Food and Drug Administration, HHS

§ 864.4020 Analyte specific reagents.

(a) Identification. Analyte specific reagents (ASR’s) are antibodies, both polyclonal and monoclonal, specific receptor proteins, ligands, nucleic acid sequences, and similar reagents which, through specific binding or chemical reaction with substances in a specimen, are intended for use in a diagnostic application for identification and quantification of an individual chemical substance or ligand in biological specimens. ASR’s that otherwise fall within this definition are not

Subpart E—Specimen Preparation Reagents

§ 864.4010 General purpose reagent.

(a) A general purpose reagent is a chemical reagent that has general laboratory application, that is used to collect, prepare, and examine specimens from the human body for diagnostic purposes, and that is not labeled or otherwise intended for a specific diagnostic application. It may be either an individual substance, or multiple substances reformulated, which, when combined with or used in conjunction with an appropriate analyte specific reagent (ASR) and other general purpose reagents, is part of a diagnostic test procedure or system constituting a finished in vitro diagnostic (IVD) test. General purpose reagents are appropriate for combining with one or more than one ASR in producing such systems and include labware or disposable constituents of tests; but they do not include laboratory machinery, automated or powered systems. General purpose reagents include cytological preservatives, decalifying reagents, fixative and adhesives, tissue processing reagents, isotonic solutions and pH buffers. Reagents used in tests for more than one individual chemical substance or ligand are general purpose reagents (e.g., Thermus aquaticus (TAQ) polymerase, substrates for enzyme immunoassay (EIA)).

Subpart E—Specimen Preparation Reagents

§ 864.3875 Automated tissue processor.

(a) Identification. An automated tissue processor is an automated system used to process tissue specimens for examination through fixation, dehydration, and infiltration.

(b) Classification. Class I (general controls). This device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §864.9.

§ 864.3800 Automated slide stainer.

(a) Identification. An automated slide stainer is a device used to stain histology, cytology, and hematology slides for diagnosis.

(b) Classification. Class I (general controls). This device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in §864.9.


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