Cellular Therapy Team Meeting
11/2023

IU Health Cellular Therapy
550 N University Bld Rm 3453
Indianapolis, IN 46202   v3.2022

2023 QUALITY INDICATORS DASHBOARD
IU Health Cellular Therapy

CLIA # 15D0902829
CAP # 7195447

Policy Code #	Cellular Therapy Quality Indicator	Threshold	Frequency	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
3.a	Occurrence Investigation: Assigned/Log/Short Term Action	100% Complete	M	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%		
3.b	Occurrence Investigation: Long Term Action Plan	100% Complete	M	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%		
3.c	Occurrence Investigation: CAPA Effectiveness	100% Complete	M	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%		
16	Equipment PM and Function Checks	100% Compliance	M	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%		
22.a	Data Integrity Audits - Electronic Record (June and December)	100% Data Retrieval	SA						100%						
22.b	Data Integrity Audits - Instrument Backup (June and December)	100% Data Retrieval	SA						100%						
7.b	BCP Scenario Drill (April and October)	100% Performed	SA					100%					100%		
7.a	Business Continuity Plan Audit (January and July)	100% Performed	SA	100%						100%					
2	Product Labeling	0 Products	M	0	0	0	0	0	0	0	0	0	0		
19	CTL Analyzer Quality Control Verification	100% Compliance	M	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%		
13	Specimen Submission, Handling, Referral	≤ 2%	M	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%		
14	Test Systems, Equip, Reagents, Supplies	100% Reviewed	M	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%		
17	Calibration and Calibration Verification	100% Reviewed	M	N/A	N/A	100%	100%	100%	N/A	N/A	N/A	100%	N/A		
20	Comparison of Test Results	100% Complete	M	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%		
18.a	Sterility Reporting (January)	100% Compliance	M	100%	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A		
11	Environmental Monitoring	100% Complete	Q			100%			100%			100%			
21	Test Formats (January)	100% Complete	A	100%											
4	Personnel Competency (December)	100% Complete	A												
6	Agreement Audit (July)	100% Complete	A							100%					

Data Submitted by: _____ Signature:

Date:

Discussion/Corrective Action/Technical Supervisor Comments: Sterility Reporting for April and May were incorrectly entered as 100%. Results were updated to "n/a" 08/15/2023 -ds

Instructions:

1. Document the value (percent or number) on month tab, or type NA on Dashboard if Not Applicable for each Quality Indicator

3. Forward to Executive Management Quality Unit for review and signature.

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Housekeeping Items

- FIT testing – Please make sure you have FIT testing performed or have the required modules for the PAPR completed.

- ID badge distribution to University
  - due to external vendor challenges, distribution of new IU Health identification badges is being paused through the end of the year.
  - All November and December badge distribution dates will be rescheduled. New dates will be communicated once the external supply chain issues have been resolved.

- Oracle Goals due 11/30/23 but I believe we all have 2023 goals entered.
  - Check what your 2023 goal was to see if you have made progress.
  - Think about your new 2024 goal. Make it something you can track and something that is attainable.
    - Enter updates into Oracle throughout the year if possible.

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Staffing updates

- Chandler Tillotson has accepted the Cellular Therapy Position.
  - She has a master's degree and is accredited by ASCP
  - I have not been sent a start date.

- Dr. Idrees is no longer the lab director for University and Riley.
  - Dr. Czader will be taking over.

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Training

- Blue Bird Bio

  -Stem Cell collections for Beta Thalassemia patients

  -Gene therapy manufacture

  -Up to 3 days of collection

  -Mainly pediatrics-mobilized

  - Everyone needs to verify if they have Box access.

    - We are working with BBB and our IT to resolves access issues.

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Year End Requirements

- Please make sure all Oracle Learn modules are complete.
  - Print your list of completions (it is not a pretty document but please print anyway).
  - Fill out the continuing education form and submit to me.
- Complete all assigned competency checklists and quizzes <u>prior to 12/20/23</u>.
  - We need to verify that everything is complete and Dr. Reddy must sign.
- Please ensure that all annual maintenance/QC will be finished on schedule.
- General supervisors must sign the CLIA form each year.

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Values Acknowledgments: Purpose, Excellence, Compassion, Team

- I would like to thank all of you for such great team work!!
  - We have made great progress on so many projects this year and there are a few more that I believe we can wrap up prior to year-end.
  - We have become a part of several protocols this year and I want to thank everyone for the extra attention and time required to finish the necessary paperwork, portal access, and training.

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Cerner Billing

- We have submitted the build sheet to IS.
  - He is working on the build and hopefully will put it into the test site mid-December.
  - We will need to validate the entry procedure and that the results appear correctly when viewed.
  - This will be a significant shift in work so we will need everyone's help.

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- FACT Inspection coming Jan 2024?
    - We have not received a date as of this time.

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Questions???

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