Device Schedule:

The **cobas® liat** Bordetella panel nucleic acid test (**cobas® liat** Bordetella panel) is an automated multiplex real-time polymerase chain reaction (PCR) assay for the rapid in vitro qualitative detection and differentiation of *B. pertussis*, *B. parapertussis*, and *B. holmesii* DNA in human nasopharyngeal swabs taken from patients with suspected pertussis respiratory infection.

Negative results do not preclude *B. pertussis*, *B. parapertussis*, or *B. holmesii* infection and should not be used as the sole basis for treatment or other patient management decisions. Conversely, positive results do not rule out co-infection with other bacteria or viruses. The agent detected may not be the definite cause of disease.

Concomitant cultures are necessary to recover organisms for epidemiological typing or for further susceptibility testing.

The **cobas® liat** Bordetella panel is intended for professional use in a clinical laboratory setting, near-patient testing, or point-of-care (POC) location in conjunction with clinical and epidemiological risk factors.

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Risk Classification**	**Basic UDI-DI**
cobas® liat Bordetella panel	09857664190	IVR 0503	Class C near-patient test	761333603191AU
cobas® liat Bordetella panel control kit	09857672190	IVR 0503	Class C near-patient test	761333603192AW