired to do so. Satisfactory carbonation results have been obtained by, for example, exposing the "meal solution" to 125 pounds per square inch of carbon dioxide pressure in the cold for a period of 12 hours; flowing the meal solution through a reservoir maintained under a carbon dioxide pressure of 125 pounds per square inch; and, injection of carbon dioxide from a pressurized cartridge into a container of the standardized meal solution.

As pointed out above the compositions of this invention may also be used as nutritional supplements, particularly in the case of convalescent and other specialized patients who must ordinarily be force fed carbohydrates. In addition the compositions of this invention are well suited as a source of quick energy.

The following examples illustrate the preparation and use of the compositions of this invention. It is to be understood that the examples are by way of illustration only and are not to be considered limitations on the composition and methods of preparation.

Example 1

To 10 gal. of distilled water was added 102 lb. of a commercially available corn syrup of intermediate acid conversion having a Dextrose Equivalent (D.E.) of 54%, and consisting of 30% dextrose, 18% maltose, 13% maltotriose and 39% higher saccharides with a viscosity of 70 poises at 100° F. There was then added 1000 cc. of concentrated Kola nut extract and 100 g. of sodium benzoate. The volume was adjusted to 100 liters with distilled water. The resulting solution was then carbonated and bottled in 7 oz. bottles.

Example 2

The procedure of Example 1 was followed except that 51 lb. of the corn syrup of Example 1 was mixed with 51 lb. of a regular acid-enzyme converted corn starch having a D.E. of 42% and consisting of 5% dextrose, 48% maltose, 12% maltotriose and 35% higher saccharides with a viscosity of 125 poises at 100° F.

Example 3

The procedure of Example 1 was followed using as the starch hydrolysis product a corn syrup having the characteristics shown in Table I.

TABLE I

Dextrose Equivalent (Percent)	Viscosity at 100° F. (Poises)	Carbohydrate Breakdown (Percent)			
		Dextrose	Maltose	Maltotriose	Higher
43	145	19.3	14.3	11.8	54.6
51	105	20.0	31.0	18.0	31.0
48	115	9.1	51.9	15.1	23.9

Since it is desirable to have most if not all of the sugars present as polymers of glucose rather than as glucose (dextrose) itself, part of the glucose may be removed from the commercially available corn syrups or other starch hydrolysis products by means of dialysis. Such treatment leaves a higher percentage of higher saccharides which is preferred.

A convenient method of preparing the carbohydrate meal of this invention is illustrated in the following example.

Example 4

Each of the corn syrups of Examples 1–3 is diluted with distilled water to 65% carbohydrate. Flavoring and preservative are added. The resulting solution is dispensed in quantities of 4 oz. by weight into 7 oz. beverage bottles, and the bottles are filled with carbonated water.

The following example illustrates the use of the carbohydrate meals of this invention in glucose tolerance testing.

Example 5

Utilizing a meal composition prepared in accordance with Example 2, samples containing 75 g. of the partially hydrolyzed starch were orally administered to 3 selected, normal adult subjects. Simultaneously a glucose test meal containing 75 g. of pure glucose was taken by 3 selected, normal adult subjects. After taking 30, 60, 90, and 120 minute blood samples a post-prandial sample of the gastric contents of each of the subject's stomachs was withdrawn by stomach tube and analyzed for retention of the test meal. In one subject there was found to be 32 g. of glucose in the stomach 1 hour after ingesting 75 g. of glucose, whereas 5 g. of total carbohydrate was found in the stomach 1 hour after ingesting 75 g. of the hydrolyzed starch product. The tests were run at intervals of 3 days.

The glucose tolerance curves for this subject are shown in FIGURE 1. The relatively close coincidence between the glucose test meal tolerance curve and that of the hydrolyzed starch attests to the efficacy of the hydrolyzed starch product of this invention in glucose tolerance testing.

Example 6

The composition of Example 2 was bottled under sterile conditions in standardized meals of 210 ml. containing hydrolyzed starch in an amount equivalent to 75 g. of pure glucose, and 280 ml. containing hydrolyzed starch in an amount equivalent to 100 g. of pure glucose.

Post-prandial blood sugar testing was conducted at 3 and 5 day intervals on normal subjects (not exhibiting a diabetic condition) no normal diets. Venous blood glucose was measured by the ferricyanide method with an auto-analyzer. Forty-six of the test subjects were given the standard meal composition of the invention containing an equivalent of 75 g. of pure glucose, and 46 subjects were given a meal of 100 g. of pure glucose dissolved in 300 ml. of distilled water. Blood sugar determinations were made on each subject at 30, 60, 90 and 120 minute intervals. The blood sugar levels were virtually identical for both of the test meals.

Thus, for practical purposes the 75 g. hydrolyzed starch product may be considered equal in efficacy to the standard 100 g. glucose test meal currently widely used.

The meal composition of this invention containing an equivalent of 100 g. of pure glucose was then given to 15 subjects, and the blood sugar level of said subjects compared at 30, 60, 90 and 120 minute intervals with the blood sugar level of 15 subjects who had each taken a 100 g. pure glucose test meal. Plotting of the blood sugar levels did not reveal any significant difference between the curves. Approximately 20% of the subjects taking the pure glucose test meal experienced nausea.

Subsequently 340 subjects were screened for diabetes mellitus utilizing the standardized test meal composition of this invention in post-prandial blood sugar determination, and not a single instance of nausea or other undesired side effect was noted. In a further study of over 3,000 individuals the incidence of adverse reactions from ingestion of the standard meal composition of the present invention was virtually nil.

What is claimed is:

1. A blood sugar test meal which comprises a carbonated cola-flavored aqueous solution in unit dosage form of a partially hydrolyzed starch product consisting essentially of about 5–30 percent dextrose, about 14–52 percent

maltose, about 11–18 percent maltotriose, about 23–55 percent higher saccharides, having a Dextrose Equivalent of about 42–54 percent and having a viscosity at 100° F. of about 70–145 poises, and wherein the unit dosage is equivalent to from about 50 to about 100 grams of pure glucose.

2. A method for blood sugar testing which comprises administering to human patients a blood sugar test meal comprising a carbonated cola-flavored aqueous solution in unit dosage form of a partially hydrolyzed starch product consisting essentially of about 5–30 percent dextrose, about 14–52 percent maltose, about 11–18 percent maltotriose, about 23–55 percent higher saccharides, having a Dextrose Equivalent of about 42–54 percent and having a viscosity at 100° F. of about 70–145 poises, and wherein the unit dosage is equivalent to from about 50 to about 100 grams of pure glucose, and measuring the blood sugar level of said patients at timed intervals thereafter.

3. A blood sugar test meal according to claim 1 wherein the partially hydrolyzed starch product has a Dextrose Equivalent of 54% and consists essentially of 30% glucose, 18% maltose, 13% maltotriose and 39% higher saccharides, said mixture having a viscosity of 70 poises at 100° F.

4. A method according to claim 2 wherein the partially hydrolyzed starch product has a Dextrose Equivalent of 54% and consists essentially of 30% glucose, 18% maltose, 13% maltotriose and 39% higher saccharides, said mixture having a viscosity of 70 poises at 100° F.

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