

# Laboratory Tests and Results

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## Laboratory Tests and Results Module: Round 3

The CTMS workgroup for the Laboratory Test/Results CRF Module began by focusing and analyzing work from Clinical Data Interchange Standards Consortium (CDISC) Clinical Data Acquisition Standards Harmonization (CDASH). Section 5.12. Laboratory Test Results\* was reviewed and used as a template for variables to include in this module. After partitioning and consideration of the CDASH fields, the workgroup added variables from the cancer community CRF inventory.

## Downloads

Laboratory Test Results NCI CRF Standards created on October 19th, 2018

- [Laboratory Test Results NCI CRF Standard in Excel](#)

Laboratory Test Results NCI CRF Standards created on June 21st, 2016

- [Laboratory Test Results NCI CRF Standards in Excel](#)

Laboratory Test Results NCI CRF Standards created on October 30th, 2014

- [Laboratory Test Results NCI CRF Standards in Excel](#)

## Changes made from September 5th, 2014 to October 19, 2018

Module	CDE	CDE Public ID	Change
Laboratory Test Results		2003746	<p>LabTest CDE 2003746 - Added PVs</p> <ol style="list-style-type: none"> <li>1. Copper, Urine</li> <li>2. Cytomegalovirus (CMV) Antibody, Serum</li> <li>3. Epstein-Barr Virus (EBV), Nuclear Antibody, IgM, Serum</li> <li>4. Hepatitis B Core (HBC) Antibody, IgG and IgM Total, Serum</li> <li>5. HIV (Human Immunodeficiency Virus) 1/2 Plus O, Antibody, Serum</li> <li>6. HIV1, Nucleic Acid Testing (NAT), Serum</li> <li>7. RPR (Rapid Plasma Reagin), Plasma</li> <li>8. Short Tandem Repeat Chimerism, Donor, Clusters of Differentiation 8 (CD8), %, Blood</li> <li>9. Short Tandem Repeat Chimerism, Donor, Clusters of Differentiation 4 (CD4), %, Blood</li> <li>10. Testosterone, Free, Serum</li> <li>11. West Nile Virus Antibody, IgG and IgM, Serum</li> <li>12. West Nile Virus, PCR, Serum</li> </ol> <p>Lab Test Unit of Measure UCUM Codes CDE 2787947 --Added PV</p> <ol style="list-style-type: none"> <li>1. umol</li> </ol>

Laboratory Test Results	Lab Test	2003746	LabTest CDE 2003746 - Added PVs <ol style="list-style-type: none"> <li>1. Bence Jones Protein, Electrophoresis, 24 hour, Urine</li> <li>2. Bence Jones Protein, Electrophoresis, Urine</li> <li>3. Beta 1 Globulin, Protein Electrophoresis, Serum</li> <li>4. Beta 2 Globulin, Protein Electrophoresis, Serum</li> <li>5. BK Virus, Polymerase Chain Reaction (PCR), Quantitative, Copies/mL, Blood</li> <li>6. Bromide, Serum</li> <li>7. Carbamazepine, Serum</li> <li>8. Carbon Dioxide, Partial Pressure, mmHg, Arterial Blood</li> <li>9. Clostridium tetani toxoid Antibody, IgG, Serum</li> <li>10. Cytomegalovirus, DNA, Polymerase Chain Reaction, Throat</li> <li>11. Cytomegalovirus, DNA, Polymerase Chain Reaction, Urine</li> <li>12. Denosumab, Serum</li> <li>13. Felbamate, Serum</li> <li>14. Fosphenytoin, Serum</li> <li>15. Glucose, Estimated Average, Blood</li> <li>16. HLA Antibody Screen, Blood</li> <li>17. IL-17, Serum</li> <li>18. Kappa/Lambda Immunoglobulin Free Light Chain Ratio, Serum</li> <li>19. Ki67, %, Tissue</li> <li>20. Lactate, Blood</li> <li>21. Light Chain Ratio, Urine</li> <li>22. Methotrexate, CSF</li> <li>23. Myoglobin, Urine</li> <li>24. Nucleated Red Blood Cell (NRBC) Count, %, Blood</li> <li>25. Oxcarbazepine, Serum</li> <li>26. Oxygen, Partial Pressure, mmHg, Arterial Blood</li> <li>27. Phenobarbital, Serum</li> <li>28. Polio Virus Antibody, Serum</li> <li>29. Primidone, Serum</li> <li>30. Reverse Triiodothyronine (T3), Free, Mass Spectrometry, Serum</li> <li>31. Thyrotropin Receptor Antibody, Serum</li> <li>32. Thyroxine (T4), Free, Mass Spectrometry, Serum</li> <li>33. Triiodothyronine (T3), Free, Mass Spectrometry, Serum</li> <li>34. Troponin I, Blood</li> <li>35. Urine M protein in mg/ 24 hrs</li> <li>36. Zinc, Serum</li> </ol>
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Status

Pilot
CTROC reviews and approves
Biostatistician reviews and approves for Cooperative Groups
A participant for each of the NCI cooperative groups approves any content that has changed since
Working group reviews and responds to changes from community review and CBIIT staff review content to insure the use of standards.
Module is distributed for community review.
Working group, with CBIIT curator matches data elements to all questions and achieves consensus on final list of elements
Working group reviews and partitions content as Mandatory, Conditional, Optional, or non-harmonized
Working group, NCI Cooperative Groups and NCI divisions aggregate and identify common content to retain, resolves discrepancies, and achieves harmonization
CBIIT staff collects existing CRFs, and creates an inventory of content



## Metrics

### CRF Stars: Working Group Membership

*\* Represents Working Group Leads*

No.	First Name	Last Name	Affiliation
1	Stephanie	Clabo	ACRIN
2	Donald	Connelly	University of Minnesota
3	Mary	Cooper	SAIC
4	Stephen	Dorian	RTOG
5	Rhonda	Facile	CDISC
6	Charlotte	Furey	Exelixis
7	David	Hillman	Mayo - NCCTG
8	Rebecca	Hills	University of Washington
9	Bob	Lanese (L)	Case Western
10	Mary	Lenzen	Octagon Research Solutions
11	Erik	Lickerman	Daedalus Software
12	Ruby	Lin	NCI CBIIT
13	Raymond	Lord	West Michigan Cancer Center
14	Riki	Ohira	Booz Allen Hamilton

15	Susan	Pannoni	City of Hope
16	Vikram	Purohit	Booz Allen Hamilton
17	Dianne	Reeves	NCI CBIIT
18	Anne	Ryan	NCI DCP
19	Julie	Smiley	Genzyme
20	Kim	Truett	CDISC
21	Joe	Uhimov	NCI TerpSys