

The University of Iowa Dezii Translational Vision Research Group

TITLE: Generating Unique GMP Identifiers

SOP Number: _____ D-GLO-PRO-014 _____

Revision Number: _____ 0 _____

Effective Date: _____ 09 Aug 2015 _____

Author: _____

Date: _____

Reviewer: _____

Date: _____

QA Approval: _____

Date: _____

A. OBJECTIVE

To outline the steps necessary to assign a lot number for a viral production batch.

B. APPLICABILITY

All stem cell products generated for autologous use will be identified by the unique Patient ID number, which is assigned by the University of Iowa Hospitals and Clinics at the time of isolation. An Operations supervisor shall assign a lot number for all gene replacement therapy vector batches produced by The University of Iowa Dezii Translational Vision Research Group (DTVR).

C. REFERENCES

None

D. PRODUCT UNIQUE IDENTIFIERS: PATIENT ID NUMBER

1. All Human Cell, Tissue, and Cellular or Tissue Based Materials (HCT/P) products are assigned the respective donor/patient ID number as the DTVR unique identifier for that product.
2. The patient ID number is assigned by the University of Iowa Hospitals and Clinics under the direction of the Internal Review Board (IRB).
 - 2.1. The ()

E. GENE THERAPY PRODUCT BATCHES

1. Each batch of Gene-Replacement Therapy (GT) vector product shall be assigned its own unique lot number.
2. The lot number shall be as follows:

AAABBCC

Where:

A - Denotes a sequential number from 1 to 999 to indicate each consecutive lot of GT product manufactured during the current year.

B - Denotes month product is manufactured from 01 - 12.

C - Denotes the last two digits of the current year.
4. When a lot number is assigned record the following in LabGuru:
 - 4.1 Lot number.

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- 4.2 Name and titer.
- 4.3 Estimated batch size, preferably in volume (i.e. ul) to be produced. For DTVR GT products this will be number of to be produced.
- 5.5 Intended use: clinical (C), development (circle D), or something else (circle O).
- 5.7 The proposed manufacturing date and the name of the project manager.

F. HISTORY

Effective Date	Revision	Change
09 Aug 2015	0	Original document