34643
CH-6291 (JUN 20)
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Indiana University Health

[redacted]

CELLULAR THERAPY PRODUCT NOTIFICATION AND FOLLOW-UP OF POSITIVE MICROBIAL CULTURE

Infusion Date: _____ DIN: W227H220850I7

Donor: ☑ Autologous ☐ Allogeneic ☐ Related ☐ Unrelated

Product: ☑ HPC,Apheresis ☐ HPC,Marrow ☐ HPC,Cord ☐ Other _____

Date CTL received notification of positive microbiology results: 02/01/22

☐ Inpatient ☐ Outpatient

Positive microbial result known ☑ prior to infusion (complete Sections A, B and C) ☐ after infusion (complete section A)

CULTURE RESULTS: Complete initial culture information, adding specific culture information as it becomes available. Please attach copy(ies) of results as they become available.

Culture positive on day 6 of 7 Gram Stain: N/A

Organism ID: Corynebacterium lipophiloflavum

Sensitivity: ☐ NA _____

NOTIFICATIONS: [at time of initial positive culture]

Transplant Physician: Dr. R. Alexander Notified on (date) 02/01/22 by (CTL Tech) JH

CTL Medical Director: Dr. Scott Goebel Notified on (date) 02/01/22 by (CTL Tech) JH

Apheresis QA: ☑ NA _____ Notified on (date) _____ by (CTL Tech) _____

Cell Therapy Lab QA: Dave Schwering / Elaine S. Notified on (date) 02/01/22 by (CTL Tech) JH

Clinical Program QA: Kristen Ervin Notified on (date) 02/01/22 by (CTL Tech) JH

Section A - Transplant Physician Acknowledgement:

I am aware of the positive microbial result of this product, have informed the recipient and/or legal guardian(s), and have provided information regarding potential risks of receiving or having received an infusion of this product.

(Please document recipient and/or legal guardian notification and information provided in Cerner)

Transplant Physician Signature: [signature] Date: 2/2/2022

Section B – Recipient Statement of Understanding:

I have been informed that there was a positive culture result for the product I will be receiving. I have been informed of the potential risks of receiving this product and have had the opportunity to discuss this issue and to ask questions.

Recipient (or legal guardian) Signature: [signature] Date: 02/02/2022

Section C - Approval to release product:

Since an alternative product is not available, this product will be infused due to urgent medical need for transplant. I take responsibility for the decision to infuse a product with a known positive microbial culture.

Transplant Physician Signature: [signature] Date: 2/2/2022

I agree with the transplant physician's decision to infuse this product and approve product release.

CTL Medical Director Signature: _____ Date: _____

ACTION PLAN:

☒ Recipient is currently on appropriate antibiotics. ☐ Recipient will be started on appropriate antibiotics.

☐ FDA Notification not required ☐ CTL QA _____ Notified FDA (Date) _____

☐ Other

OUTCOME:

_____

_____

_____

_____

Outcome Reported By: _____ Date: _____

Program Director Signature: _____ Date: _____

Clinical Program QA Signature: _____ Date: _____