§ 866.3850 Trichinella spiralis serological reagents.

(a) Identification. Trichinella spiralis serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to Trichinella spiralis in serum. The identification aids in the diagnosis of trichinosis caused by parasitic roundworms belonging to the genus Trichinella and provides epidemiological information on trichinosis. Trichinosis is caused by ingestion of undercooked, infested meat, especially pork, and characterized by fever, muscle weakness, and diarrhea.

(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 §866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 65 FR 2312, Jan. 14, 2000]

§ 866.3870 Trypanosoma spp. serological reagents.

(a) Identification. Trypanosoma spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to Trypanosoma spp. in serum. The identification aids in the diagnosis of trypanosomiasis, a disease caused by parasitic protozoans belonging to the genus Trypanosoma. Trypanosomiasis in adults is a chronic disease characterized by fever, chills, headache, and vomiting. Central nervous system involvement produces typical sleeping sickness syndrome: physical exhaustion, inability to eat, tissue wasting, and eventual death. Chagas disease, an acute and severe disease, 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.

[47 FR 50823, Nov. 9, 1982, as amended at 63 FR 59227, Nov. 3, 1998]

§ 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 virus in serum. The identification aids in the diagnosis of diseases caused by varicella-zoster virus 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 (salts) 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.

[47 FR 50823, Nov. 9, 1982, as amended at 63 FR 59227, Nov. 3, 1998]

§ 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: Sero-
logica guidance of West Nile Virus.” See §866.1(e) for the availability of this
guidance document.
[58 FR 61745, Oct. 30, 2003]

§ 866.3950 In vitro human immuno-
 deficiency virus (HIV) drug resist-
ance genotype assay.

(a) Identification. The in vitro HIV
drug resistance genotype assay is a de-
vice that consists of nucleic acid rea-
gent primers and probes together with
software for predicting drug resistance/
susceptibility based on results obtained
with these primers and probes. It is in-
tended for use in detecting HIV
somatic mutations that confer resist-
ance 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 en-
titled “Class II Special Controls Guid-
dance Document: In Vitro HIV Drug Re-
sistance Genotype Assay.” See §866.1(e)
for the availability of this guidance
document.
[72 FR 44382, Aug. 8, 2007]

§ 866.3980 Respiratory viral panel mul-
tiplex 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 ex-
tracted from human respiratory speci-
mens or viral culture. The detection
and identification of a specific viral
nucleic acid from individuals exhib-
ting signs and symptoms of respira-
tory infection aids in the diagnosis of
respiratory viral infection when used
in conjunction with other clinical and
laboratory findings. The device is in-
tended for detection and identification
of a combination of the following vi-
ruses:

(1) Influenza A and Influenza B;
(2) Influenza A subtype H1 and Influ-
enz 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 Nu-
cleic Acid Assays;” and
(3) For a device that detects and dif-
ferentiates Influenza A subtype H1 and
subtype H3, FDA’s guidance document
enrolled “Class II Special Controls
Guidance Document: Testing for Detec-
tion and Differentiation of Influenza A
Virus Subtypes Using Multiplex Nu-
cleic Acid Assays.” See §866.1(e) for the
availability of these guidance docu-
ments.
[74 FR 52138, Oct. 9, 2009]

Subpart E—Immunology Labora-
tory Equipment and Re-
agents

§ 866.4070 RNA Preanalytical Systems.

(a) Identification. RNA Preanalytical
Systems are devices intended to col-
lect, store, and transport patient speci-
mens, and stabilize intracellular RNA
from the specimens, for subsequent iso-
lation 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 Col-
lection, Stabilization and Purification
System for RT–PCR Used in Molecular
Diagnostic Testing).” See §866.1(e) for
the availability of this guidance docu-
ment.
[70 FR 49863, Aug. 25, 2005]