Utilizing LDMS Condition Codes for ACTG and IMPAACT Specimens

Preloads and condition codes can be used together in LDMS 7.2 to document issues when processing specimens. The preload adds the expected collections, and the condition code can be used to show situations that fall outside those expected results.

Some condition codes will automatically trigger that primary or aliquot to have the "never store" flag. These codes indicate that the specimen will not be stored because it does not exist or was damaged beyond recovery. Other condition codes may also warrant the "never store" flag, but the flag will not be added automatically. In these situations, the "never store" flag should be added at the user's discretion to show that the specimen has not been stored.

Table 1: Codes that will trigger "never store" automatically

Code	Description
QNS	Quantity Not Sufficient
SNC	Sample Not Collected
SNP	Specimen Not Processed
ANP	Aliquot Not Prepared
LSH	Lost Shipment
DSR	Destroyed

For a full list of condition codes, refer to the LDMS User Manual, Appendix A.

When a specimen will not be stored, the "never store" flag should be utilized rather than deleting the specimen or aliquot from the preload. This will help reduce queries and clearly document what was and was not obtained based on what was expected (e.g. the preload).

This document is intended to be a guide only. As a general rule, select the most descriptive condition code possible, determine if the specimens will or will not be stored, and set the "never store" flag as applicable.

The scenarios below show how to use condition codes when something has happened to a specimen. Each scenario also shows whether that particular condition code will trigger a "never store" and if a special qualifier should also be selected. In some situations, "never store" will not automatically be added and it may be appropriate to add it manually.

#	Scenario	Primary Condition Code	Aliquot Condition Code	Qualifier (if applicable)	Automatically Marked as "Never Store"
1	A participant did not want to be stuck with a needle so an expected sample was not collected.	SNC	SNC		SNC = yes
2	The primary specimen had a low cell count and insufficient numbers of viable cells were obtained. Only 1 of 4 aliquots was obtained.	SAT	1 aliquot =SAT 3 aliquots =ANP	Participant anomaly	ANP = yes
3	A laboratory technician dropped a frozen aliquot and it cracked, but the technician put it in a slightly larger tube to save it.	SAT	DMG	Specimen potentially compromised	DMG = no; if the specimens cannot be recovered, manually set "never store"
4	The clinic ran out of the tube they needed to collect a sample, but an alternative tube was identified as acceptable by the team and used instead.	SNC for preload, INT for alternative tube used	SNC for preload, INT alternative tube used		SNC = yes
5	The clinic ran out of the tube they needed to collect a sample, and an alternative tube was used but later determined to be unacceptable by the team	SNC for preload, DSR for alternative tube used	SNC for preload, DSR for alternative tube used		SNC = yes DSR = yes
6	A blood tube was received. Upon centrifugation, it was noted that the plasma was red tinged.	HEM	HEM		HEM = no; if the specimens cannot be recovered, manually set "never store"
7	A shipment arrived late in the work day, right before the laboratory technicians left for the day. As a result, the samples were not processed until the next day.	PST	PST	Unexpected late day specimen	PST = no
8	A bearing in a centrifuge broke while processing a specimen and destroyed the primary blood tubes being spun.	EQF	EQF		EQF = no; if the specimens cannot be recovered, manually set "never store"

#	Scenario	Primary Condition Code	Aliquot Condition Code	Qualifier (if applicable)	Automatically Marked as "Never Store"
9	The patient became frightened and pulled away while blood was being drawn, and a sample tube was only filled halfway. The patient declined to collect the rest of the sample.	SHV	SAT if volume matches preload SHV if volume is less than preload QNS if unable to process aliquot		QNS = yes SHV = no, but adjust volume
10	The clinician misread the instructions for the visit and insufficient sample volume was collected as defined by the protocol.	SHV	SAT if volume matches preload SHV if volume is less than preload QNS if unable to process aliquot		QNS = yes SHV = no, but adjust volume
11	A specimen that was received was clearly contaminated with fungus.	CTM	CTM		CTM = No; if the specimens cannot be recovered, manually set "never store"
12	A primary blood tube fell to the floor, shattered, and could not be recovered.	DMG	DMG		DMG = no; "never store" must be set manually
13	The total volume of plasma obtained from a short-filled blood tube is not sufficient to make 10x1mL aliquots. The lab opts to make 8x1mL aliquots and 2x0.5mL aliquots.	SHV	8 aliquots =SAT 2 aliquots =SHV		SHV = no, but adjust volume
14	An EDT whole blood sample was received clotted.	CLT	CLT		CLT = No; if the specimens cannot be recovered, manually set "never store"
15	A whole blood sample that was supposed to be a 5 mL draw contained only 0.5 mL and the decision was not to process it.	QNS	QNS		QNS = yes

#	Scenario	Primary Condition Code	Aliquot Condition Code	Qualifier (if applicable)	Automatically Marked as "Never Store"
16	A whole blood specimen tube is received that isn't completely full. The protocol requires 5 aliquots of cells, but there are only enough cells for 4 aliquots.	SHV	1 aliquot =QNS 4 aliquots =SAT		SHV = no, but adjust volume QNS = yes
17	A DBS was received and the technologist noted that the humidity indicator turned from blue to pink.	HUM	HUM		HUM = no
18	A urine cup was received in a zip lock bag, and the contents had leaked out of the cup into the bag (the lid of the cup fell off).	DMG	DMG	Specimen potentially compromised	DMG = no; if the specimens cannot be recovered, manually set "never store"
19	FSTRF contacts the lab and indicates that the specimens for a given PID/VID combination were collected outside the protocol defined window of collection.	OSW	OSW		OSW = no
20	A PK specimen was received by the lab ambient. Instructions in the LPC indicate the blood should have been transported on wet ice.	TNO	TNO	Other, Specify (Add details in comment field)	TNO = no
21	The nurse at the clinic processed and froze serum for metabolic testing because the serum had to be processed within 30 minutes. The nurse shipped the frozen specimens to the lab via courier under ambient conditions.	SAT	TWD	Other, Specify (Add details in comment field)	TWD = no; if the specimens cannot be recovered, manually set "never store"
22	The clinic collected a specimen, but it was lost by the courier during transport.	LSH	LSH		LSH = yes
23	A whole blood specimen was received frozen, in an unusable state.	FRO	ANP		FRO = no ANP = yes
24	During processing, the lab mixed up the identifiers and can no longer properly identify the aliquots.	SAT	LBE	Specimen Mix-up	LBE = no; if the specimens cannot be recovered, manually set "never store"

#	Scenario	Primary Condition Code	Aliquot Condition Code	Qualifier (if applicable)	Automatically Marked as "Never Store"
25	There is a mix-up at the specimen collection site that cannot be resolved before the specimens are sent for processing	SNP	SNP	Specimen Mix-up	SNP = yes

Please send any comments to DARs@hanc.info.