

NORMATIVE INSTRUCTION NO. 3, OF AUGUST 26TH, 2015

The Collegiate Board of Directors of the Brazilian National Health Surveillance Agency (ANVISA), using the powers conferred to it by the items III and IV of Art. 15 in the Law no. 9.782, of January 26th, 1999, considering the item V and paragraphs 1 and 3 of Art. 58 of the Internal Statutes approved by the terms of Annex I of Ordinance no. 29 of ANVISA, of July 21st, 2015, republished in the Federal Official Gazette of July 23rd, 2015, in section III of Art. 2, III and IV, of Art. 7 of the Law no. 9.782, of 1999, and the Regulation Process Improvement Program of the Agency, instituted by Ordinance no. 422, of April 16th, 2008, resolves:

Art. 1 The Normative Instruction hereby regulates item I of Art. 20 of the Resolution of the Collegiate Board of Directors – RDC no. 36, of August 26th, 2015, that describes the classification of risk, the schemes for control of cadastro and registro registrations and the requirements for both labeling and instructions of use for in vitro diagnostic products, including its instruments, and gives other provisions.

Art. 2 Products of the same legal manufacturer, with similar technological characteristics, methodology and indications, may be registered as registro or cadastro as a family, provided that they be fit in the same group, as determined by this Normative Instruction.

Art. 3 Family of culture media, supplements and devices for microbiology are:

- I - discs and tapes impregnated by antimicrobial agents, isolated or in groups;
- II - polyvalent serum for the identification of coli pathogens;
- III - intended for sowing and/or transportation of clinical samples;
- IV - selective for specific groups of microorganisms;
- V - for tests of susceptibility to antimicrobials;
- VI - differentiators intended for the identification of microorganisms by means of biochemical tests;
- VII - intended for anaerobic research;
- VIII - combined panels for the identification and/or susceptibility of microorganisms – Fungi.

Art. 4 The families of reagents for immunohematology are:

- I - ABO and/or RH-HR – monoclonal origin;
- II - ABO and/or RH-HR – human origin;
- III - lectins;
- IV - reagents of red blood cells and reagents of red blood cells treated with enzymes;
- V - complementary reagents for immunohematology;
- VI - rare serums for conventional methodology;
- VII - rare serums for column technology.

Art. 5 The families of systems, discs and tapes for isolated immunospecific immunoglobulin (allergens) research are:

- I - drugs;
- II - animal epithelium and proteins (respiratory tract);
- III - poultry, eggs and their derivatives;
- IV - meat, chocolate, milk and its derivatives;
- V - fish, mollusks, shellfish, others of marine origin and their derivatives;
- VI - grains, seeds and their derivatives;
- VII - flowers, fruits, honey and their derivatives;
- VIII - vegetables and legumes;
- VIII - leaves, stems, roots, spices and their derivatives;
- IX - food additives;
- X - grass pollen;
- XI - mites and dust;
- XII - insects and their poisons;
- XIII - fungi and molds;
- XIV - occupational allergens;
- XV - parasites;
- XVI - pollen from trees and shrubs;
- XVII - pollen from flowers;
- XVII - seminal fluid;
- XVIII - screening food panels;
- XIX - panels for respiratory/ inhalants screening.

Art. 6 Dye families are:

- I- microbiological dyes;
- II - hematopathological dyes;
- III - cytological dyes.

Art. 7 The families of products for histocompatibility are:

- I - HLA Serological Class I – class I anti-HLA antibodies, controls, class I complements, beads for class I;
- II - HLA Serological Class II – class II anti-HLA antibodies, controls, class II complements, beads for class II;
- III - HLA Serological – Lymphocytes panel;
- IV - HLA Serological – immunoenzymatic method;
- V - HLA Serological – cytometric flow;
- VI - HLA Molecular –HLA SSP low and medium resolution;
- VII - HLA Molecular – HLA SSP high resolution;
- VIII - HLA Molecular – HLA SSO;
- IX - HLA Molecular – HLA SBT high resolution;
- X - complementary reagents for histocompatibility.

Art. 8 Families of products for cytometric flow are:

- I - adhesion cell markers;
- II - B cell markers;
- III - carbohydrate cell markers;
- IV - cytokine markers;
- V - dendritic cell markers;
- VI - endothelial cell markers;
- VII - myeloid cell markers;
- VIII - NK cell markers;
- IX - nonspecific lineage cell markers;
- X - platelet markers;
- XI - erythrocytes markers;
- XII - stem cell markers;
- XIII - T-cell markers;
- XIV - complementary reagents for cytometric flow.

Art. 9 Families of products for immunohistochemistry are:

- I - general tumor markers;
- II - breast tumor markers;
- III - gastrointestinal tumor markers;
- IV - Germ cells tumor markers;
- V - hepatic tumor markers;
- VI - mesothelioma tumor markers;
- VII - testicular tumor markers;
- VIII - sarcoma tumor markers;
- IX - thyroid/parathyroid tumor markers;
- X - infectious disease tumor markers;
- XI - kidney and renal failure tumor markers;
- XII - lymphoma and leukemia tumor markers;
- XIII - muscle and muscle disorder tumor markers;
- XIV - nervous system tumor markers;
- XV - skin and melanoma tumor markers;
- XVI - complementary markers;
- XVII - complementary reagents for immunohistochemistry.

Art. 10 Families of probes marked for in situ hybridization are:

- I - leukemia and lymphoma markers;
- II - respiratory system pathologies and neoplasia markers;
- III - digestive system pathologies and neoplasia markers;
- IV - nervous system pathologies and neoplasia markers;
- V - reproductive system pathologies and neoplasia markers;
- VI - endocrine system pathologies and neoplasia markers;
- VII - circulatory system pathologies and neoplasia markers;
- VIII - musculoskeletal system pathologies and neoplasia markers;
- IX - chromosomal probes for analysis;
- X - complementary reagents for in situ hybridization.

Art. 11- Family of flasks or materials for collection, storage or transportation of biological samples are:

- I - blood collection tubes;
- II - devices for collection of cytological material.

Art. 12 Other families:

- I - Instruments for in vitro diagnosis with the same medication and technology;
- II - deficient plasmas in coagulation factors;
- III - calibrators and standards for a single parameter of several concentrations;
- IV - calibrators and standards for multiple parameters of several concentrations, restricted to the performance of a specific test;
- V - controls for single parameters of several concentrations;
- VI - controls for multiple parameters of several concentrations, restricted to the performance of a specific test;
- VII - reagents, controls or calibrators for a single parameter;
- VIII - multi-parameter reagents, controls or calibrators, restricted to the performance of a specific test;
- IX - products of the same composition, technology and indication, with different commercial names;

Art. 13 The conversion of a single product into a family registration after its publication in the Federal Official Gazette will not be permitted.

Art. 14 This Normative Instruction shall come into force on the date of its publication.

JARBAS BARBOSA DA SILVA JR