§ 866.3900 Varicella-zoster virus serological reagents.

(a) Identification. Varicella-zoster virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to varicella-zoster in serum. The identification aids in the diagnosis of diseases caused by varicella-zoster viruses and provides epidemiological information on these diseases. Varicella (chicken pox) is a mild, highly infectious disease, chiefly of children. Zoster (shingles) is the recurrent form of the disease, occurring in adults who were previously infected with varicella-zoster viruses. Zoster is the response (characterized by a rash) of the partially immune host to a reactivation of varicella viruses present in latent form in the patient's body.

(b) Classification. Class II (performance standards).

§ 866.3930 Vibrio cholerae serological reagents.

(a) Identification. Vibrio cholerae serological reagents are devices that are used in the agglutination (an antigen-antibody clumping reaction) test to identify *Vibrio cholerae* from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of cholera caused by the bacterium *Vibrio cholerae* and provides epidemiological information on cholera. Cholera is an acute infectious disease characterized by severe diarrhea with extreme fluid and electrolyte (salty) depletion, and by vomiting, muscle cramps, and prostration. If untreated, the severe dehydration may lead to shock, renal failure, cardiovascular collapse, and death.

(b) Classification. Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §866.9.

(72 FR 44382, Aug. 8, 2007)

§ 866.3940 West Nile virus serological reagents.

(a) Identification. West Nile virus serological reagents are devices that consist of antigens and antisera for the detection of anti-West Nile virus IgM antibodies, in human serum, from individuals who have signs and symptoms consistent with viral meningitis/encephalitis. The detection aids in the clinical laboratory diagnosis of viral meningitis/encephalitis caused by West Nile virus.

(b) Classification. Class II (special controls). The special control is FDA’s guidance entitled “Class II Special Controls Guidance Document: Serological Reagents for the Laboratory Diagnosis of West Nile Virus.” See §866.1(e) for the availability of this guidance document.

(72 FR 56023, Nov. 9, 2007)

§ 866.3950 In vitro human immunodeficiency virus (HIV) drug resistance genotype assay.

(a) Identification. The in vitro HIV drug resistance genotype assay is a device that consists of nucleic acid reagent primers and probes together with software for predicting drug resistance/susceptibility based on results obtained with these primers and probes. It is intended for use in detecting HIV genonomic mutations that confer resistance to specific antiretroviral drugs, as an aid in monitoring and treating HIV infection.

(b) Classification. Class II (special controls). The special control for this device is FDA’s guidance document entitled “Class II Special Controls Guidance Document: In Vitro HIV Drug Resistance Genotype Assay.” See §866.1(e) for the availability of this guidance document.

(72 FR 44382, Aug. 8, 2007)

§ 866.3980 Respiratory viral panel multiplex nucleic acid assay.

(a) Identification. A respiratory viral panel multiplex nucleic acid assay is a qualitative in vitro diagnostic device intended to simultaneously detect and identify multiple viral nucleic acids extracted from human respiratory specimens or viral culture. The detection and identification of a specific viral nucleic acid from individuals exhibiting signs and symptoms of respiratory infection aids in the diagnosis of respiratory viral infection when used in conjunction with other clinical and laboratory findings. The device is intended for detection and identification
of a combination of the following viruses:
(1) Influenza A and Influenza B;
(2) Influenza A subtype H1 and Influenza A subtype H3;
(3) Respiratory Syncytial Virus subtype A and Respiratory Syncytial Virus subtype B;
(4) Parainfluenza 1, Parainfluenza 2, and Parainfluenza 3 virus;
(5) Human Metapneumovirus;
(6) Rhinovirus; and
(7) Adenovirus.

(b) Classification. Class II (special controls). The special controls are:
(1) FDA’s guidance document entitled “Class II Special Controls Guidance Document: Respiratory Viral Panel Multiplex Nucleic Acid Assay;”
(2) For a device that detects and identifies Human Metapneumovirus, FDA’s guidance document entitled “Class II Special Controls Guidance Document: Testing for Human Metapneumovirus (hMPV) Using Nucleic Acid Assays;” and
(3) For a device that detects and differentiates Influenza A subtype H1 and subtype H3, FDA’s guidance document entitled “Class II Special Controls Guidance Document: Testing for Detection and Differentiation of Influenza A Virus Subtypes Using Multiplex Nucleic Acid Assays.” See §866.1(e) for the availability of these guidance documents.

[74 FR 52138, Oct. 9, 2009]

Subpart E—Immunology Laboratory Equipment and Reagents

§ 866.4070 RNA Preanalytical Systems.
(a) Identification. RNA Preanalytical Systems are devices intended to collect, store, and transport patient specimens, and stabilize intracellular RNA from the specimens, for subsequent isolation and purification of the intracellular RNA for RT–PCR used in in vitro molecular diagnostic testing.
(b) Classification. Class II (special controls). The special control is FDA’s guidance document entitled “Class II Special Controls Guidance Document: RNA Preanalytical Systems (RNA Collection, Stabilization and Purification System for RT–PCR Used in Molecular Diagnostic Testing).” See §866.1(e) for the availability of this guidance document.

[70 FR 49863, Aug. 25, 2005]

§ 866.4100 Complement reagent.
(a) Identification. A complement reagent is a device that consists of complement, a naturally occurring serum protein from any warm-blooded animal such as guinea pigs, that may be included as a component part of serological test kits used in the diagnosis of disease.
(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §866.9.


§ 866.4500 Immunoelectrophoresis equipment.
(a) Identification. Immunoelectrophoresis equipment for clinical use with its electrical power supply is a device used for separating protein molecules. Immunoelectrophoresis is a procedure in which a complex protein mixture is placed in an agar gel and the various proteins are separated on the basis of their relative mobilities under the influence of an electric current. The separated proteins are then permitted to diffuse through the agar toward a multispecific antiserum, allowing precipitation and visualization of the separate complexes.
(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §866.9.


§ 866.4520 Immunofluorometer equipment.
(a) Identification. Immunofluorometer equipment for clinical use with its electrical power supply is a device used to measure the fluorescence of fluorochrome-labeled antigen-antibody complexes. The concentration of these complexes may be measured by means