Food and Drug Administration, HHS

§ 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 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.

[70 FR 49863, Aug. 25, 2005]

§ 866.1070 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 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]

Subpart E—Immunology Laboratory Equipment and Reagents

§ 866.4500 Immunoassay 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 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.

[70 FR 49863, Aug. 25, 2005]
of reflected light. A beam of light is passed through a solution in which a fluorochrome has been selectively attached to serum protein antibody molecules in suspension. The amount of light emitted by the fluorochrome label is detected by a photodetector, which converts light energy into electrical energy. The amount of electrical energy registers on a readout system such as a digital voltmeter or a recording chart. This electrical readout is called the fluorescence value and is used to measure the concentration of antigen-antibody 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.


§ 866.4540 Immunonephelometer equipment.

(a) Identification. Immunonephelometer equipment for clinical use with its electrical power supply is a device that measures light scattering from antigen-antibody complexes. The concentration of these complexes may be measured by means of reflected light. A beam of light passed through a solution is scattered by the particles in suspension. The amount of light is detected by a photodetector, which converts light energy into electrical energy. The amount of electrical energy registers on a readout system such as a digital voltmeter or a recording chart. This electrical readout is called the light-scattering value and is used to measure the concentration of antigen-antibody 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.


§ 866.4600 Ouchterlony agar plate.

(a) Identification. An ouchterlony agar plate for clinical use is a device containing an agar gel used to examine antigen-antibody reactions. In immunodiffusion, antibodies and antigens migrate toward each other through gel which originally contained neither of these reagents. As the reagents come in contact with each other, they combine to form a precipitate that is trapped in the gel matrix and is immobilized.

(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.


§ 866.4700 Automated fluorescence in situ hybridization (FISH) enumeration systems.

(a) Identification. An automated FISH enumeration system is a device that consists of an automated scanning microscope, image analysis system, and customized software applications for FISH assays. This device is intended for in vitro diagnostic use with FISH assays as an aid in the detection, counting and classification of cells based on recognition of cellular color, size, and shape, and in the detection and enumeration of FISH signals in interphase nuclei of formalin-fixed, paraffin-embedded human tissue specimens.

(b) Classification. Class II (special controls). The special control is FDA’s guidance document entitled “Class II Special Controls Guidance Document: Automated Fluorescence in situ Hybridization (FISH) Enumeration Systems.” See §866.1(e) for the availability of this guidance document.

[70 FR 14534, Mar. 23, 2005]

§ 866.4800 Radial immunodiffusion plate.

(a) Identification. A radial immunodiffusion plate for clinical use is a device that consists of a plastic plate to which agar gel containing antiserum is added. In radial immunodiffusion, antigens migrate