

NEW IN 2021: COMPLETE YOUR HIGH THROUGHPUT COVID-19 DIAGNOSTIC TESTS WITHIN 2 CALENDAR DAYS OR MEDICARE PAYMENT DROPS TO \$75.00

BACKGROUND: On April 14, 2020, the Centers for Medicare & Medicaid Services (CMS) released Administrative Ruling [CMS-2020-01-R](#) introducing U0003 and U0004, two new HCPCS codes for COVID-19 clinical diagnostic laboratory tests (CDLT) that utilize high throughput technologies. According to CMS, high throughput technology uses a complex platform that employs automated processing of more than two hundred specimens a day. This technology involves highly sophisticated equipment that requires more intensive technician training and more time-intensive processes to assure quality. In consideration of these increased resources, Medicare set pricing for the two codes at \$100, almost double its payment for standard tests.

In an October 15, 2020, [press release](#), CMS describes how its amended ruling (CMS-2020-1-R2) incentivizes prompt turnaround time of results and explains how you will bill and be paid for COVID-19 tests run on high throughput technology come January 1, 2021.

- The base payment amount for U0003 and U0004 will drop to \$75
- New HCPCS code U0005* will become effective as an additional \$25 add-on payment to labs if they meet the following two requirements:
 - they completed the COVID-19 CDLT in 2 calendar days or less from the date of specimen collection AND
 - the majority of their COVID-19 CDLTs run on high throughput technology in the previous calendar month were completed in 2 calendar days or less for all of their patients (not just their Medicare patients)

***U0005:** *Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique, CDC or non-CDC, making use of high throughput technologies, completed within 2 calendar days from date and time of specimen collection. (List separately in addition to either HCPCS code U0003 or U0004)*

In short, labs that complete these CDLTs within 2 days of the date the specimen is collected will bill HCPCS code U0005 in addition to U0003 or U0004 to receive total payment of \$100 while laboratories that take longer will bill only U0003 or U0004 and receive \$75.

Let's look at a few of the accompanying [FAQs](#) that help to provide some additional insight.

Question: *CMS has indicated that laboratories must complete the test within 2 calendar days of the date the specimen is collected. What does it mean to "complete" the lab test?*

Answer: Per CMS 2020-1-R2, CMS considers the test to be "complete" when the results of the test are finalized and ready for release.



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Question: *What is the definition of high throughput technology under the new Administrative Ruling CMS 2020-1-R2?*

Answer: Administrative Ruling CMS 2020-1-R2 uses the same definition for high throughput technology used in April 14, 2020 Administrative Ruling CMS 2020-1-R1. The April 14 Ruling states: “A high throughput technology uses a platform that employs automated processing of more than two hundred specimens a day.”

Question: *My laboratory testing platform is not specifically listed in CMS Ruling CMS-2020- 01-R. Can my laboratory bill Medicare for tests run on my platform using U0003 and U0004?*

Answer: Laboratories may bill Medicare HCPCS codes U0003 and U0004 when the tests described in those codes make “use of high throughput technologies as described by CMS-2020-01-R.” The Ruling includes a list of examples of high throughput technology as of April 14, 2020, and states that high throughput technologies are not limited to technologies listed in the Ruling. The Ruling states: “A high throughput technology uses a platform that employs automated processing of more than two hundred specimens a day.” Laboratories should ensure that the technologies they are using meet this definition when they bill Medicare using these codes.

APS will monitor this topic and provide relevant updates as they become available. In the meantime, please reach out to your Practice Manager with any questions.