03/06/2020

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USA Covid-19 IVD

Status of “Emergency Use Authorizations”
Pathway toward a regular FDA approval

03.06.2020 Philippe Etter

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1

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Emergency Use Approval system

https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd

During a public health emergency, the FDA can use its Emergency Use Authorization (EUA) authority to allow:

- Use of unapproved medical products when no adequate, approved and available alternatives

Objective : to rapidly increase the number of COVID-19 tests on the market. By granting an EUA to a manufacturer, the FDA specifically authorizes the marketing of the particular test

Other preceeding EUA : Zika, Enterovirus, Ebola, MERS,

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2

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Recent sequence

- **March 16th**: initial Covid-19 EUA, also covering respirators, adjacent therapies : ”Full throttle”
- **March 23rd** : updated policy for diagnostics : manufacturer must submit a formal request : “First tightening”
- **April 28th** : second pathway for serology test “Umbrella EUA” – only usable for test used in accredited (CLIA) labs – limited number of test “approved” through this pathway.
- **May 4th** : updated policy for diagnostic : must submit a request with evidences : “additional tightening, also including labelling requirement”
- **May 28th**, June 1st : published list of (31) serology test removed https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2

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3

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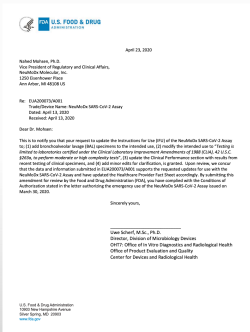
Throughput

Currently available commercial kits

- 85 entries in the database of EUA
  - 68 molecular tests
  - 13 serology tests (IgM & IgG or IgG only)
  - 1 antigen (rapid test) (probably others in development currently)

Laboratory developped (molecular)

- 32 entries


U.S. FOOD & DRUG ADMINISTRATION

April 23, 2020

Nahed Mohsen, Ph.D.
Vice President of Regulatory and Clinical Affairs,
NeuMoDx Molecular, Inc.
1250 Eisenhower Place
Ann Arbor, MI 48108 US

Re: EUA200073/A001
Trade/Device Name: NeuMoDx SARS-CoV-2 Assay
Dated: April 13, 2020
Received: April 13, 2020

Dear Dr. Mohsen:

This is to notify you that your request to update the Instructions for Use (IFU) of the NeuMoDx SARS-CoV-2 Assay to; (1) add bronchoalveolar lavage (BAL) specimens to the intended use, (2) modify the intended use to "*Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate or high complexity tests*", (3) update the Clinical Performance section with results from recent testing of clinical specimens, and (4) add minor edits for clarification, is granted. Upon review, we concur that the data and information submitted in EUA200073/A001 supports the requested updates for use with the NeuMoDx SARS-CoV-2 Assay and have updated the Healthcare Provider Fact Sheet accordingly. By submitting this amendment for review by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the NeuMoDx SARS-CoV-2 Assay issued on March 30, 2020.

Sincerely yours,

Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov

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4

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EUA process

Templates for these EUA submissions are available to help facilitate the preparation, submission, and authorization of an EUA:

- Molecular Diagnostic Template for Manufacturers (Updated May 13, 2020)
- Molecular Diagnostic Template for Laboratories (Updated May 13, 2020)
- Serology Template for Manufacturers (unchanged from May 4, 2020)
- Serology Template for Laboratories (unchanged from May 4, 2020)
- Antigen Template for Manufacturers (May 11, 2020)
- Home Specimen Collection Molecular Diagnostic Template (May 29, 2020)

Duration until response : 2 to 3 weeks.

5

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Use environment requirements

H - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform **high complexity tests**.

M - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform **moderate complexity tests**.

W - **Patient care** settings operating under a CLIA Certificate of Waiver.

6

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Standard approval of Covid-19 IVD

Class II device

Qualifies for a 510k procedure based on a predicate device.

May 27th, Timothy Stenzel, director of the FDA Office of In Vitro Diagnostics and Radiology said that:

"The agency had received an inquiry into when the EAU program will end and when the associated tests will have to move into the 510(k) premarket pathway, although he said the state of emergency declaration is "unlikely to be terminated anytime soon."

"We always do encourage developers to work toward a routine application," which might entail a petition for de novo classification of the test. "We encourage these applications as soon as the developers are ready, and we're willing to work with them right now" on converting EUA test dossiers into conventional premarket filings, he said. The FDA has some discretion to keep EUA tests on the market despite the filing of a 510(k) for one test of a particular type, and thus the agency does not anticipate that the need for EUA tests will disappear anytime soon.

This means probably another 6 months or so.

https://www.bioworld.com/articles/435380-us-fda-encouraging-covid-19-test-developers-to-file-510ks

7

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Learnings

For manufacturers:

- Get ready for a 510k from now on:
  - First de-novo will trigger and avalanche of submission
  - More and more performance requirement will develop

For the whole IVD community:

- Very fast and adaptative regulatory process by FDA
- Quite clear guidances
- Quite different from EU approach:
  - In the process of setting up a "centralized overview"
  - Trying to synchronize NCA
  - https://ec.europa.eu/info/sites/info/files/testing_kits_communication.pdf

8

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9

9