§ 866.3400 Parainfluenza virus serological reagents.

(a) Identification. Parainfluenza virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to parainfluenza virus in serum. The identification aids in the diagnosis of parainfluenza virus infections and provides epidemiological information on diseases caused by these viruses. Parainfluenza viruses cause a variety of respiratory illnesses ranging from the common cold to pneumonia.

(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]

§ 866.3402 Plasmodium species antigen detection assays.

(a) Identification. A Plasmodium species antigen detection assay is a device that employs antibodies for the detection of specific malaria parasite antigens, including histidine-rich protein-2 (HRP2) specific antigens, and pan malarial antigens in human whole blood. These devices are used for testing specimens from individuals who have signs and symptoms consistent with malaria infection. The detection of these antigens aids in the clinical laboratory diagnosis of malaria caused by the four malaria species capable of infecting humans: Plasmodium falciparum, Plasmodium vivax, Plasmodium ovale, and Plasmodium malariae, and aids in the differential diagnosis of Plasmodium falciparum infections from other less virulent Plasmodium species. The device is intended for use in conjunction with other clinical laboratory findings.

(b) Classification. Class II (special controls). The special control is FDA’s guidance document entitled “Class II Special Controls Guidance Document: Plasmodium species Antigen Detection Assays.” See §866.1(e) for the availability of this guidance document.

[73 FR 29054, May 20, 2008]

§ 866.3405 Poliovirus serological reagents.

(a) Identification. Poliovirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to poliovirus in serum. Additionally, some of these reagents consist of poliovirus antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify polioviruses from clinical specimens or from tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of poliomyelitis (polio) and provides epidemiological information on this disease. Poliomyelitis is an acute infectious disease which in its serious form affects the central nervous system resulting in atrophy (wasting away) of groups of muscles, ending in contraction and permanent deformity.

(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]

§ 866.3410 Proteus spp. (Weil-Felix) serological reagents.

(a) Identification. Proteus spp. (Weil-Felix) serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye (immunofluorescent reagents), derived from the bacterium Proteus vulgaris used in agglutination tests (a specific type of antigen-antibody reaction) for the detection of antibodies to rickettsia (virus-like bacteria) in serum. Test results aid in the diagnosis of diseases caused by bacteria belonging to the genus Rickettsiae and
provide epidemiological information on
these diseases. Rickettsia are generally
transmitted by arthropods (e.g., ticks
and mosquitoes) and produce infections
in humans characterized by rash and
fever (e.g., typhus fever, spotted fever,
Q fever, and trench fever).

(b) Classification. Class I (general con-
trols). 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.

§ 866.3415 Pseudomonas spp. sero-
logical reagents.

(a) Identification. Pseudomonas spp. se-
rological reagents are devices that con-
sist of antigens and antisera, including
antisera conjugated with a fluorescent
dye (immunofluorescent reagents),
used to identify Pseudomonas spp. from
clinical specimens or from cultured
isolates derived from clinical speci-
mens. The identification aids in the di-
agnosis of disease caused by bacteria
belonging to the genus Pseudomonas.
Pseudomonas aeruginosa is a major
cause of hospital-acquired infections,
and has been associated with urinary
tract infections, eye infections, burn
and wound infections, blood poisoning,
ascesses, and meningitis (inflamma-
tion of brain membranes). Pseudomonas
pseudomallei causes melioidosis, a
chronic pneumonia.

(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 the limitations in § 866.9.

§ 866.3470 Reovirus serological re-
agents.

(a) Identification. Reovirus serological
reagents are devices that consist of
antigens and antisera used in sero-
logical tests to identify antibodies to
reovirus in serum. The identification
aids in the diagnosis of reovirus infec-
tions and provides epidemiological in-
formation on diseases caused by these
viruses. Reoviruses are thought to
cause only mild respiratory and gastro-
intestinal illnesses.

(b) Classification. Class II (perform-
ce standards).

§ 866.3480 Respiratory syncytial virus
serological reagents.

(a) Identification. Respiratory syncytial
virus serological reagents are devices
that consist of antigens and antisera used in sero-
logical tests to identify antibodies to
respiratory syncytial virus in serum. Additionally,
some of these reagents consist of res-
piratory syncytial virus antisera con-
jugated with a fluorescent dye
(immunofluorescent reagents) and used
to identify respiratory syncytial virus
from clinical specimens or from
clinical isolates derived from
clinical specimens. The identification
aids in the diagnosis of respiratory
syncytial virus infections and provides
epidemiological information on dis-
eases caused by these viruses. Res-
piratory syncytial viruses cause a
number of respiratory tract infections,
including the common cold, pharyn-
gitis, and infantile bronchopneumonia.

(b) Classification. Class I (general con-
trols). The device is exempt from the
premarket notification procedures in