

## What is Type 1 Diabetes?

Type 1 diabetes (T1D) is an autoimmune disease. The immune system mistakenly treats the beta cells in the pancreas that create insulin as foreign invaders and destroys them. When enough beta cells are destroyed, the pancreas can't make insulin or makes so little of it that patients may require **insulin therapy for the rest of their lives**.



## How Type 1 Diabetes progresses

Type 1 Diabetes develops in three distinct stages, each marked by specific changes in the immune system, blood sugar control, and symptoms. For both stage 1 and 2, the lifetime risk of clinical diagnosis (stage 3) nears 100%.<sup>1</sup>

### Stage 1 – Normal blood sugar

#### Characteristics:

- The immune system is reacting to the insulin-producing cells in the pancreas
- Blood sugar levels are still normal (normoglycemia)
- No symptoms of diabetes yet (presymptomatic)

#### Diagnostic criteria:

- More than one type of diabetes-related antibody is found in the blood
- Blood sugar tests are normal (no impaired glucose tolerance or impaired fasting glucose)

### Stage 2 – Abnormal blood sugar

#### Characteristics:

- The immune system is attacking more of the insulin-producing cells in the pancreas
- Blood sugar levels are now starting to rise (dysglycemia)
- No symptoms of diabetes yet (presymptomatic)

#### Diagnostic criteria:

- Additional diabetes-related antibodies are found in the blood
- Tests show impaired glucose tolerance and/or impaired fasting glucose

### Stage 3 – Clinical diagnosis

#### Characteristics:

- The immune system has fully attacked the insulin-producing cells in the pancreas
- Blood sugar is now high (overt hyperglycemia)
- Symptoms of diabetes are present (such as frequent urination, thirst, or weight loss)

#### Diagnostic criteria:

- Diabetes is confirmed under standard medical testing and guidelines

*Early diagnosis prevents life-threatening diabetic ketoacidosis, reduces risk of severe complications, and enables prompt initiation of insulin therapy and patient education*

*Delayed diagnosis can result in hospitalizations and long-term organ damage*

## Industry recommended screening approach for Type 1 Diabetes

**Autoantibody testing:** Autoantibody testing is a straightforward procedure that requires only a small blood sample. The presence of two or more islet autoantibodies is highly indicative of Type 1 Diabetes, establishing autoantibody testing as a critical tool for confirming diagnosis and informing treatment strategies.

After conducting an autoantibody test, one of the following three outcomes may be observed<sup>2</sup>:

**No autoantibodies present:** At this time, no specific intervention is necessary. However, future development of autoantibodies or Type 1 Diabetes cannot be ruled out.

Additional screening before age 18 may be recommended, though may be limited.

**One autoantibody present:** Patient will come in for another blood test in one year to determine if any additional autoantibodies are present.

At this point, determination is also made for eligibility in preventative activities or trials.

**Two or more autoantibodies present:** Patient comes in for study visit that includes an Oral Glucose Tolerance Test.

It will indicate if blood sugar levels are abnormal and determine if prevention study is necessary or closer monitoring for Type 1 Diabetes is required.