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Public statement regarding the production and use of in-house devices by health care institutions

Name of healthcare institution: ***Cogentech S.R.L. Sole Proprietorship Benefit Company subject to the direction and coordination of IFOM - Molecular Oncology Foundation Institute ETS***

Address: Registered office via Adamello 16, 20139 Milan, Italy

Cogentech S.R.L. declares that the devices described in the accompanying table are manufactured and used exclusively at Cogentech S.R.L. and meet the applicable General Safety and Performance Requirements (GSPR) of the Medical Device Regulation (EU 2017/745) or the In Vitro Diagnostic Medical Device Regulation (EU 2017/746).

A reasoned justification is provided if the applicability of general safety and performance requirements is not fully met.

Place and date: Milan, 18/12/2023

Name, function and signature of the person responsible:

Marco Alessandro Pierotti
CEO of Cogentech S.R.L.

Cogentech S.R.L. Single-member Benefit Company subject to management and coordination activities By IFOM ETS- Foundation Institute for Molecular Oncology
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Table of in-house devices:

Device Identification (e.g., name, description, reference number)	Device Type (IVD/ MD)	Device hazard class	Intended purpose	Is the applicability of the GSPR fully satisfied? (Y/N)	Information and justification regarding the non-full applicability of the GSPR (using the numbering of Annex I of the IVDR/MDR).
OncoPan	IVD	C	a. The OncoPan® panel takes advantage of massively parallel sequencing or Next Generation Sequencing (NGS) technology and allows the detection of both point mutations (substitutions, small deletions/insertions or Single Nucleotide Variations, SNVs) and large rearrangements (Copy Number Variations, CNVs) due to deletion/duplication of one or more exons of the genes under investigation. b. OncoPan® is a diagnostic, prognostic, and response prediction tool for therapeutic treatment. It is used for the following applications: -Assessment of susceptibility to hereditary or syndrome-related cancers conferring susceptibility to heredo-familial cancers of the breast, ovary, colon, pancreas, prostate, various forms of polyposis, gastric cancer of the diffuse type, familial melanoma, Li Fraumeni, Cowden and Peutz-Jeghers syndromes; -Prevision of response to treatment with Parp inhibitor drugs in ovarian, breast, prostate, and pancreatic cancers; -Determination of the prognosis of endometrial cancers; -Customized risk assessment. c. The analysis should be preceded by pre-test genetic counseling and followed by post-test genetic counseling for explanation of the results	P.: 1 **S** P.: 2 **S** P.: 3 **S** P.: 4 **S** P.: 5 **S** P.: 6 **S** P.: 7 **S** P.: 8 **S** P.: 9 **S - exception P. 9.3 and 9.4** P.: 10 **S** P.: 11 **S - exception 11.1.b and 11.2 to 11.6** P.: 12 **S** P.: 13 **S - exception P. 13.2.a;**	**P. 9.3** and **9.4** The panel does not provide quantitative values and is not for self-diagnosis: it can be run only within the CGT Lab **P. 11.1.b** the components of the device reagents do not present a risk of leakage or microbial exposure **P. 11.2 to 11.6** The device is not intended for sterilization **P. 13** the device does not involve additional risks, is not subject to fire or explosion during normal conditions of use, nor does it require calibration work. The device does not measure, monitor or display the measurement scale **P. 14** The device does not have a primary analytical measurement function

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			obtained and taking care of the patient and, if necessary, his or her family members. d. The analytical process contains some partially automated steps. e. The analytical data obtained can be either qualitative or quantitative and is provided accompanied by the interpretation of the variants identified and an indication of their possible role in increasing cancer susceptibility. f. The type of sample required for analysis is DNA extracted from peripheral blood, saliva (buccal cell exfoliate), or tumor tissue. g. Patients are selected at cancer genetic counseling and meet recruitment criteria based on personal and/or family cancer history. h. The panel can be used as a companion diagnostic test for the drugs Olaparib, Rucaparib,Talazoparib The OncoPan® diagnostic tool is an IH-IVD developed within the CGT Lab, and can only be performed by authorized and trained personnel, within the health care institution, which is Cogentech.	**13.3.; 13.4;13.7** P.: 14 **N** P.: 15 **N** P.: 16 **S - exception P. 16.3** P.: 17 **N** P.: 18 **N** P.: 19 **N** P.: 20 **N**	**P. 15** The device does not emit radiation **P. 16.3** The software component of the device is intended for use with desktop computing platforms and not with mobile computing platforms. **P.t17** The device is not connected or equipped with a power source. **P. 18** The device has no mechanical or moving parts and creates no mechanical or thermal hazards. **P. 19** The device is not intended for self-diagnosis or testing near the patient. **P. 20** the Device is an IH-House test: it is not marketed with a label.
OncoPed	IVD	C	a. The OncoPed panel takes advantage of massively parallel sequencing or Next Generation Sequencing (NGS) technology and allows for the detection of both point mutations (substitutions, small deletions/insertions or Single Nucleotide Variations, SNVs) and large rearrangements (Copy Number Variations, CNVs) due to deletion/duplication of one or more exons of the genes under investigation. b. OncoPed is a diagnostic tool. It is used in the assessment of susceptibility to pediatric cancers particularly medulloblastoma, Wilms' tumor, some rare ovarian cancers (Sertoly-Leydig and SCCOTH), retinoblastoma, uveal melanoma/melanoma, renal tumors, some lymphomas, rhabdoid tumors, tumors developing in Gorlin, DICER1 and Carney syndromes. c. The analysis should be preceded by pre-test genetic counseling and followed by post-test genetic counseling for explanation of the results obtained and taking care of the patient and, if necessary, his or her family members. In the case of minors, the physician will handle the counseling with the parents. d. The analytical process contains some partially automated steps.	P.: 1 **S** P.: 2 **S** P.: 3 **S** P.: 4 **S** P.: 5 **S** P.: 6 **S** P.: 7 **S** P.: 8 **S** P.: 9 **S - exception P. 9.3 and 9.4** P.: 10 **S** P.: 11 **S - exception 11.1.b and 11.2 to 11.6** P.: 12 **S** P.: 13 **S - exception P. 13.2.a;**	**P. 9.3** and **9.4** The panel does not provide quantitative values and is not for self-diagnosis: it can be run only within the CGT Lab **P. 11.1.b** the components of the device reagents do not present a risk of leakage or microbial exposure **P. 11.2 to 11.6** The device is not intended for sterilization **P. 13** the device does not involve additional risks, is not subject to fire or explosion during normal conditions of use, nor does it require calibration work. The device does not measure, monitor or display the measurement scale **P. 14** The device does not have a primary analytical measurement function

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			e. The analytical data obtained can be either qualitative or quantitative and is provided accompanied by the interpretation of the variants identified and an indication of their possible role in increasing cancer susceptibility. f. The type of sample required for analysis is DNA extracted from peripheral blood or saliva (exfoliate of buccal cells). g. Patients tested are usually pediatric in age, are selected at oncology genetic counseling, and meet recruitment criteria based on personal and/or family history of oncology. The OncoPed diagnostic tool is an IH-IVD, developed within the CGT Lab, and can only be performed by authorized and trained personnel, within the health care institution, which is Cogentech.	**13.3.; 13.4;13.7** P.: 14 **N** P.: 15 **N** P.: 16 **S - exception P. 16.3** P.: 17 **N** P.: 18 **N** P.: 19 **N** P.: 20 **N**	**P. 15** The device does not emit radiation **P. 16.3** The software component of the device is intended for use with desktop computing platforms and not mobile computing platforms. **P. 17** The device is not connected or equipped with a power source. **P. 18** The device has no mechanical or moving parts and creates no mechanical or thermal hazards. **P. 19** The device is not intended for self-diagnosis or testing near the patient. **P. 20** the Device is an IH-House test: it is not marketed with a label.
OncoHRD	IVD	C	a. The OncoHRD panel takes advantage of massively parallel sequencing or Next Generation Sequencing (NGS) technology and allows for the detection of both point mutations (substitutions, small deletions/insertions or Single Nucleotide Variations, SNVs) and large rearrangements (Copy Number Variations, CNVs) due to deletion/duplication of one or more exons in the BRCA1 and BRCA2 genes. It also uses low-pass Whole Genome Sequencing (WGS) analysis by NGS to assess the genomic integrity of the sample (Genomic Integrity index - GI), which is predictive of Homologous Recombination Deficiency (HRD) status. b. OncoHRD is a tool for predicting response to therapeutic treatment. It is used for predicting response to treatment with Parp inhibitor drugs in ovarian cancers. c. The analysis should be preceded by oncology genetic counseling for explanation of the possible implications of the test, which could go beyond just prediction to therapy, if pathogenic variants are identified, potentially conferring susceptibility to cancers. In this case, the analysis should also be followed by post-test genetic counseling. d. The analytical process contains some partially automated steps.	P.: 1 **S** P.: 2 **S** P.: 3 **S** P.: 4 **S** P.: 5 **S** P.: 6 **S** P.: 7 **S** P.: 8 **S** P.: 9 **S - exception P. 9.3 and 9.4** P.: 10 **S** P.: 11 **S - exception 11.1.b and 11.2 to 11.6** P.: 12 **S** P.: 13 **S - exception P. 13.2.a;**	**P. 9.3** and **9.4** The panel does not provide quantitative values and is not for self-diagnosis: it can be run only within the CGT Lab **P. 11.1.b** the components of the device reagents do not present a risk of leakage or microbial exposure **P. 11.2 to 11.6** The device is not intended for sterilization **P. 13** the device does not involve additional risks, is not subject to fire or explosion during normal conditions of use, nor does it require calibration work. The device does not measure, monitor or display the measurement scale **P. 14** The device does not have a primary analytical measurement function

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			e. The analytical data obtained can be either qualitative or quantitative and is provided accompanied by the interpretation of the variants identified and an indication of their possible role in the response to Parp inhibitor drugs. f. The type of sample required for analysis is DNA extracted from tumor tissue. g. The investigated population consists of adult patients with advanced ovarian cancer. h. The panel can be used as a companion diagnostic test for the drug Olaparib in combination with Bevacizumab. The OncoHRD diagnostic tool is an IH-IVD, developed within the CGT Lab, and can only be performed by authorized and trained personnel, within the health care institution, which is Cogentech	**13.3.; 13.4;13.7** P.: 14 **N** P.: 15 **N** P.: 16 **S - exception P. 16.3** P.: 17 **N** P.: 18 **N** P.: 19 **N** P.: 20 **N**	**P. 15** The device does not emit radiation **P. 16.3** The software component of the device is intended for use with desktop computing platforms and not mobile computing platforms. **P. 17** The device is not connected or equipped with a power source. **P. 18** The device has no mechanical or moving parts and creates no mechanical or thermal hazards. **P. 19** The device is not intended for self-diagnosis or testing near the patient. **P. 20** the Device is an IH-House test: it is not marketed with a label.

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