Food and Drug Administration, HHS

§ 866.5220 Cohn fraction II immunological test system.

(a) Identification. A Cohn fraction II immunological test system is a device that consists of the reagents that contain or are used to measure that fraction of plasma containing protein gamma globulins, predominantly of the IgG class. The device may be used as a coprecipitant in radioimmunoassay methods, as raw material for the purification of IgG subclasses, and to reduce nonspecific adsorption of plasma proteins in immunoassay techniques.

§ 866.5180 Fecal calprotectin immunological test system.

(a) Identification. A fecal calprotectin immunological test system is an in vitro diagnostic device that consists of reagents used to quantitatively measure, by immunochemical techniques, fecal calprotectin in human stool specimens. The device is intended for in vitro diagnostic use as an aid in the diagnosis of inflammatory bowel diseases (IBD), specifically Crohn’s disease and ulcerative colitis, and as an aid in differentiation of IBD from irritable bowel syndrome.

(b) Classification. Class II (performance standards). The special control for these devices is FDA’s guidance document entitled “Class II Special Controls Guidance Document: Fecal Calprotectin Immunological Test Systems.” For the availability of this guidance document, see §866.1(e).

[71 FR 42598, July 27, 2006]