



Protocol

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Site Number

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Subject Number

Tobacco Implementation Guide -Routine Laboratory- Local Processing

Laboratory

What was the name of the laboratory used?

Record the laboratory name.

LBNAM

LBNAM

Was the lab performed?

Indicate whether or not lab specimen was collected or measurement performed.

☐ No

☐ Yes

LBSTAT = "NOT DONE" where LBPERF = "N" and LBSTAT = null where LBPERF = "Y"

LBPERF

What was the date of the lab specimen collection?

(DD-MMM-YYYY)

Record the date when specimen collection was done using this format.

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LBDTC

LBDAT

What was the (start) time of the lab specimen collection?

(24 hour clock)

Record time of collection (as complete as possible).

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LBDTC

LBTIM

Was the subject fasting?

Record whether the subject was fasting prior to the test being performed.

☐ No

☐ Yes

LBFAST

LBFAST

Laboratory Tests

Lab Test Name

Record the name of the Lab measurement or finding, if not preprinted on the CRF. If collected on the CRF, the applicant may provide additional instructions to ensure the data is entered as intended.

LBTEST

LBTEST

What was the result?

Record laboratory test result.

LBORRES

LBORRES

What was the lab test unit?

Record the unit of the Lab measurement or finding, if not preprinted on the CRF. If collected on the CRF, the applicant may provide additional instructions to ensure the data is entered as intended.

LBUNIT

LBORRESU

CRFs are annotated to show the collection variable (in Grey) and the tabulation target/mapping instructions (in Red).



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Laboratory Tests

What was the upper limit of the reference range for this lab test?

Record the upper limit of the reference range of the lab test.

LBORNRI

LBORNRI

What was the lower limit of the reference range for this lab test?

Record the lower limit of the reference range of the lab test.

LBORNRILO

LBORNRILO

Was this result clinically significant?

Record whether lab results were clinically significant.

- ☐ No
☐ Yes

LBCLSIG

LBCLSIG

CRFs are annotated to show the collection variable (in Grey) and the tabulation target/mapping instructions (in Red).