

Procedure Change/Revision (IMM 36-A)

Procedure: Jo-1 ELISA on the DSX (IMM 61)
Scl-70 ELISA on the DSX (IMM 128)
SSA ELISA on the DSX (IMM 126)
SSB ELISA on the DSX (IMM 158)
Smith(Sm) ELISA on the DSX (IMM 117)
SM/RNP ELISA on the DSX (IMM 127)

Change/Revision:

The upper limit of the Low Control (LC) control is no longer 0.6.

The QC guideline for the LC is as follows:

“The ELISA Low Positive control must be more than twice the ELISA Negative Control or over 0.25.”

Note: This change was made by Inova due to an improvement in the manufacturing process.

Date of Revision: 9/25/12

Director Signature/Date:

B. P. H. W.
9/25/2012

Technologist Signature/Date: