

Hennepin Healthcare Clinical Laboratory

SalivaDirect™
COVID-19 TESTING



About us

Hennepin Healthcare is an integrated system of care that includes a nationally recognized Level I Adult and Pediatric Trauma Center, an acute care hospital, as well as a clinic system with primary care clinics located in Minneapolis and across Hennepin County.

Hennepin Healthcare Clinical Laboratory is respected regionally for its clinical expertise in pathology and laboratory medicine. Particularly within the highly sophisticated specialties of **Cytogenetics, Renal Pathology, Molecular Pathology, Molecular Infectious Disease and Forensic Toxicology, our clinicians' expertise**, state-of-the-art equipment and highly skilled technical staff.

Our Clinical Laboratory is the first laboratory in the country to receive licensed authorization for SalivaDirect™, a method which utilizes saliva paired with molecular PCR testing to assess individuals for SARS-CoV-2 (COVID-19) infection. Routine testing in a large scale fashion will continue to play a critical role in monitoring transmission of COVID-19.

Clinical sensitivity for SalivaDirect™ COVID-19 testing is 90-100% with properly collected specimens, with limits of detection between 10-2,000 copies of target virus genes. The clinical specificity is 100%. SalivaDirect™ has received EUA clearance by the FDA for use in high-complexity laboratories.

Advantages

- **Easy to collect/non-invasive:** requires a small sample (2.0 mL) of saliva.
- **Rapid and safe collection:** generally takes less than one minute and is self-collected, minimizing exposure risk to health care workers.
- **Fewer supplies required:** saliva are collected in sterile containers that are routinely available, cheap, and do not require special preservatives or containers.
- **Accurate:** validated sensitivity between 90-100%.
- **Affordable:** the first RNA extraction-free saliva method, which bypasses expensive and labor-intensive steps to extract the virus's genetic material. There are also no special collection swabs, media, or certain chemical reagents, decreasing cost.



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Benefits

- Use of multi-vendor high output platforms
- Testing performed seven days a week, 24 hours a day
- Flexibility to tailor our services to your needs

Turnaround time

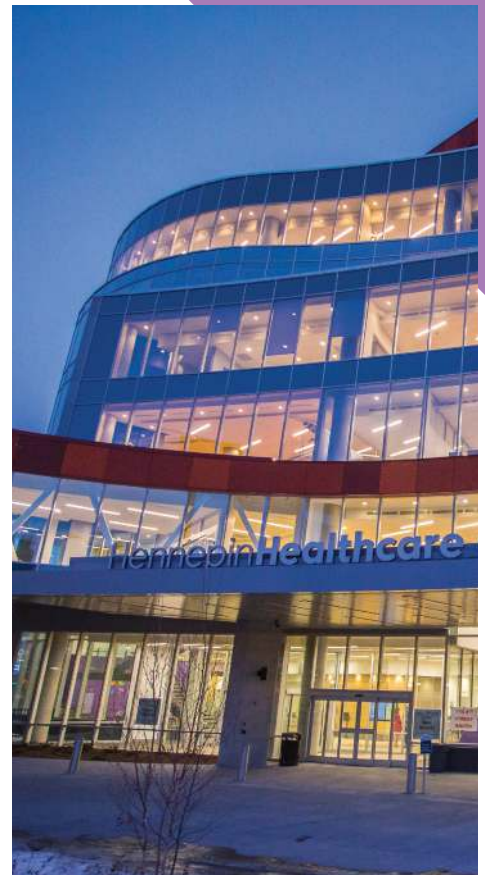
Current average turnaround time from receipt of specimen is 24 - 48 hours.

Result reporting

We provide multiple avenues for communication of test results, including:

- Fax
- Web portal
- Fully integrated report system to an electronic health record*

**Additional fees will apply for fully integrated reporting systems.*



Contact us

You can contact our sales and outreach line at **612-873-0800** or email at LabOutreach@hcmcd.org.



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