REPÚBLICA DE CUBA

MINISTERIO DE SALUD PÚBLICA

CENTRO PARA EL CONTROL ESTATAL

DE MEDICAMENTOS, EQUIPOS Y DISPOSITIVOS MÉDICOS

CECMED

Lista de Guías para Diagnosticadores

2019

Fecha de Emisión: 12 de diciembre del 2019

Fecha de Entrada en Vigor: 12 de diciembre del 2019

Calle 5ta A # 6020 entre 60 y 62, Rpto. Miramar, Playa, La Habana, Cuba, C.P. 11300, Telf: (537) 164000 E-mail: cecmed@cecmed.cu Web: www.cecmed.sld.cu

Nota a la presente edición

Este documento recoge la Lista de guías reconocidas por el CECMED para la demostración de los requisitos esenciales de seguridad, eficacia y efectividad de los Diagnosticadores.

La disposición reguladora (DR) *Lista de Normas y Guías para Diagnosticadores*, aprobada por la Resolución del CECMED No. 75/2013, del 5 de junio de 2013, se actualiza en 2019 mediante dos DDRR: (1) *Lista de Guías para Diagnosticadores*, con respecto a las guías aceptadas y (2) *Lista Regulatoria de Normas* (LRN, Lista de normas reconocidas por el CECMED para la demostración de los requisitos esenciales de seguridad, eficacia y efectividad de Equipos y Dispositivos Médicos), con respecto a las normas, mediante la inclusión en la misma de la categoría de Dispositivos Médicos para el Diagnóstico in Vitro.

En esta edición fueron adicionadas 34 guías (76 % correspondientes a la FDA), se eliminaron 24 y se actualizaron las ediciones de 4 guías. Otros cambios realizados consisten en (a) la diferenciación de las guías publicadas por Autoridades Reguladoras Nacionales de las publicadas por otros organismos internacionales; (b) modificación de la estructura de este documento, adoptando la misma que se aplica en la LRN y por último (c) se establece su revisión anual.

ÍNDICE

I. Cambios introducidos en la nueva edición 2019 de la Lista de guías reconocidas por el CECMED para la demostración de los requisitos esenciales de seguridad, eficacia y efectividad de los Diagnosticadores 4
1. Guías adicionadas 4
2. Guías eliminadas 5
3. Guías actualizadas (reemplazadas)....7
II. Lista de Guías reconocidas a partir de la presente edición 8
1. Autoridades Reguladoras Nacionales....8
1.1. Administración de Medicamentos y Alimentos de Estados Unidos de América (FDA por sus siglas en inglés) 8
1.2. Buró de Dispositivos Médicos de la Dirección de Productos Terapéuticos de Canadá (TPD, por sus siglas en inglés) 11
2. Otros organismos internacionales....12
2.1. Foro Internacional de Reguladores de Dispositivos Médicos (IMDRF, por sus siglas en inglés) 12
2.2. Organización Mundial de la Salud (WHO, por sus siglas en inglés) 12
2.3. United Kingdom Blood Transfusion Services 12

I. Cambios introducidos en la nueva edición 2019 de la Lista de guías reconocidas por el CECMED para la demostración de los requisitos esenciales de seguridad, eficacia y efectividad de los Diagnosticadores

1. Guías adicionadas

NO. GUÍA	TÍTULO DE LA GUÍA	AÑO
1400038	Class II Special Controls Guideline: In Vitro Diagnostic Devices for Bacillus spp. Detection - Guideline for Industry and Food and Drug Administration Staff	2019
17032	Logical Observation Identifiers Names and Codes for In Vitro Diagnostic Tests - Guidance for Industry and Food and Drug Administration Staff	2018
16008	Use of Public Human Genetic Variant Databases to Support Clinical Validity for Genetic and Genomic- Based In Vitro Diagnostics	2018
16009	Considerations for Design, Development, and Analytical Validation of Next Generation Sequencing (NGS) – Based In Vitro Diagnostics (IVDs) Intended to aid in the Diagnosis of Suspected Germline Diseases	2018
---	IMDRF/RPS WG/N13 FINAL. In Vitro Diagnostic Medical Device Market Authorization Table of Contents (IVD MA ToC)	2018
1143	Administrative Procedures for CLIA Categorization	2017
16046	Select Updates for Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices. Draft document.	2017
---	WHO/TGS-3. Principles of performance studies	2017
---	WHO/TGS-4. Guidance on test method validation for in vitro diagnostic medical devices	2017
---	WHO/TGS-5. Designing instructions for use for in vitro diagnostic medical devices	2017
---	WHO/TGS-6. Panels for quality assurance and quality control of in vitro diagnostic medical devices	2017
---	WHO/TGS-7. Risk management for manufacturers of in vitro diagnostic medical devices	2017
1755	Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use	2016
1756	Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use	2016
1100491	Class II Special Controls Guideline: Nucleic Acid Amplification Assays for the Detection of Trichomonas vaginalis	2015
1400051	Class II Special Controls Guideline: Multiplex Nucleic Acid Assay for Identification of Microorganisms and Resistance Markers from Positive Blood Cultures	2015
1200022	Class II Special Controls Guideline Document: Toxin Gene Amplification Assays for the Detection of Clostridium difficile	2015
1500014	Class II Special Controls Guideline Gastrointestinal Microorganism Multiplex Nucleic Acid-Based Assays for Detection and Identification of Microorganisms and Toxin Genes from Human Stool Specimens	2015
1763	Molecular Diagnostic Instruments with Combined Functions	2014

NO. GUÍA	TÍTULO DE LA GUÍA	AÑO
1400019	Class II Special Controls Guideline: Nucleic Acid-Based In Vitro Diagnostic Devices for the Detection of Mycobacterium tuberculosis Complex and Genetic Mutations Associated with Mycobacterium tuberculosis Complex Antibiotic Resistance in Respiratory Specimens	2014
1790	Class II Special Controls Guideline: John Cunningham Virus Serological Reagents	2014
1788	Class II Special Controls Guideline: Nucleic Acid-Based In Vitro Diagnostic Devices for the Detection of Mycobacterium tuberculosis Complex in Respiratory Specimens	2014
1803	Highly Multiplexed Microbiological/Medical Countermeasure In Vitro Nucleic Acid Based Diagnostic Devices	2014
100496	Class II Special Controls Guideline: Dengue Virus Serological Reagents	2014
1200027	Class II Special Controls Guideline: Dengue Virus Nucleic Acid Amplification Test Reagents	2014
1200031	Class II Special Controls Guideline: Tryptase Test System as an Aid in the Diagnosis of Systemic Mastocytosis	2014
1737	In Vitro Companion Diagnostic Devices	2014
1756	Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use	2014
1723	Distribution of In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only	2013
1660	Assay Migration Studies for In Vitro Diagnostic Devices	2013
---	WHO. Technical Report Series, No. 889. Annex 6. Guidelines for thromboplastins and plasma used to control oral anticoagulant therapy with vitamin K antagonists	2013
1587	In Vitro Diagnostic (IVD) Device Studies. Frequently Asked/Questions	2010
1588	Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable	2006
---	Preparation of an Application for Investigational Testing - In Vitro Diagnostic Devices (IVDD) V.3	1999

2. Guías eliminadas

NO. GUÍA	TÍTULO DE LA GUÍA	AÑO
1667	Draft Guidance for Industry and Food and Drug Administration Staff - Class II Special Controls Guidance Document: In Vitro Diagnostic Devices for Bacillus spp. Detection *Derogada por la FDA en 2015*	2011
1733	Draft Guidance for Industry and Food and Drug Administration Staff - Establishing the Performance Characteristics of In Vitro Diagnostic Devices for Chlamydia trachomatis and/or Neisseria gonorrhea: Screening and Diagnostic Testing *Derogada por la FDA en 2017*	2011

NO. GUÍA	TÍTULO DE LA GUÍA	AÑO
1715	Draft Guidance for Industry and Food and Drug Administration Staff - Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection of Clostridium difficile *Derogada por la FDA en 2016*	2011
1712	Draft Guidance for Industry and FDA Staff - Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection of Helicobacter pylori *Derogada por la FDA en 2017*	2010
2009/108/ CE	Especificaciones Técnicas Comunes para productos sanitarios de diagnóstico in vitro. Diario Oficial de la Unión Europea, del 10 de febrero de 2009, modificando a la 2002/364/CE. *Requisitos establecidos en las regulaciones del CECMED*	2009
1706	In Vitro Diagnostic 2009 H1N1 Tests for Use in the 2009 H1N1 Emergency *Derogada por la FDA en 2019*	2009
772	Guidance for Industry and FDA Staff - Review Criteria for Assessment of Qualitative Fecal Occult Blood In Vitro Diagnostic Devices *Derogada por la FDA en 2014*	2007
1594	In Vitro Diagnostic Devices to Detect Influenza A Viruses: Labelling and Regulatory Path - Guidance for Industry and FDA Staff *Derogada por la FDA en 2017*	2007
2231	Assayed and Unassayed Quality Control Material *Derogada por la FDA en 2017*	2007
---	Draft Guidance for Industry and FDA Staff - Total Product Life Cycle for Portable Invasive Blood Glucose Monitoring Systems *Derogada por la FDA en 2011*	2006
152	Premarket Submissions and Labelling Recommendations for Drugs of Abuse Screening Tests - Draft Guidance for Industry and FDA Staff *Derogada por la FDA en 2015*	2003
---	Radioallergosorbent Test (RAST) Methods for Allergen-Specific Immunoglobulin E (IgE) 510(k)s; Final Guidance for Industry and FDA *Derogada por la FDA en 2011*	2001
1102	In Vitro Diagnostic Bicarbonate/Carbon Dioxide Test System *Derogada por la FDA en 2018*	1998
1103	In Vitro Diagnostic Chloride Test System *Derogada por la FDA en 2018*	1998
1107	In Vitro Diagnostic Potassium Test System *Derogada por la FDA en 2018*	1998
1109	In Vitro Diagnostic Sodium Test System *Derogada por la FDA en 2018*	1998
1110	In Vitro Diagnostic Urea Nitrogen Test System *Derogada por la FDA en 2018*	1998
1105	In Vitro Diagnostic Glucose Test System *Derogada por la FDA en 2018*	1998
1104	In Vitro Diagnostic Creatinine Test System *Derogada por la FDA en 2018*	1998

NO. GUÍA	TÍTULO DE LA GUÍA	AÑO
165	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 *Derogada por la FDA en 2017*	1997
1345	Review Criteria for Assessment of Professional Use Human Chorionic Gonadotropin (hCG) In Vitro Diagnostic Devices (IVDs) *Derogada por la FDA en 2017*	1996
1631	Review Criteria for Assessment of Antimicrobial Susceptibility Test Discs (PDF Only) *Derogada por la FDA en 2017*	1996
957	Guidance Document for the Submission of Tumor Associated Antigen Premarket Notifications, [510(k)], to FDA *Derogada por la FDA en 2017*	1996
82	Review Criteria for Assessment of Alpha-Fetoprotein (AFP) in vitro Diagnostic Devices for Fetal Open Neural Tube Defects Using Immunological Test Methodologies *Derogada por la FDA en 2019*	1994

3. Guías actualizadas (reemplazadas)

NO. GUÍA	TÍTULO DE LA GUÍA	AÑO
1740	Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Human Papillomaviruses *Edición anterior: 2011*	2017
1654	Recommendations for Premarket Notifications for Lamotrigine and Zonisamide Assays *Edición anterior: 2010*	2016
---	Guidelines for the Blood Transfusion Services in the UK, 8th Edition *Edición anterior: 2005*	2013
---	WHO. Technical Report Series, No. 889. Annex 6. Guidelines for thromboplastins and plasma used to control oral anticoagulant therapy with vitamin K antagonists *Edición anterior: 1999*	2013

II. Lista de Guías reconocidas a partir de la presente edición

1. Autoridades Reguladoras Nacionales

1.1. Administración de Medicamentos y Alimentos de Estados Unidos de América (FDA por sus siglas en inglés)

NO. GUÍA	TÍTULO DE LA GUÍA	AÑO
1400038	Class II Special Controls Guideline: In Vitro Diagnostic Devices for Bacillus spp. Detection - Guideline for Industry and Food and Drug Administration Staff	2019
17032	Logical Observation Identifiers Names and Codes for In Vitro Diagnostic Tests - Guidance for Industry and Food and Drug Administration Staff	2018
16008	Use of Public Human Genetic Variant Databases to Support Clinical Validity for Genetic and Genomic- Based In Vitro Diagnostics	2018
16009	Considerations for Design, Development, and Analytical Validation of Next Generation Sequencing (NGS) – Based In Vitro Diagnostics (IVDs) Intended to aid in the Diagnosis of Suspected Germline Diseases	2018
1143	Administrative Procedures for CLIA Categorization	2017
16046	Select Updates for Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices. Draft document.	2018
1740	Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Human Papillomaviruses	2017
1654	Recommendations for Premarket Notifications for Lamotrigine and Zonisamide Assays	2016
1755	Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use	2016
1756	Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use	2016
1100491	Class II Special Controls Guideline: Nucleic Acid Amplification Assays for the Detection of Trichomonas vaginalis	2015
1400051	Class II Special Controls Guideline: Multiplex Nucleic Acid Assay for Identification of Microorganisms and Resistance Markers from Positive Blood Cultures	2015
1200022	Class II Special Controls Guideline Document: Toxin Gene Amplification Assays for the Detection of Clostridium difficile	2015
1500014	Class II Special Controls Guideline Gastrointestinal Microorganism Multiplex Nucleic Acid-Based Assays for Detection and Identification of Microorganisms and Toxin Genes from Human Stool Specimens	2015
1763	Molecular Diagnostic Instruments with Combined Functions	2014
1400019	Class II Special Controls Guideline: Nucleic Acid-Based In Vitro Diagnostic Devices for the Detection of Mycobacterium tuberculosis	2014

NO. GUÍA	TÍTULO DE LA GUÍA	AÑO
	Complex and Genetic Mutations Associated with Mycobacterium tuberculosis Complex Antibiotic Resistance in Respiratory Specimens	
1790	Class II Special Controls Guideline: John Cunningham Virus Serological Reagents	2014
1788	Class II Special Controls Guideline: Nucleic Acid-Based In Vitro Diagnostic Devices for the Detection of Mycobacterium tuberculosis Complex in Respiratory Specimens	2014
1803	Highly Multiplexed Microbiological/Medical Countermeasure In Vitro Nucleic Acid Based Diagnostic Devices	2014
100496	Class II Special Controls Guideline: Dengue Virus Serological Reagents	2014
1200027	Class II Special Controls Guideline: Dengue Virus Nucleic Acid Amplification Test Reagents	2014
1200031	Class II Special Controls Guideline: Tryptase Test System as an Aid in the Diagnosis of Systemic Mastocytosis	2014
1737	In Vitro Companion Diagnostic Devices	2014
1756	Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use	2014
1723	Distribution of In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only	2013
1660	Assay Migration Studies for In Vitro Diagnostic Devices	2013
1721	Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection of Antibodies to Borrelia burgdorferi	2013
1767	Class II Special Controls Guidance Document: Norovirus Serological Reagents	2012
1713	Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays	2011
1638	Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Influenza Viruses	2011
1587	In Vitro Diagnostic (IVD) Device Studies. Frequently Asked/Questions	2010
1672	Class II Special Controls Guidance Document: Testing for Detection and Differentiation of Influenza A Virus Subtypes Using Multiplex Assays	2009
1673	Class II Special Controls Guidance Document: Testing for Human Metapneumovirus (hMPV) Using Nucleic Acid Assays	2009
1669	Class II Special Controls Guidance Document: Respiratory Viral Panel Multiplex Nucleic Acid Assay	2009
631	Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems	2009
848	Recommendations for Anti-Nuclear Antibody (ANA) Test System Premarket (510(k)) Submissions	2009
1665	Class II Special Controls Guidance Document: Nucleic Acid Amplification Assay for the Detection of Enterovirus RNA	2009
1646	Class II Special Controls Guidance Document: Plasmodium Species Antigen Detection Assays	2008
1627	Class II Special Controls Guidance Document: Gene Expression Profiling Test System for Breast Cancer Prognosis	2007

NO. GUÍA	TÍTULO DE LA GUÍA	AÑO
1614	Class II Special Controls Guidance Document: Quality Control Material for Cystic Fibrosis Nucleic Acid Assays	2007
1549	Guidance on Pharmacogenetic Tests and Genetic Tests for Heritable Markers	2006
1599	Class II Special Controls Guidance Document: Fecal Calprotectin Immunological Test Systems	2006
1596	Class II Special Controls Guidance Document: Reagents for Detection of Specific Novel Influenza A Viruses	2006
1536	Class II Special Controls Guidance Document: Hepatitis A Virus Serological Assays	2006
1588	Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable	2006
1564	Class II Special Controls Guidance Document: CFTR Gene Mutation Detection Systems	2005
1570	Class II Special Controls Guidance Document: AFP-L3 Immunological Test Systems	2005
1246	Review Criteria for Assessment of C Reactive Protein (CRP), High Sensitivity C-Reactive Protein (hsCRP) and Cardiac C-Reactive Protein (cCRP) Assays	2005
1563	Class II Special Controls Guidance Document: RNA Pre-analytical Systems (RNA Collection, Stabilization and Purification Systems for RT-PCR used in Molecular Diagnostic Testing)	2005
1550	Class II Special Controls Guidance Document: Automated Fluorescence in situ Hybridization (FISH) Enumeration Systems	2005
1546	Class II Special Controls Guidance Document: Instrumentation for Clinical Multiplex Test Systems	2005
1551	Class II Special Controls Guidance Document: Drug Metabolizing Enzyme Genotyping System	2005
1301	Class II Special Controls Guidance Document: Newborn Screening Test Systems for Amino Acids, Free Carnitine, and Acylcarnitines Using Tandem Mass Spectrometry	2004
1300	Class II Special Controls Guidance Document: Sirolimus Test Systems	2004
1824	Class II Special Controls Guidance Document: Serological Assays for the Detection of Beta-Glucan	2004
1531	Class II Special Controls Guidance Document: Immunomagnetic Circulating Cancer Cell Selection and Enumeration System	2004
1236	Class II Special Controls Guidance Document: Factor V Leiden DNA Mutation Detection Systems	2004
1222	Class II Special Controls Guidance Document: Endotoxin Assay	2003
1206	Class II Special Controls Guidance Document: Serological Reagents for the Laboratory Diagnosis of West Nile Virus	2003
1211	Class II Special Controls Guidance Document: Breath Nitric Oxide Test System	2003
1223	510(k) Submissions for Coagulation Instruments	2003
1380	Class II Special Controls Guidance Document: Cyclosporine and Tacrolimus Assays	2002

NO. GUÍA	TÍTULO DE LA GUÍA	AÑO
1184	Class II Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells	2001
1072	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	2000
1183	Class II Special Control Guidance Document for Anti-Saccharomyces cerevisiae (S. cerevisiae) Antibody (ASCA) Premarket Notifications	2000
1172	Guidance for Over-the-Counter (OTC) Human Chorionic Gonadotropin (hCG) 510(k)s - Guidance for Industry and FDA Reviewers/Staff	2000
2242	In Vitro Diagnostic Fibrin Monomer Paracoagulation Test	1999
1247	Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators; Final Guidance for Industry	1999
364	Guidance for Submission of Immunohistochemistry Applications to the FDA	1998
122	Points to Consider for Portable Blood Glucose Monitoring Devices Intended for Bedside Use in the Neonate Nursery	1996
605	Guidance for 510(k)s on Cholesterol Tests for Clinical Laboratory, Physicians' Office Laboratory and Home Use	1995
51	Review Criteria for In Vitro Diagnostic Devices for the Assessment of Thyroid Autoantibodies using Indirect Immunofluorescence Assay (IFA), Indirect Hemagglutination Assay (IHA), Radioimmunoassay (RIA), and Enzyme Linked Immunosorbent Assay (ELISA)	1994
527	Review Criteria for In Vitro Diagnostic Devices for Detection of IgM Antibodies to Viral Agents	1992
770	Review Criteria for Premarket Approval of In Vitro Diagnostic Devices for Detection of Antibodies to Parvovirus B19	1992
182	Draft recommended methods for evaluating potency, specificity, and reactivity of anti-human globulin.	1992
181	Draft Points to consider in the design and implementation of field trials for blood grouping reagents and anti-human globulin.	1992
554	Review Criteria for Devices Intended for the Detection of Hepatitis B 'e' Antigen and Antibody to HBe	1991
658	Review Criteria for Assessment of Glycohemoglobin (Glycated or Glycosylated) Haemoglobin In Vitro Diagnostic Devices	1991
417	Review Criteria for Assessment of Cytogenetic Analysis Using Automated and Semi-Automated Chromosome Analyzers	1991

1.2. Buró de Dispositivos Médicos de la Dirección de Productos Terapéuticos de Canadá (TPD, por sus siglas en inglés)

TÍTULO DE LA GUÍA	AÑO
Preparation of an Application for Investigational Testing - In Vitro Diagnostic Devices (IVDD) V.3	1999

2. Otros organismos internacionales

2.1. Foro Internacional de Reguladores de Dispositivos Médicos (IMDRF, por sus siglas en inglés)

TÍTULO DE LA GUÍA	AÑO
IMDRF/GRRP WG/N52 FINAL. Principles of Labelling for Medical Devices and IVD Medical Devices	2019
IMDRF/RPS WG/N13 FINAL. In Vitro Diagnostic Medical Device Market Authorization Table of Contents (IVD MA ToC)	2018

2.2. Organización Mundial de la Salud (WHO, por sus siglas en inglés)

TÍTULO DE LA GUÍA	AÑO
WHO. Technical Report Series, No. 889. Annex 6. Guidelines for thromboplastins and plasma used to control oral anticoagulant therapy with vitamin K antagonists	2013
WHO/TGS-3. Principles of performance studies	2017
WHO/TGS-4. Guidance on test method validation for in vitro diagnostic medical devices	2017
WHO/TGS-5. Designing instructions for use for in vitro diagnostic medical devices	2017
WHO/TGS-6. Panels for quality assurance and quality control of in vitro diagnostic medical devices	2017
WHO/TGS-7. Risk management for manufacturers of in vitro diagnostic medical devices	2017

2.3. United Kingdom Blood Transfusion Services

TÍTULO DE LA GUÍA	AÑO
Guidelines for the Blood Transfusion Services in the UK, 8th Edition (Red Book)	2013