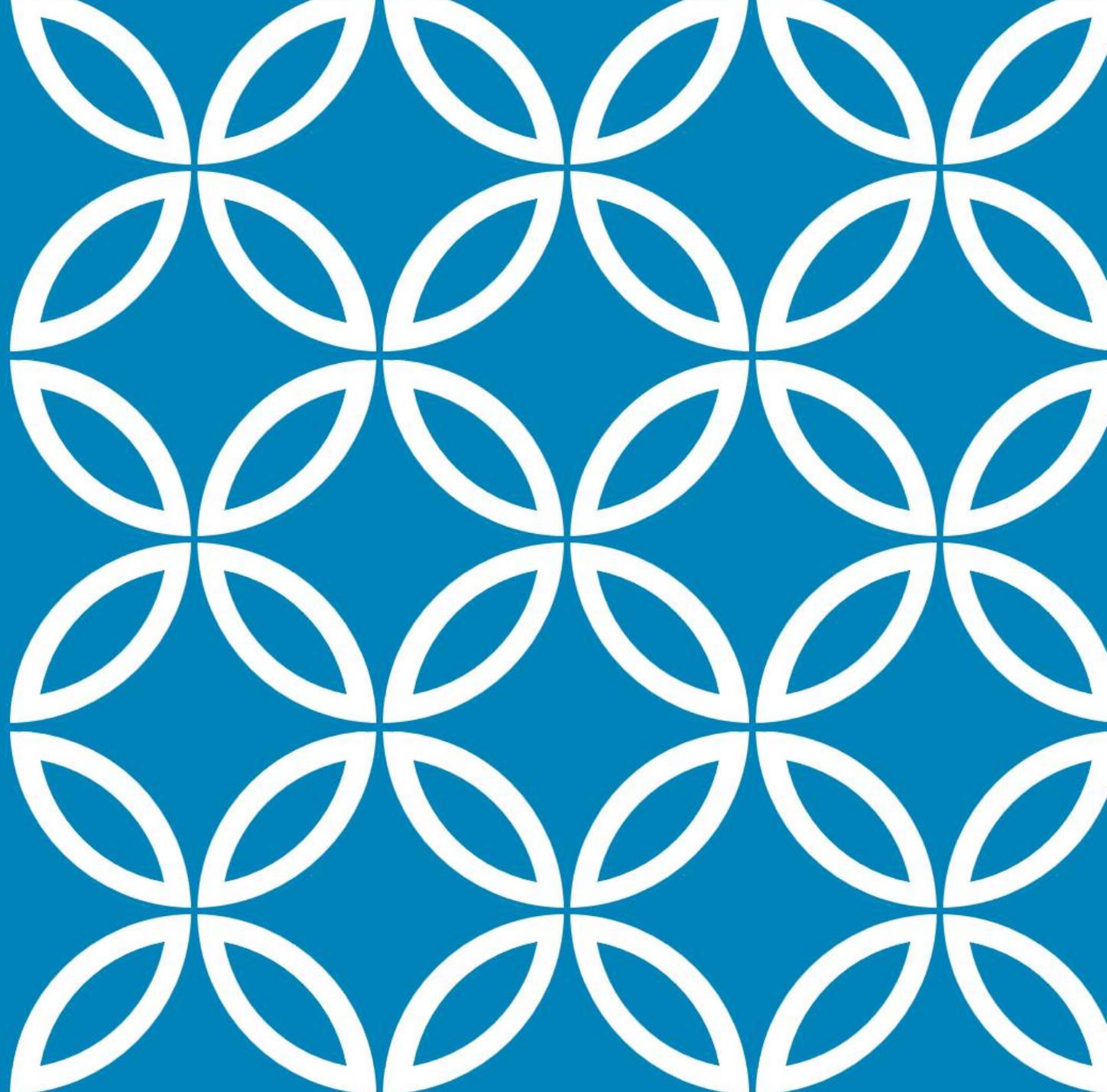


# THE ROLE OF EMERGENCY USE AUTHORIZATION (EUA) IN COVID-19 DIAGNOSTICS

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# WHAT IS THE ROLE OF THE FDA IN AUTHORIZING IN VITRO DIAGNOSTICS FOR EMERGENCY USE?

- Federal Food, Drug, and Cosmetic Act (specifically section 564(b)(1)(C))



# FEDERAL FOOD, DRUG, AND COSMETIC ACT

## SECTION 564(B)(1)(C)

1. SARS-CoV-2 can cause a serious or life-threatening disease or condition;
2. Based on the totality of scientific evidence available to the agency, it is reasonable to believe that the authorized device may be effective in diagnosing current, recent, or prior infection with SARS-CoV-2 or may be effective in some other aspect of managing COVID-19, and that the known and potential benefits of the device when used for that purpose outweigh the known and potential risks of the device; and,
3. There is no adequate, approved, and available alternative to the emergency use of the authorized devices.

# THE SECOND CRITERION:

Based on the totality of scientific evidence available to the agency, it is reasonable to believe that the authorized device *may be effective* in diagnosing current, recent, or prior infection with SARS-CoV-2 or may be effective in some other aspect of managing COVID-19,

**and**

that the *known and potential benefits of the device when used for that purpose outweigh the known and potential risks of the device.*

# WHAT HAPPENS AT THE TERMINATION OF AN EUA DECLARATION?

- When an EUA declaration is terminated, then any EUA(s) issued based on that declaration will no longer remain in effect.