



Following liver (or bone marrow) transplantation during the enrollment hospitalization:

- Daily research samples should not be collected
- Global Assessment and Physical Assessment should not be completed
- Interventions, procedures, and medications initiated after the liver (or bone marrow) transplant should not be collected. Interventions, procedures, and medications that were initiated before the liver (or bone marrow) transplant should be closed out as of the transplant date.
- Infection – only results from samples collected prior to transplantation should be recorded on the Bacterial Infections and Virals logs.
- Events captured on the Event Log should be collected

INR/Encephalopathy Criteria for Daily Data and Research Sample Collection:

During the initial hospitalization:

Lab tests (Comprehensive Metabolic Panel, CBC w/differential, Blood Gases, phosphate, and ammonia), the Global Assessment, and the Physical Assessment are to be reported and serum sample collection is to be completed once **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

If encephalopathy is not assessable because the patient is sedated, intubated, or on a ventilator, consider the encephalopathy criteria to be met.

If the INR is corrected as the result of an intervention, the INR and encephalopathy criteria are considered to be met, and daily lab tests and assessments are to be reported and the research sample should be collected. An INR should be considered as “corrected” if an intervention with the potential to impact the INR result is given within an appropriate timeframe prior to the INR measurement.

When the uncorrected INR falls below 2.0 in a patient without encephalopathy or below 1.5 in a patient with encephalopathy, daily data reporting and research sample collection do not have to be completed daily. Lab tests should be performed as clinically indicated.

An increase in the INR to ≥ 1.5 coupled with encephalopathy or an increase in INR to ≥ 2.0 with or without encephalopathy will prompt reinstatement of the daily data and sample collection. Any lab results that reinstate daily data collection should be reported.

The INR measurement obtained as part of the routine morning draw is the result used to determine whether or not the daily data should be recorded and research sample collection should be performed, regardless of whether an INR test is repeated later in the day.

The INR result obtained today will determine whether or not the daily data reporting and research sample collection should be conducted tomorrow. If INR results from the day prior are not available, then the last available INR and encephalopathy results should be used to determine if daily collection criteria are met.

The assessments should be collected as close as possible to the time of the first routine morning blood draw when lab results and research samples are obtained.

If a patient undergoes liver (or bone marrow) transplantation prior to hospital discharge, the INR and encephalopathy criteria do not apply following the transplant procedure. Lab tests performed on days following the liver (or bone marrow) transplant should be per clinical practice. These results should not be entered into the PALF study database.