Controls Guidance Document: Sero-
logical Reagents for the Laboratory Di-
agnosis of West Nile Virus.” See §866.1(e) for the availability of this
guidance document.

§ 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-
genent 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
genomic mutations that confer resist-
ce 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 Guidance
Document: In Vitro HIV Drug Re-
sistance Genotype Assay.” See §866.1(e)
for the availability of this guidance
document.

§ 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 exhibit-
ing signs and symptoms of res-
piratory 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-
uenza 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
entitled “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.

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.