

Indiana University Health

Cellular Therapy TEAM MEETING 3/2024

2

CTL Metrics

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	Callular Thorony Quality Indicator	Threshold	nenc /	Percent / Number per Indicated Frequency											
Code#	Cellular Therapy Quality Indicator	Threshold	Frequenc	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%	100%	100%
3.b	Occurrence Investigation: Long Term Action Plan	100% Complete	M	100%	100%	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%	100%	100%
16	Equipment PM and Function Checks	100% Compliance	M	100%	100%	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%						100%
22.b	Data Integrity Audits - Instrument Backup (June and December)	100% Data Retrieval	SA						100%						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	0	0
19	CTL Analyzer Quality Control Verification	100% Compliance	M	100%	100%	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%	0%	0%
14	Test Systems, Equip, Reagents, Supplies	100% Reviewed	M	100%	100%	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	N/A	N/A
20	Comparison of Test Results	100% Complete	M	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
18.a	Sterility Reporting (January)	100% Compliance	M	100%	N/A										
11	Environmental Monitoring	100% Complete	Q			100%			100%			100%			100%
21	Test Formats (January)	100% Complete	Α	100%											
4	Personnel Competency (December)	100% Complete	Α												100%
6	Agreement Audit (July)	100% Complete	Α							100%					
	Data Submitted by: Signa							,							
-	ion/Corrective Action/Technical Supervisor Comments, Stevility	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:

Health

Lab Services Promise Dashboard – January 2024





Gallup Team Member Engagement

- Overall a good survey for 2023.
 - Remember you own these results as well
- The question I would like to focus on is Q001
 - "I know what is expected of me"
 - What gaps are we missing?
 - Suggestions on why this is a concern and what we can do to improve?
- The other question I want to address is Q007 "At work, my opinion seems to count"
 - I will be creating a pre-meeting to get team member input prior to my operational meetings so that your perspective can be presented.
 - Suggestions on why this is a concern and what we can do to improve?





Housekeeping Items

- 2024 goals are due by 3/29.
- Check through your requested time off versus what is in UKG Pro to make sure nothing was lost in the transition.
 - Other areas are reporting missing PTO approvals.
 - I cannot see what was approved previously to compare to the new system.
- Aseptic Technique Surveillance is due by Friday.



Staffing Updates

- Rebecca, Timesha, Peaches, and Briana are new Apheresis nurses who will be starting in the upcoming month.
- Chandler's position is open.
- Looking into how we want to fill the Study Coordinator's position that Melissa is vacating.



New BMT forms

BLOOD and		ELL TRANSPLANT and IMMUNE CELL THERAPY PROGRAM IT ADULT AND PEDIATRIC								
	Donor FDA E	Eligibility Determination								
	F-CL-2	2.06-1, (Version 03.11.24)								
Recipient Name:		Prep Regimen Start Date:								
Recipient MRN:		Recip Wt: kg								
Related Donor (RD)		Unrelated Donor (URD)								
Name:										
MRN:		NMDP GRID:								
DOB:		1,10,2,000,00								
<u> </u>	Donor Sex: M	F Donor Wt: kg								
	Donor SexIWI	F Donor Wt:kg								
Infectious Disease Testing	Eligible Inc	complete* x Ineligible*								
Donor HHQ	x Eligible Inc	complete* Ineligible*								
FDA Eligibility: Eligible	Incomplete* Inc	eligible* but acceptable								
* Complete for RD:	Related Donor Releas									
* Complete for RD or URD:		ete Product Release (includes confirmatory IDM tests and Urgent Medical Need)								
* Complete for RD or URD:	Recipient Consent To	Receive Ineligible / Incomplete Product								
RD eligibility determined by	/: IU Health Blood and Bone M	Marrow Stern Cell Transplant and IEC Program 550 N. University Blvd., UH 5630, Indianapolis, IN 46202								
URD eligibility determined b	Case Management, Nation	onal Marrow Donor Program, 3001 Broadway St., N.E., Suite 100, Minneapolis, MN 55413								
TRANSPLANT COORDINATOR:		DONOR PHYSICIAN:								
Signature:		Signature:								
Date:		Date:								

BLOOD and BONE MARROW STEM CELL TRANSPLANT and IMMUNE CELL THERAPY PROGRAM JOINT ADULT AND PEDIATRIC DONOR EVALUATION CHECKLIST Non-Mobilized Collection (HPC-M, DLI, Cord)									Related Donor (RD) Name: MRN: DOB:			
F-CL-2.04-7b, (Version 03.11.24)									Unrelated Donor (URD)			
Recipient Name	8			-	imen Start Date:							
Recipient MRN:			p Wt:	kg	Cell Sour	ce:		▼ NMDP G	RID:			
Collection Date								Sex:	M F			
								Donor W	/t	kg		
Hematolog	PV	Chem	istry		Other L	abs	Other In	fection Testing	Infectious E	isease Tes		
WBC		Sodium			Phospho	rus				_		
Hgb	g/dL	Potassi	um		Magnesi	um	HSV IgG	Î	HBsAg	Neg/NR		
Hct	%	Chloride	2		Hgb S%		HSV IgM		HBsAb	Neg/NR		
Platelets	K/mm3	CO2			HSV PCR		EBV VCA IgG		Anti-HBc	Neg/NR		
ANC	K/mm3	BUN			EBV PCR		EBV VCA IgM		Anti-HCV	Neg/NR		
Neutrophils K/mm3		Creatinine			CMV PCR		Toxo IgG		Anti-HTLV I/I	Neg/NR		
Bands	K/mm3	Glucose	Glucose				Toxo IgM		HIV-1 NAT	Neg/NR		
Lymphocytes	K/mm3	Calcium	alcium				Varicella IgG		HCV NAT	Neg/NR		
Monocytes	K/mm3	Alk Phos	s		Urinaly:	sis	CMV IgG		Anti-HIV 1,2	Neg/NR		
Eosinophils	K/mm3	ALT					CMV IgM		STS	Neg/NR		
Sickle Cell		AST							WNV NAT	Neg/NR		
Blood Typ	e	Total Bil	li		Coagulat	ion			Chagas	Neg/NR		
ABO/Rh		Total Pr	otein		PT		_		HBV NAT	Neg/NR		
Pregnanc	Y	Albumir	1		PTT		Negative = Ab	not detected;	Anti-CMV	Neg/NR		
Serum preg		LDH			INR		Postitive = Ab	detected		I		
							2.0					
Date	Test					R	esults / Instruc	tions				
	EKG	_										
CXR Repeat CBC Days between CB Repeat Pregnancy Test			en CBC	and 1st da	v collection:	If > 30	days, CBC will need	d to be reneated	-			
							of the recipient's pres		-			
Contraception Advised						whichever comes fir						
Consents signed Cord Inf		Inform	nation Shee	et								



Values Acknowledgments: Purpose, Excellence, Compassion, Team

Thanks to Jennifer and Steven for stepping up to take care of the CD4CAR.

Thanks to Emma and Hillary for taking care of the EXCEL trial (twice!)

Thanks to Brody for not allowing a drink in the laboratory.





Questions???



