



Monobind Technical Support Memo

Subject; Troponin-I Normal and Reference Range

Date; February 2010

QUESTION:

What is the literature used to establish the reference range for Monobind's Troponin-I immunoassays? How was Monobind's Troponin-I normal range established?

ANSWER:

Troponin-I values are different in plasma and serum. In addition, plasma sample may be influenced by the additives used. For example, heparin minimally affects the results but oxalate and EDTA have significant effect. A serum sample that has been quickly separated from red cells is preferred.

Based on the clinical data gathered by Monobind in concordance with the published literature the following ranges have been assigned. These ranges should be used as guidelines only:

Adult (Normal) < 1.3 ng/ml

Although the magnitude of numbers agrees between the methods, we do not have the adequate validation to lower the cut-off.

Authorized by:

A. Shatola

Quality Representative

February 12, 2010