Av. Vereador José Diniz, 2.270
São Paulo ● SP ● Brasil/ Brazil
CEP/ Zipcode: 04604-003
Tel./ Phone: 55 11 5090 5080
Fax: 55 11 5090 5083
Site: www.latinigroup.com

NORMATIVE INSTRUCTION No. 3, OF AUGUST 26, 2015

A Collegiate Board of the National Health Surveillance Agency, in the use of the attributions conferred on it by items III and IV, of art. 15 of Law No. 9,782, of January 26, 1999, in view of the provisions of item VI and §§ 1 and 3 of art. 58 of the Internal Regulations approved pursuant to Annex I of the Resolution of the Collegiate Board - RDC No. 29, of July 21, 2015, published in the DOU of July 23, 2015, in items III of art. 2, III and IV, of art. 7 of Law No. 9,782, of 1999, and the Program for Improving the Agency's Regulation Process, instituted through Ordinance No. 422, of April 16, 2008, at a meeting held on August 20, 2015, resolves:

Art. 1 This Normative Instruction regulates item I of art. 20 of the Resolution of the Collegiate Board of Directors-RDC No. 36, of August 26, 2015, which provides for the risk classification, the registration and registration control regimes and the labeling requirements and instructions for use of in vitro diagnostic products, including its instruments and other provisions.

Art 2nd Products from the same legal manufacturer, with similar characteristics of technology, methodology and indication, may be registered or registered as a family of products, provided that they are included in the same group as determined in this Normative Instruction.

Art. 3 The families of culture media, supplements and devices for microbiology are:
I - disks and tapes impregnated with antimicrobial agents, isolated and in groups;
II - polyvalent sera for identification of coli pathogens;
III - intended for sowing and/or transport of clinical samples;
IV - selective for certain groups of microorganisms;
V - for antimicrobial susceptibility tests;
VI - differentials destined to the identification of microorganisms through biochemical tests;
VII - intended for research on anaerobes;
VIII - combined panels for identification and/or susceptibility of microorganisms - Bacteria is:
IX - combined panels for 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 - red blood cells reagents and enzyme-treated red blood cells reagents;
V - complementary reagents for immunohematology;
VI - rare sera for conventional methodology;
VII - rare sera for column technology.

Art. 5 The families of systems, disks and strips for researching isolated immunoglobulin (allergens) are:
I - drugs;
II - epithelium and animal proteins (respiratory route);
III - poultry, eggs and their derivatives;
IV - meat, chocolate, milk and derivatives thereof;
V - fish, mollusks, shellfish, others of marine origin and derivatives;
VI - cereals, seeds and derivatives thereof;

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VII - flowers, honey, fruits and derivatives thereof;
VIII - vegetables and greens;
IX - leaves, stems, roots, spices and their derivatives;
X - food additives;
XI - grass pollen;
XII - mites and dust;
XIII - insects and their poisons;
XIV - fungi and molds;
XV - occupational allergens;
XVI - parasites;
XVII - pollen from trees and bushes;
XVIII - pollen of flowers;
XIX - seminal fluid;
XX - panels for food sorting;
XXI - panels for respiratory/inhalant screening.

Art. 6 The families of dyes are:
I - microbiological dyes;
II - hematopathological dyes;
III - cytological dyes.

Art. 7 The product families for histocompatibility are:
I - HLA Serological Class I - anti-HLA class I antibodies, controls, class I complement, class I beads;
II - HLA Serological Class II - anti-HLA class II antibodies, controls, complement class II, beads for class II;
III - Serologic HLA - Lymphocyte panel;
IV - Serological HLA - immunoenzymatically method;
V - Serological HLA - flow cytometry;
VI - Molecular HLA: HLA SSP low and medium resolution;
VII - Molecular HLA: high resolution HLA SSP;
VIII - Molecular HLA: HLA SSO;
IX - Molecular HLA: high resolution SBT HLA;
X - complementary reagents for histocompatibility.

Art. 8 The product families for flow cytometry are:
I - cell adhesion markers;
II - B cell markers;
III - cell carbohydrate markers;
IV - cytokine markers;
V - dendritic cell markers;
VI - endothelial cell markers;
VII - myeloid cell markers;
VIII - NK cell markers;
IX - cell markers without specific lineage;
X - platelet markers;
XI - erythrocyte markers;
XII - stem cell markers;
XIII - T cell markers;
XIV - complementary reagents for flow cytometry.

Art. 9 The product families for immunohistochemistry are:
I - markers of carcinomas in general;

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II - breast carcinoma markers;
III - gastrointestinal tract carcinoma markers;
IV - germ cell carcinoma markers;
V - markers of hepatic carcinomas;
VI - mesothelioma markers;
VII - markers of prostate cancer;
VIII - sarcoma markers;
IX - markers of thyroid/parathyroid carcinomas;
X - infectious disease markers;
XI - markers of kidney carcinomas and kidney disorders;
XII - markers of lymphomas and leukemias;
XIII - markers of muscular carcinomas and muscular disorders;
XIV - markers of carcinomas of the nervous system;
XV - markers of skin carcinomas and melanomas;
XVI - complementary markers;
XVII - complementary reagents for immunohistochemistry.

Art. 10. The families of probes marked for in situ hybridization are:
I - leukemia and lymphoma markers;
II - markers of pathologies and neoplasms of the respiratory system;
III - markers of pathologies and neoplasms of the digestive system;
IV - markers of pathologies and neoplasms of the nervous system;
V - markers of pathologies and neoplasms of the reproductive system;
VI - markers of pathologies and neoplasms of the endocrine system;
VII - markers of pathologies and neoplasms of the circulatory system;
VIII - markers of pathologies and neoplasms of the locomotor and bone system;
IX - probes for chromosome analysis;
X - complementary reagents for in situ hybridization.

Art. 11. The families of flasks or materials for collecting, storing or transporting biological samples are:(Revoked by Normative Instruction No. 30 of March 19, 2019)
I - blood collection tubes;(Revoked given by Normative Instruction No. 30, of March 19, 2019)
II - devices for collection of cytological material. (Revoked given by Normative Instruction No. 30, of March 19, 2019)

Art. 12. Other families:
Art. 12. The following products may also be grouped into families: (Wording provided by Normative Instruction No. 30, of March 19, 2019)
I - instruments for in vitro diagnosis with the same indication and technology.
II - plasmas deficient in coagulation factors;
III - calibrators and standards for a single parameter of various concentrations;
IV - calibrators and multiparameter standards of several concentrations, exclusive for the execution of a specific assay;
V - controls for single parameter of several concentrations;
VI - multiparameter controls of several concentrations, exclusive for the execution of a specific assay;
VII - reagents, controls or calibrators for a single parameter;
VIII - reagents, controls or multiparameter calibrators, exclusive for the execution of a specific test;
IX - products of the same composition, technology and indication, with different commercial names.

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X - interdependent instruments for in vitro diagnosis grouped into a system and designed to be used in association, in which only one member of the system operates independently and the other members are dependent on that instrument to operate. (Included by Normative Instruction No. 30, of March 19, 2019)

XI- flasks or materials for collecting, storing or transporting biological samples. (Included by Normative Instruction No. 30, of March 19, 2019)

Art. 13. The transformation of a single product process into a family after its publication in the Federal Official Gazette will not be allowed.

Art. 14. This Normative Instruction comes into effect on the date of its publication.

JARBAS BARBOSA DA SILVA JR