



Kinetic Gel Stiffness of Various Lots of PureCol® Type I Bovine Collagen

The purpose of this experiment was to measure and compare the gel stiffness and collagen polymerization time in relation to the age of collagen (based on manufactured date).

Five lots of PureCol® from the last 3 years were tested. Preparation instruction from the Directions for Use (DFU) were followed including the adjustment of the salts to physiological levels and neutralizing the pH. Kinetic gel stiffness testing was conducted at 37°C using ElastoSens Bio2 that employs a non-destructive and contactless method of gelation kinetics and a rapid analysis of gel stiffness. ElastoSens Bio2 gently vibrates a sample and laser detects the response.

Following are the five lots of collagen that were tested, along with their manufacturing date:

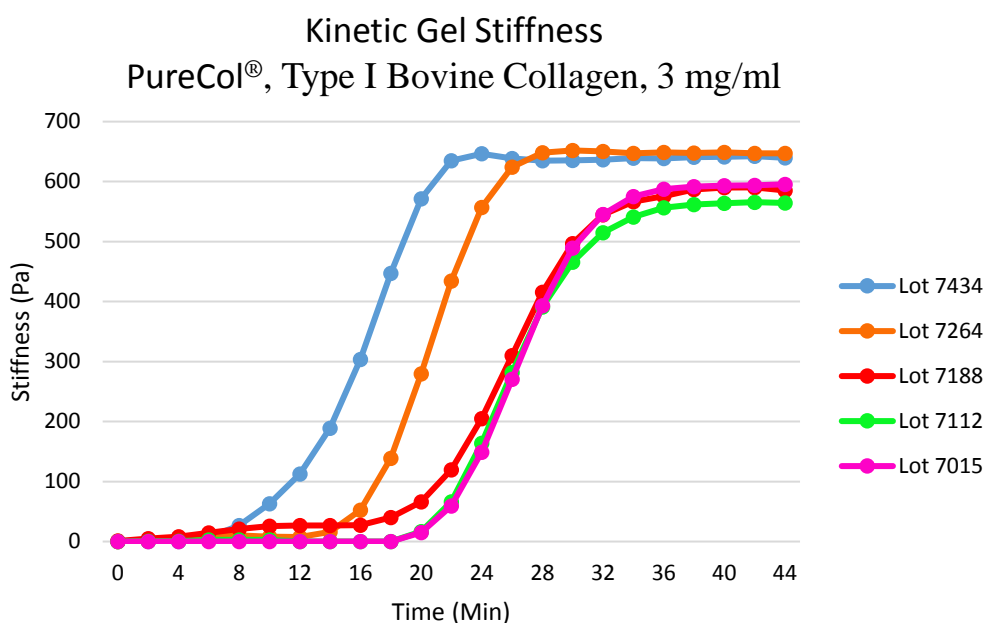
Lot: 7015
Manufactured: 02/2013

Lot: 7112
Manufactured: 05/2013

Lot: 7188
Manufactured: 12/2013

Lot: 7264
Manufactured: 09/2014

Lot: 7434
Manufactured: 12/2015



The results indicate that the polymerization times increase as the collagen ages with the gel stiffness declining only slightly with older lots of PureCol® Bovine Type I Collagen (5005-100ML).

The specification on the certificate of analysis for PureCol® indicates that the collagen must be fully polymerized by ≤ 40 minutes. These results indicate that the product meets specification even 3 ½ years after the manufactured date.

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