



**TN20 IMMUNE EFFECTS OF ORAL INSULIN TRIAL  
DIABETES ONSET FORM**

**Form IE08**

10SEP15

Version 1.0

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Site Number	_____ Participant	_____ Participant Letters:	_____
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**This form should be completed when a participant is diagnosed with diabetes.**

**Criteria for Diagnosis:**

- 1) Symptoms of diabetes plus casual plasma\* glucose concentration  $\geq 200$  mg/dL (11.1 mmol/L).
  - Casual is defined as any time of day without regard to time since last meal.
- 2) Fasting Plasma\* Glucose (FPG)  $\geq 126$  mg/dL (7.0 mmol/L). Fasting is defined as no caloric intake for at least 8 hours.
- 3) 2-hour Plasma\* Glucose (PG)  $\geq 200$  mg/dL (11.1 mmol/L) during an OGTT. The test should be performed as described by WHO, using a glucose load containing the equivalent of 1.75g/kg body weight to a maximum of 75 g anhydrous glucose dissolved in water.
- 4) Unequivocal hyperglycemia with acute metabolic decompensation (e.g. ketoacidosis)

\* Note: Serum is also acceptable

**A. REPORT INFORMATION**

1. Date of Diagnosis: \* \_\_\_\_/\_\_\_\_/\_\_\_\_  
DAY MONTH YEAR
  
3. Diagnosis made by: (check one) \*
 

<sub>1</sub> TrialNet Laboratory
 <sub>2</sub> Other Facility

a. If Other Facility, specify: \_\_\_\_\_
  
4. Date Insulin treatment started :\* \_\_\_\_/\_\_\_\_/\_\_\_\_  
DAY MONTH YEAR  
 Unknown

**B. HOSPITALIZATION INFORMATION**

1. Was the participant hospitalized at the time of diagnosis? \*  Yes  No  
 Unknown
  
- If YES,
  - a. Admission Date: \_\_\_\_/\_\_\_\_/\_\_\_\_  
DAY MONTH YEAR
  
  - b. Discharge Date: \_\_\_\_/\_\_\_\_/\_\_\_\_  
DAY MONTH YEAR

**C. SIGNS AND SYMPTOMS OF DIABETES**

Did the participant experience:

	Yes/No		a. Month/Year of Onset
1. Polyuria *	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	<i>If Yes,</i>	____/____ MONTH YEAR
2. Polydipsia *	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	<i>If Yes,</i>	____/____ MONTH YEAR
3. Polyphagia *	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	<i>If Yes,</i>	____/____ MONTH YEAR

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4. Fatigue\*

Yes  No  
 Unknown

\_\_\_\_ / \_\_\_\_  
MONTH YEAR

4. Unexplained weight loss \*

Yes  No  
 Unknown

*If Yes,*

\_\_\_\_ / \_\_\_\_  
MONTH YEAR

b. If YES, amount of weight lost

\_\_\_\_ . \_\_\_\_ kg

5. Ketoacidosis \*

Yes  No  
 Unknown

\_\_\_\_ / \_\_\_\_  
MONTH YEAR

If YES, report as many of the following as available:

	1. Result <sup>1</sup>	2. Units <sup>2</sup>	Reference Range (if available)		5. Date
			3. Low	4. High	
a. Plasma <sup>1</sup> Glucose (serum also acceptable)	____ . ____	____	____ . ____	____ . ____	____ / ____ / ____ DAY MONTH YEAR
b. pH (Serum)	____ . ____	____	____ . ____	____ . ____	____ / ____ / ____ DAY MONTH YEAR
c. Serum Ketones (acetoacetate)	____	____	____	____	____ / ____ / ____ DAY MONTH YEAR
d. Anion Gap	____	____	____	____	____ / ____ / ____ DAY MONTH YEAR
e. Bicarbonate (Serum)	____	____	____	____	____ / ____ / ____ DAY MONTH YEAR
f. Urine Ketones	____	____	____	____	____ / ____ / ____ DAY MONTH YEAR

<sup>1</sup>Results should be reported based on initial visit

<sup>2</sup>Units: 1=mg/dl 2=mmol/L 3=ug/ml 4=meq/L 5=no units

**D. GLUCOSE LEVELS**

Record information on recently measured glucose levels – meter readings are **not acceptable** diagnostic criteria.

	a. Glucose Result <sup>1</sup>	b. Units (check one)	Reference Range (if available)		e. Glucose Date	f. Glucose Type	g. Measured By
			c. Low	d. High			
1	____ . ____	<input type="checkbox"/> <sub>1</sub> mg/dl <input type="checkbox"/> <sub>2</sub> mmol/L	____ . ____	____ . ____	____ / ____ / ____ DAY MONTH YEAR	<input type="checkbox"/> <sub>1</sub> Random <input type="checkbox"/> <sub>2</sub> Fasting <input type="checkbox"/> <sub>3</sub> 2-hr OGTT	<input type="checkbox"/> <sub>1</sub> TrialNet <input type="checkbox"/> <sub>2</sub> Other Lab <input type="checkbox"/> <sub>3</sub> Meter
2	____ . ____	<input type="checkbox"/> <sub>1</sub> mg/dl <input type="checkbox"/> <sub>2</sub> mmol/L	____ . ____	____ . ____	____ / ____ / ____ DAY MONTH YEAR	<input type="checkbox"/> <sub>1</sub> Random <input type="checkbox"/> <sub>2</sub> Fasting <input type="checkbox"/> <sub>3</sub> 2-hr OGTT	<input type="checkbox"/> <sub>1</sub> TrialNet <input type="checkbox"/> <sub>2</sub> Other Lab <input type="checkbox"/> <sub>3</sub> Meter
3	____ . ____	<input type="checkbox"/> <sub>1</sub> mg/dl <input type="checkbox"/> <sub>2</sub> mmol/L	____ . ____	____ . ____	____ / ____ / ____ DAY MONTH YEAR	<input type="checkbox"/> <sub>1</sub> Random <input type="checkbox"/> <sub>2</sub> Fasting <input type="checkbox"/> <sub>3</sub> 2-hr OGTT	<input type="checkbox"/> <sub>1</sub> TrialNet <input type="checkbox"/> <sub>2</sub> Other Lab <input type="checkbox"/> <sub>3</sub> Meter
4	____ . ____	<input type="checkbox"/> <sub>1</sub> mg/dl <input type="checkbox"/> <sub>2</sub> mmol/L	____ . ____	____ . ____	____ / ____ / ____ DAY MONTH YEAR	<input type="checkbox"/> <sub>1</sub> Random <input type="checkbox"/> <sub>2</sub> Fasting <input type="checkbox"/> <sub>3</sub> 2-hr OGTT	<input type="checkbox"/> <sub>1</sub> TrialNet <input type="checkbox"/> <sub>2</sub> Other Lab <input type="checkbox"/> <sub>3</sub> Meter

<sup>1</sup>Glucose levels must be based on plasma or serum

**E. OTHER LABORATORY VALUES**



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**Reference Range**  
*(if available)*

<b>Laboratory Values</b>	<b>a. Result</b>	<b>b. Low</b>		<b>c. High</b>	<b>d. Date</b>
1. HbA1c <i>(only if obtained outside of TrialNet)</i>	_____ . ____ %	_____ . ____ %	_____ . ____ %	_____ . ____ %	____ / ____ / ____ DAY MONTH YEAR