



**CDISC Laboratory Standards
Release Notes**

for

**Base Model Version 1.0.1
Schema Version 1.0.1
Microbiology Extension Review Version**

Revision History

Date	Version	Summary of Changes	Primary Author
9-September-2003	1.0	Final version of document	Julie Evans
14-April-2004	1.1	Updated document to reflect that the XML schema is now the final version instead of review version.	Julie Evans

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CDISC LAB Model

Release Notes

1 Purpose

In September 2003, the CDISC LAB Base Model Version 1.0.1 was released to industry for implementation. This update incorporated changes to model specifications to address minor bugs and to harmonize with CDISC's Operational Data Model and Submissions Data Standards Model. In April 2004, the CDISC LAB Team released the final XML schema representation of the model for implementation. The Microbiology Extension is under review by the LAB team. In addition, sample datasets are provided to further illustrate the use of the Lab Model. Comments on the draft microbiology extension as well as any comments on LAB Model Version 1.0.1 (Base and/or XML Schema) can be submitted via the CDISC Discussion Forum.

2 History of the Lab Model

The first version of the Lab Model, the CDISC Lab Model V1.0.0, was published in November 2002. It was developed by the CDISC Lab Team, which includes representatives from pharmaceutical companies, central laboratories, contract research organizations (CROs) and technology application developers. The Lab Model has been developed through multiple iterations and tested with representative laboratory data. The Model was then further revised to address comments provided by a 65 member Laboratory Review Committee of industry experts and a 60-day public review. V1.0 provided the base content model, which was independent of technology implementation. Feedback from industry emphasized the need for the XML schema representation of the model and the microbiology extension, which are being provided in the current release.

3 Components of this Release

The Lab V1.0.1 release consists of the Base Model, the Schema Representation, and the Microbiology Extension, which can be accessed on the CDISC website on the [Lab Standards Page](#). These files documenting each of these components are described below

The following files document the Base model Version 1.0.1 and are being posted for implementation:

File Name	Description
Lab1-0-1-Specification.pdf	The Lab Model V1.0.1 specification in pdf format
Lab1-0-1-BaseDataFields.xls	The Lab Base Model V1.0.1 data fields in Excel spreadsheet format
Lab1-0-1-ReferenceRanges.xls	The Lab Model V1.0.1 reference ranges in Excel spreadsheet format
Lab1-0-1-BaseSampleData.dat	Base model sample data for use with SAS and ASCII

The following files document the XML schema implementation of the Base model and are posted as final versions for implementation:

File Name	Description
Lab1-0-1-BaseSchema.xsd	Base model XML schema
Lab1-0-1-Base.doc	Text outline for the base model XML schema

Lab1-0-1-BaseSampleData.xml	Base model sample data in XML format
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The following files document the Microbiology Extension and are posted as drafts for comment:

File Name	Description
LabReviewMicroDataFields.xls	The Lab Microbiology extension data fields in Excel spreadsheet format
LabReviewMicroSchema.xsd	Microbiology extension XML schema
LabReviewMicro.doc	Text outline for the microbiology extension XML schema
LabReviewMicroSampleData.xml	Microbiology extension sample data in XML format
LabReviewMicroSampleData.dat	Microbiology extension sample data for use with SAS and ASCII

4 Detailed list of Changes between V1.0.0 and V1.0.1

4.1 Specification Document Changes

The following changes were made the Lab Model Specification for Version 1.0.1:

Section	Change Description
Section 2.1 Team Members, page 5	Updated Team Member List
Section 3.3.2 Code Lists, pages 10, 11	Provided more information about LOINC and HL7 code lists
Section 3.4.6 Subject, page 14	Provided additional instructions for Race
Section 3.4.6 Subject, page 15	Added variable Visit Type Modifier
Section 3.4.13 Base Result, page 19	Updated instructions for Reported Text Result
Section 3.4.13 Base Result, page 20	Updated instructions for Reported Result Type
Section 3.4.13 Base Result, page 22	Added additional instructions for Transaction Type based on implementation type (Flat file or XML)
Section 3.5.3 Transmission Agreements, pages 23, 24	Updated Transmission Agreements
Section 5 Next Steps, pages, page 26	Updated plans for Lab team and added request for sharing of implementation experience
Section 6 Directions for Submitting Comments, page 26	Added paragraph inviting comments

4.2 Data Field Spreadsheet Changes

The following SAS variable names were changed:

SAS Variable Name Changed From (V1.0.0)	SAS Variable Name Changed To (V1.0.1)
BRTHDT	BRTHDTM
CNLBNUM	LBNUM
CNLBNAM	LBNAM
LACTDTTM	LACTDTM
RCVDDTM	RCVDTM
TSTTX	TSTDESC
TOXGRADE	TOXGR
TOXGDCD	TOXGRCD
RPTDTTM	RPTDTM
SPECMNAM	LBSPEC
LBTEST	LBTESTCD
LBTSTNAM	LBTEST
TSTNUM	TSTCD