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HPTN NL Communique

HPTN 057

This is official study documentation for the HPTN 057 trial. Please circulate it among relevant staff for their review, print it out, and place it at the end of your 057 SSP Manual, Section 10: Laboratory Communiques.

UPDATES

There are no updates at this time.

CLARIFICATIONS

1. If it is confirmed that an infant has become infected with HIV-1, it is not necessary to perform subsequent HIV-1 RNA or HIV-1 DNA PCR assays in real time. Blood should continue to be collected according to the schedule in Table 10.2 of the Laboratory Section of the SSP, but plasma should be stored for viral load and genotyping. The site may continue to perform HIV-1 RNA or HIV-1 DNA assays if results are required for clinical management of the patient. These results can then be submitted to SCHARP via Laboratory Results Forms. Otherwise, the HIV-1 RNA assay will be performed at the end of the study on samples selected by the protocol virologist.
2. The DAIDS toxicity table lists only corrected calcium. Because this table is used to grade adverse events (AEs), laboratories will need to measure total calcium and albumin and use that data to calculate the corrected calcium. This calculation should be performed on all samples that have both total calcium and albumin results. Corrected calcium results should be reported in mg/dL on the Laboratory Results case report forms.

For these calculations, assume a normal albumin level is 4.0 g/dL.

The effect of correcting the calcium is:

Correct the total calcium upward by 0.08 mg/dL for every 0.1 g/dL fall in albumin.

Correct the total calcium downward by 0.08 mg/dL for every 0.1 g/dL rise in albumin.

For example, if the albumin level is 3.3 g/dL (decreased by 0.7), and the calcium level is 9.8 mg/dL, the corrected calcium would be 10.4 mg/dL.

This formula for calculation is:

Corrected Ca = [(4.0 – measured albumin) x 0.8] + Measured Ca
(when calcium is expressed in mg/dl and alb is expressed in g/dL)

When calculating corrected calcium values, you must use the values recorded on the Mother or Infant Laboratory Results CRF, not the values from the laboratory source documentation, especially if the values were converted to different units or rounded before they were on the CRF.

Note: Albumin is measured only to determine the severity grade for calcium levels. Corrected calcium levels will be monitored for safety. Therefore, separate grading and reporting of AEs for albumin is not required per HPTN057 Clarification Memo #1 dated 1 May 2007.

UPCOMING

The Laboratory Section (10) of the HPTN 057 SSP is being updated.