

Labtest Package 4 Terminology

The **Laboratory Terminology (Labtest) Project Team** is comprised of CDISC SDS, lab and terminology team members and has developed a fourth set of approximately 165 laboratory test names, definitions and synonyms. This terminology set is known as Labtest Package 4. The first 3 sets of laboratory test short names completed public review in 2007 and 2008. These sets of approximately 450 of the most commonly used Labtest terms are currently in production. For completeness, these terms have been included in the spreadsheet within individual worksheets. The new terms are in a separate worksheet, "New Terms for P4", for ease of review. The final tab "New Synonyms only - P4" includes 5 terms that have previously been approved in Package 3. Only the synonyms are new.

There is one **Comment Form** for comments regarding all five spreadsheets. Please be sure to complete all columns, especially the "Spreadsheet Name" and "Spreadsheet Tab" columns so that we can reference your comment. Please do not add additional columns to the spreadsheet during your review. We will be combining all comments into one spreadsheet.

Please provide comments only on the new terms and/or new synonyms.

Rules for Test Codes for Laboratory Test Names:

The rules for developing lab test short 8 character names are stated below. During this development cycle numbers 22-26 were added and are shown in red below.

1. test names must be limited to 8 characters, and cannot start with a number, nor can they contain characters other than letters,
2. variable descriptive names (labels), up to 40 characters, should be provided as data variable labels. This is a correction to the 32 characters noted as a limitation in the FDA guidance document, Providing Regulatory Submissions in Electronic Format – NDAs (January 1999).
3. use the entire test name for the variable if the text name is 8 characters or less.
4. test names do not contain the matrix of the specimen. This information is populated in the specimen type field (LBSPEC).
5. lab tests where results can be expressed as qualitative, semi-quantitative or quantitative should all have the same variable name.
6. if there are multiple tests with the same base, (eg, Bilirubin, Direct Bilirubin, Indirect Bilirubin) the base text goes first and the qualifiers are suffixes; BILI, BILDIR, BILIND.
7. for all differential test names the absolute count is a short defined term (eg, EOS, BASO) and the ratio/percentage has the same short mnemonic with a second short mnemonic for the denominator eg, LE for leukocytes (EOSLE, Eosinophils/Leukocytes), LY for lymphocytes (LYMMCELY, Lymphoma Cells/Lymphocytes), RBC for erythrocytes (RETIRBC, Reticulocytes/Erythrocytes). LY will be used when there is a denominator. When lymphocyte(s) is part of the core test name use LYM.
8. rule 7 above states that LY will be used when there is a denominator. When lymphocyte(s) is part of the core test name use LYM.
9. use HPO for hypo and HPR for hyper as prefix.
10. use 'biological specimen' instead of 'biological sample' in the definition
11. use BLST as a prefix for blasts so that all blasts sort together
12. use CY as a prefix for crystals
13. use CS as a prefix for casts
14. use AB as a suffix for antibody
15. use AG as a suffix for antigen
16. use AC as an abbreviation for acid
17. use CE as an abbreviation for cells
18. use EPI as an abbreviation for epithelial