

Device Schedule:

Intended Purpose as per the Instructions for Use:

The **cobas® liat** SARS-CoV-2 v2 nucleic acid test is an automated real-time reverse transcription polymerase chain reaction (RT-PCR) test intended for the qualitative detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) nucleic acids in self-collected anterior nasal (nasal) swab specimens (directly observed by a healthcare-provider) and healthcare provider-collected nasal swab and nasopharyngeal swab specimens from individuals suspected of SARS-CoV-2 infection by their healthcare provider (including symptomatic individuals and asymptomatic individuals at high or low risk of exposure).

The test is meant to be used in conjunction with other clinical and epidemiological information and laboratory findings. SARS-CoV-2 nucleic acids are generally detectable in nasal swab and nasopharyngeal swab specimens during the acute phase of infection. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for diagnosis, treatment or other patient management decisions. Conversely, positive results do not rule out co-infection with other organisms. The agent(s) detected may not be the definite cause of disease.

The **cobas® liat** SARS-CoV-2 v2 nucleic acid test is intended for professional use in a point of care location, near-patient setting or clinical laboratory.

Device Name	Model	Type (Codes as per (EU) 2017/2185)	Risk Classification	Basic UDI-DI
cobas® liat SARS-CoV-2 v2 nucleic acid test	09049339190	IVR 0503	Class B near-patient test	761333603137AN