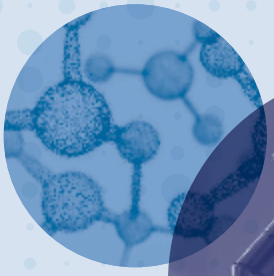
U.S. FOOD & DRUG ADMINISTRATION

FY2024 MCMi Program Update



FDA MEDICAL COUNTERMEASURES INITIATIVE

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Background

What are medical countermeasures[1]?

Medical countermeasures, or MCMs, are FDA-regulated products, including biological products, drugs, and medical devices, that may be used to diagnose, prevent, or treat diseases or conditions associated with CBRN threat agents, including emerging infectious diseases.

The U.S. Food and Drug Administration plays a critical role in protecting the U.S. from the health impacts of chemical, biological, radiological, and nuclear (CBRN) threats, including emerging infectious diseases, such as pandemic flu, COVID-19, and mpox. The FDA facilitates timely development of and access to safe and effective **medical countermeasures** (MCMs) to counter such threats.

In 2010, the FDA launched its Medical Countermeasures Initiative (**MCMi**) Program to focus increased resources on MCM development. The FDA's MCMi Program also facilitates preparedness and response efforts for CBRN threats by prioritizing implementation of **legal authorities** that foster MCM development and availability. The Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (**PAHPRA**)[2] requires the FDA to issue an annual report detailing specific MCM activities. This report responds to that requirement for fiscal year (FY) 2024 (October 1, 2023 – September 30, 2024).[3]

In 2024, FDA reorganized. FDA's MCM-related regulatory science portfolio became part of the Office of the Chief Scientist's new **Office of Regulatory and Emerging Science** (**ORES**) and a new office, the **Office of Public Health Preparedness and Response** (**OPHPR**), was established to facilitate public health emergency preparedness and response functions, among others.

We have taken this opportunity to streamline this fiscal year (FY) 2024 MCMi report. Codified in section 565(g) of the Federal Food, Drug, and Cosmetic Act (**21 USC § 360bbb-4**), the FDA is required to report specific MCM-related activities each year. In prior years the required annual report became increasingly robust as additional work in the FDA's preparedness and response portfolio, publicly reported elsewhere, was also included.

This FY 2024 MCMi report focuses on the statutory reporting requirements with links added to the FDA's web information — updated throughout the year — detailing the FDA's comprehensive activities

[1] Medical countermeasures (MCMs) include qualified countermeasures as defined in section 319F–1(a)(2)(A) of the Public Health Service Act (PHS Act) (42 U.S.C. § 247d–6a(a))(2)(A); qualified pandemic or epidemic products as defined in section 319F–3(i)(7) of the PHS Act (42 U.S.C. § 247d–6d(i)(7)); and security countermeasures as defined in section 319F-2(c)(1)(B) of the PHS Act (42 U.S.C. § 247d–6b(c)(1)(B)). Some medical products (e.g., traumatic brain injury diagnostics) and some activities (e.g., combatting antimicrobial resistance) discussed in this report may not meet the statutory definition of MCMs or relate directly to products defined as MCMs, but were included in this report as examples of additional work supported by the FDA's Medical Countermeasures Initiative (MCMi) Program staff because of their connection to public health preparedness. Inclusion of such examples is not intended as comprehensive reporting on agency activities related to these topics.

[2] Public Law (P.L.) 113-5, 127 Stat. 161 (2014).

[3] Detailed information on the FDA's MCM development and review activities covering FYs 2011-2023 can be found on the **FDA Medical Countermeasures Publications and Reports** webpage.

Box 1: Key FDA activities to prepare for and respond to public health emergencies by facilitating development of and access to MCMs (FY 2024)

Providing **regulatory advice, guidance, and technical assistance** to developers, manufacturers, researchers, and others, including extensive engagements with U.S. government (USG) partners, in the development of repurposed, new, and innovative MCMs

Providing feedback on proposals for development and use of MCMs, including clinical trial design, set-up and data collection for studies, and expediting regulatory reviews of marketing submissions and approving[4] those that meet applicable review standards for use during public health emergencies (PHEs), including for use in outbreaks in other countries

Working with the USG partners and international partners to facilitate access, if necessary, to MCMs that are not approved for the proposed use through an appropriate regulatory mechanism (e.g., clinical trials, expanded access[5], and **emergency use authorities including Emergency Use Authorizations (EUAs)**[6], including participating in USG responses during outbreaks in other countries

Addressing issues related to import and export of MCMs during PHEs

Working with USG partners to improve clinical trial infrastructure and the ability to **monitor and assess MCMs** used during PHEs

Advancing FDA capacities to monitor MCM **supply chains** to: identify product shortages and support adequate supplies of MCMs through such efforts as extending the shelf life of certain stockpiled MCMs; to prevent the distribution of misbranded, counterfeit, adulterated, or unapproved products; and to support interagency collaboration on efforts to support strengthen MCM supply chain resiliency

Identifying and catalyzing the resolution of regulatory science challenges and sustaining the **MCM Regulatory Science Program** to create tools, standards, and approaches to help develop and assess MCM safety, efficacy, quality, and performance

Encouraging approaches to produce MCMs through **advanced manufacturing technologies**

Identifying and catalyzing the resolution of regulatory policy challenges and ensuring that the FDA **legal, regulatory, and policy framework** adequately supports MCM development availability, enabling preparedness and response activities

Sustaining the **MCMi professional development program** to ensure that FDA personnel maintain the requisite skills and abilities to support the FDA's MCM mission

Advancing global health security through provision of technical expertise and global leadership in regulatory harmonization efforts, supporting the **Global Health Security Agenda** and **International Health Regulations Monitoring and Evaluation Frameworks**

to advance the development and availability of MCMs to protect against CBRN threats, including emerging infectious diseases. The scope of the FY 2024 report is limited to new, innovative MCMs and supplements for new MCM indications, particularly those for which development is funded by U.S. government agencies. It excludes the many supplements for minor changes, such as those to MCM chemistry, labeling and storage, and products developed specifically for seasonal flu, respiratory syncytial virus, antimicrobial resistance and others, all of which remain integral to preparedness and response.

Though this report may be more streamlined than in previous years, the FDA's preparedness and response activities are both agile and comprehensive as we work collaboratively to protect and promote public health. Key FDA activities are highlighted in **Box 1**.

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[4] For purposes of this document, the term "approve" is used generally to refer to products that are FDA approved, licensed, cleared, or granted marketing authorization under sections 505, 510(k), 512, 513(f)(2), 515, or 571 of the FD&C Act or section 351 of the PHS Act. When referring specifically to medical devices marketed under a premarket approval application, 510(k) premarket notification, or De Novo classification request, the term "cleared" or "granted" is used, as applicable. The term "approve" does not include authorization under section 564 of the FD&C Act.

[5] Section 561 of the FD&C Act (21 U.S.C. § 360bbb).

[6] Section 564 of the FD&C Act (21 U.S.C. § 360bbb-3).

FY 2024 Resources for MCM Activities

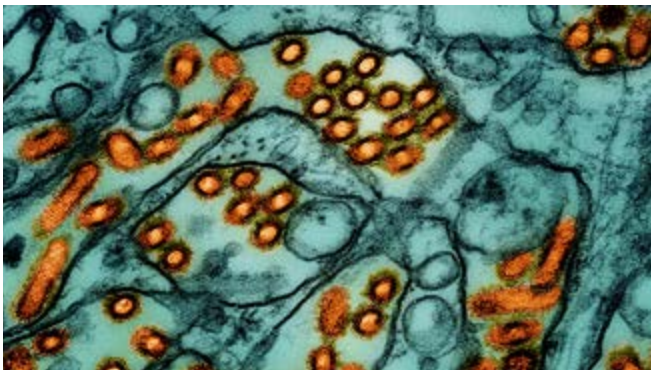
The FDA obligated an estimated $264.3 million in FY 2024 to support MCM activities to prepare for and respond to CBRN threats, COVID-19, and pandemic flu **(Table 1)**. These resources comprised a combination of base funding and no-year funding. This funding supported 639 full-time equivalents (FTEs).

Table 1: FY 2024 resources obligated to MCM activities

	FY 24 Enacted (dollars in millions)	**FY 24 FTE Enacted**
CBRN Base Funding	$177.2	549
Pandemic Flu Base Funding	$29.9	90
Subtotal	**$207.1**	**639**
COVID-19 Supplemental Funding	$57.2	0
Total	**$264.3**	**639**

Responding to Health Emergencies

In addition to COVID-19 MCMs, the FDA worked to advance the development, regulatory review, and availability of MCMs for the following infectious disease outbreaks of significance.



H5N1 virus. Photo credit: CDC/NIAID

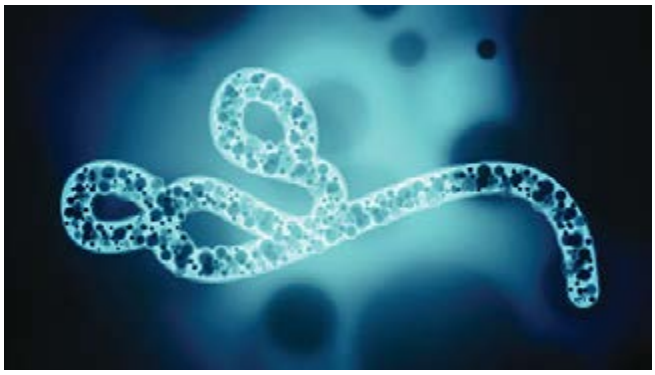
Highly Pathogenic Avian Influenza A (H5N1)

The FDA has been actively involved in USG activities to address highly pathogenic avian influenza (HPAI) A (H5N1) outbreaks occurring in poultry, dairy cows, and other birds and mammals in the U.S. With the first-ever detection of **H5N1 in dairy cows** in March 2024 and subsequent reports of human infections associated with both dairy cow and bird exposures, the FDA has led efforts to ensure the safety of milk, dairy products, and animal feed. The FDA has also supported USG efforts to facilitate access to MCMs, including suitable testing, personal protective equipment (PPE), therapeutics, and vaccines, should they be needed.

Mpox

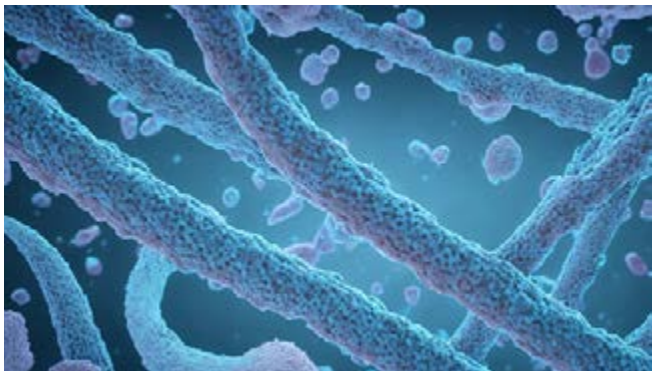
While continuing to **address U.S. response needs**, the FDA has been supporting the USG response to the global outbreak centered in Africa by:

- Continuing to support availability of suitable diagnostic tests, with extensive USG coordination to address clade specific testing options.



Monkeypox virus, the virus that causes mpox

- Addressing expiration dating issues and availability of the **Jynneos vaccine** for donation, as well as address questions related to the **ACAM 2000** vaccine.
- Continuing to encourage and communicate the importance of informative clinical trials, such as the National Institutes of Health (NIH) Study of Tecovirimat for Human Monkeypox Virus (**STOMP**) clinical trial, and utilization of appropriate clinical criteria for expanded-access uses of antivirals.



Marburg virus

Marburg

The FDA supported USG response efforts to an outbreak of Marburg virus disease in Rwanda by facilitating access to diagnostic kits and investigational therapeutics and vaccines.

Medical Countermeasure Approvals

During FY 2024 the FDA continued to review marketing submissions for MCMs against CBRN, emerging infectious disease threats and approve[7] safe and effective MCMs. MCM approvals are listed in ***Appendix 1***. Here are a few notable highlights from FY 2024, based on novelty and impact to public health preparedness and response:

Pandemic Flu Preparedness

- The FDA approved a supplemental application that expanded use of **Xofluza (baloxavir marboxil)** tablets and granules for oral suspension to include the treatment of pediatric patients between the ages of 5 and less than 12 years old with acute uncomplicated flu who are at high risk of developing flu-related complications; Xofluza is currently approved for use in patients 5 years of age and older.
- The FDA sought to ensure access to suitable testing by assessing certain FDA approved and emergency use authorized in vitro diagnostic (IVD) tests' ability to detect the 2024 influenza A (H5N1) strain. In addition to the combination COVID-19/flu and other multiplex tests, the FDA approved 3 IVD tests for seasonal flu subtyping which help identify samples where unsubtypeable results would suggest a possible emerging flu strain and may help facilitate additional preparedness for both seasonal and emerging flu virus strains.

Mpox

The FDA approved ACAM 2000, a vaccine previously approved for prevention of smallpox, to prevent mpox disease in individuals determined to be at high risk for mpox infection.

[7] See footnote 4.

Anthrax

The FDA cleared the **SensiTox B. anthracis Toxin Test** (product code QUU) for the rapid, qualitative detection of lethal factor, a biomarker associated with Bacillus anthracis (B. anthracis) in whole blood, as an aid in the diagnosis of inhalation anthrax.

COVID-19

The FDA approved:

- Two mRNA COVID-19 vaccines with new formulations that more closely corresponded with the circulating variant strains of SARS-CoV-2, **Comirnaty** and **Spikevax** vaccine.
- An expansion of the indication to **Veklury (remdesivir)** to provide for use in the neonatal population.
- **Tofidence (tocilizumab-bavi)**, a biosimilar biological product that references U.S.-licensed Actemra for intravenous administration, for hospitalized adult patients with COVID-19.
- Three SARS-CoV-2 IVD tests for detection of SARS-CoV-2 only and 10 IVD tests for detection of SARS-CoV-2 and other microbial agents, including 5 IVDs for use in near-patient settings (under the product codes **QOF**, **QQX**, **QWR** and **QVF**). In addition, the FDA approved 6 antigen IVDs (product code **QYT**) and 1 molecular IVD test (product code **QWB**) for over-the-counter (OTC) use.

Sepsis

The FDA approved/granted:

- Two IVD tests as aids in the early detection of sepsis[8] in high-risk patients presenting to intensive care units (product codes **PRE** and **SCX**).
- An artificial intelligence/machine learning-based software, the **Sepsis ImmunoScore**, that identifies patients at risk for having or developing sepsis.

Radiological and/or Nuclear Agents

The FDA approved/cleared:

- Two biosimilar products, **Nypozi (filgrastim-txid)** and Ziextenzo (pegfilgrastim-bmez), for hematopoietic subsyndrome of acute radiation syndrome.
- A new indication for the **Silverlon** Wound Contact, Burn Contact Dressings to manage acute cutaneous radiation injury.

Agents that May Cause Harm to US Military Forces

The FDA approved/cleared the following medical products specific for military uses:

- A **mobile health application** intended for use as a risk assessment tool to help military health care providers screen for hemorrhage risk after a physically traumatic event and stratify casualties who need immediate attention.
- Two IVD tests, the **i-STAT TBI Cartridge with the i-STAT Alinity System** and the **VIDAS TBI (GFAP, UCH-L1)**, to aid in the evaluation of patients presenting with suspected mild traumatic brain injury.
- A **system** indicated for use to warm blood, blood products, colloids, and crystalloid solutions prior to parenteral administration, fitting the specific

[8] While not considered a CBRN or emerging infectious disease threat, the USG considers **sepsis a threat to health security** that can be caused by any infection or injury whether it originates from a CBRN event, or an emerging infectious disease like COVID-19.

criteria needed to be used by special operation medics to prevent hypothermia in trauma patients.

Additional Marketing Submissions in Progress

Thirty-three additional marketing submissions for new MCMs or new MCM indications remained under FDA review at the end of the reporting period. While the FDA is working toward meeting the goal date for a decision for each of these submissions, the FDA is generally prohibited from disclosing any determinations regarding the filing or approvability of any marketing submission, as well as earlier-stage interactions, for a medical product under applicable statutory and regulatory provisions unless the submission is approved or other grounds for disclosure apply.

Photo credit: DoD

Enabling Access to MCMs Under FDA's Emergency Use Authorities

In FY 2024, the FDA continued to work with USG partners and product sponsors[9] to provide support for enhanced development and potential availability of candidate MCMs.[10] When circumstances warrant and with availability of appropriate data for FDA review, the FDA has a number of mechanisms to facilitate access to certain candidate MCMs that do not have approved indications for the intended use. One way the FDA does this is by issuing emergency use authorizations (EUAs). The EUA authority[11] allows the FDA to authorize the use of an unapproved medical product, or the unapproved use of an approved medical product, in anticipation of a potential emergency or during an actual emergency involving CBRN agents, or, for the Department of Defense (DOD) purposes, other agents that may cause, or are otherwise associated with, an

9 For purposes of this document, the term "sponsor" is used synonymously with the term "applicant," referring to submitters of applications.

10 This support includes numerous activities, including availability of pre-investigational new drug application (IND) consultations for drug development proposals and pre-market consultations for device development proposals, advice and feedback on clinical trial preparation, discussions related to expanded access protocols and pre-EUA discussions. For example, in FY 2024, the FDA Center for Devices and Radiological Health (CDRH) received 16 new pre-EUA requests for IVDs (10 for COVID-19, and 6 for mpox).

11 Section 564 of the FD&C Act (21 U.S.C.S § 360bbb-3).

imminently life-threatening and specific risk to U.S. military forces, if certain statutory criteria are met.[12]

Lists of **current EUAs** are published on the FDA website. The FDA, to the extent appropriate and permitted by law, publicly posts reviews of scientific data and information supporting the issuance, revision or revocation of EUAs for mpox or COVID-19 drug or biological products, including **vaccines**. Similarly, data and information supporting EUA issuance for in vitro diagnostics (IVDs) is included in the Instructions for Use or EUA Summary documents **published** for every **IVD EUA**.

New MCM EUAs issued in FY 2024 include:

Agents that May Cause Harm to US Military Forces

The FDA continued to support DOD needs for MCMs against agents that may cause or are associated with an imminently life-threatening and specific risk to US military forces. In August 2024, the FDA issued an EUA for **octaplasLG Powder** (blood group types A and AB), a freeze-dried plasma product, for U.S. military forces for the treatment of hemorrhage or coagulopathy during an emergency involving agents of military combat when plasma is not available or when its use is not practical.

COVID-19

- In March 2024 (and then subsequently amended in May and September), the FDA issued an **EUA for Pemgarda (pemivibart)** for pre-exposure prophylaxis (prevention) of COVID-19 in certain adults and adolescents, who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARS-CoV-2 and who have moderate-to-severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments and are unlikely to mount an adequate immune response to COVID-19 vaccination.
- The FDA issued EUAs for 22 COVID-19 IVD tests primarily focused on multi-analyte tests and/or IVDs that can be used for near-patient or over-the-counter (OTC) testing. Of note, seven of the new IVD EUAs were for OTC SARS-CoV-2/flu antigen tests. The FDA also continued to support the Administration for Strategic Preparedness and Response in their distribution of OTC COVID-19 antigen tests through the U.S. Postal Service program. For example, the FDA helped provide established processes for inspection of the test kits received to ensure that products were appropriately authorized, provided up-to-date information to ensure that test kits met specifications, and helped identify and resolve potential program risks.

Table 2: COVID-19 EUA Summary

Product type	New COVID-19 EUAs issued in FY 2024	Total COVID-19 EUAs issued since 2020*
IVDs	22	553
Drugs and biological therapeutics	1	22
Vaccines	0	4
Other devices**	0	63
Total	**23**	**642**

**This total includes EUAs that are no longer active (i.e., EUAs that have been revoked or terminated).*

***Multiple devices were authorized for use under a single "umbrella" EUA in some cases, including certain tests, personal protective equipment, and ventilators/accessories. Each umbrella EUA is counted here as a single EUA.*

[12] The Project BioShield Act of 2004 (P.L. 108-276) amended section 564 to the FD&C Act, granting the Secretary of HHS the authority to declare that circumstances exist that justify the authorization of "emergency use" of unapproved MCMs, or unapproved uses of approved MCMs, under certain terms and conditions. The authority to issue EUAs, after the declaration by the Secretary that issuance of such EUAs is justified, was delegated to the FDA Commissioner. Section 564 of the FD&C Act was amended by PAHPRA in 2013, the 21st Century Cures Act (Cures Act) in 2016 (P.L. 114-255), P.L. 115-92 in 2017, and section 2504 of the Consolidated Appropriations Act of 2023 (P.L. 117-328).

Mpox

The FDA **authorized** the first home collection kit for the collection of lesion swab specimens at home by individuals 18 years of age or older (self-collected) presenting with acute, generalized pustular or vesicular rash suspected of mpox when determined to be appropriate by a healthcare provider. The collection kit is then transported to a laboratory for testing.

EUA Revisions

The FDA also modified or amended EUAs as appropriate, including revisions to EUA fact sheets and instructions for use.[13] Multiple revisions were made to COVID-19 vaccine, therapeutic, and device EUAs in FY 2024 — a substantial and ongoing effort. The latest information is available on the **FDA website**. Some revisions that warranted EUA reissuance include:

- In August 2024, the FDA reissued the EUAs **for all three authorized COVID-19 vaccines for new formulations** that corresponded more closely with the circulating variant strains of SARS-COV-2.
- The FDA authorized 58 EUA IVD revisions[14] and 6 therapeutic EUA revisions.

EUA Revocations

The FDA may also revoke an individual EUA prior to the termination of its underlying EUA declaration.[15] Information about revoked and terminated EUAs is available on the FDA webpage **Emergency Use Authorization—Archived Information** and published in the Federal Register. In FY 2024, the FDA revoked 22 EUAs: 1 for a COVID-19 drug and 21 IVDs for COVID-19.

Other Emergency Use Authorities

The FDA can also allow unapproved uses of an "eligible," approved MCMs without issuing EUAs.[16] The following highlights key uses of these authorities in FY 2024.

Emergency Use Instructions for Novel or Pandemic Flu

In July 2024, the Centers for Disease Control and Prevention (CDC), under the terms of the existing **Memorandum of Understanding between the FDA and CDC for coordination regarding emergency use instructions for MCMs**, issued **emergency use instructions (EUI) for oseltamivir** for treatment or post-exposure prophylaxis of pandemic influenza A viruses and novel influenza A viruses with pandemic potential.[17] Note that the HHS underlying determination to support use of EUI and other emergency use activities such as expiration dating extensions[18] was amended in July 2024 to allow for these activities.[19]

Expiration Dating Extensions

When appropriate, the FDA helps to ensure adequate supplies of MCMs by extending the expiration date of certain, stockpiled MCMs based on review of scientific data. The FDA can use several regulatory mechanisms to extend expiration dates, including issuing or revising EUAs, approving Biologics License Application

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[13] Section 564(g)(2) of the FD&C Act.

[14] The FDA authorized 1,494 revisions to COVID-19 IVD EUAs from March 2020 through September 2024.

[15] Section 564(g)(2) of the FD&C Act. Examples of circumstances that may make revocation appropriate to protect the public health or safety are described in the FDA Guidance Document: **Emergency Use Authorization of Medical Products and Related Authorities**.

[16] Section 564A of the FD&C Act (21 U.S.C. 360bbb-3a); for additional information, see FDA Guidance Document: **Emergency Use Authorization of Medical Products and Related Authorities** and **webpage**.

[17] See **Emergency Use Instructions** (EUI) for Oseltamivir. The EUI authority under section 564A(e) of the FD&C Act is delegated to CDC; see Delegation of Authority Under Section 564(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-3a(e), 87 FR 66707, November 4, 2022.

[18] Subsections 564A(e) and (b) of the FD&C Act (21 U.S.C. 360bbb-3a(e) and (b)), respectively.

[19] 89 FR 59919, July 24, 2024. The section 564(b)(1)(c) determination was originally issued on April 19, 2013.

(BLA) supplements, and using emergency use authorities (section 564A(b) of the FD&C Act). FDA also may express its intent not to object to extensions that violate approvals when scientifically supportable. The FDA maintains an updated list of certain MCM expiration dating extensions that are publicly available. For example, the FDA provided an alert to stakeholders about updates to expiration dating extensions **for certain auto-injectors** and extended the shelf life of seven at-home OTC COVID-19 and OTC COVID-19/flu diagnostic tests. For easy reference by consumers, the FDA continually updates a separate **list** of expiration dating extensions for these tests.

In addition, the FDA continues to review applicable data through the **Shelf-Life Extension Program (SLEP)** to assess whether, if properly stored, certain lots of federally-stockpiled MCM drug products can continue to be held and used for an emergency response beyond the original labeled expiration date for a period specified by the FDA, to help ensure ready access to these products. The FDA developed a controlled accelerated aging approach, combining computer modeling with laboratory testing of both original and aged products to accurately predict the long-term stability of their active components. This laboratory testing provides high-quality data on the condition of stockpiled products, ensuring they remain viable for deployment when needed. In FY 2024, SLEP testing conducted by the FDA to assess drug stability and quality led to shelf-life extensions for approximately 866 lots of MCM drug products, resulting in over $2 billion in cost savings for the U.S. government.

Regulatory Advice and Guidance

During FY 2024, the FDA continued to provide regulatory advice and scientific guidance to sponsors of MCMs and our federal partners funding MCM development, to help foster the development and availability of various MCMs. The FDA provides regulatory advice and guidance through a variety of mechanisms including direct engagement with sponsors, issuing **guidance documents**, and holding **advisory committee** meetings and public workshops.

FDA medical product review centers engage with MCM sponsors throughout the product life cycle. The FDA established policies and procedures for conducting formal meetings with product sponsors. Formal meetings[20] are held — as needed — at the request of a product sponsor, and requests for meetings are granted (unless there is a substantive reason for denying the request (e.g., the product for which the meeting is requested is not sufficiently developed to warrant the type of meeting sought)).

[20] There are four meeting formats: In person face-to-face, virtual face-to-face, teleconference, and Written Response Only. See FDA Guidance Document, **Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products**.

When the FDA denies a request for a meeting, the FDA's letter will explain the reason for the denial. Formal meetings may also be rescheduled or canceled as described in FDA guidance.

Types and Numbers of Drug and Biologic Product Meetings

Under the Prescription Drug User Fee Act (PDUFA), the FDA Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER) categorize **formal meetings** with product sponsors of new drug applications and biologics license applications as Type A, B, C, and D. In FY 2024, CBER provided written responses or held 43 formal meetings with MCM sponsors, and CDER provided written responses or held 55 formal meetings **(Table 3)** and 59 other MCM-related meetings.

Table 3: FY 2024 formal meetings between CBER or CDER and MCM sponsors

Meeting Type	CBER	CDER
Type A	0	0
Type B	15	27
Type C	27	20
Type D	1	7
INTERACT	0	1
Total	**43**	**55**

Types and Numbers of Medical Device Meetings

The FDA Center for Devices and Radiological Health (CDRH) received 110 Pre-Submission (Pre-Sub) and 16 Submission Issue Request (SIR) meeting requests (related to marketing submissions) for MCM devices in FY 2024. CDRH provided extensive written feedback on the Pre-Subs, and many of these sponsors elected to cancel meetings after receiving this written feedback, as they did not see the need for the originally requested meeting. If the sponsor wanted to further discuss the written Pre-Sub feedback, a Pre-Sub meeting was held. The FDA holds SIR meetings sometimes to discuss deficiencies identified during premarket review of device marketing submissions and to provide clarification of the FDA's questions or to discuss an approach to address complex issues identified. In FY 2024, CDRH provided written feedback for 89 MCM Pre-Subs or SIRs and held 32 Pre-Sub and 8 SIR meetings with MCM sponsors **(Table 4)**.

Table 4: FY 2024 meetings between CDRH and MCM sponsors

Meeting Type	CDRH
Pre-Sub	32
SIR meetings	8
Total	**40**

Other Regulatory Advice and Guidance

In addition, eligible MCM sponsors can request a **Regulatory Management Plan** (RMP), setting forth a process where the terms for interactions between the FDA and the product sponsor can be delineated. The FDA did not receive any written MCM-related RMP requests in FY 2024.

Collaborations Through Action Teams

The FDA engages extensively with its federal partners (e.g., White House, HHS Administration for Strategic Preparedness and Response, HHS Biomedical Advanced Research and Development Authority and sister HHS agencies and offices, and DOD) often under established federal coordinating structures.[21] The FDA's interagency collaborations include numerous engagements through the Public Health Emergency Medical Countermeasures Enterprise (**PHEMCE**) and with the DOD to ensure FDA resources are appropriately used for review of MCMs targeting the USG's highest priority threats.[22] MCM approvals and authorizations during FY 2024 can be attributed to the success of these enhanced engagements year after year.

The FDA provided subject matter expertise and technical assistance through approximately 100 standing interagency and HHS/PHEMCE and DOD-specific committees and working groups[23] that develop MCM requirements, plans, priorities, and policies and conduct program oversight and integration. These standing committees and working groups met as needed to address a range of topics across the full spectrum of activities associated with MCMs including threat assessment, requirements setting, product development, proposal reviews, procurement, stockpiling, utilization, and monitoring and assessment of MCMs after they have been dispensed or administered.

FDA/DOD Enhanced Engagements Action Team

The FDA works to facilitate the development, regulatory review and availability of MCMs to support the unique needs of American military personnel, including under a **joint program**[24] established under Public Law (P.L.)115-92[25] to prioritize the efficient development of safe and effective medical products intended for deployed American military personnel.

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[21] The FDA's national and global health security roles and responsibilities are guided by U.S. and HHS strategic frameworks. See, e.g., **The National Biodefense Strategy and Implementation Plan**, October 2022, and the **U.S. Government Global Health Security Strategy**, April 2024.

[22] **PHEMCE high-priority threats**.

[23] **PAHPRA**'s reporting requirements refer to "Action Teams" established under section 565(b)(4) of the FD&C Act, which codified the multidisciplinary teams established under the MCMi Program to advance MCMs for priority threats by working with internal and external entities — as appropriate — to identify and catalyze the resolution of regulatory and scientific challenges to MCM development. While the FDA engages in many other enhanced engagements, such as support for PHEMCE Working Groups, the highlighted collaborations in this section reflect enhanced engagements that function as "MCMi Action Teams".

[24] The DOD Action Team preceded P.L.115-92; DOD-FDA's current enhanced engagements function under the P.L. 115-92 framework. The FDA and DOD entered into a **Memorandum of Understanding** setting forth the framework for the ongoing partnership and the creation of a robust program that can better serve the health care needs of American military personnel and building upon the work of both agencies to foster and prioritize the efficient development of safe and effective medical products intended to save the lives of American service members.

[25] Dec. 12, 2017 (131 Stat. 2023).

Under the framework, DOD develops and maintains a Medical Product Priority List, reflecting the most important and urgent MCMs based on needs and easibility that require increased engagement. For calendar year 2024, there were a total of 27 MCMs identified by DOD on the list, which DOD occasionally updates. MCM approvals and authorizations during FY 2024 attributable to these enhanced engagements are listed in ***Appendix 1*** and ***2***, with some highlighted above.

In addition, P.L. 115-92 requires semi-annual review of DOD's listed priorities between DOD and the FDA's three medical product centers and quarterly meetings between DOD and CBER. In practice, the statutory meetings are held quarterly with MCM experts and executive-level officials from all three medical product centers participating. There are also monthly "Action Officer" meetings where MCM experts can troubleshoot DOD priority development challenges. These enhanced engagements undergird the FDA's formal regulatory meetings with DOD performers, ensuring maximally efficient discussions.

Microbial Sequencing and Multiplex In Vitro Diagnostics Action Team

This Action Team supports sequence-based diagnostic device development, including multiplex diagnostic devices that test for multiple pathogens simultaneously from a single clinical specimen.

Key activities during FY 2024 included:

- Continuing to facilitate scientists' work to populate the **FDA-ARGOS**, a publicly available database of regulatory-grade microbial genomic sequences, through the use of a newly developed genome assembly quality assessment tool, and expanding the **FDA-ARGOS database** with a current focus of adding respiratory pathogen regulatory-grade sequences, including additional influenza strains and biothreat agents. Ultimately this will allow the FDA to publish sequence information for pathogens that can be used in regulatory work.
- Identifying and characterizing use-cases and validation approaches for next-generation sequencing technology in infectious disease medical devices through an interagency agreement with the National Institute of Standards and Technology, and, together with USG partners, coordinating efforts on the use of threat-agnostic testing devices in pandemic preparedness.
- Collaborating with DOD to assess the impact of viral mutations on PCR (polymerase chain reaction) test performance.

Acute Radiation Syndrome Action Team

This Action Team supports development of MCMs to combat radiological and nuclear threats. These MCMs improve survival and mitigate or treat injuries from radiological/nuclear events and determine exposures in a nuclear detonation.

Key activities during FY 2024 included:

- Engaging with the USG partners, including through the ASPR Blizzard (radiological/nuclear) Working Group and MCM Requirement Working Group, to:
  - Facilitate development of MCMs for lung- and gastrointestinal-ARS and radiation biodosimetry devices;
  - Provide regulatory input on MCM requirement setting; and
  - Update the **HHS Radiation Emergency Medical Management (REMM)** guidance.
- Addressing regulatory and scientific challenges associated with development of these MCMs for children, including pediatric use of Neulasta and its biosimilars with prefilled syringes.
- Continuing to provide FDA reviewers training on scientific advancements such as potential methods in analysis of circulating cell-free methylated DNA to monitor tissue/organ responses to radiation exposure.

Medical Countermeasure Regulatory Science

The goal of the **Medical Countermeasure Initiative (MCMi) Regulatory Science Program** is to develop tools, standards, and approaches to assess MCM safety, efficacy, quality, and performance, and to help translate cutting-edge science and technology into innovative, safe, and effective MCMs, including for specific populations. In FY 2024, the FDA continued to implement the MCMi Regulatory Science Program to sustain priority research areas through **intramural** and **extramural** collaborative research, as well as through partnerships with USG agencies, academia, and industry. Intramural FDA MCM regulatory science is funded through a competitive challenge grant process. Extramural MCM regulatory science is funded primarily through a Broad Agency Announcement, "**Food and Drug Administration Broad Agency Announcement for the Advanced Research and Development of Regulatory Science**."

To ensure that the MCMi Regulatory Science Program is appropriately targeted and coordinated with USG MCM priorities, the FDA coordinates with interagency partners including representatives from the National Institutes of Health, Centers for Disease Control and Prevention, Biomedical Advanced Research Development Authority, and Department of Defense, to evaluate MCMi Regulatory Science Program research proposals for scientific/technical merit, feasibility, and alignment with Public Health Emergency Medical Countermeasures Enterprise priorities.

In addition to the many regulatory science projects described in detail under the "Collaborations through Action Teams" section and referenced in FDA webpages, the following projects warrant highlighting because of their novelty and potential impact to public health preparedness and response:

- Continuing to update COVID-19 reference panels to aid in the evaluation of COVID-19 diagnostic tests, to provide test developers with a secondary standard to compare the sensitivity and specificity of different molecular diagnostic tests.
- Collaborating with USG partners and academia to assess at-home COVID-19/flu combination antigen in vitro diagnostic (IVD) test performance and develop methods to predict and/or assess SARS-CoV-2 mutation impacts on antigen and molecular IVD performance.
- Supporting development of animal models that might help with preliminary evaluation of candidate COVID-19 vaccines and therapeutics.
- Supporting development of animal models to facilitate MCM evaluation of CBRN threat agents (e.g., botulinum neurotoxin (BoNT) and nerve agents).
- Supporting development of in vitro models (including microphysiological systems) relevant to exploration of CBRN MCM activity.
- Developing assays to support evaluation of vaccine and therapeutic responses.
- Characterizing SARS-CoV-2 variants and host-pathogen responses.
- Describing responses (e.g., MCM activity and pathogenicity) in nonclinical and clinical samples of SARS-CoV-2, including variants of concern.

- Exploring a model in pediatric and adult patients toward predicting long-term health effects after COVID-19.
- Using systems biology and machine learning approaches to enable comparison between in vitro and in vivo models and clinical data of host-pathogen responses, enabling enhanced and host-directed MCM screening methods.
- Continuing to address diagnostic challenges through the **FDA Diagnostic Data Program**.
- Developing computational models for personal protective equipment (PPE) integrity to support supply chain resiliency and determining the true shelf life of PPE held in the Strategic National Stockpile.
- Published research efforts on **characterization of pediatric facemasks**, **modification on fit evaluation methods**, and **assessment of efficacy and breathability** of additively manufactured facemasks.

Appendix 1: FY 2024 Medical Countermeasure Approvals – Drug and Biological Products

Medical Countermeasure	Sponsor	Date of Approval or Change	Indication and/or Change Approved
COVID-19			
Tofidence (tocilizumab-bavi)	Biogen MA Inc.	July 22, 2024	Biosimilar to U.S.-licensed Actemra, approved for intravenous (IV) administration for hospitalized adult patients with COVID-19 who are receiving systemic corticosteroids and require supplemental oxygen, noninvasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation
Veklury (remdesivir) injection/for injection	Gilead Sciences Inc.	February 28, 2024	For certain patients with COVID-19, provides for the use of Veklury in pediatric patients from birth to less than 28 days of age weighing at least 1.5 kg to less than 3 kg
SPIKEVAX **(Moderna COVID-19 Vaccine, mRNA)** (2024-2025 Formula)	ModernaTX, Inc..	August 22, 2024	Approved to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older
COMIRNATY (COVID-19 Vaccine, mRNA) (2024-2025 Formula)	Pfizer, Inc. and BioNTech Manufacturing GmbH	August 22, 2024	Approved to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older
Pandemic Flu Preparedness[26]			
Xofluza (baloxavir marboxil) **NDA 210854** **NDA 214410**	Genentech Inc.	March 1, 2024	To expand the patient population to include the treatment of pediatric patients between the ages of 5 to less than 12 years old with acute uncomplicated influenza who are at high risk of developing influenza-related complications
Smallpox/Mpox			
ACAM2000 Smallpox and Mpox (Vaccinia) Vaccine, Live	Emergent Product Development Gaithersburg, Inc.	August 29, 2024	To prevent mpox disease in individuals determined to be at high risk for mpox infection

[26] For the FY 2024 MCM Progress Report, we are no longer listing approvals for MCMs specific to seasonal flu that are not directly funded or supported by USG development programs.

Medical Countermeasure	Applicant	Key Dates	Indication and/or Change Approved
Rad/Nuc			
Nypozi (filgrastim-txid)	Tanvex BioPharma USA, Inc.	June 28, 2024	Biosimilar to U.S.-licensed Neupogen To increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Subsyndrome of Acute Radiation Syndrome) See FDA **Nypozi label** for detailed information
Ziextenzo (pegfilgrastim-bmez)	Sandoz Inc.	February 28, 2024	Biosimilar to U.S.-licensed Neulasta To increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Subsyndrome of Acute Radiation Syndrome) See FDA **Ziextenzo label** for detailed information

Appendix 2: FY 2024 Medical Countermeasure Clearances/Grants – Devices

Medical Countermeasure	Applicant/ Submitter	Date	Indication and/or Change Cleared/Granted
Automated Processing of the Physiological Registry for Assessment of Injury Severity (APPRAISE)-Hemorrhage Risk Index (HRI) (K233249)	The Surgeon General, Department of the Army (TSG-DA) U.S. Army Medical Materiel Research & Development Command	April 5, 2024	The APPRAISE-HRI is a mobile health app intended to provide a means for military healthcare providers to screen U.S. service members for hemorrhage risk after a physically traumatic event and stratify casualties who need immediate attention and emergency evacuation from those who are injured but may not be at risk for hemorrhage. The APPRAISE-HRI is not intended to diagnose or direct treatment. Rather, it is intended to provide situational awareness and inform clinical management of potentially hemorrhagic casualties by identifying those at the greatest risk of hemorrhage.
eCARTv5 Clinical Deterioration Suite ("eCART") (K233253)	AgileMD, Inc	June 21, 2024	eCART is a software product that provides automated risk stratification and early warning for impending patient deterioration, signified as the composite outcome of death or ICU transfer. It is intended to be used on hospitalized ward patients 18 years of age or older by trained medical professionals. As a clinical decision support device, eCART's risk score and trend analysis is intended to aid clinical teams in identifying which patients are most likely to clinically deteriorate. eCART provides additional information and does not replace the standard of care or clinical judgment. eCART scoring is initiated by the documentation of any vital sign on an adult ward patient. The device calculates risk only from validated EHR data, such as vitals that have been confirmed by a registered nurse; unvalidated data streaming from monitors/devices will not be used until confirmed by a healthcare professional. The product predictions are for reference only and no therapeutic decisions should be made based solely on the eCART scores.
°M Warmer System (K232107)	MEQU A/S	May 31, 2024	The °M Warmer System is indicated for use to warm blood, blood products, colloids and crystalloid solutions prior to parenteral administration. It is intended to be used by healthcare professionals in hospital, clinical and field environments to help prevent hypothermia. The field environment includes road, rotary and fixed-wing ambulances.

Medical Countermeasure	Applicant/ Submitter	Date	Indication and/or Change Cleared/Granted
Sepsis ImmunoScore (DEN230036)	Prenosis, Inc.	April 2, 2024	The Sepsis ImmunoScore is an artificial intelligence/machine learning based software that identifies patients at risk for having or developing sepsis. The Sepsis ImmunoScore uses up to 22 predetermined inputs from the patient's electronic health record to generate a risk score and to assign the patient to one of four discrete risk stratification categories, based on the increasing risk of sepsis. The Sepsis ImmunoScore is intended to be used in conjunction with other laboratory findings and clinical assessments to aid in the risk assessment for presence of or progression to sepsis within 24 hours of patient assessment. It is intended to be used for patients admitted to the emergency department or hospital for whom sepsis is suspected, and a blood culture was ordered as part of the evaluation for sepsis. It should not be used as the sole basis to determine the presence of sepsis or risk of developing sepsis within 24 hours.
Silverlon Wound Contact, Burn Contact Dressing (K241225)	Argentum Medical LLC	July 31, 2024	Over-The-Counter Indications Local management of superficial wounds, minor burns, abrasions and lacerations. Prescription Use Silverlon Wound Contact, Burn Contact Dressings are indicated for use up to 7 days for partial and full thickness wounds including traumatic wounds, surgical wounds (donor and graft sites, incisions), first and second-degree thermal burns, as well as dermal ulcers (stage I-IV pressure sores, venous stasis ulcers, arterial ulcers, diabetic ulcers), vascular access or peripheral IV sites, orthopedic external pin sites, and wound drain sites. Silverlon Wound Contact, Burn Contact Dressings are indicated for use up to 7 days for decontaminated stable unroofed first- and second-degree mustard-induced vesicant injuries not requiring skin grafting. Silverlon Wound Contact, Burn Contact Dressings are indicated for use up to 7 days for radiation dermatitis. Silverlon Wound Contact, Burn Contact Dressings are indicated for use up to 7 days for acute cutaneous radiation injury including moist desquamation without full thickness skin ulceration and/or necrosis. Silverlon Wound Contact, Burn Contact Dressings are indicated for the management of infected wounds, as the silver in the dressing provides an antimicrobial barrier that may be helpful in managing these wounds. In addition, the moist wound healing environment and control of wound bacteria within the Silverlon Wound Contact, Burn Contact Dressings may help reduce the risk of wound infection and support the body's healing process. Silverlon Wound Contact, Burn Contact Dressings may be used for the management of painful wounds. Silverlon Wound Contact, Wound Burn Dressings are a non-adherent wound contact layer that reduces pain during dressing changes and evaporation of moisture in the dressing may soothe the wound.

Medical Countermeasure	Applicant/ Submitter	Date	Indication and/or Change Cleared/Granted
PBC Separator (K223493)	Selux Diagnostics, Inc	February 15, 2024	The PBC Separator with Selux AST System is an automated inoculum preparation system that uses lysis, centrifugation and sequential optical density measurements to generate a McFarland-equivalent suspension from positive blood culture samples that can be used for quantitative in vitro antimicrobial susceptibility testing by the Selux AST System. Samples are processed directly from blood culture samples identified as positive by a continuous monitoring blood culture system. Samples should be confirmed as monomicrobial, gram negative rods by Gram stain. Organism identification is required for AST result interpretation and reporting, per the Selux AST System instructions for use. Inoculum preparation by the PBC Separator was evaluated for use with the Selux AST System. Performance was demonstrated for the antimicrobial agents and organisms identified in the Indications for Use.
VITEK REVEAL GN AST Assay and VITEK REVEAL AST System (K230675)	Specific Diagnostics, LLC	June 20, 2024	The VITEK REVEAL AST System is an automated system for quantitative and qualitative antimicrobial susceptibility testing (AST) of organisms direct from positive blood culture. The VITEK REVEAL AST System does not provide organism identification. The VITEK REVEAL AST System is an automated system that uses an array of sensors to detect volatile organic compounds emitted by growing bacteria for the in vitro quantitative and qualitative determination of antimicrobial susceptibility. The VITEK REVEAL GN AST Assay is indicated for susceptibility testing direct from positive blood culture samples signaled as positive by a continuous monitoring blood culture system and confirmed to contain gram negative bacilli by Gram stain. Organism identification is required for AST result interpretation and reporting. This test is performed by laboratory health professionals in a clinical diagnostic setting. Results may be used as an aid to clinicians in determining appropriate antimicrobial therapy. Test results from the VITEK REVEAL AST System should be interpreted in conjunction with other clinical and laboratory findings. Standard laboratory protocols for processing positive blood cultures should be followed to ensure availability of isolates for supplemental testing. Sub-culturing is necessary to support further testing for: bacteria and antimicrobials not on the VITEK REVEAL GN AST Assay panel, inconclusive results, epidemiologic testing, recovery of organisms present in positive blood cultures samples, and susceptibility testing of bacteria in polymicrobial samples.

Medical Countermeasure	Applicant/ Submitter	Date	Indication and/or Change Cleared/Granted
QScout Lab; QScout RLD (K230878)	Ad Astra Diagnostics, Inc.	November 14, 2023	The QScout Lab is a quantitative multi-parameter automated hematology analyzer intended for in vitro diagnostic use in screening patient populations 18 years and older found in clinical laboratories and point-of-care (POC) settings. The QScout Lab is used with the QScout RLD test to enumerate and classify the following parameters in venous K2/K3EDTA whole blood: • White blood cell count (WBC) • Neutrophils (NEUT#) • Lymphocytes (LYMPH#) • Monocytes (MONO#) • Eosinophils (EOS#) • Basophils (BASO#) • Immature Granulocytes (IG#) • Percent Neutrophils (NEUT%) • Percent Lymphocytes (LYMPH%) • Percent Monocytes (MONO%) • Percent Eosinophils (EOS%) • Percent Basophils (BASO%) • Percent Immature Granulocytes (IG%) • Neutrophil to Lymphocyte Ratio (NLR)
i-STAT TBI Cartridge with the i-STAT Alinity System (K234143)	Abbott Point of Care	March 27, 2024	The i-STAT TBI test is a panel of in vitro diagnostic immunoassays for the quantitative measurements of glial fibrillary acidic protein (GFAP) and ubiquitin carboxyl-terminal hydrolase Li (UCH-Li) in whole blood and a semi-quantitative interpretation of test results derived from these measurements, using the i-STAT Alinity instrument. The interpretation of test results is used, in conjunction with other clinical information, to aid in the evaluation of patients, 18 years of age or older, presenting with suspected mild traumatic brain injury (Glasgow Coma Scale score 13-1 5), which may include one of the following four clinical criteria: 1) any period of loss of consciousness, 2) any loss of memory for events immediately before and after the accident, 3) any alteration in mental state at the time of accident, and/or 4) focal neurological deficits, within 24 hours of injury, to assist in determining the need for a CT (computed tomography) scan of the head. A 'Not Elevated' test interpretation is associated with the absence of acute traumatic intracranial lesions visualized on a head CT scan. The test is to be used with venous whole blood collected with EDTA anticoagulant in point of care or clinical laboratory settings by a healthcare professional.

VIDAS TBI (GFAP, UCH-L1) (**K240279**)	Biomerieux Inc.	May 1, 2024	The VIDAS TBI (GFAP, UCH-L1) test is composed of two automated assays - VIDAS TBI (GFAP) and VIDAS TBI (UCH-L1) - to be used on the VIDAS 3 instrument for the quantitative measurement of Glial Fibrillary Acidic Protein (GFAP) and Ubiquitin C-terminal Hydrolase (UCH-L1) in human serum using the ELFA (Enzyme Linked Fluorescent Assay) technique. The results of both assays are required to obtain an overall qualitative test interpretation. The overall qualitative VIDAS TBI (GFAP, UCH-L1) test result is used, in conjunction with clinical information, to aid in the evaluation of patients (18 years of age or older), presenting within 12 hours of suspected mild traumatic brain injury (Glasgow Coma Scale score 13-15), to assist in determining the need for a Computed Tomography (CT) scan of the head. A negative interpretation of VIDAS TBI (GFAP, UCH-L1) test is associated with the absence of acute intracranial lesions visualized on a head CT scan.

In addition to the devices listed in more detail in the previous table, the FDA cleared an additional 31 diagnostic tests under the product codes listed in the chart below in FY 2024.

Additional information about these diagnostic test device clearances and grants of de novo classification can be found in the FDA Medical Devices Databases, including the 510(k) Premarket Notification Database. To locate records for a particular type of device, search FDA medical device databases (the **510(k) Premarket Notification Database**[27]) for the product code associated with that device type, or by going to the link in the Clearances in FY 24 column.[28]

Regulation	Regulation Description	Product Code	Product Code Name	Clearances in FY24
866.2950	Microbial nucleic acid storage and stabilization device	QBD	Microbial Nucleic Acid Storage and Stabilization Device	K212878 K221547 K233324 K222771
866.3046	Simple in vitro diagnostic device for the detection of secreted proteins from Bacillus species (spp.) in human clinical samples	QUU	Simple In Vitro Diagnostic Device for The Detection of Secreted Proteins from Bacillus Spp. In Human Clinical Samples	K232545
866.3120	Chlamydia serological reagents	MKZ	DNA Probe, Nucleic Acid Amplification, Chlamydia	K230451
866.3215	Device to detect and measure non-microbial analyte(s) in human clinical specimens to aid in assessment of patients with suspected sepsis	PRE	RT-QPCR Assay For mRNA Transcript Immune Biomarkers	K232095
866.3215	Device to detect and measure non-microbial analyte(s) in human clinical specimens to aid in assessment of patients with suspected sepsis	SCX	Immunoassay For Host Biomarkers of Sepsis	K240041
866.3328	Influenza virus antigen detection test systems	PSZ	Devices Detecting Influenza A, B, And C Virus Antigens	K232434
866.3980	Respiratory viral panel multiplex nucleic acid assay	OCC	Respiratory Virus Panel Nucleic Acid Assay System	K232775
866.3980	Respiratory viral panel multiplex nucleic acid assay	OZE	Influenza A And Influenza B Multiplex Nucleic Acid Assay	K241110

[27] Although FDA maintains a **De Novo Classification Database**, there were no listings for FY 2024.

[28] The FY 2024 MCM Progress Report only lists diagnostic tests for seasonal flu that are not directly funded or supported by USG development programs or useful for differentiating novel, pandemic strains of influenza.

Regulation	Regulation Description	Product Code	Product Code Name	Clearances in FY24
866.3981	Device to detect and identify nucleic acid targets in respiratory specimens from microbial agents that cause the SARS-CoV-2 respiratory infection and other microbial agents when in a multi-target test	QOF	Multi-Target Respiratory Specimen Nucleic Acid Test Including SARS-CoV-2 And Other Microbial Agents	K233410 K231758 K232954 K233100 K241194 K241240
866.3981	Device to detect and identify nucleic acid targets in respiratory specimens from microbial agents that cause the SARS-CoV-2 respiratory infection and other microbial agents when in a multi-target test	QQX	Respiratory Specimen Nucleic Acid SARS-CoV-2 Test	K230440 K233453
866.3982	Simple point-of-care device to directly detect SARS-CoV-2 viral targets from clinical specimens in near-patient settings	QVF	Simple Point-Of-Care Device to Directly Detect SARS-CoV-2 Viral Targets from Clinical Specimens in Near-Patient Settings	K233688 K231187 K232377 K233358
866.3982	Simple point-of-care device to directly detect SARS-CoV-2 viral targets from clinical specimens in near-patient settings	QWR	Simple Point-Of-Care Device to Detect SARS-CoV-2 Nucleic Acid Targets from Clinical Specimens in Near-Patient Settings	K223783
866.3984	Over-the-counter test to detect SARS-CoV-2 from clinical specimens	QWB	Over-The-Counter Molecular Test to Detect SARS-CoV-2 From Clinical Specimens	K232643
866.3984	Over-the-counter test to detect SARS-CoV-2 from clinical specimens	QYT	Over-The-Counter COVID-19 Antigen Test	K230828 K231795 K233373 K233842 K240728 K241317

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