Participant flow

Study assessed was observational in design and utilised leftover pre-characterised clinical samples (n=500) therefore no participants were directly involved.

Baseline Characteristics

Characteristic	Details
Age: range	1 day to 54 years
Gender: no. (%)	
Male	227 (46%)
Female	271 (54%)
Disease State: no.	
Non-diabetic	200
T1D (early onset <18 years)	100
T1D (late onset >18 years)	100
T2D	198
Ethnicity:	
White British	372
White Irish	11
Other White	105
Asian	1
Black	1
Chinese	1
Mixed	3
Arabic, North African	1
Jewish	1
Lithuanian	1
White & Asian	1

Outcome Measures

Acceptance Criteria	**Result**	**Acceptance Criteria met/unmet**
Input DNA of sufficient quantity (7.5ng/µl) and quality (260/280 ratio ≤ 3.0)	Range: 7.2-7.8 ng/µl; 260/280 ratio 1.60-2.58	✓
Workbook14793-QC covering all tested clinical samples with available genotypes, GRSs and risk level (low, medium or high)	Workbook14793-QC provided for each clinical sample	✓
≥ 90% agreement with established reference method of clinical samples' genotypes, GRSs and risk level (low, medium or high)	100% genotypes and GRSs	✓
Diagnostic Sensitivity ≥ 90%	91%	✓
Diagnostic Specificity ≥ 90%	92%	✓
Likelihood Ratios >10 or <0.1	11.26 [+LR] 0.10 [-LR]	✓
ROC AUC ≥ 0.75	≥ 0.8 (95% CI)	✓

Adverse Events

No subject enrolment in the study was carried out as the clinical study was observational in design and utilised leftover pre-characterised clinical samples. Such study design posed no additional risks to test subjects or potential for adverse event(s).