Supplementary Appendix for:

Validating combination throat-nasal swabs for COVID-19 tests would improve early detection, especially for the most vulnerable

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Table of Contents

Supplemental Table. Demonstration of flexibilities exhibited by the U.S. Food and Drug Administration (FDA) in the emergency use authorization (EUA) of COVID-19 tests.

	Title	Description of flexibility	Reference
1	Authority for Emergency Use Authorization (EUA)	Under law, the EUA authorities allow a lower bar for test development and validation. The FDA made full use of this flexibility during the COVID-19 pandemic, as well as in other emergencies.	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities
2	Validation specimen type	With few patient specimens available early in the COVID-19 pandemic, contrived positive specimens were used for clinical evaluation.	https://www.fda.gov/media/136112/download?attachment (See *Clinical evaluation*)
3	Scaling of manufacturing	To accommodate emergency response needs in the production of COVID-19 EUA tests, the FDA is permitted to waive otherwise-applicable current good manufacturing practice (CGMP) requirements (e.g., storage or handling).	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities (See Section IV.C)
4	Specimen Pooling	To increase capacity, pooling of specimens for testing by a previously authorized test was allowed without FDA review of pooled specimen performance, if single specimen validation data supported compatibility.	https://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2#amendment (See *Pooling and Serial Testing Amendment for Certain Molecular Diagnostic Tests for SARS-CoV-2*)
5	Extension of test expiration dates	Expiration dates for at-home, over-the-counter (OTC) COVID-19 tests were extended when test manufacturers provided data demonstrating a longer shelf-life than was known when the test was first authorized.	https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/home-otc-covid-19-diagnostic-tests (See *Authorized At-Home OTC COVID-19 Diagnostic Tests and Expiration Dates*) https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities#expdate (See Section IV.B)
6	Multi-analyte tests	Multi-analyte (multi-pathogen) tests were authorized under COVID-19 EUA.	https://www.fda.gov/media/176728/download?attachment
7	Performance accounting for study population	Positive Percent Agreement during clinical evaluation was modeled to adjust for the viral load of participants in the study population.	https://www.fda.gov/media/157544/download?attachment (See *Section 2.6*)
8	At-home testing	Simulated home test environments for over-the-counter (OTC) test validation were considered.	https://www.fda.gov/media/157544/download?attachment (See *Section 2.6*)

9	Asymptomatic screening	Screening of asymptomatic patients using tests were allowable for tests that did not initially include asymptomatic claims.	https://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2#SerialTesting (See *Antigen EUA Revisions for Serial (Repeat) Testing*)
10	Serial testing	The FDA exhibited flexibility to allow asymptomatic claims with serial testing.	https://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas (See *Umbrella EUA for SARS-CoV-2 Molecular Diagnostic Tests for Serial Testing* and *Antigen EUA Revisions for Serial (Repeat) Testing*)
11	Performance with serial testing	Cumulative Positive Percent Agreement through serial testing, rather than one-time testing, was considered in the review of test performance for EUA.	https://thehill.com/opinion/healthcare/515628-fda-were-constantly-working-on-covid-testing-options/ https://www.fda.gov/medical-devices/covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2#SerialTesting