Biochemistries
(CP, CD, BG, PL)

Prior to enrollment in the PALF Cohort Study: results from lab tests on the CP, CD, and BG are to be collected, when available, from up to 7 days prior to enrollment. Lab results from the first blood draw of the day should be recorded. If labs are performed at the referring hospital and the PALF hospital on the day of transfer, the first available results from the PALF hospital should be recorded for that day.

Results from lab tests on the PL are to be collected, when available, from the onset of the episode of ALF.

During the initial hospitalization: laboratory tests are to be performed on samples obtained at the time of the first routine blood draw of the day. If a specific test is performed more than once in a given day, record the result from the first test performed that day. If a test is not performed from the same draw as the majority of the tests for that date, but is performed from another draw on the same day, indicate the time that the sample was drawn for that specific lab result under the "Time (if different from above)" column.

Lab tests (Comprehensive Metabolic Panel, phosphate, ammonia, CBCs, and Blood Gases) are to be performed **daily** when the patient meets the following INR and encephalopathy criteria:

INR ≥ 1.5 and INR < 2.0 with encephalopathy or
INR ≥ 2.0 with or without encephalopathy

Refer to page 2 of the Data Collection Timeline or Flowsheet for detailed information on the INR and encephalopathy criteria.

At follow-up visits: laboratory tests are to be performed at the 8 week, 6 month, and 12 month visits. If the patient is still hospitalized during a follow-up visit, laboratory tests are to be performed on samples obtained at the time of the first routine blood draw of the day.

GENERAL INSTRUCTIONS

Record the Patient ID and the date and time that the sample was drawn. The date is recorded in month/day/year format and the time in 24 hour, military time (i.e. 00:00=midnight, 06:00=6 a.m., 12:00=noon, and 8 p.m.=20:00). If any part of the date or time is unknown, enter -3 for the unknown part and enter the other parts of the date or time that are known. If the entire date or time is unknown, check "Unknown".

Record the timepoint for labs obtained at one of the follow-up evaluations. A timepoint is not required for labs performed during the in-hospital period. The default timepoint in the data system will be "In-hospital".

Record each result and indicate the unit of measure. If the unit of measure is not listed, contact the DCC.

The lower and upper level of the normal range must be provided for some of the laboratory tests. These normal ranges are needed because laboratory assays may vary across clinical centers and could vary within a center over time. During the in-hospital period, record the normal range the first time the lab is obtained and is not required during the rest of the in-hospital period. The normal range must be provided at each follow-up timepoint if the lab was obtained.

If a result is determined to be below the level of detection of the assay *(not below the normal range)*, enter -6.
If a result is determined to be above the level of detection of the assay *(not above the normal range)*, enter -7.

If a test was performed more than once on a given day, record the result from the first routine blood draw of the day or earliest result of the day.

Check "Not Done" when a lab test is not performed. The default value in the data system for every lab test will be "Not done".

SPECIFIC INSTRUCTIONS

COMPREHENSIVE PANEL (CP)

INR: indicate whether the result was corrected or uncorrected as a result of an intervention. An INR should be considered as "corrected" if an intervention with the potential to impact the INR result is given within 24 hours prior to the INR measurement. The intervention could be: Vitamin K (parenteral), FFP, cryoprecipitate. Refer to the information provided by the investigator on the corresponding Global Assessment (GA) form.

Bicarbonate (HCO_3- or CO_2) is *not* Standard Bicarbonate (SBC_e).

Phosphate (PO4): required test while INR/encephalopathy criteria are met. Phosphorous is the same as phosphate.

Bilirubin: record the available results – Indirect, Direct or Conjugated, Unconjugated. If a specific test was not performed leave the result as "Not Done". Do not calculate results.

Lactate and Pyruvate: are not considered part of the comprehensive metabolic panel but should be recorded when available. If the test is not performed leave the result as "Not Done". Lactic acid is the same as lactate. Pyruvic acid is the same as pyruvate.

Venous and Arterial ammonia: required test while INR/encephalopathy criteria are met.

Serum samples for storage: Serum for storage should be collected according to the INR/encephalopathy criteria used to determine whether daily labs are performed. When criteria are met for daily labs, a serum sample for storage must also be collected on those days, along with the first routine blood draw of the day. Record whether or not a serum sample for storage (sample for research) was collected. If "Yes", enter all sample information into the Sample Tracking System. If "No", indicate the reason the sample was not collected. If the lab sample date is prior to the PALF enrollment date check "N/A, prior to enrollment."

CBC WITH DIFFERENTIAL (CD)

Neutrophils (PMN), Lymphocytes, Monocytes, Eosinophils and Basophils are collected as %'s of the WBC value given on this same form; *do not* enter the absolute count.

BLOOD GASES (BG)

pH: values should be arterial. If the patient does not have an arterial pH but has a venous pH, record the venous reading. Indicate whether the pH is arterial or venous.

O_2 saturation must be collected in % and from a pulse oximeter reading

Estimating PaO_2 from a given O_2 sat.:		Estimating PaO_2 from a given O_2 sat.:	
O_2 sat. (%)	**PaO_2 (mmHg)**	**O_2 sat. (%)**	**PaO_2 (mmHg)**
80	44	90	60
81	45	91	62
82	46	92	65
83	47	93	69
84	49	94	73
85	50	95	79
86	52	96	86
87	53	97	96
88	55	98	112
89	57	99	145

PROCEDURAL LABS (PL)

Procedural labs are used to determine or confirm a diagnosis. It is important to perform the relevant tests for specified diagnoses, per the Diagnosis Definition Guidelines.

Procedural lab results should be captured regardless of when they are performed. For procedural labs completed on dates after the initial hospitalization discharge and not associated with a follow-up timepoint (8 week, 6 month, or 12 month), indicate the timepoint as Not Applicable.

Specified in the Diagnoses definitions:

Acetaminophen level:	Indeterminate, APAP chronic, APAP acute, APAP therapeutic misadventure, Adenovirus, Enterovirus, Hep A, Autoimmune marker positive ALF, Sinusoidal obstruction syndrome, Ischemic hepatopathy, Sepsis, Cardiac, Mushroom toxicity, Valproic acid induced liver failure
Alpha-fetoprotein:	Tyrosinemia
Ceruloplasmin:	Indeterminate, Adenovirus, Autoimmune marker positive ALF, Drug-induced hepatotoxicity, Wilson's disease
Ferritin:	Indeterminate, Hemophagocytic lymphohistiocytosis (HLH), Neonatal hemochromatosis (NH)
Serum copper:	Wilsons' disease
Urine copper:	Wilson's disease