APPENDIX 1

DEMOGRAPHIC AND LABORATORY CHARACTERISTICS OF THE STUDY SUBJECTS AND INCLUSION CRITERIA

Group or category	N	M:F (%/%)	Age, years X ± sx (interval)	Glucose, mmol/l[a] X ± sx (interval)	C-peptideb X ± sx (interval)
DM1	169	99:70 (59:41)	8.4±4.3 (1.1–18.3)	22±6.5 (7.2–44)	37±21 (0–99)
C	169	94:75 (56:54)	12.1±11.2 (0.05–69)	7.2±2.7 (3–22)	228±288 (0–1350)
Category 1	104	60:44 (58:42)	9.2±5.4 (0.3–31)	5.2±0.6 (3.6–6.9)	150±139 (38–800)
Category 2	18	11:7 (61:59)	14.2±2.1 (9.2–17.5)	7±1.9 (5.1–11)	636±329 (117–1350)
Category 3	10	7:3 (70:30)	39.1±19.4 (12.2–69)	10.9±4.4 (6.8–19.6)	701±462 (170–1256)
Category 4	1	0:1 (0:100)	60	22	0
Category 5	2	0:2 (0:100)	2.5±0.3 (2.3–2.7)	3.5±0.6 (3–3.9)	73±76 (19–127)
Category 6	34	16:18 (47:53)	11.3±10.7 (0.05–45)	8.3±2.2 (6.2–15)	96±75 (4–259)

Notes: the DM1 group included patients on the basis of the following criteria:
- age from 1 month to 19 years;
- clinical diagnosis of type 1 DM established in the endocrinology department according to generally accepted criteria [1, 2];
- presence of at least one symptom of DM1 before hospitalisation from the following list: polydipsia, polyuria, weight loss, skin itching, slow healing of skin wounds, pyoderma, vulvitis in girls and balanitis in boys;
- insulin therapy prescribed within the first 3 days after hospitalisation;
- before the onset of insulin therapy, the glucose level in venous blood plasma was ≥ 7 mmol/l fasting or ≥11.1 mmol/l at any time;
- presence of ketosis or ketoacidosis before the onset of insulin therapy; and
- blood samples for simultaneous determination of ICA, GADA and IA-2A were taken no later than 3 months after the onset of insulin therapy;
- the C-peptide level in the serum in the fasting state, measured in the hospital before the onset of insulin therapy or within 3 days after its initiation, did not exceed the lower limit of the reference interval for the measurement method used.

The group C included the following categories of subjects:
Category 1: healthy adult blood donors and healthy volunteers who participated in clinical trials of medicines or medical products as well as healthy children, adolescents and adults who underwent laboratory examinations on an outpatient basis.
Category 2: children, adolescents and adults with obesity (body mass index > 27 kg/m2).
Category 3: patients with a diagnosis of DM2, established in the endocrinology hospital or in an outpatient clinic according to generally accepted criteria [1, 2].
Category 4: DM patients after pancreas resection.
Category 5: patients with hypoglycaemia of organic genesis (insulinoma, nesidioblastosis, mutations of KIR or SUR genes).
Category 6: patients with any variant of monogenic DM, confirmed by molecular genetic examination.

Additional criteria for inclusion in group K:
- for categories 1 and 2, absence of any type of DM according to clinical and laboratory data;
- for categories 1, 2 and 3, absence of diagnosis of DM1 or prescribed insulin therapy for at least 2 years from the date of antibody identification; and
- for all categories, absence of immediate relatives with DM1.