

Customer Response: CMS Ruling 2020-1-R

On April 14, 2020 CMS issued a Ruling (<https://www.cms.gov/files/document/cms-2020-01-r.pdf>) that increases reimbursement from \$51 to \$100 for tests that detect SARS-CoV-2 that involve high throughput machines. CMS defines a high throughput technology as one that “uses a platform that employs automated processing of more than 200 specimens a day”, and includes, *but is not limited to* ... “the GeneXpert Infinity System.” Based on this, we believe that Customers running Xpert® Xpress SARS-CoV-2 tests* on a system(s) comprised of **8 modules or more such as:**

1. Any GeneXpert® Infinity System;
2. Any GeneXpert XVI-XVI;
3. Any GeneXpert XVI-XII;
4. Any GeneXpert XVI-VIII

can meet the definition of using a high throughput technology capable of processing more than 200 specimens per day and should be able to report their tests using¹:

U0003: 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, making use of high throughput technologies as described by CMS-2020-01-R.

We also believe that customers running Xpert Xpress SARS-CoV-2 tests on any two or more GeneXpert IV-IV systems in the same laboratory in a hospital or hospital system under the same CLIA license also have an automated platform capable of processing more than 200 specimens per-24-hour day. In fact, GeneXpert test modules function the same way in the instrument family from GeneXpert IV-IV systems to Infinity System in the GeneXpert instrument family listed above, processing each specimen in the same manner in the same amount of time. As such, U0003, which requires making use of high throughput technologies, would appear to apply to this platform configuration as well.

Customers running Xpert Xpress SARS-CoV-2 tests on multiple GeneXpert IV-IV machines in different areas of the same hospital under the same CLIA license or in separate hospitals in a network that share

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* For use under an Emergency Use Authorization (EUA) only.

the same CLIA license should consult with their CMS Medicare Administrative Contractor (MAC), or other commercial payer(s) for more guidance on whether they meet the definition to use U0003.

We believe that customers running Xpert Xpress SARS-CoV-2 tests on system(s) with less than 8 modules, would report tests using:

87635: 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

Rationale

The entire GeneXpert family of instruments is based on the same fundamental principle, and each individual module – regardless of instrument cabinet size – functions the same. A specimen is loaded into the cartridge, the cartridge is loaded into a module, and the specimen is processed. For all instruments included in the GeneXpert family, specimen processing includes *fully automated* nucleic acid extraction, amplification, amplified probe detection, and result reporting.

Once a cartridge is loaded into a module, the total time to result is about 45 minutes for any Xpert Xpress SARS-CoV-2 test. Allowing for an additional 5 minutes to unload and re-load a cartridge (total 50 minutes), **each module is capable of running 28 Xpert Xpress SARS-CoV-2 tests per 24-hour day.** Extrapolated, assuming instruments are running only Xpert Xpress SARS-CoV-2, the following instrument configurations have the capacity to run >200 patient specimens in a 24-hour day, and would be considered high throughput according to CMS Ruling 2020-12-R:

Instrument configuration	# modules	Capacity/24 hr day
2 GX-IV, 4	8	224
GX-XVI, 8	8	224
GX-XVI, 16	16	448
GX-INF, 24	24	672
GX-INF, 48	48	1344
GX-INF, 80	80	2240

If you have any questions, please visit: <https://www.codemap.com/cepheid/index.cfm?> or contact Cepheid Reimbursement at: GA@cepheid.com.