

[0004] The shelf life of the GALA formulation is limited due to the instability of various components of the formulation. The relatively short shelf life of the GALA formulation can limit its usefulness. Thus, there is a need to improve the GALA formulation to improve the stability of its components and thereby lengthen its shelf life.

#### **SUMMARY**

[0005] Described herein are improvements to the GALA formulation having improved stability and increased shelf life over the original formulation. Also described are methods of using the improved formulations. In an aspect, there is provided a kit for preserving the function of a tissue or organ comprising: a first container containing a first solution, wherein the first solution is comprised of water, a balanced salt solution, a sugar, and L-arginine and has a pH of at least 7.0; a second container containing a second solution, wherein the second solution consists of water, reduced glutathione, and ascorbic acid and has a pH of below 4.0. In another aspect, there is provided a method of preparing a formulation for preserving the function of a tissue or organ comprising: providing a first solution wherein the first solution includes water, a balanced salt solution, a sugar, and L-arginine and has a pH of at least 7.0; providing a second solution, wherein the second solution consists of water, reduced glutathione, and ascorbic acid and has a pH of below 4.0; and mixing the first solution with the second solution to form the complete formulation for preserving the function of a tissue or function. In yet another aspect, there is provided a method of preserving the function of a tissue or organ comprising: providing a first solution wherein the first solution includes water, a balanced salt solution, a sugar, and L-arginine and has a pH of at least 7.0; providing a second solution, wherein the second solution includes water, reduced glutathione, and ascorbic acid and has a pH of below 4.0; mixing the first solution with the second solution to form the complete formulation for preserving the function of a tissue or function; and contacting a tissue or organ with the complete formulation.

[0006] The present ~~invention~~-disclosure is premised on the realization that the stability of tissue preservation formulations, particularly the GALA formulation, can be improved by separating the formulation into a first solution having a pH of at least 7 and a second solution having a pH of less than 7. The first solution includes components with improved stability when stored at a pH of 7.0 or above, and the second solution includes components with improved stability when stored at a pH below 7.0. The first solution includes water, a balanced salt solution, a sugar such as D-glucose, and L-arginine at a pH of at least 7.0 and preferably at a pH that ranges from pH 7.0 to about pH 8.5. The second solution includes water, an antioxidant such as ascorbic acid, and a reducing agent such as reduced glutathione at a pH of less than 7.0 and preferably from pH 6.9 to about pH 2.8. At the point of use, the first and second solutions are mixed together to form a final formulation that can be used at a physiological pH of around pH 7.4 to preserve the function of the tissue or organ.

#### **BRIEF DESCRIPTION OF THE DRAWINGS**

[0007] The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate various embodiments of the invention and, together with a general description of the invention given above and the detailed description of the embodiments given below, serve to explain the embodiments of the invention.