

To:

All Member States participating in EFC17504

23rd January 2024

Product Code/Name: SAR441344 / Frexalimab

Protocol Code: EFC17504

Protocol Title: A randomized, double-blind, Phase 3 study comparing efficacy and safety of frexalimab

(SAR441344) to placebo in adult participants with nonrelapsing secondary progressive

multiple sclerosis

Universal trial number: U1111-1280-7114

EU trial number: 2023-504359-29

Subject: Clinical Trial Application - Request for Initial authorization

Dear Madam, Dear Sir,

Sanofi-Aventis Recherche & Développement hereby submits a Clinical Trial Application for the Clinical Study EFC17504

EFC17504 is a Phase III randomized, double-blind, 2-arm, placebo-controlled, parallel group, multicenter study, in adult participants with non-relapsing secondary progressive form of Multiple Sclerosis.

The purpose of this study is to assess the efficacy of frexalimab in delaying disability progression, its safety and tolerability in participants.

We propose Czech Republic as the Reporting Member State.

The Sponsor wishes to highlight that another frexalimab Phase III study (EFC17919 [EU CTR number 2023-504358-36-00]) has been submitted prior to the hereby application. The Sponsor therefore proposes to request the same Reporting Member State (Czech Republic) for both studies for optimization of review and future maintenance.

For the same purpose, the Sponsor would like to point out that in terms of the Quality information, the IMPD Quality provided as part of this application for study EFC17504 is the same as the one that has been provided for the EFC17919 application. The exception being that study EFC17919 uses a comparator and comparator placebo, whereas EFC17504 does not.

The following Countries are proposed to take part in the study:

- Bulgaria
- Belgium
- Czech Republic
- Germany
- France
- Greece
- Hungary
- Italy
- Netherlands
- Poland
- Portugal
- Spain
- Sweden

The anticipated date of the next DSUR submission is 12-Jan-2024

We confirm that the contact details of the main contact of the sponsor are included in the patient card (as per the Annex VI of the Regulation, paragraph 3 of section A.1).

For administrative information, please see Administrative information.

For any additional information, please see **Specificities**.

Should you have any queries on the enclosed, please do not hesitate to contact us

Yours sincerely,

Sanofi-Aventis Research & Development

Administrative information

Information		Location of the Information in the Application Dossier
Proposed Reporting Member State	Czech Republic	Not Applicable
Specific features of the clinical trial population	 □ Subjects not able to give informed consent □ Minors □ Pregnant or breastfeeding women ⋈ None of the above 	Please refer to Structure Data in the Part I \ Trial details \ Trial information \ Population of trial subjects
Does the clinical trial involve the first administration of a new active substance to humans?	☐ Yes ☑ No	Not Applicable
Has a scientific advice relating to the clinical trial or the investigational medicinal product SAR441344 / Frexalimab been given by the Agency, a Member State or a third country?	Yes □ No	Please refer to Structure Data in the Part I \ Trial details \ Scientific advice and Paediatric Investigation Plan (PIP)
Is the clinical trial part or will it be part of a Paediatric Investigation Plan (PIP)?	☐ Yes ☑ No	Please refer to Structure Data in the Part I \ Trial details \ Scientific advice and Paediatric Investigation Plan (PIP)
Has the investigational medicinal product SAR441344 / Frexalimab obtained an orphan designation?	☐ Yes ☑ No	Please refer to Structure Data in the Part I \ Products \ SAR441344 / Frexalimab \ Orphan Designation
Is the clinical trial considered by the sponsor to be a low-intervention clinical trial?	☐ Yes ☑ No	Please refer to Structure Data in the Part I \ Trial details \ Trial information \ Trial Category
Does the methodology of the clinical trial require that groups of subjects rather than individual subjects are allocated to receive different investigational medicinal products in a clinical trial?	☐ Yes ☑ No ☐ Yes	
If Yes, will the informed consent be obtained by simplified means?	☐ No	

The Investigational Medicinal Product in this clinical study is:

Investigational Medicinal Product	Regulatory status	Reference Safety Information localisation	Additional information
SAR441344 / Frexalimab	□ Approved in the EU ☑ Not Approved in the EU	Section 8 (Determination of expectedness and the table of expected adverse drug reactions) of the Investigator's Brochure Edition 5 dated 17-Apr-2023	Is the IMP a: - narcotic: □ Yes; ⋈ No - psychotropic: □ Yes; ⋈ No -radiopharmaceutical: □ Yes; ⋈ No (Please refer to Structure Data in the Part I \ Products \
			SAR441344 / Frexalimab \ Product characteristics) Does the IMP consist of or contain a genetically-modified organism or organisms? ☐ Yes; ☒ No
			(Please refer to Structure Data in the Part I \ Products \ SAR441344 / Frexalimab \ Advanced Therapy Medicinal Product)

The auxiliary medicinal products in this clinical study are:

Auxiliary medicinal product	Regulatory status	Additional information
MRI contrast- enhancing Preparations (ATC code: V08CA)	☑ Approved in the EU☐ Not Approved in the EU	Sourcing by the site/patient for all countries. Sourcing by/on behalf of the Sponsor: No

No medical devices are being investigated as part of the clinical trial. The in vitro diagnostic medical devices which are to be included in this clinical trial but which are not part of the investigational medicinal product or products are:

Medical device	Additional Information
Activated Partial Thromboplastin Time – CLOT	This test is CE-marked for the intended use.
DETECTION	
anti-Hepatitis B Surface Antigen 2 (aHBs2) -	This test is CE-marked for the intended use.
CHEMILUMINESCENCE	
Anti-Mitochondrial Antibody – INDIRECT FLUORESCENT	This test is CE-marked for the intended use.
ANTIBODY	
Antinuclear Antibody (ANA) – INDIRECT FLUORESCENT	This test is CE-marked for the intended use.
ANTIBODY	
Anti-Smooth Muscle Antibody – INDIRECT	This test is CE-marked for the intended use.
FLUORESCENT ANTIBODY	
Beta hCG - CHEMILUMINESCENCE	This test is CE-marked for the intended use.
Chemistry Panel – VARIES BY ANALYTE	This test is CE-marked for the intended use.
Cytomegalovirus IgM - CHEMILUMINESCENCE	This test is CE-marked for the intended use.
D-Dimer – COAGULATION ANALYZER	This test is CE-marked for the intended use.

Double Stranded DNA Antibodies, IgG = INDIRECT This test is CE-marked for the intended use.		
Epstein-Barr VCA igM - CHEMILUMINESCENCE Ferritin - CHEMILUMINESCENCE Ferritin - CHEMILUMINESCENCE Follide Strimulating Hormone (FSH) - CHEMILUMINESCENCE Full liver panel - VARIES BY ANALYTE Gliber Syndrome Screening for UGT1A1*28 This test is CE-marked for the intended use. Hortis Syndrome Screening for UGT1A1*28 Gliber Syn	_	This test is CE-marked for the intended use.
Ferritin - CHEMILUMINESCENCE Follice Stimulating Hormone (FSH) - CHEMILUMINESCENCE Full liver panel – VARIES BY ANALYTE Full River panel – VARIES BY ANALYTE Full Repatitis A Igm Antibody - CHEMILUMINESCENCE Full Repatitis B Core Igm Antibody - CHEMILUMINESCENCE Full Repatitis B Core Igm Antibody - CHEMILUMINESCENCE Full Repatitis B Surface Antigen II - CHEMILUMINESCENCE Full Repatitis B Surface Antigen II - CHEMILUMINESCENCE Full Repatitis E Igm Antibody - CHEMILUMINESCENCE Full Repatitis E Igm Anti	Epstein-Barr VCA IgG- CHEMILUMINESCENCE	This test is CE-marked for the intended use.
Follicle Stimulating Hormone (FSH) - CHEMILUMINESCENCE Full liver panel – VARIES BY ANALYTE Gilbert Syndrome Screening for UGT1A1*28 Gilscose – CHEMISTRY COBAS 5800 HDV NAN – RT-PCR COBAS 6800 HDV NAN – RT-PCR COBAS 6800 HCW RNA – RT-PCR COBAS 6800 HCW RNA – RT-PCR COBAS 6800 HCW RNA – RT-PCR COBAS 6800 HEMBOOLOGY HEMBORY STATES HAVE A STA	Epstein-Barr VCA IgM - CHEMILUMINESCENCE	This test is CE-marked for the intended use.
CHEMILUMINESCENCE Full liver panel — VARIES BY ANALYTE Full Remotology Differential — LIGHT SCATTERING Full liver panel — VARIES BY ANALYTE Full liver panel — VARIES BY ARALYTE Full liver panel — VARIES BY ANALYTE Full liver panel — Varies is CE-marked for the intended use. Full liver panel — Varies and pa	Ferritin - CHEMILUMINESCENCE	This test is CE-marked for the intended use.
Full liver panel – VARIES BY ANALYTE Gilbert Syndrome Screening for UGT1A1*28 Gildert Streening For UG	Follicle Stimulating Hormone (FSH) -	This test is CE-marked for the intended use.
Gilbert Syndrome Screening for UGT1A1*28 (rs8175347) polymorphism — RT-PCR Gilucose — CHEMISTRY COBAS 701/702 This test is CE-marked for the intended use. HBV DNA — RT-PCR COBAS 6800 This test is CE-marked for the intended use. HCV RNA — RT-PCR COBAS 680 Hematology Differential — LIGHT SCATTERING Hematology Hemogram Panel — VARIES BY ANALYTE Hematology Hemogram Panel — VARIES BY ANALYTE Hepatitis A IgM Antibody - CHEMILUMINESCENCE Hepatitis B Core IgM Antibody - CHEMILUMINESCENCE Hepatitis B Core IgM Antibody - CHEMILUMINESCENCE Hepatitis B Core Total - CHEMILUMINESCENCE Hepatitis B Core Total - CHEMILUMINESCENCE Hepatitis E Surface Antigon II - CHEMILUMINESCENCE Hepatitis E Surface Antigon I - CHEMILUMINESCENCE Hepatitis E Surface Antigon II - CHEMILUMINESCENCE Hepatitis E IgM Antibody - ENZYME IMMUNOASSAY His test is CE-marked for the intended use. Hepatitis E IgM Antibody - ENZYME IMMUNOASSAY This test is CE-marked for the intended use. Hepatitis E IgM Antibody - ENZYME IMMUNOASSAY This test is CE-marked for the intended use. Hepatitis E IgM Antibody - This test is CE-marked for the intended use. Hepatitis E IgM Antibody - This test is CE-marked for the intended use. Hepatitis E IgM Antibody - This test is CE-marked for the intended use. Hepatitis E IgM Antibody - This test is CE-marked for the intended use. Hepatitis E IgM Antibody - This test is CE-marked for the intended use. Hepatitis E IgM Antibody - This test is CE-marked for the intended use. Hepatitis E IgM Antibody - This test is CE-marked for the intended use. Hepatitis E IgM Antibody - This test is CE-marked for the intended use. Hepatitis E IgM Antibody - This test is CE-marked for the intended use. Hilv 1/2 Ag/Ab Combo (CHIV) - CHEMILUMINESCENCE Hilv 1/2 Ag/Ab Combo (CHIV) - CHEMILUMINESCENCE HIIV-1 Antibody Supplemental - This test is CE-marked for the intended use. HIIV-1 RNA - RT-PCR This test is CE-marked for the intended use. Immunoglobulin G - CHEMISTRY COBAS C 701/702 This test is CE-marked for the intended use. International Nor	CHEMILUMINESCENCE	
(rs8175347) polymorphism — RT-PCR Glucose — CHEMISTRY COBAS 701702 This test is CE-marked for the intended use. HBV DNA — RT-PCR COBAS 6800 This test is CE-marked for the intended use. HCV RNA — RT-PCR COBAS 6800 This test is CE-marked for the intended use. HEMD DNA — RT-PCR COBAS 6800 This test is CE-marked for the intended use. Hematology Differential — LIGHT SCATTERING This test is CE-marked for the intended use. Hematology Differential — LIGHT SCATTERING This test is CE-marked for the intended use. Hepatitis A IgM Antibody - CHEMILUMINESCENCE This test is CE-marked for the intended use. Hepatitis B Core IgM Antibody - CHEMILUMINESCENCE This test is CE-marked for the intended use. Hepatitis B Core Total - CHEMILUMINESCENCE This test is CE-marked for the intended use. Hepatitis C Virus Antibody - CHEMILUMINESCENCE This test is CE-marked for the intended use. Hepatitis E IgM Antibody - ENZYME IMMUNOASSAY This test is CE-marked for the intended use. Herpestimplex Virus Type 1 IgG Antibody - This test is CE-marked for the intended use. Herpes Simplex Virus Type 2 IgG Antibody - This test is CE-marked for the intended use. Herpes Simplex Virus Type 2 IgG Antibody - This test is CE-marked for the intended use. Herpes Simplex Virus Type 1-2 IgM Antibody - This test is CE-marked for the intended use. HHIV-1 Antibody Supplemental, Geenius - This test is CE-marked for the intended use. HIV-1 ARIADO Supplemental, Geenius - This test is CE-marked for the intended use. HIV-1 ARIADO Supplemental, Geenius - This test is CE-marked for the intended use. HIV-1 ARIADO Supplemental, Geenius - This test is CE-marked for the intended use. HIV-2 ARIADO Supplemental, Geenius - This test is CE-marked for the intended use. HIMUNOCHROMATOGRAPHIC HIV-1 RNA — RT-PCR This test is CE-marked for the intended use. Immunoglobulin M — CHEMISTRY COBAS C 701/702 This test is CE-marked for the intended use. Immunoglobulin M — CHEMISTRY COBAS C 701/702 This test is CE-marked for the intended use. Immunoglobulin M — CHEMISTRY COBAS C 701/702 This	•	This test is CE-marked for the intended use.
HBV DNA – RT-PCR COBAS 6800 HCV RNA – RT-PCR COBAS 6800 This test is CE-marked for the intended use. HCW RNA – RT-PCR COBAS 680 This test is CE-marked for the intended use. Hematology Differential – LIGHT SCATTERING Hematology Hemogram Panel – VARIES BY ANALYTE Hematology Hemogram Panel – VARIES BY ANALYTE Hepatitis A IgM Antibody - CHEMILUMINESCENCE Hepatitis B Core Total - CHEMILUMINESCENCE Hepatitis C Virus Antibody - CHEMILUMINESCENCE Hepatitis C Virus Antibody - CHEMILUMINESCENCE Hepatitis E JgM Antibody - CHEMILUMINESCENCE Hepatitis E JgM Antibody - CHEMILUMINESCENCE Hepatitis E IgM Antibody - ENZYME IMMUNOASSAY Herpes Simplex Virus Type 1 IgG Antibody - Herpes Simplex Virus Type 1 IgG Antibody - Herpes Simplex Virus Type 2 IgG Antibody - Herpes Simplex Virus Type 2 IgG Antibody - Herpes Simplex Virus Type 1 IgM Antibody - HIV 1 Antibody Supplemental, Geenius - HIV 1/2 Ag/Ab Combo (CHIV) - CHEMILUMINESCENCE HIV 1/2 Antibody Supplemental - HIW 1/2 Antibody Supplem	,	This test is CE-marked for the intended use.
HCV RNA – RT-PCR COBAS 680 Hematology Differential – LIGHT SCATTERING Hematology Differential – LIGHT SCATTERING Hepatitis A IgM Antibody - CHEMILUMINESCENCE Hepatitis B Core IgM Antibody - CHEMILUMINESCENCE Hepatitis B Core IgM Antibody - CHEMILUMINESCENCE Hepatitis B Core IgM Antibody - CHEMILUMINESCENCE Hepatitis B Surface Antigen II - CHEMILUMINESCENCE Hepatitis B Surface Antigen II - CHEMILUMINESCENCE Hepatitis C Virus Antibody - CHEMILUMINESCENCE Hepatitis C Virus Antibody - CHEMILUMINESCENCE Hepatitis C Virus Antibody - CHEMILUMINESCENCE Hepatitis E IgM Antibody - CHEMILUMINESCENCE Herpes Simplex Virus Type 1 IgG Antibody - This test is CE-marked for the intended use. Herpes Simplex Virus Type 1 IgG Antibody - This test is CE-marked for the intended use. Herpes Simplex Virus Type 1-12 IgM Antibody - This test is CE-marked for the intended use. HIV-12 Ag/Ab Combo (CHIV) - CHEMILUMINESCENCE HIV-13 Antibody Supplemental, Geenius - Immunosia Supplemental, Geenius - Immunosia Supplemental - This test is CE-marked for the intended use. HIV-14 RNA – RT-PCR This test is CE-marked for the intended use. HIV-15 RNA – RT-PCR This test is CE-marked for the intended use. Immunoglobulin G – CHEMISTRY COBAS C 701/702 This test is CE-marked for the intended use. International Normalized Ratio – CLOT DETECTION This test is CE-marked for the intended use. International Normalized Ratio – CLOT DETECTION This test is CE-marked for the intended use. International Normalized Ratio – CLOT DETECTION This test is CE-marked for the intended use. International Normalized Ratio – CLOT DETECTION This test is CE-marked for the intended use. This test is CE-marked for the intended use. T	Glucose – CHEMISTRY COBAS 701/702	This test is CE-marked for the intended use.
Hematology Differential – LIGHT SCATTERING Hematology Hemogram Panel – VARIES BY ANALYTE Hepatitis A IgM Antibody - CHEMILUMINESCENCE Hepatitis B Core IgM Antibody - CHEMILUMINESCENCE Hepatitis B Core Total - CHEMILUMINESCENCE Hepatitis B Core Total - CHEMILUMINESCENCE Hepatitis B Surface Antigen II - CHEMILUMINESCENCE Hepatitis B Surface Antigen II - CHEMILUMINESCENCE Hepatitis C Virus Antibody - ENZYME IMMUNOASSAY Herpes Simplex Virus Type 1 IgG Antibody - CHEMILUMINESCENCE Herpes Simplex Virus Type 1 IgG Antibody - CHEMILUMINESCENCE Herpes Simplex Virus Type 2 IgG Antibody - CHEMILUMINESCENCE Herpes Simplex Virus Type 1+2 IgM Antibody - CHEMILUMINESCENCE HIV 1/2 Ag/Ab Combo (CHIV) - CHEMILUMINESCENCE HIV 1/2 Ag/Ab Combo (CHIV) - CHEMILUMINESCENCE HIV-1 Antibody Supplemental, Geenius - IMMUNOCHROMATOGRAPHIC HIV-2 Antibody Supplemental - IMMUNOCHROMATOGRAPHIC HIV-2 RNA – RT-PCR This test is CE-marked for the intended use. HIMUNOCHROMATOGRAPHIC HIV-2 RNA – RT-PCR This test is CE-marked for the intended use. Immunoglobulin G – CHEMISTRY COBAS C 701/702 This test is CE-marked for the intended use. Liver Kidney Microsome Antibody – ENZYME IMMUNOASSAY Polyomavirus JC – RT PCR This test is CE-marked for the intended use. This test is CE-marked	HBV DNA – RT-PCR COBAS 6800	This test is CE-marked for the intended use.
Hematology Hemogram Panel – VARIES BY ANALYTE Hepatitis A IgM Antibody - CHEMILUMINESCENCE Hepatitis B Core IgM Antibody - CHEMILUMINESCENCE Hepatitis B Core Total - CHEMILUMINESCENCE Hepatitis B Surface Antigen II - CHEMILUMINESCENCE Hepatitis B Surface Antigen II - CHEMILUMINESCENCE Hepatitis B Surface Antigen II - CHEMILUMINESCENCE Hepatitis C Virus Antibody - CHEMILUMINESCENCE Hepatitis E IgM Antibody - ENZYME IMMUNOASSAY Herpets Simplex Virus Type 1 IgG Antibody - Herpets Simplex Virus Type 1 IgG Antibody - Herpes Simplex Virus Type 2 IgG Antibody - Herpes Simplex Virus Type 2 IgG Antibody - Herpes Simplex Virus Type 1+2 IgM Antibody - HiV-1 Antibody Supplemental, Geenius - IMMUNOCHROMATOGRAPHIC HIV-1 RNA - RT-PCR HIV-2 Antibody Supplemental - IMMUNOCHROMATOGRAPHIC HIV-2 RNA - RT-PCR This test is CE-marked for the intended use. Immunoglobulin G - CHEMISTRY COBAS C 701/702 This test is CE-marked for the intended use. Liver Kidney Microsome Antibody - ENZYME IMMUNOASSAY Polyomavirus JC - RT PCR This test is CE-marked for the intended use. This test is CE-marked	HCV RNA – RT-PCR COBAS 680	This test is CE-marked for the intended use.
Hepatitis A IgM Antibody - CHEMILUMINESCENCE Hepatitis B Core IgM Antibody - CHEMILUMINESCENCE Hepatitis B Core Total - CHEMILUMINESCENCE Hepatitis B Surface Antigen II - CHEMILUMINESCENCE Hepatitis B Surface Antigen II - CHEMILUMINESCENCE Hepatitis C Virus Antibody - CHEMILUMINESCENCE Hepatitis C Virus Antibody - CHEMILUMINESCENCE Hepatitis E IgM Antibody - CHEMILUMINESCENCE Hepatitis E IgM Antibody - CHEMILUMINESCENCE Hepatitis E IgM Antibody - ENZYME IMMUNOASSAY Herpes Simplex Virus Type 1 IgG Antibody - CHEMILUMINESCENCE Herpes Simplex Virus Type 2 IgG Antibody - CHEMILUMINESCENCE Herpes Simplex Virus Type 2 IgG Antibody - CHEMILUMINESCENCE Herpes Simplex Virus Type 1+2 IgM Antibody - CHEMILUMINESCENCE Herpes Simplex Virus Type 1+2 IgM Antibody - CHEMILUMINESCENCE HIV 1/2 Ag/Ab Combo (CHIV) - CHEMILUMINESCENCE HIV 1/2 Ag/Ab Combo (CHIV) - CHEMILUMINESCENCE HIV-1 Antibody Supplemental, Geenius - IMMUNOCHROMATOGRAPHIC HIV-2 RNA - RT-PCR This test is CE-marked for the intended use. HIV-2 Antibody Supplemental - IMMUNOCHROMATOGRAPHIC HIV-2 RNA - RT-PCR This test is CE-marked for the intended use. Immunoglobulin G - CHEMISTRY COBAS C 701/702 This test is CE-marked for the intended use. Immunoglobulin G - CHEMISTRY COBAS C 701/702 Inis test is CE-marked for the intended use. International Normalized Ratio - CLOT DETECTION This test is CE-marked for the intended use. International Normalized Ratio - CLOT DETECTION This test is CE-marked for the intended use. Immunoglobulin M - CHEMISTRY COBAS C 701/702 This test is CE-marked for the intended use. International Normalized Ratio - CLOT DETECTION This test is CE-marked for the intended use. International Normalized Ratio - CLOT DETECTION This test is CE-marked for the intended use. International Normalized Ratio - CLOT DETECTION This test is CE-marked for the intended use. International Normalized Ratio - CLOT DETECTION This test is CE-marked for the intended use. International Normalized Ratio - CLOT DETECTION This test is CE-marked for the intended use. This t	Hematology Differential – LIGHT SCATTERING	This test is CE-marked for the intended use.
Hepatitis B Core IgM Antibody - CHEMILUMINESCENCE Hepatitis B Surface Antigen II - CHEMILUMINESCENCE Hepatitis C Virus Antibody - CHEMILUMINESCENCE Hepatitis C Virus Antibody - CHEMILUMINESCENCE Hepatitis E IgM Antibody - ENZYME IMMUNOASSAY Hepatitis E IgM Antibody - ENZYME IMMUNOASSAY Hepatitis E IgM Antibody - ENZYME IMMUNOASSAY Herpes Simplex Virus Type 1 IgG Antibody - CHEMILUMINESCENCE Herpes Simplex Virus Type 2 IgG Antibody - CHEMILUMINESCENCE Herpes Simplex Virus Type 1+2 IgM Antibody - CHEMILUMINESCENCE Herpes Simplex Virus Type 1+2 IgM Antibody - CHEMILUMINESCENCE HIV 1/2 Ag/Ab Combo (CHIV) - CHEMILUMINESCENCE HIV-1 Antibody Supplemental, Geenius - IMMUNOCHROMATOGRAPHIC HIV-2 Antibody Supplemental — HIV-2 RIP Antibody Supplemental — HIV	Hematology Hemogram Panel – VARIES BY ANALYTE	This test is CE-marked for the intended use.
Hepatitis B Core Total - CHEMILUMINESCENCE Hepatitis B Surface Antigen II - CHEMILUMINESCENCE Hepatitis C Virus Antibody - CHEMILUMINESCENCE Hepatitis E IgM Antibody - ENZYME IMMUNOASSAY Herpes Simplex Virus Type 1 IgG Antibody - CHEMILUMINESCENCE Herpes Simplex Virus Type 2 IgG Antibody - CHEMILUMINESCENCE Herpes Simplex Virus Type 2 IgG Antibody - CHEMILUMINESCENCE Herpes Simplex Virus Type 1+2 IgM Antibody - CHEMILUMINESCENCE Herpes Simplex Virus Type 1+2 IgM Antibody - CHEMILUMINESCENCE Herpes Simplex Virus Type 1+2 IgM Antibody - CHEMILUMINESCENCE HIV 1/2 Ag/Ab Combo (CHIV) - CHEMILUMINESCENCE HIV-1 Antibody Supplemental, Geenius - IMMUNOCHROMATOGRAPHIC HIV-1 RNA - RT-PCR This test is CE-marked for the intended use. IMMUNOCHROMATOGRAPHIC HIV-2 Antibody Supplemental - IIMV-2 RNA - RT-PCR This test is CE-marked for the intended use. Immunoglobulin G - CHEMISTRY COBAS C 701/702 This test is CE-marked for the intended use. International Normalized Ratio - CLOT DETECTION This test is CE-marked for the intended use. IIMMUNOASSAY Polyomavirus JC - RT PCR This test is CE-marked for the intended use. IIMMUNOASSAY This test is CE-marked for the intended use. IIIMMUNOASSAY This test is CE-marked for the intended use. IIIMMUNOASSAY This test is CE-marked for the intended use. IIIMMUNOASSAY This test is CE-marked for the intended use. IIIMMUNOASSAY This test is CE-marked for the intended use. IIIMMUNOASSAY This test is CE-marked for the intended use. IIIMMUNOASSAY This test is CE-marked for the intended use. IIMMUNOASSAY This test is CE-marked for the intended use. IIMMUNOASSAY This test is CE-marked for the intended use. IIMMUNOASSAY This test is CE-marked for the intended use. IIMMUNOASSAY This test is CE-marked for the intended use. IIMMUNOASSAY This test is CE-marked for the intended use. IIMMUNOASSAY This test is CE-marked for the intended use. IIMMUNOASSAY This test is CE-marked for the intended use. IIMMUNOASSAY This test is CE-marked for the intended use. IIMMUNOASSAY This test is CE-marked for the intended use	Hepatitis A IgM Antibody - CHEMILUMINESCENCE	This test is CE-marked for the intended use.
Hepatitis B Surface Antigen II - CHEMILUMINESCENCE Hepatitis C Virus Antibody - CHEMILUMINESCENCE Hepatitis E IgM Antibody - ENZYME IMMUNOASSAY Herpes Simplex Virus Type 1 IgG Antibody - CHEMILUMINESCENCE Herpes Simplex Virus Type 2 IgG Antibody - CHEMILUMINESCENCE Herpes Simplex Virus Type 2 IgG Antibody - CHEMILUMINESCENCE Herpes Simplex Virus Type 1+2 IgM Antibody - CHEMILUMINESCENCE Herpes Simplex Virus Type 1+2 IgM Antibody - CHEMILUMINESCENCE Herpes Simplex Virus Type 1+2 IgM Antibody - CHEMILUMINESCENCE HIV 1/2 Ag/Ab Combo (CHIV) - CHEMILUMINESCENCE HIV 1/2 Ag/Ab Combo (CHIV) - CHEMILUMINESCENCE HIV-1 Antibody Supplemental, Geenius - IMMUNOCHROMATOGRAPHIC HIV-2 Antibody Supplemental - IMMUNOCHROMATOGRAPHIC HIV-2 Antibody Supplemental - IMMUNOCHROMATOGRAPHIC HIV-2 RNA - RT-PCR This test is CE-marked for the intended use. Immunoglobulin G - CHEMISTRY COBAS C 701/702 This test is CE-marked for the intended use. International Normalized Ratio - CLOT DETECTION Liver Kidney Microsome Antibody - ENZYME IMMUNOASSAY Polyomavirus JC - RT PCR This test is CE-marked for the intended use. This test is CE-marked fo	Hepatitis B Core IgM Antibody - CHEMILUMINESCENCE	This test is CE-marked for the intended use.
Hepatitis C Virus Antibody - CHEMILUMINESCENCE Hepatitis E IgM Antibody - ENZYME IMMUNOASSAY Herpes Simplex Virus Type 1 IgG Antibody - CHEMILUMINESCENCE Herpes Simplex Virus Type 2 IgG Antibody - CHEMILUMINESCENCE Herpes Simplex Virus Type 2 IgG Antibody - CHEMILUMINESCENCE Herpes Simplex Virus Type 1+2 IgM Antibody - CHEMILUMINESCENCE Herpes Simplex Virus Type 1+2 IgM Antibody - CHEMILUMINESCENCE Herpes Simplex Virus Type 1+2 IgM Antibody - CHEMILUMINESCENCE HIV 1/2 Ag/Ab Combo (CHIV) - CHEMILUMINESCENCE HIV-1 Antibody Supplemental, Geenius - IMMUNOCHROMATOGRAPHIC HIV-1 RNA - RT-PCR This test is CE-marked for the intended use. HIV-2 Antibody Supplemental - IMMUNOCHROMATOGRAPHIC HIV-2 RNA - RT-PCR This test is CE-marked for the intended use. Immunoglobulin G - CHEMISTRY COBAS C 701/702 This test is CE-marked for the intended use. International Normalized Ratio - CLOT DETECTION Liver Kidney Microsome Antibody - ENZYME IMMUNOASSAY Polyomavirus JC - RT PCR This test is CE-marked for the intended use. Prothrombin Time - CLOT DETECTION This test is CE-marked for the intended use. This test is CE-marked for the intended use. Reticulocyte Count - FLOW CYTOMETRY This test is CE-marked for the intended use.	Hepatitis B Core Total - CHEMILUMINESCENCE	This test is CE-marked for the intended use.
Hepatitis E IgM Antibody – ENZYME IMMUNOASSAY Herpes Simplex Virus Type 1 IgG Antibody - CHEMILUMINESCENCE Herpes Simplex Virus Type 2 IgG Antibody - CHEMILUMINESCENCE Herpes Simplex Virus Type 1+2 IgM Antibody - CHEMILUMINESCENCE Herpes Simplex Virus Type 1+2 IgM Antibody - CHEMILUMINESCENCE HIV 1/2 Ag/Ab Combo (CHIV) - CHEMILUMINESCENCE HIV-1 Antibody Supplemental, Geenius - IMMUNOCHROMATOGRAPHIC HIV-1 RNA – RT-PCR This test is CE-marked for the intended use. HIV-2 Antibody Supplemental - IMMUNOCHROMATOGRAPHIC HIV-2 RNA – RT-PCR This test is CE-marked for the intended use. Immunoglobulin G – CHEMISTRY COBAS C 701/702 This test is CE-marked for the intended use. Immunoglobulin M – CHEMISTRY COBAS C 701/702 This test is CE-marked for the intended use. Liver Kidney Microsome Antibody – ENZYME IMMUNOASSAY Polyomavirus JC – RT PCR Prothrombin Time – CLOT DETECTION This test is CE-marked for the intended use. QuantifERON-TB Gold Plus – ENZYME IMMUNOASSAY This test is CE-marked for the intended use. This test is CE-marked for the intended use. QuantifERON-TB Gold Plus – ENZYME IMMUNOASSAY This test is CE-marked for the intended use. QuantifERON-TB Gold Plus – ENZYME IMMUNOASSAY This test is CE-marked for the intended use. QuantifERON-TB Gold Plus – ENZYME IMMUNOASSAY This test is CE-marked for the intended use. QuantifERON-TB Gold Plus – ENZYME IMMUNOASSAY This test is CE-marked for the intended use. This test is CE-marked for the intended use. QuantifERON-TB Gold Plus – ENZYME IMMUNOASSAY This test is CE-marked for the intended use. QuantifERON-TB Gold Plus – ENZYME IMMUNOASSAY This test is CE-marked for the intended use. This test is CE-marked for the intended use. This test is CE-marked for the intended use.	Hepatitis B Surface Antigen II - CHEMILUMINESCENCE	This test is CE-marked for the intended use.
Herpes Simplex Virus Type 1 IgG Antibody - CHEMILUMINESCENCE Herpes Simplex Virus Type 2 IgG Antibody - CHEMILUMINESCENCE Herpes Simplex Virus Type 1+2 IgM Antibody - CHEMILUMINESCENCE Hiver Simplex Virus Type 1+2 IgM Antibody - CHEMILUMINESCENCE HIV 1/2 Ag/Ab Combo (CHIV) - CHEMILUMINESCENCE HIV-1 Antibody Supplemental, Geenius - IMMUNOCHROMATOGRAPHIC HIV-1 RNA - RT-PCR This test is CE-marked for the intended use. HIV-2 Antibody Supplemental - IMMUNOCHROMATOGRAPHIC HIV-2 Antibody Supplemental - IMMUNOCHROMATOGRAPHIC HIV-2 Antibody Supplemental - IMMUNOCHROMATOGRAPHIC HIV-2 Intibody Supplemental - IThis test is CE-marked for the intended use. Intibody Supplemental - IThis test is CE-marked for the intended use. Intibody Supplemental - IThis test is CE-marked for the intended use. Intibody Supplemental - IThis test is CE-marked for the intended use. Intibody Supplemental - IThis test is CE-marked for the intended use. Intibody Supplemental - IThis test is CE-marked for the intended use. Intibody Supplemental - IThis test is CE-marked for the intended use. Intibody Supplemental - IThis test is CE-marked for the intended use. Intibody Supplemental - IThis test is CE-marked for the intended use. Intibody Supplemental - ITHIS test is CE-marked for the intended use. Intibody Supplemental - ITH	Hepatitis C Virus Antibody - CHEMILUMINESCENCE	This test is CE-marked for the intended use.
CHEMILUMINESCENCE Herpes Simplex Virus Type 2 IgG Antibody - CHEMILUMINESCENCE Herpes Simplex Virus Type 1+2 IgM Antibody - CHEMILUMINESCENCE HIV 1/2 Ag/Ab Combo (CHIV) - CHEMILUMINESCENCE HIV-1 Antibody Supplemental, Geenius - IMMUNOCHROMATOGRAPHIC HIV-1 RNA - RT-PCR This test is CE-marked for the intended use. HIV-2 Antibody Supplemental - IMMUNOCHROMATOGRAPHIC HIV-2 Intibody Supplemental - INTIBODY Suppl	Hepatitis E IgM Antibody – ENZYME IMMUNOASSAY	This test is CE-marked for the intended use.
Herpes Simplex Virus Type 2 IgG Antibody - CHEMILUMINESCENCE Herpes Simplex Virus Type 1+2 IgM Antibody - CHEMILUMINESCENCE HIV 1/2 Ag/Ab Combo (CHIV) - CHEMILUMINESCENCE HIV-1 Antibody Supplemental, Geenius - IMMUNOCHROMATOGRAPHIC HIV-1 RNA - RT-PCR This test is CE-marked for the intended use. HIV-2 Antibody Supplemental - IMMUNOCHROMATOGRAPHIC HIV-2 RNA - RT-PCR This test is CE-marked for the intended use. Immunoglobulin G - CHEMISTRY COBAS C 701/702 International Normalized Ratio - CLOT DETECTION Liver Kidney Microsome Antibody - ENZYME IMMUNOASSAY Polyomavirus JC - RT PCR This test is CE-marked for the intended use.	Herpes Simplex Virus Type 1 IgG Antibody -	This test is CE-marked for the intended use.
CHEMILUMINESCENCE Herpes Simplex Virus Type 1+2 IgM Antibody - CHEMILUMINESCENCE HIV 1/2 Ag/Ab Combo (CHIV) - CHEMILUMINESCENCE HIV-1 Antibody Supplemental, Geenius - Improved Intervence Interven		
Herpes Simplex Virus Type 1+2 IgM Antibody - CHEMILUMINESCENCE HIV 1/2 Ag/Ab Combo (CHIV) - CHEMILUMINESCENCE HIV-1 Antibody Supplemental, Geenius - IMMUNOCHROMATOGRAPHIC HIV-2 Antibody Supplemental — IMMUNOCHROMATOGRAPHIC HIV-2 RNA — RT-PCR This test is CE-marked for the intended use. HIW-1 RNA — RT-PCR This test is CE-marked for the intended use. Immunoglobulin G — CHEMISTRY COBAS C 701/702 This test is CE-marked for the intended use. International Normalized Ratio — CLOT DETECTION This test is CE-marked for the intended use. Liver Kidney Microsome Antibody — ENZYME IMMUNOASSAY Polyomavirus JC — RT PCR This testing will be performed at a laboratory within Europe that qualifies for in-house testing exemption under Article 5(5) of EU IVDR. Prothrombin Time — CLOT DETECTION This test is CE-marked for the intended use. QuantiFERON-TB Gold Plus — ENZYME IMMUNOASSAY Reticulocyte Count — FLOW CYTOMETRY This test is CE-marked for the intended use. Total Iron — CHEMISTRY COBAS C 701/702 This test is CE-marked for the intended use. Total Iron — CHEMISTRY COBAS C 701/702 This test is CE-marked for the intended use.	, , , , , , , , , , , , , , , , , , , ,	This test is CE-marked for the intended use.
CHEMILUMINESCENCE HIV 1/2 Ag/Ab Combo (CHIV) - CHEMILUMINESCENCE HIV-1 Antibody Supplemental, Geenius - IMMUNOCHROMATOGRAPHIC HIV-1 RNA - RT-PCR This test is CE-marked for the intended use. HIV-2 Antibody Supplemental - IMMUNOCHROMATOGRAPHIC HIV-2 RNA - RT-PCR This test is CE-marked for the intended use. HIW-1 RNA - RT-PCR This test is CE-marked for the intended use. IMMUNOCHROMATOGRAPHIC HIV-2 RNA - RT-PCR This test is CE-marked for the intended use. Immunoglobulin G - CHEMISTRY COBAS C 701/702 This test is CE-marked for the intended use. International Normalized Ratio - CLOT DETECTION This test is CE-marked for the intended use. Liver Kidney Microsome Antibody - ENZYME IMMUNOASSAY Polyomavirus JC - RT PCR This testing will be performed at a laboratory within Europe that qualifies for in-house testing exemption under Article 5(5) of EU IVDR. Prothrombin Time - CLOT DETECTION This test is CE-marked for the intended use. QuantiFERON-TB Gold Plus - ENZYME IMMUNOASSAY Reticulocyte Count - FLOW CYTOMETRY This test is CE-marked for the intended use. Total Iron - CHEMISTRY COBAS C 701/702 This test is CE-marked for the intended use. Total Iron - CHEMISTRY COBAS C 701/702 This test is CE-marked for the intended use.		This test is CC assumed for the integral of the
HIV 1/2 Ag/Ab Combo (CHIV) - CHEMILUMINESCENCE HIV-1 Antibody Supplemental, Geenius - IMMUNOCHROMATOGRAPHIC HIV-1 RNA – RT-PCR HIV-2 Antibody Supplemental – IMMUNOCHROMATOGRAPHIC HIV-2 Antibody Supplemental – IMMUNOCHROMATOGRAPHIC HIV-2 RNA – RT-PCR This test is CE-marked for the intended use. HIV-2 RNA – RT-PCR This test is CE-marked for the intended use. Immunoglobulin G – CHEMISTRY COBAS C 701/702 International Normalized Ratio – CLOT DETECTION Liver Kidney Microsome Antibody – ENZYME IMMUNOASSAY Polyomavirus JC – RT PCR Prothrombin Time – CLOT DETECTION This test is CE-marked for the intended use.		This test is CE-marked for the intended use.
HIV-1 Antibody Supplemental, Geenius - IMMUNOCHROMATOGRAPHIC HIV-1 RNA – RT-PCR HIV-2 Antibody Supplemental – IMMUNOCHROMATOGRAPHIC HIV-2 Antibody Supplemental – IMMUNOCHROMATOGRAPHIC HIV-2 RNA – RT-PCR This test is CE-marked for the intended use. Immunoglobulin G – CHEMISTRY COBAS C 701/702 Immunoglobulin M – CHEMISTRY COBAS C 701/702 International Normalized Ratio – CLOT DETECTION Liver Kidney Microsome Antibody – ENZYME IMMUNOASSAY Polyomavirus JC – RT PCR Prothrombin Time – CLOT DETECTION Prothrombin Time – CLOT DETECTION This test is CE-marked for the intended use. Quantiferon-TB Gold Plus – ENZYME IMMUNOASSAY Reticulocyte Count – FLOW CYTOMETRY This test is CE-marked for the intended use.		This test is CF-marked for the intended use
IMMUNOCHROMATOGRAPHIC HIV-1 RNA – RT-PCR This test is CE-marked for the intended use. HIV-2 Antibody Supplemental – IMMUNOCHROMATOGRAPHIC HIV-2 RNA – RT-PCR This test is CE-marked for the intended use. Immunoglobulin G – CHEMISTRY COBAS C 701/702 Immunoglobulin M – CHEMISTRY COBAS C 701/702 International Normalized Ratio – CLOT DETECTION Liver Kidney Microsome Antibody – ENZYME IMMUNOASSAY Polyomavirus JC – RT PCR Prothrombin Time – CLOT DETECTION This test is CE-marked for the intended use. This testing will be performed at a laboratory within Europe that qualifies for in-house testing exemption under Article 5(5) of EU IVDR. Prothrombin Time – CLOT DETECTION This test is CE-marked for the intended use. QuantiFERON-TB Gold Plus – ENZYME IMMUNOASSAY Reticulocyte Count – FLOW CYTOMETRY This test is CE-marked for the intended use. Total Iron – CHEMISTRY COBAS C 701/702 This test is CE-marked for the intended use. Total Iron – CHEMISTRY COBAS C 701/702 This test is CE-marked for the intended use. Total Iron – CHEMISTRY COBAS C 701/702 This test is CE-marked for the intended use.		
HIV-1 RNA – RT-PCR HIV-2 Antibody Supplemental – IMMUNOCHROMATOGRAPHIC HIV-2 RNA – RT-PCR This test is CE-marked for the intended use. Immunoglobulin G – CHEMISTRY COBAS C 701/702 Immunoglobulin M – CHEMISTRY COBAS C 701/702 International Normalized Ratio – CLOT DETECTION Liver Kidney Microsome Antibody – ENZYME IMMUNOASSAY Polyomavirus JC – RT PCR Prothrombin Time – CLOT DETECTION This test is CE-marked for the intended use. This testing will be performed at a laboratory within Europe that qualifies for in-house testing exemption under Article 5(5) of EU IVDR. Prothrombin Time – CLOT DETECTION This test is CE-marked for the intended use. QuantiFERON-TB Gold Plus – ENZYME IMMUNOASSAY Reticulocyte Count – FLOW CYTOMETRY This test is CE-marked for the intended use. SARS-COV2 Qualitative – RT-PCR This test is CE-marked for the intended use. Total Iron – CHEMISTRY COBAS C 701/702 This test is CE-marked for the intended use.		
IMMUNOCHROMATOGRAPHIC HIV-2 RNA – RT-PCR Immunoglobulin G – CHEMISTRY COBAS C 701/702 Immunoglobulin M – CHEMISTRY COBAS C 701/702 International Normalized Ratio – CLOT DETECTION Liver Kidney Microsome Antibody – ENZYME IMMUNOASSAY Polyomavirus JC – RT PCR Prothrombin Time – CLOT DETECTION This test is CE-marked for the intended use. This testing will be performed at a laboratory within Europe that qualifies for in-house testing exemption under Article 5(5) of EU IVDR. Prothrombin Time – CLOT DETECTION This test is CE-marked for the intended use. QuantiFERON-TB Gold Plus – ENZYME IMMUNOASSAY Reticulocyte Count – FLOW CYTOMETRY This test is CE-marked for the intended use. SARS-CoV2 Qualitative – RT-PCR This test is CE-marked for the intended use. Total Iron – CHEMISTRY COBAS C 701/702 This test is CE-marked for the intended use.		This test is CE-marked for the intended use.
HIV-2 RNA – RT-PCR Immunoglobulin G – CHEMISTRY COBAS C 701/702 Immunoglobulin M – CHEMISTRY COBAS C 701/702 International Normalized Ratio – CLOT DETECTION Liver Kidney Microsome Antibody – ENZYME IMMUNOASSAY Polyomavirus JC – RT PCR Prothrombin Time – CLOT DETECTION Prothrombin Time – CLOT DETECTION This test is CE-marked for the intended use. QuantiFERON-TB Gold Plus – ENZYME IMMUNOASSAY Reticulocyte Count – FLOW CYTOMETRY This test is CE-marked for the intended use.	HIV-2 Antibody Supplemental –	This test is CE-marked for the intended use.
Immunoglobulin G - CHEMISTRY COBAS C 701/702 This test is CE-marked for the intended use.	IMMUNOCHROMATOGRAPHIC	
International Normalized Ratio – CLOT DETECTION Liver Kidney Microsome Antibody – ENZYME IMMUNOASSAY Polyomavirus JC – RT PCR Prothrombin Time – CLOT DETECTION Reticulocyte Count – FLOW CYTOMETRY SARS-CoV2 Qualitative – RT-PCR International Normalized Ratio – CLOT DETECTION This test is CE-marked for the intended use. This test is CE-marked for the intended use. This testing will be performed at a laboratory within Europe that qualifies for in-house testing exemption under Article 5(5) of EU IVDR. This test is CE-marked for the intended use.	HIV-2 RNA – RT-PCR	This test is CE-marked for the intended use.
International Normalized Ratio – CLOT DETECTION Liver Kidney Microsome Antibody – ENZYME IMMUNOASSAY Polyomavirus JC – RT PCR Prothrombin Time – CLOT DETECTION QuantiFERON-TB Gold Plus – ENZYME IMMUNOASSAY Reticulocyte Count – FLOW CYTOMETRY This test is CE-marked for the intended use. Total Iron – CHEMISTRY COBAS C 701/702 This test is CE-marked for the intended use.	Immunoglobulin G – CHEMISTRY COBAS C 701/702	This test is CE-marked for the intended use.
Liver Kidney Microsome Antibody – ENZYME IMMUNOASSAY Polyomavirus JC – RT PCR This testing will be performed at a laboratory within Europe that qualifies for in-house testing exemption under Article 5(5) of EU IVDR. Prothrombin Time – CLOT DETECTION This test is CE-marked for the intended use. QuantiFERON-TB Gold Plus – ENZYME IMMUNOASSAY Reticulocyte Count – FLOW CYTOMETRY This test is CE-marked for the intended use. SARS-CoV2 Qualitative – RT-PCR This test is CE-marked for the intended use. Total Iron – CHEMISTRY COBAS C 701/702 This test is CE-marked for the intended use.	Immunoglobulin M – CHEMISTRY COBAS C 701/702	
Polyomavirus JC – RT PCR This testing will be performed at a laboratory within Europe that qualifies for in-house testing exemption under Article 5(5) of EU IVDR. Prothrombin Time – CLOT DETECTION QuantiFERON-TB Gold Plus – ENZYME IMMUNOASSAY Reticulocyte Count – FLOW CYTOMETRY SARS-CoV2 Qualitative – RT-PCR Total Iron – CHEMISTRY COBAS C 701/702 This test is CE-marked for the intended use. This test is CE-marked for the intended use. Total Iron – CHEMISTRY COBAS C 701/702 This test is CE-marked for the intended use.	International Normalized Ratio – CLOT DETECTION	This test is CE-marked for the intended use.
Europe that qualifies for in-house testing exemption under Article 5(5) of EU IVDR. Prothrombin Time – CLOT DETECTION QuantiFERON-TB Gold Plus – ENZYME IMMUNOASSAY Reticulocyte Count – FLOW CYTOMETRY SARS-CoV2 Qualitative – RT-PCR Total Iron – CHEMISTRY COBAS C 701/702 This test is CE-marked for the intended use. Total Iron – CHEMISTRY COBAS C 701/702 This test is CE-marked for the intended use.	·	This test is CE-marked for the intended use.
under Article 5(5) of EU IVDR. Prothrombin Time – CLOT DETECTION This test is CE-marked for the intended use. QuantiFERON-TB Gold Plus – ENZYME IMMUNOASSAY This test is CE-marked for the intended use. Reticulocyte Count – FLOW CYTOMETRY This test is CE-marked for the intended use. SARS-CoV2 Qualitative – RT-PCR This test is CE-marked for the intended use. Total Iron – CHEMISTRY COBAS C 701/702 This test is CE-marked for the intended use.	Polyomavirus JC – RT PCR	This testing will be performed at a laboratory within
Prothrombin Time – CLOT DETECTION QuantiFERON-TB Gold Plus – ENZYME IMMUNOASSAY This test is CE-marked for the intended use. Reticulocyte Count – FLOW CYTOMETRY This test is CE-marked for the intended use. SARS-CoV2 Qualitative – RT-PCR This test is CE-marked for the intended use. Total Iron – CHEMISTRY COBAS C 701/702 This test is CE-marked for the intended use.		Europe that qualifies for in-house testing exemption
QuantiFERON-TB Gold Plus – ENZYME IMMUNOASSAYThis test is CE-marked for the intended use.Reticulocyte Count – FLOW CYTOMETRYThis test is CE-marked for the intended use.SARS-CoV2 Qualitative – RT-PCRThis test is CE-marked for the intended use.Total Iron – CHEMISTRY COBAS C 701/702This test is CE-marked for the intended use.		under Article 5(5) of EU IVDR.
Reticulocyte Count – FLOW CYTOMETRY SARS-CoV2 Qualitative – RT-PCR Total Iron – CHEMISTRY COBAS C 701/702 This test is CE-marked for the intended use. Total Section 1 This test is CE-marked for the intended use.	Prothrombin Time – CLOT DETECTION	This test is CE-marked for the intended use.
SARS-CoV2 Qualitative – RT-PCR This test is CE-marked for the intended use. Total Iron – CHEMISTRY COBAS C 701/702 This test is CE-marked for the intended use.	QuantiFERON-TB Gold Plus – ENZYME IMMUNOASSAY	This test is CE-marked for the intended use.
Total Iron – CHEMISTRY COBAS C 701/702 This test is CE-marked for the intended use.	Reticulocyte Count – FLOW CYTOMETRY	This test is CE-marked for the intended use.
·	SARS-CoV2 Qualitative – RT-PCR	This test is CE-marked for the intended use.
Total Iron Binding Capacity - CALCULATION This test is CE-marked for the intended use.	Total Iron – CHEMISTRY COBAS C 701/702	This test is CE-marked for the intended use.
	Total Iron Binding Capacity - CALCULATION	This test is CE-marked for the intended use.

Toxoplasma Antibody IgG - CHEMILUMINESCENCE	This test is CE-marked for the intended use.
Toxoplasma Antibody IgM - CHEMILUMINESCENCE	This test is CE-marked for the intended use.
Unsaturated Iron-Binding Capacity – CHEMISTRY COBAS C701/702	This test is CE-marked for the intended use.
Urinalysis, Dipstick – REFLECTANCE PHOTOMETRY	This test is CE-marked for the intended use.
Urinalysis, Microscopic – MICROSCOPIC ANALYZER	This test is CE-marked for the intended use.

Specificities

Local pre-Scientific Advice meeting according to KBPV has not taken place in Germany Radiation protection assessment by Ethics Committee is not required in Germany

The proposed Ethics Committee for Italy is:

Comitato Etico Territoriale della Regione Siciliana

email: cetsicilia@policlinico.pa.it

Stamp duty virtually paid pursuant to Art. 15 of DPR 642 of 26.10.1972, authorization no. 267351 of 9.11.2020 issued by the Revenue Agency, provincial direction of Milan 2

The proposed Ethics Committee for Netherlands is:

MREC Z, mevrouw mr. S.A.E., Vanhouwe, PO Box 5500, 6130 MB Sittard, The Netherlands, +31 88 459 01 2, metc@zuyderland.nl

The proposed Ethics Committee for Spain is:

CEIm Parc, TauliParx, Taulu, 1-Edifici Santa Fe, ala izquierda planta 2a, localided: Sadabell CP: 08208

REec user: <u>es-reg-estudiosclinicos@sanofi.com</u>