

APPENDIX 2

OPERATIONAL PARAMETERS OF SINGLE TESTS FOR ANTIBODIES AND THEIR COMBINATIONS

Test	Result	DSens (95% CI). %	DSpec (95% CI). %	LC ⁺ (95% CI)	LC ⁻ (95% CI)	PVPR (95% CI). %	PVNR (95% CI). %
Single tests							
ICA	ICA+	91.72 (86.49–95.40)	98.23 (94.90–99.63)	51.67 (16.82–158.74)	0.084 (0.051–0.139)	98.10 (94.39–99.37)	92.22 (87.77–95.14)
GADA	GADA+	73.37 (66.04–79.87)	89.94 (84.38–94.03)	7.29 (4.61–11.55)	0.296 (0.229–0.382)	87.94 (82.16–92.03)	77.16 (72.35–81.34)
IA-2A	IA-2A+	66.27 (58.61–73.35)	96.45 (92.43–98.69)	18.67 (8.45–41.26)	0.350 (0.283–0.433)	94.92 (89.41–97.63)	74.09 (69.79–77.97)
Combination of two tests							
ICA and GADA	ICA+. GADA–	23.67 (17.48–30.81)	98.82 (95.79–99.86)	20.00 (4.91–81.43)	0.772 (0.709–0.841)	95.24 (83.09–98.79)	56.42 (54.31–58.51)
	ICA+. GADA+	68.05 (60.45–75.00)	99.41 (96.75–99.99)	115.00 (16.25–813.91)	0.321 (0.258–0.401)	99.14 (91.20–99.88)	75.68 (71.40–79.50)
	≥ 1 AT ^a	97.04 (93.23–99.03)	88.76 (83.00–93.09)	8.63 (5.65–13.20)	0.033 (0.014–0.079)	89.62 (84.95–92.96)	96.77 (92.66–98.62)
ICA and IA-2A	ICA+. IA-2A–	27.22 (20.67–34.59)	98.82 (95.8–99.9)	23.00 (5.67–93.23)	0.737 (0.671–0.809)	95.83 (85.02–98.94)	57.59 (55.28–59.86)
	ICA+. IA-2A+	64.50 (56.78–71.69)	99.41 (96.75–99.99)	109.00 (15.39–771.81)	0.357 (0.291–0.438)	99.09 (93.90–99.87)	73.68 (69.55–77.44)
	≥ 1 AT ^a	93.49 (88.65–96.71)	95.27 (90.89–97.93)	19.75 (10.03–38.89)	0.068 (0.039–0.121)	95.18 (90.93–97.49)	93.61 (89.20–96.20)
GADA and IA- 2A	GADA+. IA-2A–	20.12 (14.35–26.96)	90.53 (85.08–94.49)	2.13 (1.22–3.7)	0.892 (0.806–0.965)	68.00 (54.96–78.73)	53.13 (50.88–66.36)
	GADA–. IA-2A+	13.02 (8.34–19.04)	97.04 (93.23–99.03)	4.40 (1.71–11.35)	0.896 (0.841–0.956)	81.48 (63.05–91.90)	52.73 (51.14–54.33)
	GADA+. IA-2A+	53.25 (45.44–60.96)	99.41 (96.75–99.99)	90.00 (12.69–638.49)	0.470 (0.400–0.553)	98.90 (92.69–99.84)	68.02 (64.41–71.42)
	≥ 1 AT ^a	86.39 (80.28–91.17)	86.98 (80.96–91.66)	6.64 (4.47–9.84)	0.156 (0.107–0.230)	86.91 (81.73–90.78)	86.47 (81.32–90.37)
Combination of three tests							
ICA, GADA and IA- 2A	ICA+. GADA–. IA-2A–	11.24 (6.91–17.00)	98.82 (95.79–99.86)	9.50 (2.25–40.15)	0.898 (0.849–0.950)	90.48 (69.21–97.57)	52.68 (51.28–54.08)
	ICA+. GADA+. IA-2A–	15.98 (10.80–22.39)	99.41 (96.73–99.99)	26.84 (3.69–195.28)	0.845 (0.791–0.904)	96.43 (78.77–99.49)	54.05 (52.38–55.70)
	ICA+. GADA–. IA-2A+	12.43 (7.86–18.37)	100.00 (97.84–100.00)	∞ (0.190 – ∞)	0.876 (0.827–0.927)	100 –	53.31 (51.90–54.72)
	ICA+. GADA+. IA-2A+	52.07 (44.27–59.80)	99.41 (96.75–99.99)	88.00 (12.40–624.45)	0.482 (0.412–0.564)	98.88 (92.54–99.84)	67.47 (63.92–70.83)
	≥ 1 AT ^a	97.63 (94.05–99.35)	85.80 (79.61–90.68)	6.88 (4.74–9.97)	0.028 (0.010–0.073)	87.30 (82.59–90.88)	97.32 (93.22–98.97)

Notes: DSens. diagnostic sensitivity; DSpec. diagnostic specificity; LC⁺. the likelihood coefficient of the positive result of the test; LC⁻. the likelihood coefficient of the negative result of the test; PVPR. the predictive value of a positive result; PVNR. the predictive value of a negative result; 95% CI. 95% confidence interval. PVPR and PVNR were calculated for the PtP of DM1 equal to 50%.

^aPositive result of at least one of several tests.