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| Test Reagent Kit | Xpert Xpress CoV-2 plus | |
| Catalog Number | XP3SARS-COV2-10 | |
| Technology | Real-time RT-PCR | |
| Targets | RdRP: RNA-dependent RNA polymerase gene N2: nucleocapsid gene E: envelope gene | |
| Batch or On-Demand | On-Demand | |
| Minimum Batch Size | 1 | |
| Sample Types | Specimen Collection: Nasopharyngeal, Anterior nasal swabs Transport Media¹: UTM/VTM, eNAT, or Saline | |
| Sample Extraction | Automated/integrated | |
| Precision Pipetting | Not required | |
| TAT | Approximately 30 min. 20 min with early assay termination ² | |
| Hands-on Time | <1 minute | |
| Controls: Process | Sample Processing Control | |
| Controls: Probe Function/Detection | Probe Check Control | |
| Symptomatic | Positive Percent Agreement | Negative Percent Agreement |
| Nasopharyngeal | 100% (95% CI: 95.4%–100.0%) | 96.5% (95% CI: 90.1%–98.8%) |
| Nasal specimens | 100% (95% CI: 92.3%–100.0%) | 100% (95% CI: 94.4%–100.0%) |
| Asymptomatic³ | 100% (95% CI: 82.4%–100.0%) | 99.0% (95% CI: 94.7%–99.8%) |
| Sample Storage | 15–30 °C for up to 48 hours 2–8 °C for up to 7 days in viral transport medium, eNAT or saline until testing is performed | |
| Kit Storage | 2–28 °C | |
| Commercial Controls | Refer to Xpert Xpress CoV-2 plus Package Insert or contact Cepheid Technical Support | |

¹ Specimen transport media, other than eNAT, that contains guanidine thiocyanate (GTC) may interfere with the test causing false negative results.

² With Early Assay Termination (EAT) for positive results.

³ PPA and NPA for asymptomatic specimens includes both nasopharyngeal and nasal specimens.

Refer to most current package insert (for GeneXpert[®] and GeneXpert Infinity systems) for complete details. CE-IVD. *In Vitro* Diagnostic Medical Device. Not available in all countries.

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