

The Genetic Testing Unit (GTU)

A unique identifier for every genetic test,
accessible royalty-free by all

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v1.0

EXECUTIVE SUMMARY

The genetic testing market is growing fast and evolving rapidly. With more than 160,000 clinically orderable genetic tests on the market,¹ stakeholders are struggling to communicate effectively and efficiently across the Genetic Health Information Network.^{2,3} One significant challenge is communication between parties about specific genetic tests. Concert Genetics is addressing this problem by making its unique test identifier, the Concert GTU (genetic testing unit), available to the industry.⁴

For years, the GTU has played an essential role in enabling Concert to track and organize the industry's genetic tests. Because ambiguity in test identification remains a persistent challenge for the healthcare system, Concert's proven method for test identification has broad utility and value. This paper describes the GTU, including the desired outcomes, guiding principles, design descriptions, anticipated uses and anticipated industry benefits. The paper concludes with a summary of how stakeholders may access and use the GTU.

OBJECTIVES

“Which genetic test?” is a common question asked during the patient care journey. Unfortunately, the information resources available to all parties today do not provide a clear answer. The GTU answers this question clearly and unequivocally for all genetic tests, and makes the answer available to everyone. By providing a comprehensive and precise method of test identification, the GTU will significantly improve communication about genetic tests. Consistent with Concert's vision, the GTU will further advance precision medicine through transparency and efficiency.

Desired outcomes include:

1. Reduction in time and effort determining which genetic test was clinically appropriate, ordered, authorized, contracted, and reimbursed.
2. Automation of clinical and administrative processes.
3. Removal of care delivery obstacles.

¹ Concert Genetics data. 166,703 GTUs as of October 1, 2020. Concert uses the term Genetic Testing Unit (GTU) for any orderable combination of analytes (e.g., genes or other targets) and techniques at a specific point in time, sold by a laboratory as a single item in the laboratory's catalog.

² Concert Genetics. May 2017. Connecting the Genetic Health Information Network: Critical Steps to Realizing the Potential of Precision Medicine. Available at: <https://www.concertgenetics.com/blog/connecting-genetic-health-information-network-whitepaper/>

³ Hooker, GW. Building an infrastructure to enable delivery of genomic medicine. *Am J Med Genet Part C*. 2021; 187C: 95– 99. <https://doi.org/10.1002/ajmg.c.31881>

⁴ Concert's systems and methods for maintaining the GTU system are described in Patent [US10223501](https://www.uspto.gov/patents/US10223501). The GTU identification system is made available on a royalty-free basis as described in this paper, and can be licensed from Concert for additional uses, including derivative works.

GUIDING PRINCIPLES & DESIGN

The Concert GTU was originally developed in accordance with the two guiding principles below:

1. **Every test has one.** Establish a unique identifier for every uniquely-marketed test.
2. **It does not disappear.** Ensure that unique identifier is persistent/permanent, regardless of the current availability of the respective test.

In adapting the GTU for external use, Concert has applied three more guiding principles:

3. **Compatible with existing communication methods and systems.** Structure the identifier so that existing systems and processes can collect, store and pass it.
4. **Complement existing terminologies.** Does not conflict with the other classification and identification systems already in use.
5. **Available to all.** Anyone can access the GTU royalty-free on the Concert website. Licenses for additional uses, including derivative works, can be obtained by contacting Concert Genetics.

1. Every Uniquely-Marketed Genetic Test Has a GTU

To establish a unique identifier for every uniquely-marketed test, every test must first be known. Concert's database of genetic tests is widely recognized as the most comprehensive and accurate compendium of genetic tests. As such, it is the ideal foundation upon which to establish and manage unique identifiers for every uniquely marketed test.

2. A Test's GTU Does Not Disappear

A test retains its GTU even after the test is no longer available on the market. This will ensure that historical/retrospective analytics and other uses will be supported. When tests are sunset, their GTUs will be reserved and linked to any related tests' GTUs.

3. GTUs are Compatible with Existing Communication Methods and Systems

Because the GTU has so many potential uses and there are so many genetic tests, an important and challenging design criteria for the Concert GTU is compatibility with existing communication methods and systems. One of the most important and constraining uses is on healthcare claims. While healthcare claims forms and transactions are standardized, critical supporting systems often adhere to these standards only loosely. After reviewing a wide range of healthcare informatics systems, Concert designed the GTU to be a five-digit alphanumeric sequence. This design ensures that parties will be able to place this information somewhere on the claim form. The section below includes a table of communication methods and Concert's recommendations for communicating the GTU.

Each GTU is structured as a five-digit alphanumeric character sequence as follows:

Character 1	Character 2	Character 3	Character 4	Character 5
Numeric Any number	Alphanumeric Any number or alphabetical character	Alphanumeric Any number or alphabetical character	Alphanumeric Any number or alphabetical character	G, C, A or T A letter that is either G, C, A or T

Examples: 8A3SG, 17D4G, 5PS7G, 3B9TC, 965TA, 2B67T

4. GTUs Complement Existing Terminologies

There are many terminologies and classifications in healthcare with distinct and valuable uses. The GTU system has been designed not to replace them, but to augment and complement them. To ensure the GTU does not conflict with five-digit alphanumeric terminologies and classifications that are in use, Concert does not recommend placing the GTU in the claim form field that contains procedure codes. However, if data exchange partners are unable to avoid using this field, Concert has structured the GTU sequence to avoid conflict with terminologies that currently use that field (HCPCS Level I/II codes and ABC codes).

5. GTUs are Available to All

Concert is making the GTU available royalty-free on the Concert Platform. Anyone may create a user account, browse the Concert test database, see the Concert GTU, and look up tests by GTU. Universal access to the Concert GTU ensures that Concert improves communication about genetic tests equitably, streamlining/automating administrative processes, and ultimately increasing patient access to precision care.

Concert will also license the GTU, Concert database and other Concert content for additional uses, including derivative works. If interested, please contact info@concertgenetics.com.

USES OF THE CONCERT GTU

The GTU aids decision-making in any situation where a specific test must be known. Some common situations and categories are outlined below.

<p>Providers & Laboratories</p> <ul style="list-style-type: none"> • Which test(s) is clinically appropriate for the patient? • Who is responsible (lab, physician, facility) for billing the health plan for <i>this test</i>? • How do I clearly communicate to the health plan which test I want to order/bill? • Will <i>this test</i> be covered by the patient's health plan? • Is there an <i>equivalent test</i> that has better insurance coverage? • Is prior authorization from the health plan required for <i>this test</i>? • What information does the health plan need to determine coverage for <i>this test</i>? • How should I code <i>this test</i> [for this specific health plan]? • What will the health plan reimburse for <i>this test</i>? • Some claim lines that I billed for <i>this test</i> were denied. What was the rationale, and what should I do next? • What should I bill the patient for <i>this test</i>? • What other bills should the patient expect for <i>this test</i>? 	<p>Selecting</p> <p>Authorizing</p> <p>Ordering</p> <p>Resulting</p> <p>Billing</p> <p>Appealing</p>
<p>Health Plans</p> <ul style="list-style-type: none"> • Which test is being authorized or adjudicated? • Is <i>this test</i> clinically-appropriate for this patient/member? • Is prior-authorization required for <i>this test</i>? • Did the provider/lab satisfy prior-authorization requirements for <i>this test</i>? • Is the lab that offers <i>this test</i> in-network? • Is there an <i>equivalent test</i> available from an in-network lab? • What codes do I expect to be billed for <i>this test</i>? • What codes were actually billed for <i>this test</i>? • Is there a discrepancy between codes expected and codes billed for <i>this test</i>? How do I resolve it? • What will I reimburse the provider/lab for <i>this test</i>? • Upon appeal, how do I decide whether to uphold or overturn a denial for <i>this test</i>? • How much should I reimburse for tests like this one? 	<p>Authorizing</p> <p>Covering</p> <p>Contracting</p> <p>Adjudicating</p> <p>Claim editing</p> <p>Paying</p>

COMMUNICATING THE CONCERT GTU

Concert recommends always including the GTU when communicating about a specific test.

In non-standardized or unstructured communications (as encountered with authorizations, orders, requisitions, contracts, fee schedules, etc.), always include the five-digit GTU at least once in the communication. To ensure everyone in the communication chain can identify the exact test, the GTU should be included even if an alternative ID/code/# is also referenced. If nine characters can be passed, Concert recommends adding the prefix of “GTU-” to the GTU, for example “GTU-8DC5G.”

The most common structured communication is the healthcare claim. For different claim types, Concert recommends:

Claim type	Recommendation
HCFA/CMS 1500 Form (Professional Claims)	Place five-digit GTU in box 19. Optionally add “GTU-” prefix.
837P Transaction (Professional Claims)	Place five-digit GTU in SV101-7 element. Optionally add “GTU-” prefix.
UB-04 Form (Institutional Claims)	Place five-digit GTU in block 80. Optionally add “GTU-” prefix.
837I Transaction (Institutional Claims)	Place five-digit GTU in SV202-7 element. Optionally add “GTU-” prefix.

Additionally, the GTU may be used as an additional identifier in other systems of record such as electronic health records (for example, in a notes field related to a lab order to identify the exact test that occurred).

To discuss specific use cases or inquire about incorporating GTUs into a software/IT system, please contact info@concertgenetics.com.

CONCLUSION

With the launch of the Concert GTU, everyone in the healthcare industry will be able to communicate explicitly about any genetic test for the first time. Combining the GTU with Concert’s test database, medical policies, reimbursement policies and claim edits, the GTU will further streamline and automate many processes--and expand access to evidence-based and affordable precision care.