§ 113.454 Clostridium Perfringens Type C Antitoxin.

Clostridium Perfringens Type C Antitoxin is a specific antibody product containing antibodies directed against the toxin of Clostridium perfringens Type C. Each serial shall be tested as provided in this section. Any serial found unsatisfactory by a prescribed test shall not be released.

(a) Each serial shall meet the applicable general requirements provided in §113.450.

(b) Potency test. Bulk or final container samples of completed product from each serial shall be tested using the two-stage test provided in this section.

(1) In the first stage, each of 40 Swiss mice, each weighing 16 to 20 grams, shall be injected subcutaneously with 0.1 ml of product (dried product shall be rehydrated according to label directions). Twenty-four hours postinjection, the injected mice and 10 additional mice designated controls shall be challenged subcutaneously with the same culture of Erysipelothrix rhusiopathiae.

(2) If less than eight of the 10 controls die from erysipelas within 7 days postchallenge, the test is invalid. All dead mice shall be examined to determine if the cause of death was Erysipelothrix rhusiopathiae infection.

(3) The mice injected with product shall be observed for 10 days postchallenge and all deaths recorded. The second stage shall be required when 7-10 of the mice injected with product die in the first stage. The second stage shall be conducted in a manner identical to the first stage.

(4) The results of the test shall be evaluated according to the following table:

<table>
<thead>
<tr>
<th>Stage</th>
<th>Number of vaccinates</th>
<th>Cumulative number of vaccinates</th>
<th>Cumulative total number of deaths for a satisfactory test</th>
<th>Cumulative total number of deaths for an unsatisfactory test</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>40</td>
<td>40</td>
<td>6 or 1 less</td>
<td>11 or more</td>
</tr>
</tbody>
</table>

§ 113.455 [Reserved]