used to measure by immunochemical

techniques the specific antibody for
gastric parietal cells in serum and
other body fluids. Gastric parietal cells
are those cells located in the stomach
that produce a protein that enables vi-
tamin B\textsubscript{12} to be absorbed by the body.
The measurements aid in the diagnosis
deficiency (or pernicious
anemia), atrophic gastritis (inflamma-
tion of the stomach), and autoimmune
connective tissue diseases (diseases re-
sulting when the body produces anti-
bodies against its own tissues).

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

§ 866.5120 Antismooth muscle antibody

immunological test system.

(a) Identification. An antismooth mus-
cle antibody immunological test sys-

tem is a device that consists of the re-
agents used to measure by immunochemical
techniques the antismooth muscle antibodies (anti-
bodies to nonstriated, involuntary
muscle) in serum. The measurements
aid in the diagnosis of chronic hepa-
titis (inflammation of the liver) and autoimmune
connective tissue diseases (diseases resulting from antibodies pro-
duced against the body’s own tissues).

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

§ 866.5130 Alpha\textsubscript{-1}-antitrypsin

immunological test system.

(a) Identification. An alpha\textsubscript{-1}-
antitrypsin immunological test system
is a device that consists of the reagents
used to measure by immunochemical techniques the alpha-

antitrypsin (a plasma protein) in serum, other body
fluids, and tissues. The measurements
aid in the diagnosis of several condi-
tions including juvenile and adult cir-
rhosis of the liver. In addition, alpha-
antitrypsin deficiency has been associ-
ated with pulmonary emphysema.

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

§ 866.5150 Bence-Jones proteins

immunological test system.

(a) Identification. A Bence-Jones pro-
teins immunological test system is a
device that consists of the reagents
used to measure by immunochemical techniques the Bence-Jones proteins in

urine and plasma. Immunoglobulin
molecules normally consist of pairs of polypeptide chains (subunits) of unequal size (light chains and heavy chains) bound together by several di-
sulfide bridges. In some cancerous con-
ditions, there is a proliferation of one plasma cell (antibody-producing cell) with excess production of light chains of one specific kind (monoclonal light chains). These free homogeneous light
chains not associated with an
immunoglobulin molecule can be found in urine and plasma, and have been called Bence-Jones proteins. Measure-
ment of Bence-Jones proteins and de-
termination that they are monoclonal
aid in the diagnosis of multiple
myeloma (malignant proliferation of plasma cells), Waldenstrom’s
macroglobulinemia (increased produc-
tion of large immunoglobulins by spleen and bone marrow cells), leukemia (cancer of the blood-forming or-
gans), and lymphoma (cancer of the
lymphoid tissue).

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

§ 866.5160 Beta-globulin immunolog-
ical test system.

(a) Identification. A beta-globulin

immunological test system is a device that consists of reagents used to mea-
sure by immunochemical techniques beta globulins (serum protein) in serum and other body fluids. Beta-globulin

proteins include beta-lipoprotein,

transferrin, glycoproteins, and com-
plement, and are rarely associated with
specific pathologic disorders.

(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 §866.9.

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

§ 866.5170 Breast milk immunological
test system.

(a) Identification. A breast milk

immunological test system is a device that consists of the reagents used to measure by immunochemical tech-

iques the breast milk proteins.

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