

Shiaqga Assay Interpretation

Prepared by Dr. Landis (National Board Certified Naturopath)
For Demonstrational Purposes Only

LIMULUS AMEBOCYTE LYSATE (LAL) TEST RESULTS

Report Date 3/24/2004

Glucan Lot # 855010

Customer # NE041

LAL Reagent Water (LRW) lot # 308-376

IC # 0304-129

Refer to actual assay report in this presentation.

Control: Standard Concentrations – 3.125 and 50.0 pg/mL.

Assay Result: 13,438,587 pg/mL

To understand the purpose of using picograms in this assay it is important to realize that the pg is approximately the size of the single glucan molecule. The molecule of glucan is the unit size which fills the receptor sites on the surface of the macrophage and programs the macrophage to begin the non-selective immune cascade resulting in dramatic immunomodulation.

Because the B-glucans are acid resistant and are not digested in the stomach, they pass directly into the intestines. The lack of beta 1,3 glucanase in the intestine does not allow for its digestion into glucose or di-glucose. Because of this, the glucan is absorbed directly through the intestinal wall. The Macrophages that inhabit the intestinal wall pick up the glucan particles through glucan receptors. Immediate activation of these cells follows and later, they are able to travel back to the local lymph nodes (Payers Patches) as a part of their natural antigen-presenting function, to release cytokines (Il-1, Il -6, GM-CSF, Interferons) and induce systemic immune activation.

The assay indicates that for every mL of the Shiaqga extract sample, 13,438,587 pg of B1-3 glucan is delivered to the digestive tract. This means that in a single suggested serving of the Shiaqga product will deliver to the digestive tract over 94,000,000 beta glucans. This explains why the small dose of Shiaqga has the same efficacy of the larger doses of processed yeast-based glucan.

This assay finding verifies the efficacy of Shiaqga as a natural supply of Beta glucan and underscores the importance of this traditional Native American Medicine.

LIMULUS AMEBOCYTE LYSATE (LAL) TEST RESULTS
Kinetic Glucan Assay

Report Date: 3/24/2004

Glucan lot#: 855010

Customer #: NE041

LAL Reagent Water (LRW) lot #: 308-376

IC #: 0304-129

Reference Standard Glucan lot #: 962002. The sensitivity of the assay is the least concentration of standard used to construct the standard curve. Standard concentrations ranged between 3.125 and 50.0 pg/mL. The absolute value for the correlation coefficient for the regression of log onset time on log endotoxin concentration was greater than 0.980. The negative control, LRW, was tested in triplicate and was less than 3.125 pg/mL.

Procedure: The sample was preparational herbal solids in water (227 g/3,785 mL). The preparation was diluted 1:10,000, 1:100,000 and 1:1,000,000 in LRW and tested in triplicate. Positive product controls were performed in parallel on each dilution “spiked” with additional glucan equivalent to 12.5 pg/mL. Results are reported for the dilution(s) necessary to overcome inhibition or enhancement (recover the spike concentration within 50% to 200% of the nominal concentration) and give a concentration of endotoxin that could be calculated from the standard curve.

The glucan assay is for “Research Use” only. Testing was consistent with the *Guideline on Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices*, (FDA, December, 1987), the *Interim Guidance for Human and Veterinary Drug Products and Biologicals, Kinetic LAL Techniques* (FDA, July 1991) and *Bacterial Endotoxins Test, USP 27 <85>*. Studies were conducted in compliance with GMP as applied to performance of in-vitro laboratory tests.

Results:

Date of Test: 3/24/2004

Technician: P. Waters

Sample Identification

Glucan Concentration

Dilution

Shiaqqa, lot# 001

13,438,587 pg/mL (223,976 pg/g)

1:1,000,000

Results reviewed by:

John T. Lohr, Ph.D.