

Clinical Pharmacology Quality Assurance and Quality Control (CPQA) **Instructions for Use of CPQA Approved Cross-Network Pharmacology Specialty Laboratory Drug Assay Directory**

1. **Overall use/introduction/intent** – The CPQA Program, along with Frontier Science Technology & Research Foundation (FSTRF) have developed a new resource, the CPQA Approved Cross-Network Pharmacology Specialty Laboratory Drug Assay Directory. The Drug Assay Directory is a searchable database, downloadable as an excel spreadsheet and allows users to easily identify the CPQA approved assay methods at DAIDS funded PSLs (including non-network PSLs). The database includes each assay's details for acceptable specimen collection, processing and storage, as well as other pertinent information.

2. **Definitions of each heading with brief explanation ***

Labid – Numeric Lab ID of testing laboratory

Lab Name – Name of testing laboratory

Proxy? – If **No**, indicates a method was submitted directly by the testing lab. If **Yes**, indicates a method was submitted by the CPQA Central Lab on behalf of the testing lab.

Submissionid – AVR SOP Utility assigned identifier for the submission

Submission name – Name of the method as defined by the testing lab

Score – **1**= Accepted Submission. **2**= Submission needs minor edits

Associated DAIDS Network Protocols If defined by the lab, the relevant DAIDS network protocols for the AVR method will be displayed.

Analyte – Analyte abbreviation

Matrix – Specimen type

Primary – Primary specimen type abbreviation

Additive – Specimen additive type abbreviation

Derivative – Specimen derivative type abbreviation

Sub-Derivative – Additional derivative type abbreviation

Preparation Platform – Method preparation platform

Separation Platform – Method separation platform

Detection Platform – Method detection platform

LLOQ – Lower limit of quantification

Minimum Primary Collection Volume – The minimum primary collection tube volume needed of aliquot minimum samples to run the assay

Preferred Primary Collection Volume – The preferred primary collection tube volume needed of aliquot minimum samples to run the assay

Processing Temperature (C) – Processing temperature in degrees Celsius

Max Processing Time (Hours): Maximum time between collection and processing in hours

Max Processing Time (Minutes): Maximum time between collection and processing in minutes

Special Primary Vial – The type of primary collection vial to be used, if applicable

Volume per Aliquots – The volume per aliquot needed to run the assay

Minimum Aliquots – The minimum number of aliquots needed to run the assay

Special Aliquot Vial – The type of aliquot vial to be used, if applicable

Storage Temperature(C) – Preferred storage temperature of aliquots in degrees Celsius

High Storage Temperature(C) – Upper limit for storage temperature of aliquots in degrees Celsius

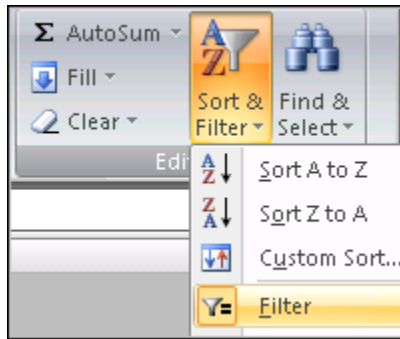
Shipping Temperature – Temperature of the shipment **when aliquots are mobilized**

**Contact the testing lab directly if further clarification is needed regarding method details*

3. Examples of how to filter and sort AVR Report:

Example A- Filtering for a Lab or Analyte

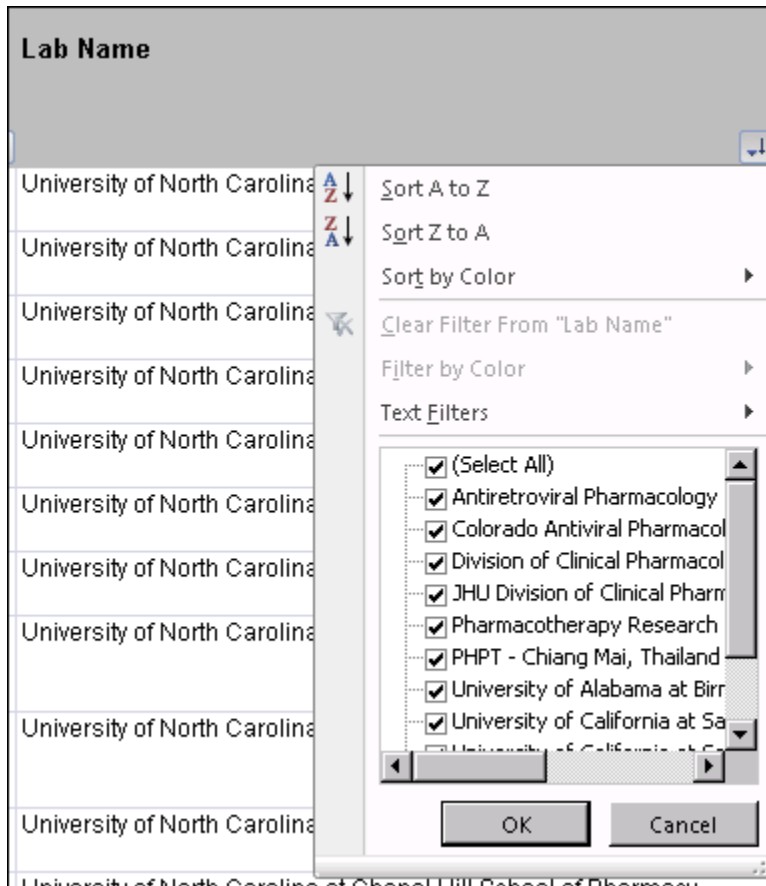
1. Click **Sort and Filter** on the Home Ribbon.
2. Click **Filter**.



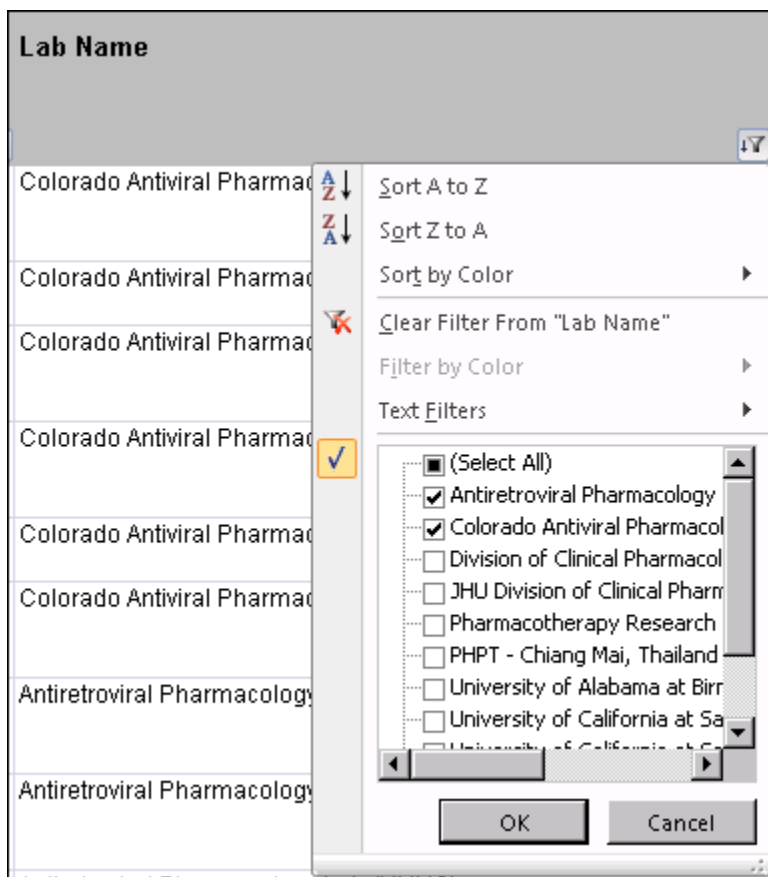
Arrow boxes will appear in the column headers.



3. Click on the arrow box in the **Lab Name** or **Analyte** header.



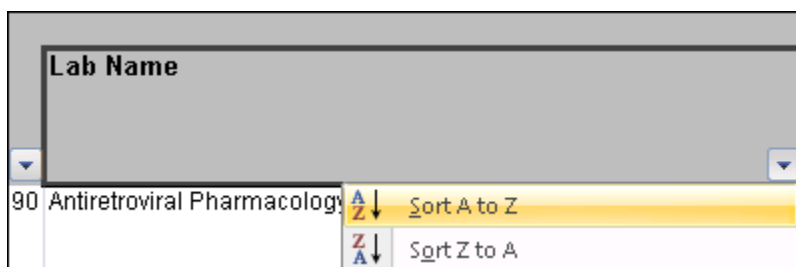
4. Click the checkbox marked **(Select All)**. This will deselect all of the filters.
5. Click the checkbox next to the **Lab Name** or **Analyte** you wish to view.



6. Click **OK**.
7. The report now displays only entries for the filters you selected.

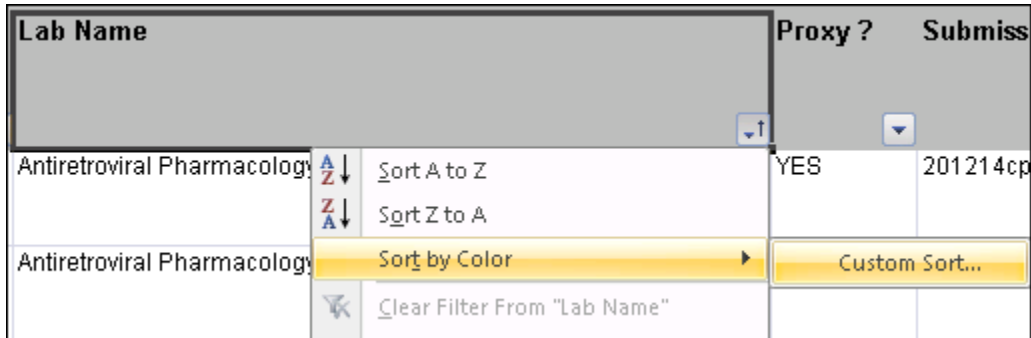
Example B- Sorting by Lab or Analyte

1. Click on the arrow box on the **Lab Name** or **Analyte** header.
2. To sort alphabetically, click on **Sort A to Z** or **Sort Z to A**



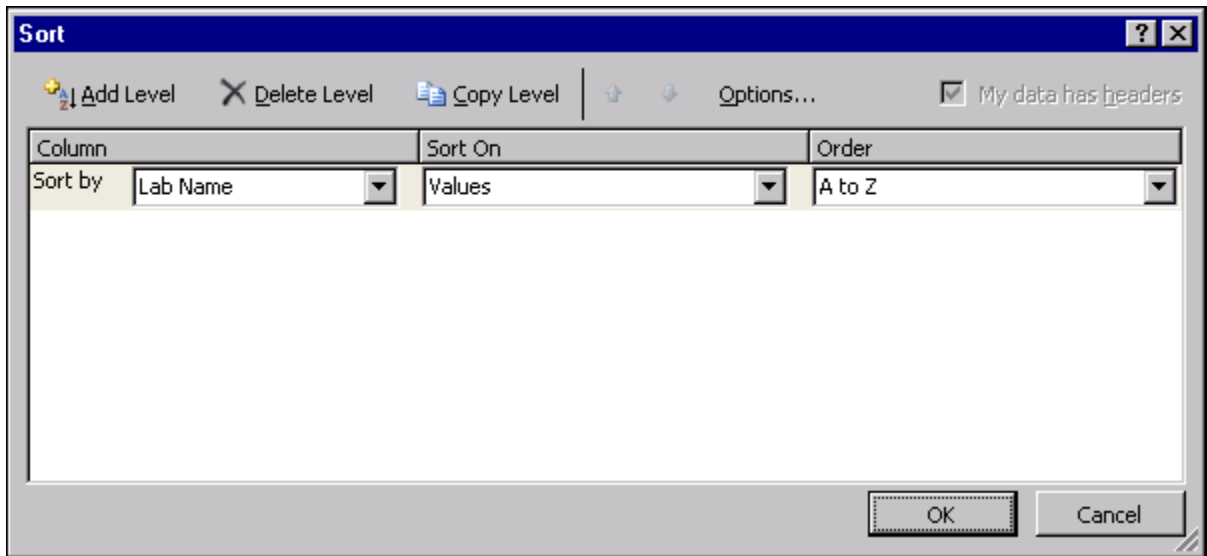
Example C- Multiple Variable Sort

1. Click on the arrow box on any of the header rows.
2. Select **Sort by Color**. Click on **Custom Sort**.



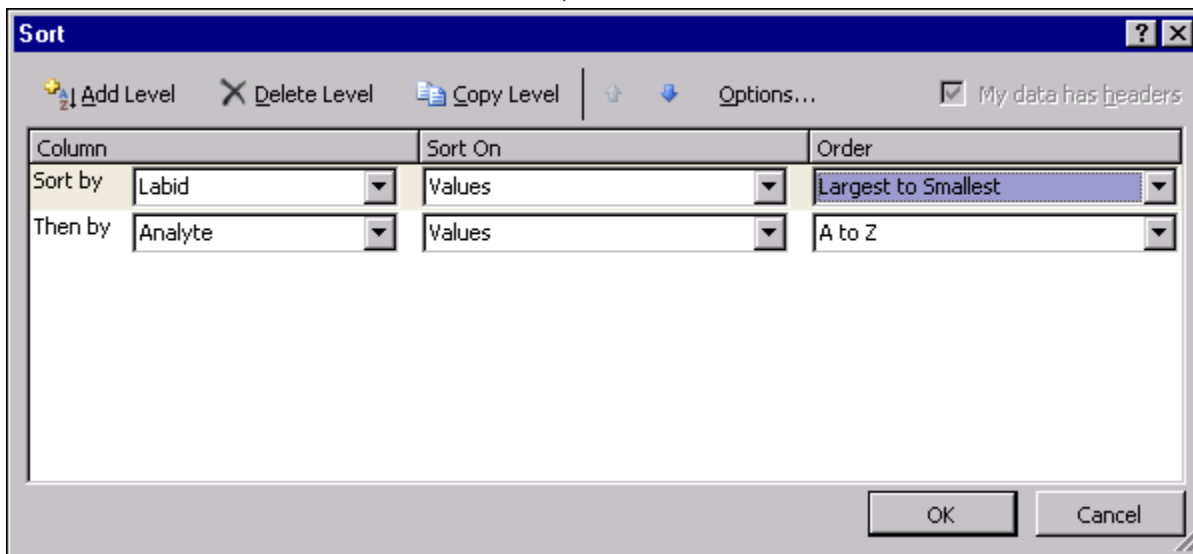
Lab Name	Proxy ?	Submit
Antiretroviral Pharmacology	YES	201214cp
Antiretroviral Pharmacology		

The **Sort** grid opens.

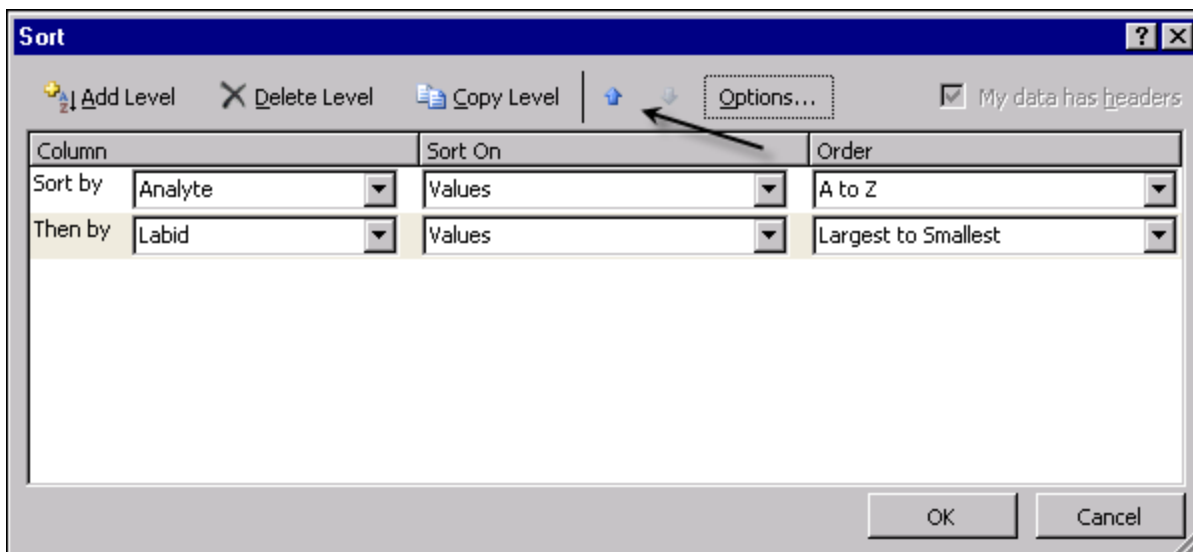


3. Select the criteria you wish to sort by in the **Sort by** drop down menu. Then select the sort order from the **Order** drop down menu.

4. To add an additional level of criteria, click the **Add Level** button



The level order decides which criteria will be used to sort first. To change the level order, highlight a level, then use the blue arrows to move the level up or down.



5. Repeat steps 3 and 4 until you have selected all the desired criteria.
6. Click **OK**.

4. **Contact information**

If you already have a FSTRF Portal account, you may access the report through the ACTG or IMPAACT projects, under the Pharmacology heading. Users directly associated with the CPQA project can also reach the report through the CPQA tab of the Portal. If you do not have a FSTRF Portal account, you'll need to register at

https://www.fstrf.org/register/web_register.html. Note: When registering, make sure to select as a project/affiliation all of the projects that you are working on.

If you have any questions regarding this report or the CPQA Program, please contact cpgasupport@fstrf.org or contact the testing lab directly for further details on the method.

Appendix 1

Analyte Abbreviations

3TC	Lamivudine
ABC	Abacavir
APV	Amprenavir
ATV	Atazanavir
CORT	Cortisol
DDC	Zalcitabine
DDI	Didanosine
DRV	Darunavir
EFV	Efavirenz
EMB	Ethambutol
ETR	Etravirine
FTC	Emtricitabine
IDV	Indinavir
INH	Isoniazid
LPV	Lopinavir
LVF	Levofloxacin
M8	M8 (metabolite of NFV)
MXF	Moxifloxacin
NFV	Nelfinavir
NVP	Nevirapine
PMPA	Phosphonomethoxypropyl Adenine
R405	N-monodesmethyl
RFB	Rifabutin
RFP	Rifapentine
RGV	Raltegravir
RTV	Ritonavir
SQV	Saquinavir
TDF	Tenofovir
TFVDP	Tenofovir Diphosphate
ZDV	Zidovudine

Appendix II

Lab Contacts

Lab Name (number)	Lab Name	Director	Network	E-mail Address
UNMC (190)	University of Nebraska Medical Center	Courtney Fletcher	ACTG, IMPAACT	cfletcher@unmc.edu
UAB (191)	University of Alabama at Birmingham	Edward Acosta	ACTG, IMPAACT	eacosta@uab.edu
UCSF (192)	University of California at San Francisco	Francesca Aweeka	ACTG, IMPAACT	faweeka@sfghsom.ucsf.edu
JHU (194)	Johns Hopkins University	Namandje Bumpus	HPTN, MTN	nbumpus1@jhmi.edu
UB (195)	University at Buffalo	Gene Morse	ACTG	emorse@buffalo.edu
UCSD (196)	University of California at San Diego	Edmund Capparelli	IMPAACT	ecapparelli@ucsd.edu
UNC (199)	University of North Carolina at Chapel Hill	Angela Kashuba	Contracted	akashuba@unc.edu
Thailand (251)	PHPT Laboratory, Thailand	Tim Cressy	IMPAACT	tim@phpt.org
Cape Town, SA (499)	University of Cape Town	Peter Smith	ACTG	peter.smith@uct.ac.za
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UCHS (2005)	University of Colorado Denver	Peter L. Anderson	Investigator U01	Peter.Anderson@ucdenver.edu