

ANTIBODY TESTING

A. Import and notification of antibody testing results

The Barbara Davis Center laboratory enters results data into FamIca which is stored on a network drive which we are able to access (S:\BDC\FAMICA). Data is imported into the BDCImport database each week.

Import Results and Generate Reports

Open S:\DAISY DATABASES\BDCImport.mdb. Run the antibody import between 9:00 and 10:00 on Fridays.

Import BDC data: This button runs *mcrSwitchLabResults.import* which imports the data from FamIca and puts it in a temporary table, FamIca in this database.

Comparison: This button invokes *mcrSwitchLabResults.Compare* whose purpose it is to compare the data imported last week to the data currently in the BDC database. These comparisons are made only for DAISY samples by linking the BDC tables to *tblClinicVisit* in the comparison queries (the BDC database contains data for thousands of samples not belonging to DAISY). The two queries that are run are: *qryFamIcaComparison* and *qryFamIcaComparisonNew*. The results of *qryFamIcaComparisonNew* are new results. There should be no records listed as a result of running *qryFamIcaComparison*. If any are listed then the Autoantibody lab is contacted to determine why the result has been changed since last week.

Transfer Results: This button invokes *mcrSwitchLabResults.TransferResults* which first appends new records in *tblClinicVisit* to *tblClinicDaisy* and then updates antibody results in *tblClinicDaisy*. The queries included in this macro are: *qryAppendClinVisToClinDaisy*, *qryUpdateDaisyResults2*, *qryUpdateDaisyResultsQC1b*, *qryUpdateDaisyResultsQC2b*, *qryUpdateDaisyResultsNegB* and *qryFamIcaNotTransfer*. The last query lists any new results (from *qryFamIcaComparisonNew*) that did not transfer into *tblClinicDaisy*. This query should come up empty -- if any records are listed they should be investigated. Frequent problems include QCLabID field is not null (a space is there instead) use a query to update to null if this is the case.

Calculate Outcome: This button invokes *mcrSwitchLabResults.Outcome* which calculates the GaaOut, BDC512Out, and IaaOut fields in *tblClinicDaisy*. These fields qualitatively summarize the results of the original sample and the QC samples (if any). They take on the values:

Negative	Original value is negative
Positive	Original value is positive and subject is diabetic
Pending Positive	Original value is positive, subject is not diabetic, no QC's
Confirmed Negative	Original value and one QC are negative
Confirmed Positive	Original value and one QC are positive
False Negative	Original value is negative and 2 QC's are positive
False Positive	Original value is positive and 2 QC's are negative

Inconclusive

Original value and 1st QC do not agree (one positive, one negative)

Calculate Final Results: This button invokes *mcrSwitchLabResults.FinalResults* which calculates the FinalGaa, FinalBDC512 and FinalIaa fields in *tblClinicDaisy*. These fields give the final antibody result which takes the original and QC samples into consideration. No final result is given if the outcome calculated above is a Pending Positive or Inconclusive. If the outcome is Negative, Positive, or Confirmed Neg/Pos, then the final result is the same as the original sample result. If the outcome is False Neg/Pos then the outcome is the same as the 1st QC result. This macro also runs *qryUpdatePosRep* which updates the PosReport field in *tblSubject* to “Yes” if any of the antibody results are positive.

Positive History Reports: This button invokes an Event Procedure that runs *repPositiveHistory* which is based on *qryPositiveHistory*. This query selects subjects who had an original (not QC) antibody result imported on the current date, and the current result is positive or they have had a positive result in the past. Based on these reports decisions are made about requesting QC’s, contacting the family about the results, and making changes to the clinic protocol (put on fast track, return to normal track, etc.). See follow-up for reports below for how to determine the appropriate action for each subject.

Results Letters Neg: This button invokes *mcrSwitchLabResults.ResultsLettersNeg* which runs eight reports that produce antibody results letters for subjects and family members with negative results. These reports are printed on DAISY letterhead. When each report is closed a different macro is invoked. These macros are in the macro group, *mcrSwitchLabResults* and otherwise have the same name as the letter query. These macros each run a single query that appends each record to *tblLetSent* which is later used to update the FINLET and FINDATE fields in *tblClinicDaisy* so that it is possible to look up what type of letter was printed and when it was printed. Because these are append queries the database user is warned that records are about to be appended and gives the user the chance to cancel the query. The query should be cancelled only if the letters were not printed.

Results Letters Pos: This button invokes *mcrSwitchLabResults.ResultsLettersPos* which runs six reports that produce antibody results letters for subjects and family members with positive results. These reports are printed on DAISY letterhead. (See Appendix ** for sample letters). When each report is closed a different macro is invoked. These macros are in the macro group, *mcrSwitchLabResults* and otherwise have the same name as the letter query. These macros each run a single query that appends each record to *tblLetSent* which is later used to update the FINLET and FINDATE fields in *tblClinicDaisy* so that it is possible to look up what type of letter was printed and when it was printed. Because these are append queries the database user is warned that records are about to be appended and gives the user the chance to cancel the query. The query should be cancelled only if the letters were not printed.

Filter Paper Letters: This button invokes *mcrSwitchLabResults.FilterPaperLet* which runs eighteen reports that produce antibody results letters for adult family members, young siblings and enrolled children respectively. These letters are printed on DAISY letterhead. (See

Appendix ** for sample letters). When each report is closed a different macro is invoked. These macros each run a single query that appends each record to *tblLetSent* which is later used to update the FINLET and FINDATE fields in *tblClinicDaisy* so that it is possible to look up what type of letter was printed and when it was printed. Because these are append queries the database user is warned that records are about to be appended and gives the user the chance to cancel the query. The query should be cancelled only if the letters were not printed.

Letter Labels: This button invokes *mcrSwitchLabResults.Labels* which runs two reports to produce mailing labels for letters. One report generates labels for filter paper letters and one for non-filter paper letters.

Lab Reports: This button invokes *mcrSwitchLabResults.LabReports* which runs four queries. A list of new results imported on the current date is generated by *qryListFinalResults* and a similar list is generated for filter paper results by *qryListFinalResultsFp*. A list of QC results is generated by *qryNewBdcResultsQc* and a list of late results is generated by *qryClinicResultsLate* (for samples without antibody results that were sent to the BDC more than 21 days prior).

Update Class/IVY: This button invokes *mcrSwitchLabResults.PosClass* which runs a series of four queries. The first three queries update the DaisyClass field in *tblSubject* to the most current classification code from *tblClinicDaisy*. The fourth query, *qryIvyPositiveUpdate*, updates the IVY field in *tblProtocol* to “Yes” for new positive subjects. The last query produces a list of subjects who have been assigned to the IVY protocol on the current date. RUN THIS BUTTON LAST.

qryIvyPositiveUpdate

Table	tblProtocol	tblProtocol	tblSubject	tblSubject	tblSubject
Field	IVY	IvyDate	DaisyClass	Enrolled	CDCOHORT
Update to:	“Yes”	Date()			
Criteria	“No”		Not (F, X, E, E-, *IDDM, TP)	“Enrolled” or “CEDAR Enrolled-7”	Not like “Adult*”

Follow-up on reports generated

Positive History Reports

- 1) Determine why each Positive History Report was printed:
 - a) New positive
 - b) Formerly positive and still positive
 - c) Formerly positive and now negative
- 2) Determine whether letters for subjects who were formerly positive and are now negative should be sent or should be held for QC's. If they should be held then pull them from the letter stack and take the mailing label and attach it to an envelope to be kept with the letter.
- 3) For new positives less than 1 year of age, check to see if mom was positive for same antibody at that visit.
- 4) Determine which samples require a QC. Generally, if one antibody is positive and needs a QC sample then QC samples are sent for all three antibodies, exception is for filter paper. Filter papers just send QC for BDC515 & GAA or IAA, not enough for both. IAA will require 2 full circles for 1 QCs. A QC should be sent if the one of the last two visits was positive even if the current result is negative. After 2 consecutive negative visits for all 3 antibodies there is no need to send a QC if the current visit is also negative.

Letters

- 1) The filter paper letters and non-filter paper letters are kept separate. Each type is put in order by family ID.
- 2) There should be a label with parents name for each letter, families go together in one envelope.
- 3) On the report 'List Final Results' each record with a matching letter is checked off.
- 4) If a letter wasn't generated the reason why is determined. Possible reasons include:
 - a) Proband (letters are not sent to diabetics)
 - b) Letter printed previously (a negative letter was already printed, we now got a QC back confirming the result)
 - c) Positive result is pending – no confirming QC results are back yet.
- 5) All positive letters are scanned and saved by year in L:\DAISY Positive Letters
- 6) All letters that haven't been pulled (for QC results) are mailed to the families.

Late Clinic Results

A list of late clinic results is emailed to Liping Yu in the BDC lab each week. He will then check on the status of the samples. He is sent a list of labids only – not the ID's that go with them.

Update Class/IVY

Updates DaisyClass in tblSubject adds new positives to IVY. Run this button LAST after following instructions below.

BDC QC List

Select IDs to QC: This button creates a list of subjects who may need QC samples send to the lab and a second list to choose a negative control. Enter import date twice, 1st is for positive 2nd

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X:\NIDDK\niddk-dr_studies1\DAISY\private_created_data\Study Docs for Website\DAISY MOO\P-Antibody Results Reporting\Procedures\A-AntibodyImport.doc

is for negative controls. If no negative subjects imported for the week run again with last weeks import date for 2nd import date. Using the positive history reports to determine who needs a QC click the check box for those individuals. Do the same to choose a negative control, only one negative control is needed for every 11 positive subjects. If there are more than 11 positive subject select two negative controls.

Print BDC QC List: This button creates the pull list for the lab with IDs, name, box and space, etc. Confirm the number of QCs with the positive history reports that need QCs. If a serum tube needs to be thawed and aliquoted highlight the box number. Print list double sided.

No QCs Available?: Looks for subjects who do not have enough serum to send a QC. Always double check the clinic visit to see what happened. If not enough blood pull positive history from QC stack and put aside. Change QC1 and QC2 in tblClinicDaisy to -4.444 and update the final results to match the first result.

Update QCs Sent: This button runs 4 queries that update serum sent for all QCs. First QC updates all volume in tblSampleQC to 0, usually number updated matches number on BDC QC list. Second query appends records to tblSampleQCSent to show that sample was sent to the BDC lab. This query will ask for a date enter the following Tuesday. Third query updates tblSampleSerum volume -200 and thaw +1, this is extremely rare and usually only occurs when subject is positive 1st time for both Cedar and Daisy on the same visit. Fourth query adds records to tblSampleSerumSent for any serum tube samples used.

Update QC pull table: This button adds records from the BDC QC list to a temp table tblBDCNewQCLABIDs this table is used for the lab staff to add new QC labids and easily update tblSampleSent.

Positive Follow-Up Reports

Select Positive Rpt to Print: This button first adds records from the BDC QC list to a table, it will ask for a QC sent date, enter the following Tuesday. Then give you a list of subjects who have a previous positive history report. Check the lab reports QC list to see which subjects we have received the QC results. Click the box for those who have results and anyone from the current week who didn't have serum to send for QCs. Close the page.

Print Positive Follow-Up Reports: This button creates a positive follow-up report for each subject selected above. It is printed on the back of each subject's positive history report. Be sure to double check the order it prints with the stack of positive history reports.

- **Resolve Positives-**Using the QC lab result list record the new QC results on the positive history report for each subject. Look at past results to determine who needs to be contacted by Michelle Hoffman or Jen Barker. If contact is need and result is positive hold the letter, if contacted is needed and result is negative send the letter. First time antibodies increase from 1 to 2 or 2 to 3 Jen Barker will call the family. Subjects should be negative for one year before they revert to a normal/every year protocol.
 - **Contact needed/Positive Code-brief also look at C-AntibodyPositiveFup.doc**

- C or C2 or T+ always needs call before letter sent
- A previously a C or T+ needs a call before letter sent
- A previously an A and number of antibodies increases (they have never had this antibody before) needs a call before letter sent
- A previously an A or C2 antibodies the same or increases back 2 or 3 (they've had those before) send letter no contact needed
- B send letter and contact
- R previously a B send letter no contact
- D previously a C send letter and contact
- D or R or T- previously a D or R or T- and normal protocol or every 3/6 mo and less than a year since positive visit send letter, no contact needed
- D or R or T- previously a D or R or T- and every 3/6 mo protocol and more than a year since positive visit select revert to yearly, send letter and contact needed to confirm change to yearly protocol.
- T- previously a T+ send letter and contact

Enter New DAISY Class

Daisy Positive Follow-Up: Opens form so the new PosClass can be entered in tblClinicDaisy for that visit. Look up subjects by current visit's LABID #. If unable to look up a subject it's because last PosClass was an F or X. Go to backend and change field PosReport to yes, only needs to be done once for each subject.

Update Class All Results: Updates the PosClass code for all subjects. For those who need to be contacted and the letter is being held enter "WAIT FOR CALL" in letter comment. If the letter is being sent enter today's date and put a check mark on the top right corner of the positive follow-up page. Be sure to enter those PosClass for subjects who did not need a QC sent. Click Update Class/IVY after closing the form.

Copies/Contact

Make 2 copies double sided, one to send to Marian (no need to staple subjects separately) and one for Shell (separate and staple each subject). Put those needing contact on top. Originals can be put in the filing basket except those that need to be contacted. If holding a letter, paper clip the letter to the follow-up report and put in the red file. If letter is being sent just keep the follow-up report in the red file.

BDC FP QC List

Select FP QC/Resends: This button creates a list of filter paper subjects who may need QC sample(s) send to the lab, a second list to choose a negative control and a third list with possible resends. Enter import date three times, 1st is for positive, 2nd is for negative controls and 3rd is for resends.

- **Postive QCs and Negative Control:** Using the positive history reports to determine who needs a QC and what antibody should be tested. Two full or at least 70% circles are required for one IAA QC. If subject is positive for IAA then it is only possible to send

one QC. If subject is positive for GAD or BDC512 then two QCS can be sent if they have two full or at least 70% circles left. Choose a negative control with 2 full circles and choose the same antibody as the positive subjects. If sending just QCs for one type of antibody then only one corresponding negative control is needed. If testing both IAA and GAD/BDC512 send two negative control one for each antibody.

- **Resends:** Resends are automatically added to tblFPBDCList and QCNum is *Resend*. A list of those needing resends will also be in the lab reports printed above. Determine whether or not a resend can be sent by how much blood is on the remaining circles. If not at least 70% for both circles it is not possible to send IAA again, then delete that row from the table so it won't be on the final Filter Paper BDC QC list, fill in -4.444 for that antibody in tblClinicDaisy and print the missing antibody letter from the Filter Paper Letters button. This happens frequently with resends. If less than 60% for all remaining it is not possible to resend for any antibodies. It is not possible to resend all 3 antibodies for filter paper. If all three antibodies came back as -8.888 and there is enough blood to retest just send GAD/BDC512. If all three antibodies came back as -8.888 and there is not enough blood to resend email filter paper coordinator to contact family and let them know there was not enough blood to test. They have the option of resending a kit or waiting until next year to try again.

Print FP QC list: This button bring up a report with filter paper QCs and resends. Print double sided.

Print Positive Follow-up Filter Paper: This button brings up the positive follow report for each filter paper. Enter the LABID and print each one individually. Follow steps above for assigning PosClass code, needing contact and entering PosClass code.

Filter Paper sample collection discontinued in 2015.