Food and Drug Administration, HHS

§ 866.3395 Norovirus serological reagents.

(a) Identification. Norovirus serological reagents are devices that consist of antigens and antisera used in serological tests to detect the presence of norovirus antigens in fecal samples. These devices aid in the diagnosis of norovirus infection in the setting of an individual patient with symptoms of acute gastroenteritis when the individual patient is epidemiologically associated with the outbreak.