

ANTIBODY TESTING

C. Positive Follow-up

Positive History Reports

Positive history reports will print for any subject who has had a previous positive result except those who were false positive.

There are two sides to the positive report: the *Positive Follow-Up* and the *Positive History Report*.

Positive History Report- this report generates all results for all visits, including the most recent visit. This information will be used to determine if qc samples need to be sent for the most recent visit.

Determining if QC samples need to be sent:

QC: Yes

Two qc samples (for all antibodies: IAA, GAA, BDC512, ZnT8) will need to be sent if the results are as follows:

- The subject is positive on this visit.
- The subject was positive on one of their previous two visits.
- The subject was unconfirmed at their last visit.

If qcs are required hole punch the form and file it in the qc book in the order they are requested on the *Request for BDC QC* form. Be sure to file any new forms after the ones currently in the BDC QC notebook. This will keep them in order of their qc lab id's and make it easier once the results come in.

*As you are filing the forms in the notebook it might be best to check the letters and pull any letters for which a qc sample is being sent and file them in the "Waiting for Qc" yellow folder in the same notebook. Letters do not print for anyone with a positive result, but they will print if the results are negative even if they still need to be qc'd for confirmation.

Positive Follow-Up – this report is printed from the import database after QC results have been received.

Creating the *Request for BDC QC* form (instructions also located with Antibody import) using the buttons in the BDC QC List in the BDCimport.mdb database:

1. 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 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.

2. 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.

3. 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.

4. 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.

5) Give the form to the DAISY laboratory personnel.. They will pull the samples and assign a QC Lab ID entering this information in the Lab.mdb database.

Once the qc's are completed the lab staff will return the form to you:
File in the DAISY QC binder.

QC: No

No qc samples need to be sent if the results are as follows:

- The subject, (positive at some point during follow-up) has been negative on the two visits preceeding this visit and is also negative on this visit.
- If contact is not needed to change protocol then no need to print positive follow-up report and positive history can be shredded after updating the PosClass.

QC Results

Using the *qryNewBDCResultsQc* form which printed during the import process, complete the *Positive Follow-Up* form as follows:

1. 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.

2. 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.
3. On the Positive History Report, (back side of the Positive Follow-Up), fill in the qc values under the appropriate columns (ie: IAA QC1, IAA QC2.....).
4. Subjects that do not have a form in the DAISY QC notebook are most likely negative controls. To confirm this go to last week's BDC QC list in the binder.

Determining Protocol

1. Determine IDDM class using the DAISY Classification table.
2. Determine what protocol the subject should follow based on the results from this visit and previous visits using the following criteria, (parents are always on "Other"): Review the protocol the subject is on by looking at visit type on the Positive History Report.

Negative Results

If the subject is on Every year and is still negative at this visit select: No Change, Stay on Yearly.

If the subject is on Every 3 or 6 mos and has been for the past year select: Revert to Yearly.

If the subject is on Every 3 or 6 mos and has only been negative for less than a year select: No change, Stay on Fast Track.

Positive Results

If the subject is on Every year and is now positive at this visit select: Redraw.

If the subject is positive on a redraw visit, select: Fast Track, Daisy

If the subject is on Every 3 or 6 mos and is still positive at this visit select: No change, Stay on Fast Track.

Letters/Contacting Families

1. Leave positive letters on top and sort/file the negative letters by family ID (most except sibs and previously positives now negative will already be in order by FAMID).
2. Using the qryListFinalResults page check off all of the letters that printed matching the DAISY id.
3. Currently, letters do not print for probands and IDDM subjects.
4. If a letter did not print troubleshoot the following:
 - Do any of the results say Pending? If so, qc's need to be requested and a final outcome must be determined before a letter can print.
 - Does the subject have current record in tblProtocol and tblClinicVisitLast.
 - Was the sample a negative qc from a previous set of results (look at FINDATE on qryListFinalResults page, does it show an earlier date?)
5. If the subject has final results (qc's were sent to confirm original) fill out the date the letter was sent on the Positive History Report,.

6. If you are sending a QC **do not send the letter**, even if the subject is negative. Place the letter in the DAISY QC notebook in the yellow file, "Waiting for QC." It is very important that letters do not go out for anyone who has been qc'd until the results of the qc come back.

Confirmed QC's

7. If the subject is a new positive or has developed a second/third antibody, write "Wait for call" underneath the Send Letter section and circle: Yes for Notify by phone. Michelle will be the person contacting the family.

Copying Positive History Reports (PHRs)

Copies of the positive history/follow-up are made for Marian and Shell, only copy reports for those who needed QC or needed to be contacted.

Lab Reports

2. qryClinicResultsLate: email Liping about any non-filter paper late results each week, later filter paper email once a month.
3. qryNewBDCResultsQc: see section above "QC Results". After completing, file in the DAISY BDC results notebook.
2. qryListFinalResults: once all of the id's are checked off (indicating a letter printed) this report is filed in the DAISY BDC results notebook.

Data Entry-in BDCimport database

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. Enter current visit's 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.