



COLLEGE of AMERICAN
PATHOLOGISTS

FDA LDT Rule: Understanding Test Risk Classification and Its Impact on Your Laboratory

Donald Karcher, MD, FCAP
CAP President

September 18, 2024

Today's Presenters

Donald S. Karcher, MD, FCAP

- President, College of American Pathologists
- Board-certified in anatomic, clinical, and hematopathology
- Professor and Immediate Past Chair of Pathology, George Washington University Medical Center, where he's been a faculty member since 1984
- An academic pathologist who has been active in many national and international medical and pathology organizations
- 30+ years as a CAP leader
- Served as Association of Pathology Chairs (APC) President from 2014 to 2016
- Published over 100 peer-reviewed articles and abstracts, co-authored several book chapters, and co-edited six books spanning his subspecialties



Today's Presenters

Timothy Stenzel, MD, PhD

- CEO Grey Haven LLC
- Board certified in pathology and genetics
- Former Director of the FDA's Office of In Vitro Diagnostics
- Over 25 years in executive leadership, innovation, companion diagnostics, molecular diagnostics, molecular genetics, immunology, infectious diseases, surgical pathology, and laboratory medicine
- Received his MD and PhD in microbiology and immunology from Duke University
- Founded the Duke Clinical Molecular Diagnostics laboratory; clinical and research laboratories in Japan and China respectively, and molecular diagnostics at QuidelOrtho



Background: FDA Oversight of LDTs

- Oversight of LDTs by FDA has been an issue for more than 10 years.
- When a legislative solution (VALID Act) didn't pass in 2022, FDA said they would regulate LDTs under their existing statutory authority.
- FDA released proposed oversight rule on Sept. 29, 2023, and final rule on April 29, 2024.



Background: FDA Oversight of LDTs

- **Basic provisions:**
 - Employs a three-tiered, risk-based structure.
 - Phases out general enforcement discretion in five stages by May 2028.
- **While the FDA regulation includes exemptions, most LDTs must meet requirements for at least Stages 1, 2 , and parts of 3.**

Stage 1

- **May 6, 2025**
- Compliance with medical device reporting, correction and removal reporting, and quality system requirements for complaints.

Stage 2

- **May 6, 2026**
- Compliance with registration and listing, labeling, and investigational use requirements.

Stage 3

- **May 6, 2027**
- Compliance with all quality system requirements.

Stage 4

- **November 6, 2027**
- Pre-market review for high-risk LDTs.

Stage 5

- **May 6, 2028**
- Pre-market review for moderate- and low-risk LDTs.

Background: CAP Advocacy on LDT Oversight

- CAP advocacy principles on LDT oversight:
 - Protect patients.
 - Allow for continued innovation of new tests.
 - Develop a framework that is the least burdensome and costly for pathologists and their laboratories.
- We oppose the final FDA rule.
 - CAP supports legislation to reduce regulatory burdens on laboratories.
 - CAP supports legal efforts to stop the regulation's implementation.
- At the same time, the CAP will continue to prepare members and laboratories to comply with FDA regulations.

Background: What is an LDT?

- The FDA defines LDTs as “in vitro diagnostic products (IVDs) that are 1) intended for clinical use; 2) designed, manufactured, and used within a single clinical laboratory that is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA); and 3) meets the regulatory requirements under CLIA to perform high complexity testing.”
- By definition, all LDTs are high complexity.

Background: FDA Test Risk vs. CLIA Test Complexity

- FDA test risk classification is different from CLIA test complexity.
- CLIA regulations categorize tests as moderate or high complexity.
- CLIA categorization criteria (determined during FDA test authorization):
 - Knowledge needed to perform
 - Training and experience needed to perform
 - Reagents and materials preparation
 - Characteristics of operational steps
 - Calibration, quality control, and proficiency testing materials
 - Test system troubleshooting and equipment maintenance required
 - Interpretation and judgement required

Background: FDA Risk Classification

- FDA uses a system based on patient risk to classify medical devices/tests:
 - Low Risk (Class I)
 - Moderate Risk (Class II)
 - High Risk (Class III)
- The FDA's classification is based on the “intended use” and risk posed by the device/test to patients.



Understanding the Impact of the FDA's LDT Risk Classification on Your Laboratory

Tim Stenzel, MD, PhD, Former Director, FDA Office of In Vitro Diagnostics
Grey Haven LLC

Disclaimers & Notes

Notes:

- 1) I will generally use lay/non-FDA language in this presentation to facilitate understanding of the concepts. However, FDA will typically use legal terms for most items. This is a new language to many and sometimes difficult to decipher. Most of the language is defined by law and regulations and is not intentionally meant to complicate understanding.
- 2) Much of the content in this presentation mirrors an FDA Webinar on this topic held on July 16, 2024. The first link at the end of this presentation is to that FDA Webpage.
- 3) I will focus my presentation on clinical laboratory tests.

Agenda

- Reclassification (Down) of Some CDx tests and Other IVDs
- Final LDT Rule and Potential Legislation
- FDA Classification Process/System
- Determining Classifications with Examples
- Communications with FDA
- Helpful Links
- Q&A

Down Classification of Some CDx Tests and Other IVDs

- On January 31, 2024 the FDA made known its decision to initiate a reclassification process for most IVDs that are currently Class III to Class II
- The FDA has prior exempted more than 1,000 IVDs from FDA review
- FDA reclassified HCV on November 19, 2021. Per Timothy Stenzel....‘Today’s action allows manufacturers of...HCV tests...to seek marketing clearance...rather than...a PMA” ...
- In 2023, FDA began the process of reclassifying HBV and certain other IVDs to class II

FDA reclassification process (usually down but can be up)

The original classification of a device can be changed through reclassification.

The FDA follows a process that includes issuing a proposed order, convening an expert panel, receiving and considering public comment, and issuing a final order.

The process usually takes ~2 years.

Final LDT Rule and Potential Legislation

- The Final rule was announced on 29APR2024, “grandfather” ended 06MAY2024, in force 60 days after publishes ~06JUL2024. Makes one change to the definition of an IVD product “including when the manufacturer of these products is a laboratory.”
- Phaseout Period (by end of each period)
 - 1 Year – comply with MD(AE) reporting and reporting of corrections and removals
 - 2 Years – comply with labeling, registration and listing, and investigational use requirements
 - 3 Years – QS [v light, light and full] – records and sometimes design controls and purchasing controls
 - 3.5 Years – comply with **high risk (class III)** premarket review requirements (PMA)
 - 4 Years – comply with **moderate and low risk** premarket review requirements moderate and low
- Enforcement Discretion (ED) continues for Forensic, HLA, PH Surveillance and pre-1976 type LDTs (manual)
- Excluded from ED – EUAs, DTC (stay tuned for more details) and donor screening

FDA Classification System

The FDA uses a risk-based classification system for all medical devices, including Laboratory Developed Tests/IVDs, into Classes I, II, or III according to the level of regulatory control (mitigations) that are deemed necessary by the FDA to ensure accurate results.

The classification of a clinical laboratory test determines the appropriate premarket regulatory process.

The FDA also examines the intended use of the test when making a classification decision.

Indications for/Intended use

Purpose of the test – aid in diagnosis, CDx, MRD, etc

Disease or condition the test is designed for – Leukemia, diabetes, etc

Test methodology used – PCR, NGS, novel, etc

Intended patient population for the test – Ages, high risk, low risk, cancer, etc

Where testing the test is performed – LDTs will be performed in high complexity laboratories

Indications for/Intended use example

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H. Indications for Use:

1. Indications for Use:

The MSK-IMPACT assay is a qualitative in vitro diagnostic test that uses targeted next generation sequencing of formalin-fixed paraffin-embedded tumor tissue matched with normal specimens from patients with solid malignant neoplasms to detect tumor gene alterations in a broad multi gene panel. The test is intended to provide information on somatic mutations (point mutations and small insertions and deletions) and microsatellite instability for use by qualified health care professionals in accordance with professional guidelines, and is not conclusive or prescriptive for labeled use of any specific therapeutic product. MSK-IMPACT is a single-site assay performed at Memorial Sloan Kettering Cancer Center.

2. Special conditions for use statement(s):

For prescription use.

For in vitro diagnostic use.

3. Special instrument requirements:

Illumina HiSeq™ 2500 Sequencer (qualified by MSK)

I. Device Description:

A description of required equipment, software, reagents, vendors, and storage conditions

Risk levels

Low Risk – Class I

Tests with minimal risk for harm

Moderate Risk – Class II

Mid range risk for harm

High Risk – Class III

Tests to support or sustain human life which present a potential for unreasonable risk of harm

For tests already classified look to the FDA databases for their classifications

A straightforward way for a test developer to determine the classification of a test that has already been classified by FDA is to search the FDA product classification database. There are separate databases for 510(k), PMA, and De Novo submissions.

May also be helpful in understanding what specific IVDs fall within a given device type and how such IVDs are regulated.

What if your specific sample/specimen type or technology is not in the data

Usually, it does not alter the classification except for when the sample/specimen type or technology is novel. However, where differences in specimen type or technology between a subject IVD test system and those specified in a classification regulation raise different questions of safety and effectiveness, the classification regulation describing use for a specific specimen type or technology would not be appropriate for a different specimen type or technology. If manufacturers have questions regarding the classification of a specific test, they can submit a Pre-Submission or 513(g) request to obtain specific feedback.

For tests not already classified (typically novel tests)

An IVD may be of a type that has not already been classified by FDA and, therefore, would not be in the product classification database. As a reminder, device types that have not been classified by FDA previously, and that were not on the market prior to the enactment of the Medical Device Amendments on May 28, 1976, are automatically Class III unless they are reclassified by the FDA. If an IVD has not been classified, manufacturers should assess the risk of their IVD and submit the appropriate premarket submission based on the assessed risk. If the manufacturer believes their IVD is high risk, a PMA is likely required. If the manufacturer believes their IVD is low or moderate risk, the IVD may be eligible for De Novo classification. The De Novo process provides a pathway to Class I or Class II classification for medical devices for which general controls or general and special controls provide a reasonable assurance of safety and effectiveness but for which there is no legally marketed device.

What is a product code?

An FDA product code identifies the generic category of a test for FDA. A classification regulation may have multiple product codes associated with it. In this case, classification product codes help to delineate technology and indication subgroups within a regulation. However, a product code is only associated with one classification regulation or no regulation at all. In the latter case, they serve to categorize unclassified or Class III, PMA devices. Classification product codes are assigned and maintained by the FDA.

FDA product classification webpage

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Product Code Classification Database

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Classify Your Medical Device

[Does the Product Emit Radiation?](#)

[How to Determine if Your Product is a Medical Device](#)

[Medical Device Accessories](#)

[Device Classification Panels](#)

[Class I and Class II Device](#)

The [Product Classification Database](#) contains medical device names and associated information developed by the Center for Devices and Radiological Health (CDRH) in support of its mission. This database contains device names and their associated product codes. The name and product code identify the generic category of a device for FDA. The Product Code assigned to a device is based upon the medical device product classification designated under 21 CFR Parts 862-892.

These files are updated every Sunday.

- [Search the on-line product code database](#)
- [Information on how to classify a device](#)
- [Download Product Code files](#)

Information on Devices Regulated by other Centers

- [Devices regulated by CBER](#) (Center for Biologics Evaluation and Research)
- [Intercenter Agreements](#) which are working agreements developed

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Product Classification

FDA Home Medical Devices Databases

This database includes:

- a list of all medical devices with their associated classifications, product codes, FDA premarket review organizations, and other regulatory information.

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Device	<input type="text"/>	Product Code	<input type="text"/>
Review Panel	<input type="text"/>	Regulation Number	<input type="text"/>
Submission Type	<input type="text"/>	Third Party Elligible	<input type="text"/>
Implanted Device	<input type="text"/> Life-Sustain/Support Device <input type="text"/>	Device Class	<input type="text"/>
Summary Malfunction Reporting	<input type="text"/>		

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First Example – Lactic Acid – Class I Exempt

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Lactic Acid

First page

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Product Classification

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1 to 3 of 3 results Result

Lactic Acid

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Product Code	Device	Regulation Number
LPG	Material, Dressing, Surgical, Polylactic Acid	
KHP	Acid, Lactic, Enzymatic Method	Lactic Acid Test System 862.145
NGD	Test, Lactic Acid, Over The Counter	Lactic Acid Test System 862.145

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Lactic Acid – Enzymatic Method

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Product Classification

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Device	Acid, Lactic, Enzymatic Method
Regulation Description	Lactic acid test system.
Regulation Medical Specialty	Clinical Chemistry
Review Panel	Clinical Chemistry
Product Code	KHP
Premarket Review	Office of In Vitro Diagnostics (OHT7) Division of Chemistry and Toxicology Devices (DCTD)
Submission Type	510(K) Exempt
Regulation Number	862.1450
Device Class	1
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Eligible

Note: FDA has exempted almost all class I devices (with the exception of [reserved devices](#)) from the premarket notification requirement, including those devices that were exempted by final regulation published in the *Federal Registers* of December 7, 1994, and January 16, 1996. It is important to confirm the exempt status and any limitations that apply with [21 CFR Parts 862-892](#). Limitations of device exemptions are covered under 21 CFR XXX.9, where XXX refers to Parts 862-892.

If a manufacturer's device falls into a generic category of exempted class I devices as defined in [21 CFR Parts 862-892](#), a premarket notification application and fda clearance is not required before marketing the device in the U.S. however, these manufacturers are required to register their establishment. Please see the [Device Registration and Listing website](#) for additional information.

Implanted Device?	No
Life-Sustain/Support Device?	No
Third Party Review	Not Third Party Eligible

PCR – Class II Example

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Product Classification

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Product Code	Device	Regulation Number
OBF	Assay, Genotyping, Hepatitis C Virus Nucleic Acid-Based Hepatitis C Virus Rib...	866.3170
OYX	Bcr/Abl1 Monitoring Test BCR-ABL Quantitation Test	866.6060
PAN	Braf Mutation Kit	
OJQ	Cardiac Allograft Gene Expression Profil ... Cardiac Allograft Gene Expression Profil...	862.1163
PAB	Cytomegalovirus (Cmv) Dna Quantitative Assay	
PCA	Dna Genetic Analyzer Instrumentation For Clinical Multiplex T...	862.2570
PHG	Droplet Digital Pcr System Instrumentation For Clinical Multiplex T...	862.2570
OQO	Herpes Simplex Virus Nucleic Acid Amplif ... Herpes Simplex Virus Serological Assays	866.3305
QUM	Human Immunodeficiency Virus (Hiv) Viral ... Human Immunodeficiency Virus (HIV) Viral...	866.3958
OYV	Inherited Nucleotide Repeat Disorder Dna Test	866.5970

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BCR-ABL Monitoring

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Product Classification

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Device	Bcr/Abl1 Monitoring Test
Regulation Description	BCR-ABL quantitation test.
Definition	<p>A BCR/ABL1 Monitoring Test is a quantitative in vitro diagnostic device used to monitor the BCR/ABL1 to ABL1 ratio by reverse-transcriptase quantitative polymerase chain reaction (RQ-PCR) on whole blood or bone marrow of diagnosed Philadelphia chromosome positive (Ph+) chronic myeloid leukemia (CML) patients expressing BCR-ABL1 fusion transcripts such as e13a2 and/or e14a2. It is intended for use during monitoring of treatment response by reporting results on the international scale (%IS) and as log molecular reduction (MR) value.</p>
Physical State	Multiplex quantitative RT-PCR assay to detect chromosome translocation fusion transcripts and control transcripts test system.
Technical Method	The test uses multiplex reverse-transcriptase polymerase chain reaction to detect and determine BCR-ABL1 (such as e13a2 and/or e14a2) fusion transcript levels and quantifies them relative to levels of ABL1 transcript (or other validated control gene). The test may utilize other technologies and/or quantification methods.
Target Area	Peripheral human whole blood or bone marrow.
Regulation Medical Specialty	Molecular Genetics
Review Panel	Pathology
Product Code	OYX
Premarket Review	Office of In Vitro Diagnostics (OHT7) Division of Molecular Genetics and Pathology (DMGP)
Submission Type	510(k)
Regulation Number	866.6060
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Eligible
Implanted Device?	No
Life-Sustain/Support Device?	No
Third Party Review	Not Third Party Eligible

Tumor Profiling – Class II

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Product Classification

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1 to 4 of 4 Results
for *Tumor profiling*

Product Code	Device	Regulation Number
NYI	Classifier, Prognostic, Recurrence Risk ... Gene Expression Profiling Test System Fo...	866.6040
SBY	High Throughput Sequencing Based Tumor Profiling Test Of Circulating Cell-Free Nucleic Acids	866.6085
PZM	Next Generation Sequencing Based Tumor P ... Next Generation Sequencing Based Tumor P...	866.6080
QFK	Tumor Gene Profiling Test	

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Tumor Profiling Example

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Product Classification

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Device Definition	High Throughput Sequencing Based Tumor Profiling Test Of Circulating Cell-Free Nucleic Acids
Physical State	A high throughput sequencing based tumor profiling test of circulating cell-free nucleic acids is a qualitative in vitro diagnostic test intended for next generation sequencing analysis of circulating cell-free nucleic acids from plasma samples collected from peripheral whole blood to detect mutations in a panel of targeted genes to aid in the management of previously diagnosed cancer patients by qualified health care professionals. The results of the test are not prescriptive or conclusive for use of any specific therapeutic product.
Technical Method	The test may include specimen handling, nucleic acid purification methods, library preparation, target enrichment, and sequencing reagents, instrument systems and software. Should not include devices intended to aid in the diagnosis, prognosis, screening of cancer, or make or recommend treatment decisions.
Target Area	The test system uses high throughput sequencing technology, including molecular reagents for library preparation, target enrichment, and sequencing, sequencing instrumentation and bioinformatics software, to detect variants in cell free nucleic acids isolated from peripheral whole blood in specified genes associated with malignant neoplasms.
Regulation Medical Specialty	Human peripheral whole blood specimens
Review Panel	Pathology
Product Code	Pathology
Premarket Review	SBY
Submission Type	Office of In Vitro Diagnostics (OHT7)
Regulation Number	Division of Molecular Genetics and Pathology (DMGP)
Device Class	510(k)
Total Product Life Cycle (TPLC)	866.6085
GMP Exempt?	2
Summary Malfunction Reporting	TPLC Product Code Report
Implanted Device?	No
Life-Sustain/Support Device?	Ineligible
Third Party Review	No
	Not Third Party Eligible


Cancer search – Class III

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Product Classification

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Product Code	Device	Regulation Number
MJB	Antigen, Cancer 549	
PAA	Automated Breast Ultrasound	
OEO	Automated Digital Image Manual Interpret ... Immunohistochemistry Reagents And Kits	864.1860
PAN	Braf Mutation Kit	
OAW	Cancer Monitoring Test System, Soluble Mesothelin-Related Peptides, Epithelioid/Biphasic Mesotheliom...	
NVA	Cancer Monitoring Test System, Soluble M ... Tumor-Associated Antigen Immunological T...	866.6010
QAZ	Cancer Predisposition Risk Assessment System	866.6090
PJG	Cancer-Related Germline Gene Mutation Detection System	
NYQ	Chromogenic In Situ Hybridization, Nucleic Acid Amplification, Her2/Neu Gene, Breast Cancer	
QSA	Circulating Tumor Cell (Ctc) Enrichment Device	866.6110

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Class III – Her2/Neu

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Product Classification

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Device Definition	Chromogenic In Situ Hybridization, Nucleic Acid Amplification, Her2/Neu Gene, Breast Cancer This device is intended to detect her2 gene amplification in formalin-fixed, paraffin-embedded breast carcinoma tissue sections using chromogenic in situ hybridization and brightfield microscopy. Indicated as an aid in the assessment of patients for whom herceptin. (trastuzumab) treatment is being considered. Interpretation of test results must be made within the context of the patients clinical history by a qualified pathologist.
Physical State	brightfield microscopy
Technical Method	Chromogenic In Situ Hybridization
Target Area	breast carcinoma tissue sections
Review Panel	Immunology
Product Code	NYQ
Premarket Review	Office of In Vitro Diagnostics (OHT7) Division of Immunology and Hematology Devices (DIHD)
Submission Type	PMA
Device Class	3
Total Product Life Cycle (TPLC)	TPLC Product Code Report
GMP Exempt?	No
Summary Malfunction Reporting	Ineligible
Implanted Device?	No
Life-Sustain/Support Device?	No
Third Party Review	Not Third Party Eligible

De Novo Database Search - HCV

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Device Classification Under Section 513(f)(2)(De Novo)

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Device Name: *Hcv* Decision Date To: 09/18/2024







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Device Name	Requester	De Novo Number	510(k) Number	Decision Date
Xpert HCV; GeneXpert Xpress System	Cepheid	DEN240016		06/27/2024

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De Novo Search - HCV

Device Classification Under Section 513(f)(2)(De Novo)

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Device Classification Name	Simple Point-Of-Care Nucleic Acid-Based Hepatitis C Virus Ribonucleic Acid Test
De Novo Number	DEN240016
Device Name	Xpert HCV; GeneXpert Xpress System
Requester	Cepheid 904 Caribbean Drive Sunnyvale, CA 94089
Contact	Suzette Chance
Regulation Number	866.3171
Classification Product Code	SBP
Date Received	04/16/2024
Decision Date	06/27/2024
Decision	Granted (DENG)
Classification Advisory Committee	Microbiology
Review Advisory Committee	Microbiology
Reclassification Order	Reclassification Order
Type	Direct

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HCV De Novo – Additional Information

7:14 AM Wed Sep 18

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Cepheid
Wei Zhang
Manager, Regulatory Affairs, New Product Development
904 Caribbean Drive
Sunnyvale, California 94089

June 27, 2024

Re: DEN240016
Trade/Device Name: Xpert HCV; GeneXpert Xpress System
Regulation Number: 21 CFR 866.3171
Regulation Name: Simple point-of-care nucleic acid-based hepatitis C virus ribonucleic acid test
Regulatory Class: Class II
Product Code: SBP
Dated: April 15, 2024
Received: April 16, 2024

Dear Wei Zhang:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Xpert HCV; GeneXpert Xpress System, a prescription device with the following indications for use:

The Xpert HCV test, performed on the GeneXpert Xpress System, is an automated, in vitro reverse

De Novo HCV – Special Controls

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In combination with the general controls of the FD&C Act, the simple point-of-care nucleic acid-based HCV RNA test is subject to the following special controls:

- (1) Any sample collection device used must be FDA-cleared, -approved, or -classified as 510(k) exempt (standalone or as part of a test system) for the collection of the sample types with which this device is intended to be used; alternatively, the sample collection device must be cleared in a premarket submission as a part of this device.
- (2) The labeling required under 21 CFR 809.10(b) must include:
 - (i) A prominent statement that the test is not intended for use as a donor screening test for the presence of HCV RNA from human cells, tissues, and cellular and tissue-based products;
 - (ii) A detailed explanation of the principles of operation and procedures for performing the assay;
 - (iii) Detailed descriptions of the performance characteristics of the device for each specimen type identified in the intended use based on the required analytical and clinical studies;
 - (iv) A brief reference sheet (Quick Reference Instructions) for the intended user(s) that includes the name and intended use of the test, step-by-step instructions of all control and sample testing procedures for the identified specimen types, the result(s) interpretation recommendations, warnings and limitation statements, and information for troubleshooting or technical assistance with the device; and
 - (v) Limitations, which must be updated to reflect current clinical practice and disease presentation and management. These limitations must include statements that indicate:
 - (A) The specimen types for which the device has been cleared and that use of this test kit with specimen types other than those specifically cleared for this device may result in inaccurate test results.
 - (B) When applicable, that assay performance characteristics have not been established in

Some thoughts when communicating with the FDA

The FDA staff are bright, hardworking, dedicated and want to be helpful to developers. They are prepared to be disrespected, as they too often are. Just like anything else, honey may be more effective in the long run than vinegar as it allows for free-flowing two-way problem-solving communication. If a developer asks for help they are usually more than willing to help.

They will use legal/regulatory language as their work must be ready to hold up in court, if needed. You might be surprised how often the FDA is threatened with legal action, even outside of LDTs.

They approach things from a scientific basis. New technologies are examined from this perspective, and they are sure to benefit from a brief primer on your technology.

New technologies may require different FDA approaches, always feel free to suggest approaches that may work.

Links

FDA Webinar - In Vitro Diagnostic Product (IVD): Classification [Webinar - In Vitro Diagnostic Product \(IVD\): Classification - 07/16/2024 | FDA](#)

Product Classification Database <https://www.fda.gov/medical-devices/classify-your-medical-device/product-code-classification-database>

PMA Class III Database <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm>

De Novo Database (typically Class II) -
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm>

510(k) Database (Class I, Class II and/or Exempt)
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>

De Novo Classification Process <https://www.fda.gov/media/72674/download>

Q-Submission <https://www.fda.gov/media/114034/download>

Questions and Answers



Top 5 Takeaways

- FDA classifies medical devices based on risk and intended use of the device.
 - CLIA has its own separate system for categorizing test complexity. Risk does not equate to complexity.
- Factors to consider to determine if your LDTs is Class I, II or III are **intended use** and **risk posed to patients**.
- The risk and intended use also determines the extent of regulatory controls.
- The FDA recommends searching the medical device database for examples to help determine the appropriate regulatory controls for IVDs.
- Device determination and pre-submission requests are available to assist with classification and regulatory pathway questions.

Six-Part Webinar Series on LDTs

- Register for our other webinar programs:
Understand and Prepare for the Impact of the FDA's LDT Final Rule
 - How You Meet Stage 1's Adverse Event Reporting Requirement (November 7, 2024)
 - Stage 1 Basics on Corrective Action and Removal Reporting (January 9, 2025)
 - The Stage 1 Rules on Quality Systems Complaints (March 20, 2025)
 - How Enforcement Discretion Categories & Modification Rules Apply to Your LDTs (May 8, 2025)
 - Navigating FDA LDT Oversight Requirements During Public Health Emergencies (July 10, 2025)





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