[0087] While various embodiments have been described above, it should be understood that they have been presented only as illustrations and examples of the present technology, and not by way of limitation. It will be apparent to persons skilled in the relevant art that various changes in form and detail can be made therein without departing from the spirit and scope of the present technology. Thus, the breadth and scope of the present technology should not be limited by any of the above-described embodiments, but should be defined only in accordance with the appended claims and their equivalents. It will also be understood that each feature of each embodiment discussed herein, and of each reference cited herein, can be used in combination with the features of any other embodiment. All patents and publications discussed herein are incorporated by reference herein in their entirety.

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CLAIMS

1. A method of detecting an endotoxin in a sample at a sensitivity of less than 0.001 EU/mL using a chromogenic assay, the method comprising:

    a. contacting the sample with a reagent comprising limulus amebocyte lysate (LAL) and a chromogenic peptide substrate;

    b. measuring a chromogenic effect resulting from an enzymatic cleavage of a chromophore from the chromogenic peptide substrate in the presence of endotoxin in the sample;

    wherein the LAL has less than 0.5% (wt/wt) of coagulogen relative to total protein in the LAL as measured by SDS-PAGE with protein stain.

2. The method of claim 1, wherein the chromogenic peptide substrate is Ac-Ile-Glu-Ala-Arg-pNA.

3. The method of claim 1 or 2, wherein the enzymatic cleavage is cleavage of pNA from Ac-Ile-Glu-Ala-Arg-pNA (SEQ ID NO: 1).

4. The method of any one of claims 1 to 3, wherein the chromogenic effect is measured by detecting absorbance at 405 nm.

5. The method of any one of claims 1 to 4, wherein the reagent is an aqueous liquid.

6. The method of any one of claims 1 to 5, wherein the LAL is lyophilized, and then reconstituted prior to contacting with the sample.

7. The method of any one of claims 1 to 6, wherein the chromogenic peptide substrate is lyophilized, and then reconstituted prior to contacting with the sample.

8. The method of any one of claims 1 to 7, wherein the sample is selected from the group consisting of a parenteral dosage form, vaccine, antibiotic, therapeutic protein, therapeutic nucleic acid, therapeutic antibody, and biological product.