



September 2021

Dear Valued Customer,

The applicable codes for the Xpert® **Xpress** CoV-2/Flu/RSV **plus** test are:

| PLA or CPT code Applicable | Assay Target(s) | Code Descriptor |
|---|---------------------------|---|
| 0241U | SARS-CoV-2 / Flu / RSV | Infectious disease (viral respiratory tract infection), pathogen-specific RNA, 4 targets (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2], influenza A, influenza B, respiratory syncytial virus [RSV]), upper respiratory specimen, each pathogen reported as detected or not detected |
| 0240U | SARS-CoV-2 / Flu | Infectious disease (viral respiratory tract infection), pathogen-specific RNA, 3 targets (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2], influenza A, influenza B), upper respiratory specimen, each pathogen reported as detected or not detected |
| 87635 or U0003* | SARS-CoV-2 | 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 Or |
| *U0003 is only applicable for high- throughput instruments | | 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. |
| U0005 Billed with U0003 when criteria are met | SARS-CoV-2 | 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 of specimen collection (list separately in addition to either hcpcs code u0003 or u0004) as described by cms-2020-01-r2 |

Proprietary Laboratory Analyses (PLA) Codes are an addition to the CPT® code set approved by the AMA CPT® Editorial Panel. They are alphanumeric CPT codes with a corresponding descriptor for labs or manufacturers that want to more specifically identify their test.¹ PLA codes can be beneficial as they allow a payer to recognize certain proprietary characteristics of a particular test. PLA codes are specific to a single test informing the payer of the exact test they are providing reimbursement for, where CPT codes are generally applicable to all tests meeting the code descriptor.

¹ "CPT® PLA Codes." *American Medical Association*, 2020, www.ama-assn.org/practice-management/cpt/cpt-pla-codes.



The LOINC codes applicable for the Xpert® Xpress CoV-2/Flu/RSV **plus** test are:

| Assay Target(s) | LOINC Code ² | LOINC Component | LOINC Property | LOINC Time | LOINC System | LOINC Scale | LOINC Method |
|------------------------|-------------------------|--|----------------|------------|--------------|-------------|---------------|
| SARS-CoV-2 / Flu / RSV | 95941-1 | Influenza virus A & Influenza virus B & SARS coronavirus 2 & Respiratory syncytial virus RNA panel | - | Pt | Respiratory | - | Probe.amp.tar |
| SARS-CoV-2 / Flu | 95422-2 | Influenza virus A & Influenza virus B & SARS coronavirus 2 RNA panel | - | Pt | Respiratory | - | Probe.amp.tar |
| SARS-CoV-2 | 94500-6 | SARS coronavirus 2 RNA | PrThr | Pt | Respiratory | Ord | Probe.amp.tar |

Note: The available LOINC codes do not differentiate specific respiratory specimen types. Refer to the Xpert Xpress SARS-CoV-2/FLU/RSV plus Package Insert for specific specimen type information.

<https://loinc.org/sars-cov-2-and-covid-19/#lab>

Thank you for your continued business and your trust in Cepheid. If you have any questions or concerns, please contact Cepheid Government Affairs at US-GA@cepheid.com

Sincerely,

Michele Schoonmaker, PhD
Vice President, Government Affairs
Cepheid

² "SARS-CoV-2 and COVID-19 Related LOINC Terms." *LOINC*, 21 July 2020, loinc.org/sars-cov-2-and-covid-19/.

Disclaimer: The final decision regarding the appropriate code(s) is the responsibility of the testing laboratory, subject to physician orders and results reported to the patient medical record; actual codes appropriate for billing may differ based on individual patient circumstances.

For use under the Emergency Use Authorization (EUA) only

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