

ANTIBODY TESTING

E. Antibody Result Notification

Additional testing will occur in any child (or family member) who tests positive for any diabetes antibody.

Purpose:

#1 To identify elevated blood glucose in children who have tested positive for autoantibodies.

#2 To facilitate referral to a Pediatric Endocrinologist for diagnosis.

Maternal samples will be tested at the earliest visit to determine her autoantibody status. If mother does not have diabetes and is antibody negative then autoantibody status of the child is discussed as independent. If mother has diabetes or is antibody positive, the status of the child will be discussed with the family in terms of possible maternal transmission but the child will still be seen on an accelerated schedule every 3-6 months.

All antibody positive children will stay on an accelerated schedule "Fast Track" until they have been antibody negative 2 visits in a row at least 6 months apart. Random glucose and HbA1c will be obtained at all visits until the child returns to "Normal" yearly visits.

All first positive, first multiple antibody positive and revert notifications will be over the phone prior to letters being mailed.

A. First time positive:

1 autoantibody:

Family will be notified of result via telephone by study nurse prior to results letter being mailed. We would retest the child again within 1 month of notification. All redraw visits will be scheduled at the family's earliest convenience and will constitute a full clinic visit, height, weight, viral cultures, urine and blood testing. An additional illness questionnaire will be collected with the time line being from the last visit to current visit.

In addition to full clinic visit, the venous blood will be tested for random glucose on clinic meters and HbA1c measured with DCA Vantage, the results documented on the clinic visit sheet and entered into the database. Urine can also be tested with ketodiastix for presence of glucose and ketones. (If a child was Ivy
– NO meaning no routine urine obtained, a urine sample will still be obtained using standard methods, cotton balls in diaper or direct collection.) This is not in the formal DAISY protocol but is deemed good practice. Urine is usually obtained prior to the blood draw, testing this for glucose and ketones allows some preparation time for staff before having to notify the family of a possibly elevated random glucose. Results of urine glucose and ketones will be documented on the clinic visit sheet.

B. Continued autoantibody positive for 1 antibody.

If results of redraw testing continue to show 1 positive antibody we will continue to test the child every 3-6 months. We will encourage every 3 months but due to family obligations can test every 6 months. Education about the signs and symptoms of diabetes will be discussed with the family.

If the child was not previously included in IVY testing their status will then be changed to IVY-YES and blood will be alliquoted as per IVY protocol and urine will be obtained at every visit.

An additional illness questionnaire will be collected with the time line being from the last visit to current visit.

A full clinic visit will occur with every visit and in addition the venous blood will be tested for random glucose on clinic meters and HbA1c measured with DCA Vantage and the results documented on the clinic visit sheet and entered into the database. Urine can also be tested with ketodiastix for presence of glucose and ketones.

The child will be on a “Fast Track” until they meet the criteria for diagnosis of diabetes or revert to yearly schedule.

C. Autoantibody Positive for 2 or more antibodies.

If a child tests positive for 2 or more autoantibodies, the study nurse will review the results and the family history. The full clinic results information plus family history, demographics and contact information will be e-mailed to a Pediatric Endocrinologist for review. The Pediatric Endocrinologist then notifies the family of antibody status over the phone and discusses with the family that risk of diabetes has increased, discusses diabetes and signs and symptoms of diabetes with the family, encouraging questions. Results letters will be mailed only after telephone discussion occurs. If we are unable to contact the family by telephone and all means of contact have been extinguished, only then can the results letter be mailed prior to discussion.

Results letters for multiple antibody positive will include the following information:

Because your child is at a higher risk, it is important for you to be aware of the early symptoms of diabetes, which are:

Increased thirst	Decreased appetite for solid foods
Increased urination	Bed wetting in a previously dry child
Nausea	Yeast infection with a rash (especially in diaper area)
Vomiting (without diarrhea)	Decreased energy

If your child has two or more of the above symptoms please call our study nurse, your child's physician, or the Barbara Davis Center and ask for Dr. Steck or Dr. Frohnert.

Update: 2019, families are referred to Dr. Brigitte Frohnert, Dr. Andrea Steck, Dr. Kimber Simmons or the Physician on call.

Nights and weekends: Answering Service 303-388-2626, pager 303-266-2400

Every 3 month clinic visits are strongly encouraged.

The Endocrinologist then notifies the study nurse of the discussion, the study nurse then calls the family again to discuss any additional questions they may have and to evaluate family response, understanding and need for additional support.

Update 2017: Study Dr. will speak with families and determine need for additional education via, CDE, or Social Work.

At the next scheduled clinic visit, or the first visit the family is "ready" for training, the family will be given:

1. A home glucose meter, lancets, supplies and instructions on how to do home glucose monitoring.
2. A package of ketodiastix for urine testing.
3. Any approved literature appropriate for their level of understanding.

Depending on the family's comfort level, testing instruction can be given by the study nurse, trained clinic staff or arrangements can be made for child and parents to visit the Barbara Davis Center.

D. Home Testing Guidelines

For one week after training for home glucose monitoring has occurred the family will test the child on a daily basis and record the results. If all results are within a normal limit testing can then decrease to:

- 1-2 times per month
- whenever the family has concerns about the child
- whenever the child is "sick".

The family will bring in the record book to each clinic visit for review.

Guidelines for NORMAL glucose readings:

Random >60 and <175 depending on time since food intake

Fasting <126

Any reading outside of these parameters and the family will call the study nurse for evaluation of symptoms and to schedule an immediate visit and possible referral to an Endocrinologist for evaluation.

E. Referral to Endocrinologist Guidelines

At any time the clinical staff feel a referral to the BDC would be helpful to the family for education or to introduce the family to possible future care takers arrangements can be made for consultation.

During a clinic visit, the venous blood will be tested for glucose using a standard glucose meter and an HbA1c will be run on a DCA Vantage. Referral to an Endocrinologist will occur if any of the following criteria are met:

Random Glucose \geq 200

HbA1c \geq 6.3

Presence of Glucose/Ketones in Urine Sample

Patient displays any symptoms of diabetes, Polyuria, Polydyspia, Polyphagia, weight loss etc.

When above criteria are met an immediate referral to the Barbara Davis Center will occur for diagnosis. If the family has a previous relationship with any of the BDC physicians the referral will be made to that Physician. If they do not have a previous relationship with an Endocrinologist, the referral will be made to bdc Dr on call. The family will be taken to the BDC by the staff, for evaluation and diagnosis.

If the family is familiar with a Pediatric Endocrinologist from a practice other than the Barbara Davis Center and meets above criteria, the study nurse will call the Dr. office per families request with the visit information and facilitate immediate referral.

If the child is diagnosed with type 1 diabetes per the Endocrinologist, their participation with the DAISY study ends.