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MEMORANDUM

To: ACTG and IMPAACT Laboratories
From: ACTG and IMPAACT Laboratory Center in collaboration with the Laboratory Technologist Committee
Date: 20 March 2025
Subject: LDMS Additive Codes for EDTA and DPE

This memo describes an update to the use of the LDMS additive code "DPE" (spray dried EDTA). Spray dried EDTA is typically required for pharmacokinetic (PK) studies to prevent any dilution effect that may be associated with liquid anticoagulants. Historically, liquid EDTA formulations were more readily available so the LDMS additive code of DPE was created to clearly document that spray dried EDTA was used for these collections.

More recently, spray dried EDTA is the most commonly available additive for blood collection. As such, the ACTG and IMPAACT Laboratory Centers have agreed to the use of DPE as the default additive for EDTA in the LDMS for all specimens processed from EDTA blood, including stored plasma, PBMCs and PK specimens. This is not a mandate that only spray dried blood may be used for clinical trial testing, it is simply the default additive code that will be used in Laboratory Processing Charts (LPCs) moving forward. If a site must collect blood in a tube that contains the liquid formulation due to supply shortages, then the additive code in the LDMS should be changed to EDT and a comment should be added to confirm that liquid EDTA was used. This will not be deemed a protocol deviation, unless the additive description for that specimen indicates that a spray dried EDTA should be used (e.g., PK specimens).

This change will be implemented in the development of new LPCs and does not reflect a change in the process for collecting blood in EDTA additives, it simply reflects a change in the most common EDTA additive that is used by laboratories and simplifies the data entry in the LDMS. For instance, instead of using the LDMS additive code of TBD (To Be Determined) to allow for either EDT or DPE, the LDMS will now default to DPE, and users will need to modify the additive code only if blood was collected in a tube with the liquid formulation of EDTA. In general, the use of EDTA or DPE is essentially the same and has no impact on the quality or integrity of the specimen for most testing. PK testing is the only specimen in the LDMS that requires spray dried EDTA and may be impacted by the dilution associated with liquid additives, especially in the case of small blood volumes (e.g., pediatric collections).

Please direct any questions regarding this memorandum to the ACTG Laboratory Center (ACTG: actg.labcenter@fstrf.org; IMPAACT Laboratory Center: impaact.qaqc@fstrf.org).