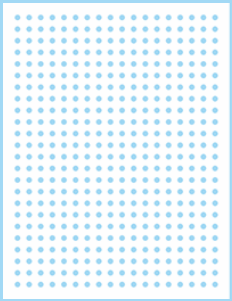
Certificate of Analysis



Olink® Explore 1536

PROJECT NAME	Demo
ISSUE DATE	2020-06-03
CUSTOMER	Olink Demo
	demo-customer@olink.com
BUSINESS DEVELOPMENT MANAGER	Olink Sales
	sales@olink.com
ANALYSIS LAB	Analysis Service Uppsala
	service@olink.com

1. Project information

No. of samples	No. of plates	Normalization method
212	3	Intensity normalization

1.1 Sample type

Plasma

1.2 Project specific comments

N/A

2. Quality control

Three internal controls are added to each sample to monitor the quality of assay performance, as well as the quality of individual samples:

1 Incubation control

2 Extension control

3 Amplification Control

The following parameters are evaluated in the Quality Control (QC):

1 The average matched counts[1] for each sample. To pass QC, there should be at least 500 counts, otherwise the sample receives a QC warning status.

2 The deviation from the median value of the incubation- and amplification controls for each individual sample. To pass QC, the deviation should not exceed +/-0.3 NPX for either of the internal controls, otherwise the sample will receive a QC warning status.

3 The percent matched counts in the extension control for each sample. To pass QC, the extension control should not exceed 15% of the total counts, otherwise the sample receives a QC warning status.

[1] The number of reads for each specific combination of sample and assay

Data from all samples is included in the data output file. Samples that did not pass the QC are indicated in columns named "QC warning". Data points from samples that do not pass QC should be treated with caution.

2.1 QC summary

Olink Explore 1536	No. of samples that passed QC / Total no. of samples	Passed samples (%)
CARDIOMETABOLIC	175 / 212	83
INFLAMMATION	175 / 212	83
NEUROLOGY	133 / 212	63
ONCOLOGY	186 / 212	88

2.2 Intra- and Inter-assay Coefficient of Variance (%CV)

Intra- and inter-CVs are based on the control samples (pooled plasma samples) included on each sample plate. Calculations are made for each assay using NPX-values. Average % CV for all assays on a panel is presented in section 2.2.1. The number of assays with CVs within defined intervals are presented in sections 2.2.2 and 2.2.3.

2.2.1 Average %CV

Olink Explore 1536	Intra-assay %CV	Inter-assay %CV
CARDIOMETABOLIC	9	14
INFLAMMATION	10	15
NEUROLOGY	11	17
ONCOLOGY	11	16

2.2.2 Intra-assay %CV distribution

Olink Explore 1536	<5%	5-10%	10-15%	>15%	N/A*
CARDIOMETABOLIC	136	76	39	73	46
INFLAMMATION	101	96	49	61	63
NEUROLOGY	81	74	55	86	75
ONCOLOGY	93	73	41	83	80

*Assays where CV is not possible to calculate

2.2.3 Inter-assay %CV distribution

Olink Explore 1536	<10%	10-20%	20-30%	>30%	N/A*
CARDIOMETABOLIC	123	146	55	14	32
INFLAMMATION	91	170	51	18	40
NEUROLOGY	87	150	54	28	52
ONCOLOGY	84	152	61	21	52

*Assays where CV is not possible to calculate

3. Protein detection results

3.1 Number of proteins detected in >50% of the samples

Olink Explore 1536	No. of detected proteins / Total no. of proteins	Detected proteins (%)	Expected detectability in EDTA plasma* (%)
CARDIOMETABOLIC	343 / 370	93	N/A
INFLAMMATION	315 / 370	85	N/A
NEUROLOGY	249 / 371	67	N/A
ONCOLOGY	312 / 370	84	N/A

*The expected detectability is based on EDTA plasma from healthy donors. These values are intended as guidelines only and protein levels are expected to vary depending on different pathological conditions, sample matrices, or sample preparation methods.

3.2 Data output

Data is presented as NPX (Normalized Protein eXpression) values. NPX is Olink's relative protein quantification unit on log2 scale. NPX values from Explore 1536 are calculated from the number of matched counts, using NGS (Next Generation Sequencing) as readout. The NPX values are presented in a separate results file delivered in the MyData cloud. Data values for measurements below limit of detection (LOD) are reported for all samples.