CLAIMS

1. A method of making limulus amebocyte lysate (LAL) substantially free of coagulogen, wherein the LAL substantially free of coagulogen comprises less than 5% (wt/wt) of coagulogen relative to total protein in the LAL as measured by SDS-PAGE with protein stain, the method comprising:

   subjecting a composition comprising LAL, wherein the LAL comprises coagulogen to tangential flow filtration (TFF) using a 20 kDa to 50 kDa TFF filter, wherein the TFF produces a retentate and a filtrate; and

   collecting the retentate, thereby obtaining the LAL substantially free of coagulogen.

2. The method of claim 1, wherein the TFF is performed at a flow rate of 300 ml/min to 600 ml/min.

3. The method of claim 2, wherein the TFF is performed at a flow rate of 350 ml/min to 500 ml/min.

4. The method of any one of claims 1 to 3, wherein the composition comprising LAL is in a buffer.

5. The method of claim 4, wherein the buffer is a Tris buffer or MES buffer.

6. The method of claim 4 or 5, wherein the buffer has a pH of about 6.0 to about 9.0.

7. The method of claim 6, wherein the buffer has a pH of about 7.0 to 8.0.

8. The method of any one of claims 1 to 7, wherein the TFF filter comprises a membrane selected from modified polyethersulfone (mPES), polysulfone (PS) and polyethersulphone (PES).

9. The method of claim 8, wherein the TFF filter comprises a mPES membrane filter.

10. The method of any one of claims 1 to 9, wherein the LAL substantially free of coagulogen comprises less than 1% (wt/wt) of coagulogen relative to total protein in the LAL as measured by SDS-PAGE with protein stain.

11. The method of claim 10, wherein the LAL substantially free of coagulogen comprises less than 0.5% (wt/wt) of coagulogen relative to total protein in the LAL as measured by SDS-PAGE with protein stain.