Key Summary of Published Article

SARS-CoV-2
Specimen Stability Study

Quest Diagnostics®

Do **transport medium**, **storage temperature**, and **time** affect detection of SARS-CoV-2 RNA?

Background

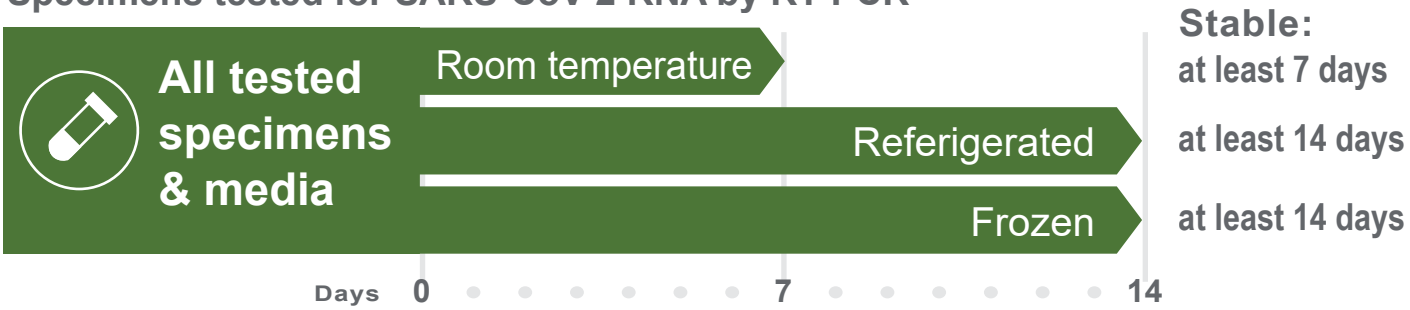
The COVID-19 pandemic has caused shortages of viral transport media, which has led to the use of alternatives. However, information about the stability of clinical specimens in alternative media and storage conditions is limited.

Variables tested

Specimens and media	Upper respiratory swabs in 5 media: VCM • UTM®-RT • ESwab™ • M4 • Saline	Bronchoalveolar lavage	Sputum
Storage temperature	Room temperature 18°C to 26°C	Refrigerated 2°C to 8°C	Frozen -10°C to -20°C
Storage time	7 days room temp	14 days referigerated or frozen	

Results

Specimens tested for SARS-CoV-2 RNA by RT-PCR



SARS-CoV-2 RNA remains detectable from clinical specimens under a range of transport and storage conditions.

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SARS-CoV-2
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Article Title: "Evaluation of Transport Media and Specimen Transport Conditions for the Detection of SARS-CoV-2 Using Real Time Reverse Transcription PCR"

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Background

- Testing for COVID-19 has led to a worldwide shortage of laboratory supplies, including viral transport media.[1]
- Addressing this shortage, the United States Food and Drug Administration has recommended using alternative viral transport media.[1]
- Data on the detection of SARS-CoV-2 RNA in alternative transport media and storage conditions are limited.
- **Objective:** The investigators examined the stability of SARS-CoV-2 specimens when alternative media and storage conditions were used for a real-time reverse transcription (rRT-PCR) assay.

Methods

- Three specimen types and 5 media were evaluated (7 combinations): nasopharyngeal/oropharyngeal swabs in 5 different transport media, bronchoalveolar lavage, and sputum (processed in 1X PBS).
  - The 5 media examined were VCM, UTM®-RT, ESwab™, M4, and saline (0.9% NaCl).
- A SARS-CoV-2–positive specimen was used to spike pools of remnant SARS-CoV-2–negative specimens. Spiked samples were divided and stored at room temperature (18°C to 26°C) for up to 7 days, refrigerated (2°C to 8°C) for up to 14 days, or frozen (-10°C to -30°C) for up to 14 days.
- Samples were tested on day 0 and at multiple timepoints up to 14 days using the Quest Diagnostics Infectious Disease (QDID) SARS-CoV-2 RNA, qualitative rRT-PCR EUA (emergency use authorization).
  - Additional testing using normal saline (0.9% NaCl) was also performed at a Marlborough, MA Quest location using either the QDID SARS-CoV-2 assay or Roche Diagnostics Cobas® SARS-CoV-2 EUA tests.
- Samples were considered stable at a given timepoint if the mean Ct was within 3 Ct of the value at day 0.

Results

- SARS-CoV-2 RNA was consistently detected across all tested media and specimen types, storage temperatures, and timepoints.
  - At the Marlborough, MA location, saline samples yielded detectable SARS-CoV-2 RNA and consistent Ct values for at least 14 days at all assayed temperatures, regardless of the testing platform used.
- Although some combinations of specimens and storage conditions yielded increasing Ct values, changes would not affect the qualitative interpretation of positive results.

Conclusions

- These findings support the use of alternative transport media and storage conditions for detecting SARS-CoV-2 RNA using a sensitive rRT-PCR assay.

Reference

1. US Food & Drug Administration. FAQs on diagnostic testing for SARS-CoV-2. Accessed April 14, 2020. https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2