$866.5080 \textbf{Alpha-1-antichymotrypsin immunological test system.} \\
(a) \textit{Identification.} An \textit{alpha-1-antichymotrypsin} immunological test system is a device that consists of the reagents used to measure by immunochemical techniques \textit{alpha-1-antichymotrypsin} (a protein) in serum, other body fluids, and tissues. \textit{Alpha-1-antichymotrypsin} helps protect tissues against proteolytic (protein-splitting) enzymes released during infection.

(b) \textit{Classification.} Class II (performance standards).

$866.5090 \textbf{Antimitochondrial antibody immunological test system.} \\
(a) \textit{Identification.} An \textit{antimitochondrial antibody} immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the antimitochondrial antibodies in human serum. The measurements aid in the diagnosis of diseases that produce a spectrum of autoantibodies (antibodies produced against the body’s own tissue), such as primary biliary cirrhosis (degeneration of liver tissue) and chronic active hepatitis (inflammation of the liver).

(b) \textit{Classification.} Class II (performance standards).

$866.5100 \textbf{Antinuclear antibody immunological test system.} \\
(a) \textit{Identification.} An \textit{antinuclear antibody} immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the autoimmune antibodies in serum, other body fluids, and tissues that react with cellular nuclear constituents (molecules present in the nucleus of a cell, such as ribonucleic acid, deoxyribonucleic acid, or nuclear proteins). The measurements aid in the diagnosis of systemic lupus erythematosus (a multisystem autoimmune disease in which antibodies attack the victim’s own tissues), hepatitis (a liver disease), rheumatoid arthritis, Sjögren’s syndrome (arthritis with inflammation of the eye, eyelid, and salivary glands), and systemic sclerosis (chronic hardening and shrinking of many body tissues).

(b) \textit{Classification.} Class II (performance standards).

$866.5110 \textbf{Antiparietal antibody immunological test system.} \\
(a) \textit{Identification.} An \textit{antiparietal antibody} immunological test system is a device that consists of the reagents 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 vitamin B₁₂ to be absorbed by the body. The measurements aid in the diagnosis of vitamin B₁₂ deficiency (or pernicious anemia), atrophic gastritis (inflammation of the stomach), and autoimmune connective tissue diseases (diseases resulting when the body produces antibodies against its own tissues).

(b) \textit{Classification.} Class II (performance standards).

$866.5120 \textbf{Antismooth muscle antibody immunological test system.} \\
(a) \textit{Identification.} An \textit{antismooth muscle antibody} immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the antismooth muscle antibodies (antibodies to nonstriated, involuntary muscle) in serum. The measurements aid in the diagnosis of chronic hepatitis (inflammation of the liver) and autoimmune connective tissue diseases (diseases resulting from antibodies produced against the body’s own tissues).

(b) \textit{Classification.} Class II (performance standards).

$866.5130 \textbf{Alpha-1-antitrypsin immunological test system.} \\
(a) \textit{Identification.} An \textit{alpha-1-antitrypsin} immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the \textit{alpha-1-antitrypsin} (a plasma protein) in serum, other body fluids, and tissues. The measurements aid in the diagnosis of several conditions including juvenile and adult cirrhosis of the liver. In addition, \textit{alpha-1-antitrypsin}}