



Unique Device Identifier Guidance Document

IncellDx, Inc.
1541 Industrial Road,
San Carlos, CA 94070
Tel: 1.650.777.7630
Fax: 1.650.587.1528
Email: info@incelldx.com

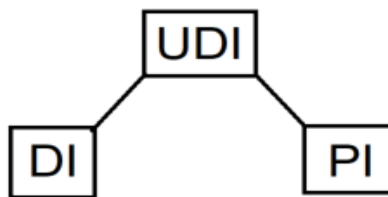
For support:
Call: 1.650.777.7630
Fax: 1.650.587.1528 or
Email: support@incelldx.com



In order to comply with US FDA regulations, we have added a Unique Device Identifier (UDI) to our Analyte Specific Reagents (ASR). The UDI is a series of numeric and alphanumeric characters that will help you identify key device information on the Global Unique Device Identification Database (GUDID) website.

What is UDI (Unique Device Identifier)?

The **UDI** is a series of numeric and alphanumeric characters that is created through a globally accepted device identification and coding standard. The UDI barcode can be broken down into two parts: the device identifier (DI) and production identifier (PI).



DIs indicate the device model and the company that is the "labeler."

PIs may not be included in all UDI barcodes. A PI will be different for each batch or for each serialized device. Depending on the type of medical device, PIs might include a:

- Serial number
- Batch number
- Expiration date
- Manufacture date
- And/or a specific code that is required for certain human tissue or cellular-based products that are regulated as devices

How to view the product’s information?

Steps to perform are as follows:

1. Click on the link for AccessGUDID: <https://accessgudid.nlm.nih.gov/>
2. In the search section, type/enter “IncellDx” or “Product name” or “Catalog number” or “Scan the barcode”

Please note: The UDI barcode will be on the outer baggie of the finished goods; please save the outer baggie if you plan to use that barcode to access AccessGUDID for the critical product information.

What information is included?

1. Company Name
2. Brand Name
3. GMDN Term
4. FDA Product Code Name
5. FDA Product Code
6. Device Packaged as Sterile
7. Sterilization Prior to Use
8. Device Size
9. Device Class

Following is the screenshot of Access GUDID with an example of IncellDx’s product:

The screenshot shows the Access GUDID search interface. At the top, there is a search bar containing the text "IncellDx" and a search icon. To the right of the search bar are navigation links: HOME, ABOUT, NEWS, API, DOWNLOAD, and HELP. Below the search bar, the search results are displayed for the query "IncellDx" (1 result). The results section includes a list of filters on the left, such as Company Name, Brand Name, GMDN Term, FDA Product Code Name, FDA Product Code, Device Packaged As Sterile, Sterilization Prior To Use, Issuing Agency, Device Size, and Device Class. The main content area shows the search results for "HPV E6, E7 mRNA Probe - B766C311000". The description states: "HPV E6, E7 mRNA Probe is specific for Human Papillomavirus types 16 and 18 E6,E7 mRNA. HPV E6,E7 genes are transcribed as a single transcript using a common promoter and early polyadenylation site. HPV E6, E7 mRNA Probe is comprised of a cocktail of 85% pure full-length dual fluorescein-labelled molecules as verified by Reverse Phase HPLC." Below the description, the company name is listed as "Company Name: INCELLDX, INC." and the version or model is "Version or Model: C31100". There is also a pagination control showing "1" of 1 results.