AMBITO REGULADOR

ÓRGANO OFICIAL REGULATORIO
CENTRO PARA EL CONTROL ESTATAL DE LOS MEDICAMENTOS, EQUIPOS Y DISPOSITIVOS MÉDICOS
CECMED

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INFORMACIÓN A LOS LECTORES: En esta edición de nuestro Boletín publicamos la siguiente información:

Resolución No. 44/2012. Lista de Normas y Guías Reconocidas por el CECMED para la Evaluación del Desempeño de los Diagnosticadores.

REPÚBLICA DE CUBA
MINISTERIO DE SALUD PÚBLICA
CENTRO PARA EL CONTROL ESTATAL DE LOS MEDICAMENTOS, EQUIPOS Y DISPOSITIVOS MÉDICOS

RESOLUCIÓN No. 44 / 2012

POR CUANTO: Por Resolución **No. 263** de fecha 11 de mayo del año 2011, del Ministerio de Economía y Planificación, se autorizó la fusión de las unidades presupuestadas denominadas Buró Regulatorio para la Protección de la Salud, Centro para el Control Estatal de Calidad de los Medicamentos y Centro de Control Estatal de Equipos Médicos, y la creación de la unidad presupuestada denominada Centro para el Control Estatal de Medicamentos, Equipos y Dispositivos Médicos, en forma abreviada CECMED, todas subordinadas al Ministerio de Salud Pública.

POR CUANTO: Por Resolución **No. 153** de fecha 27 de junio del año 2011, del Ministerio de Salud Pública, se creó el Centro para el Control Estatal de Medicamentos, Equipos y Dispositivos Médicos, en forma abreviada CECMED, donde se dispuso que los bienes, recursos, derechos y obligaciones de toda índole de las unidades presupuestadas que se autorizaron fusionar se transfieren al CECMED, la cual se subroga en sus lugares y grados a todos los efectos legales según corresponda.

POR CUANTO: Por Resolución **No. 155** de fecha 27 de junio del año 2011, del Ministerio de Salud pública, el que suscribe fue designado como Director General del CECMED.

POR CUANTO: Mediante la Resolución Ministerial **No. 154** de fecha 21 de agosto del año 2003 se puso en vigor el Reglamento para el Registro Sanitario de Diagnosticadores, el cual establece los procedimientos necesarios para autorizar la comercialización de los diagnosticadores en el territorio nacional y faculta al Director del Buró Regulatorio para la Protección de la Salud para emitir cuantas disposiciones complementarias resulten necesarias para la mejor aplicación de los procedimientos regulados o para emitir las nuevas ediciones que del mismo se elaboren.

POR CUANTO: La Regulación No.8-2001 Requisitos Generales para el Registro de los Diagnosticadores, aprobada mediante la Resolución **No. 24** de fecha 24 de julio del 2001 del Director del CECMED, establece la evaluación del desempeño como uno de los requisitos que deben cumplir los diagnosticadores para su Registro Sanitario. Dicha evaluación consiste en un estudio que se realiza con el objetivo de demostrar que las características funcionales del diagnosticador responden al propósito para el cual fue diseñado.

POR CUANTO: La Regulación no. 47-2007 Requisitos para la evaluación del desempeño de los diagnosticadores, aprobada mediante la Resolución **No. 35** de fecha 22 de mayo del 2007 del Director del CECMED, establece en el apartado 8 el uso de normas, guías, u otros documentos internacionales o nacionales, en caso de que existan, para realizar la evaluación del desempeño de un diagnosticador.

POR CUANTO: El CECMED ha identificado un conjunto de documentos de carácter y procedencia diversos que establecen pautas para la evaluación del desempeño de los diagnosticadores, los cuales, de ser adoptados oficialmente, contribuirían a armonizar y brindar transparencia al proceso de Autorización de Comercialización de los Diagnosticadores.

POR TANTO: En el ejercicio de las facultades que me están conferidas,

RESUELVO:

PRIMERO: Aprobar y poner en vigor la Lista de **N**ormas y Guías Reconocidas por el CECMED para la Evaluación del Desempeño de los Diagnosticadores.

SEGUNDO: El CECMED revisará la Lista anualmente, la actualizará cada vez que sea necesario y la publicará en su sitio web.

TERCERO: La presente Resolución entrará en vigor a partir de la fecha de su firma.

COMUNÍQUESE a, Cuantas personas naturales y/o jurídicas proceda.

ARCHÍVESE, la presente Resolución quedará archivada en el protocolo de la Asesoría Jurídica del Centro desde el que se emitirán las copias fieles que sean menester.

PUBLÍQUESE, en el Ámbito Regulador, órgano oficial del CECMED, para su general conocimiento.

DADA en La Habana a los 8 días del mes de marzo del año 2012.

"Año 54 de la Revolución"

Dr. RAFAEL B. PÉREZ CRISTIÁ
Director General

1. Normas Cubanas (NC).

1.1 NC 376:2004 Terminología sobre Laboratorios Clínicos y Diagnosticadores.

2. Normas de la Organización Internacional de Estandarización (ISO).

2.1 ISO 20776-1:2006 - Clinical laboratory testing and in vitro diagnostic test systems - Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devices - Part 1: Reference method for testing the in vitro activity of antimicrobial agents against rapidly growing aerobic bacteria involved in infectious diseases.

2.2 ISO 20776-2:2007 - Clinical laboratory testing and in vitro diagnostic test systems - Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devices - Part 2: Evaluation of performance of antimicrobial susceptibility test devices**.**

2.3 ISO 18153:2003 - In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values for catalytic concentration of enzymes assigned calibrators and control materials.

2.4 ISO 15197:2003 - In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.

2.5 ISO 17511:2003 - In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials.

2.6 ISO/TS 11133-2:2003 Microbiology of food and animal feeding stuffs - Guidelines on preparation and production of culture media - Part 2: Practical guidelines on performance testing of culture media.

3. Normas del Instituto de Estándares de Laboratorio Clínico (CLSI).

3.1 EP05-A2 Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline-Second Edition.

3.2 EP06-A Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline.

3.3 EP07-A2 Interference Testing in Clinical Chemistry; Approved Guideline- Second Edition.

3.4 EP09-A2-IR Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline - Second Edition (Interim Revision).

3.5 EP10-A3 Preliminary Evaluation of Quantitative Clinical Laboratory Measurement Procedures; Approved Guideline - Third Edition.

3.6 EP12-A2 User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline - Second Edition.

3.7 EP14-A2 Evaluation of Matrix Effects; Approved Guideline-Second Edition.

3.8 EP15-A2 User Verification of Performance for Precision and Trueness; Approved Guideline - Second Edition.

3.9 EP17-A Protocols for Determination of Limits of Detection and Limits of Quantitation; Approved Guideline.

3.10 EP18-A2 Risk Management Techniques to Identify and Control Laboratory Error Sources; Approved Guideline-Second Edition.

3.11 GP10-A Assessment of the Clinical Accuracy of Laboratory Tests Using Receiver Operating Characteristic (ROC) Plots; Approved Guideline.

3.12 X05-R Metrological Traceability and Its Implementation; A Report.

3.13 MM5-A Nucleic Acid Amplification Assays for Molecular Hematopathology; Approved Guideline.

3.14 MM03-A2 Molecular Diagnostic Methods for Infectious Diseases; Approved Guideline - Second Edition.

3.15 MM9-A Nucleic Acid Sequencing Methods in Diagnostic Laboratory Medicine; Approved Guideline.

3.16 MM12-A Diagnostic Nucleic Acid Microarrays; Approved Guideline.

3.17 MM17-A Verification and Validation of Multiplex Nucleic Acid Assays; Approved Guideline.

3.18 M100-S20-U Performance Standards for Antimicrobial Susceptibility Testing; Twentieth Informational Supplement.

4. Normas Europeas (EN).

4.1 EN 12322:1999/A1:2001 Productos sanitarios para diagnóstico in vitro. Medios de cultivo para microbiología. Criterios para las características funcionales de los medios de cultivo.

4.2 EN 14136:2004 Utilización de programas de evaluación externa de la calidad en la evaluación del desempeño de los procedimientos de diagnóstico in vitro.

5. Guías de la Administración de Drogas y Alimentos (FDA).

5.1 Draft Guidance for Industry and Food and Drug Administration Staff - Recommendations for Premarket Notifications for Lamotrigine and Zonisamide Assays (08/06/2010).

5.2 Guidance for Industry and FDA Staff - In Vitro Diagnostic 2009 H1N1 Tests for Use in the 2009 H1N1 Emergency (11/06/2009).

5.3 Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Testing for Detection and Differentiation of Influenza A Virus Subtypes Using Multiplex Assays (10/09/2009).

5.4 Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Testing for Human Metapneumovirus (hMPV) Using Nucleic Acid Assays (10/09/2009).

5.5 Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Respiratory Viral Panel Multiplex Nucleic Acid Assay (10/09/2009).

5.6 Draft Guidance for Industry and FDA Staff - Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Human Papillomaviruses (09/09/2009).

5.7 Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems (08/28/2009).

5.8 Recommendations for Anti-Nuclear Antibody (ANA) Test System Premarket (510(k)) Submissions (01/22/2009).

5.9 Class II Special Controls Guidance Document: Nucleic Acid Amplification Assay for the Detection of Enterovirus RNA (01/02/2009).

5.10 Class II Special Controls Guidance Document: Plasmodium Species Antigen Detection Assays (05/20/2008).

5.11 Establishing Performance Characteristics of In Vitro Diagnostic Devices for Detection or Detection and Differentiation of Influenza Viruses (02/12/2008).

5.12 Guidance for Industry and FDA Staff - Review Criteria for Assessment of Qualitative Fecal Occult Blood In Vitro Diagnostic Devices (08/08/2007).

5.13 Guidance on Pharmacogenetic Tests and Genetic Tests for Heritable Markers (02/09/2006).

5.14 Guidance for Industry and FDA Staff - Assayed and Unassayed Quality Control Material (06/07/2007).

5.15 Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Gene Expression Profiling Test System for Breast Cancer Prognosis (05/09/2007).

5.16 In Vitro Diagnostic Devices to Detect Influenza A Viruses: Labeling and Regulatory Path - Guidance for Industry and FDA Staff (05/01/2007).

5.17 Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays (04/03/2007).

5.18 Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Quality Control Material for Cystic Fibrosis Nucleic Acid Assays (01/10/2007).

5.19 Draft Guidance for Industry and FDA Staff - Total Product Life Cycle for Portable Invasive Blood Glucose Monitoring Systems (10/24/2006).

5.20 Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Fecal Calprotectin Immunological Test Systems (07/27/2006).

5.21 Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Reagents for Detection of Specific Novel Influenza A Viruses (03/22/2006).

5.22 Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Hepatitis A Virus Serological Assays (02/09/2006).

5.23 Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: CFTR Gene Mutation Detection Systems (10/26/2005).

5.24 Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: AFP-L3 Immunological Test Systems (10/04/2005).

5.25 Guidance for Industry - Review Criteria for Assessment of C Reactive Protein (CRP), High Sensitivity C-Reactive Protein (hsCRP) and Cardiac C-Reactive Protein (cCRP) Assays (09/22/2005).

5.26 Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: RNA Preanalytical Systems (RNA Collection, Stabilization and Purification Systems for RT-PCR used in Molecular Diagnostic Testing) (08/25/2005).

5.27 Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Automated Fluorescence in situ Hybridization (FISH) Enumeration Systems (03/23/2005).

5.28 Class II Special Controls Guidance Document: Instrumentation for Clinical Multiplex Test Systems - Guidance for Industry and FDA Staff (03/10/2005).

5.29 Class II Special Controls Guidance Document: Drug Metabolizing Enzyme Genotyping System - Guidance for Industry and FDA Staff (03/10/2005).

5.30 Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Newborn Screening Test Systems for Amino Acids, Free Carnitine, and Acylcarnitines Using Tandem Mass Spectrometry (11/24/2004).

5.31 Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Sirolimus Test Systems (09/30/2004).

5.32 Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Serological Assays for the Detection of Beta-Glucan (09/23/2004).

5.33 Class II Special Controls Guidance Document: Immunomagnetic Circulating Cancer Cell Selection and Enumeration System - Guidance for Industry and FDA Staff (05/11/2004).

5.34 Class II Special Controls Guidance Document: Factor V Leiden DNA Mutation Detection Systems - Guidance for Industry and FDA Staff (03/16/2004).

5.35 Premarket Submissions and Labeling Recommendations for Drugs of Abuse Screening Tests - Draft Guidance for Industry and FDA Staff (12/02/2003).

5.36 Class II Special Controls Guidance Document: Endotoxin Assay - Guidance for Industry and FDA Staff (10/31/2003).

5.37 Class II Special Controls Guidance Document: Serological Reagents for the Laboratory Diagnosis of West Nile Virus - Guidance for Industry and FDA Staff (10/30/2003).

5.38 Class II Special Controls Guidance Document: Breath Nitric Oxide Test System - Guidance for Industry and FDA Staff (07/07/2003).

5.39 510(k) Submissions for Coagulation Instruments - Guidance for Industry and FDA Staff (06/19/2003).

5.40 Class II Special Controls Guidance Document: Cyclosporine and Tacrolimus Assays; Guidance for Industry and FDA (09/16/2002).

5.41 Class II Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells; Final Guidance for Industry and FDA (12/04/2001).

5.42 Radioallergosorbent Test (RAST) Methods for Allergen-Specific Immunoglobulin E (IgE) 510(k)s; Final Guidance for Industry and FDA (08/22/2001).

5.43 Class II Special Control Guidance Document for B-Type Natriuretic Peptide Premarket Notifications; Final Guidance for Industry and FDA Reviewers; Final Guidance for Industry and FDA Reviewers; Final Guidance for Industry and FDA Reviewers (11/30/2000).

5.44 Class II Special Control Guidance Document for Anti-Saccharomyces cerevisiae (S. cerevisiae) Antibody (ASCA) Premarket Notifications - Guidance for Industry and FDA Reviewers (08/23/2000).

5.45 Guidance for Over-the-Counter (OTC) Human Chorionic Gonadotropin (hCG) 510(k)s - Guidance for Industry and FDA Reviewers/Staff (07/22/2000).

5.46 In Vitro Diagnostic Fibrin Monomer Paracoagulation Test; Final Guidance for Industry and FDA Reviewers/Staff (06/24/1999).

5.47 Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators; Final Guidance for Industry (02/22/1999).

5.48 In Vitro Diagnostic Bicarbonate/Carbon Dioxide Test System; Final Guidance for Industry (07/06/1998).

5.49 In Vitro Diagnostic Chloride Test System; Final Guidance for Industry (07/06/1998).

5.50 In Vitro Diagnostic Potassium Test System; Final Guidance for Industry (07/06/1998).

5.51 In Vitro Diagnostic Sodium Test System; Final Guidance for Industry (07/06/1998).

5.52 In Vitro Diagnostic Urea Nitrogen Test System; Final Guidance for Industry (07/06/1998).

5.53 In Vitro Diagnostic Glucose Test System; Final Guidance for Industry (07/06/1998).

5.54 In Vitro Diagnostic Creatinine Test System; Final Guidance for Industry (07/06/1998).

5.55 Guidance for Submission of Immunohistochemistry Applications to the FDA; Final Guidance for Industry (06/03/1998).

5.56 Review Criteria For Assessment Of Rheumatoid Factor (Rf) In Vitro Diagnostic Devices Using Enzyme-Linked Immunoassay (Eia), Enzyme Linked Immunosorbent Assay (Elisa), Particle Agglutination Tests, And Laser And Rate Nephelometry **(**02/21/1997).

5.57 Review Criteria for Assessment of Professional Use Human Chorionic Gonadotropin (hCG) In Vitro Diagnostic Devices (IVDs) (11/06/1996).

5.58 Review Criteria for Assessment of Antimicrobial Susceptibility Test Discs (PDF Only) (10/30/1996).

5.59 Guidance Document for the Submission of Tumor Associated Antigen Premarket Notifications, [510(k)], to FDA (09/19/1996).

5.60 Points to Consider for Portable Blood Glucose Monitoring Devices Intended for Bedside Use in the Neonate Nursery (02/20/1996).

5.61 Review Criteria for In Vitro Diagnostic Devices that Utilize Cytogenetic In Situ Hybridization Technology for the Detection of Human Genetic Mutations (Germ Line and Somatic) (02/15/1996).

5.62 Review Criteria Assessment of Portable Blood Glucose Monitoring In Vitro Diagnostic Devices Using Glucose Oxidase, Dehydrogenase or Hexokinase Methodology (02/28/1997).

5.63 Guidance for 510(k)s on Cholesterol Tests for Clinical Laboratory, Physicians' Office Laboratory and Home Use (07/13/1995).

5.64 Review Criteria for Assessment of Alpha-Fetoprotein (AFP) in vitro Diagnostic Devices for Fetal Open Neural Tube Defects Using Immunological Test Methodologies (07/15/1994).

5.65 Review Criteria for In Vitro Diagnostic Devices for the Assessment of Thyroid Autoantibodies using Indirect Immunofluorescence Assay (IFA), Indirect Hemagglutination Assay (IHA), Radioimmunoasay (RIA), and Enzyme Linked Immunosorbent Assay (ELISA) (02/01/1994).

5.66 Review Criteria for Assessment of In Vitro Diagnostic Devices for Direct Detection of Mycobacterium Spp. [Tuberculosis (TB)] (07/06/1993).

5.67 Review Criteria for Assessment of Laboratory Tests for the Detection of Antibodies to Helicobacter pylori (09/17/1992).

5.68 Draft Guidance Document for 510(k) Submission of Immunoglobulins A,G,M,D and E Immunoglobulin System In Vitro Devices (09/01/1992).

5.69 Review Criteria for In Vitro Diagnostic Devices for Detection of IgM Antibodies to Viral Agents (08/01/1992).

5.70 Review Criteria For Premarket Approval of In Vitro Diagnostic Devices for Detection of Antibodies to Parvovirus B19 (05/15/1992).

5.71 Review Criteria for Devices Intended for the Detection of Hepatitis B 'e' Antigen and Antibody to HBe (12/30/1991).

5.72 Review Criteria for Assessment of Glycohemoglobin (Glycated or Glycosylated) Hemoglobin In Vitro Diagnostic Devices (09/30/1991).

5.73 Draft Guidance for 510(k) Submission of Lymphocyte Immunophenotyping IVDs using Monoclonal Antibodies (09/26/1991)**.**

5.74 Review Criteria for Assessment of Cytogenetic Analysis Using Automated and Semi-Automated Chromosome Analyzers (07/15/1991)**.**

5.75 Assessing the Safety and Effectiveness of Home-Use In Vitro Diagnostic Devices (IVDs): Draft Points to Consider Regarding Labeling and Premarket Submissions (10/05/1988).

5.76 Draft Recommended methods for blood grouping reagents evaluation. DOCKET NO. 84S-0181, CBER, Marzo 1992.

5.77 Draft Recommended methods for evaluating potency, specificity, and reactivity of anti-human globulin. DOCKET NO. 84S-0182, CBER, Marzo 1992.

5.78 Draft Points to consider in the design and implementation of field trials for blood grouping reagents and anti-human globulin. DOCKET NO. 91N-04671 , CBER, 1992

6. Otras guías internacionales.

6.1 Guidelines for the Blood Transfusion Services in the UK, 7th Edition, Octubre 2005. ISBN 0 11 703371 5. Published by TSO (The Stationery Office) and available from Online www.tsoshop.co.uk

6.2 NIST Technical Note 1297 Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results, Barry N. Taylor and Chris E. Kuyatt, 19

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