4064-A-2209

Stability of cholera vaccine CVD 103-HgR under varying environmental conditions

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Background: The attenuated recombinant Vibrio cholerae O1 strain CVD 103-HgR (Vaxchora®), is supplied as buffer and active vaccine packets to be mixed in water and ingested. They are stored at 2-8°C and consumed within 15 minutes of reconstitution.

Methods: To assess the stability of Vaxchora vaccine beyond current prescribing parameters, potency was measured under a variety of environmental conditions. Vaccine/buffer packets were removed from 2-8°C refrigeration and stored at 25°C for up to 7 days, at 30°C for up to 24 hours, and at 32°C for up to 12 hours. Vaccine was then reconstituted in 100 mL water at defined intervals; potency was estimated via a colony forming unit (CFU) assay. To assess the stability of reconstituted vaccine, buffer/vaccine packets were reconstituted with 100 mL of water and left at room temperature; potency was measured at 0.5, 1, 2, and 4 hours. Finally, long-term potency was measured after vaccine/buffer packets were removed from 2-8°C refrigeration, cycled up to 3 times at 25°C for a total of 24 hours, and stored again at 2-8°C. Potency is defined as 4 x 108 - 2 x 109 CFUs per dose.

Results: Vaccine/buffer packets maintained potency for up to 5 days at 25°C, for up to 12 hours at 30°C, and for up to 6 hours at 32°C. Following a 24-hour excursion at 25°C, long-term potency at 2-8°C was not affected. Reconstituted vaccine maintained potency for 4 hours at room temperature.

Conclusions: Vaxchora vaccine maintains stability under a variety of environmental conditions, facilitating self-administration.