



Organisme belge d'Accréditation  
Belgische Accreditatieinstelling  
Belgische Akkreditierungsstelle  
Belgian Accreditation Body

EA MLA Signatory

## Certificat d'Accréditation n° 653-TEST

En application des dispositions de l'arrêté royal du 31 janvier 2006 créant BELAC, le Bureau d'Accréditation atteste avoir délivré une accréditation conformément aux exigences de la norme EN ISO/IEC 17025:2017 à:

**Pfizer sa**  
**Boulevard de la Plaine 17**  
**1050 Ixelles**

L'organisme a démontré posséder la compétence pour effectuer les activités réalisées dans les sites d'activités mentionnés dans la portée d'accréditation 653-TEST qui fait partie intégrante du présent certificat.

La version en vigueur de la portée d'accréditation est disponible via [www.belac.be](http://www.belac.be).

Ce certificat reste valable à condition que l'organisme continue de répondre aux conditions d'accréditation.

La Présidente du Bureau d'Accréditation BELAC,

Maureen LOGGHE

Version : 3

Période de validité : 2022-12-12 - 2027-12-11



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## Accreditatiecertificaat nr. 653-TEST

In uitvoering van de beschikkingen van het koninklijk besluit van 31 januari 2006 tot oprichting van BELAC, verklaart het Accreditatiebureau accreditatie conform de eisen van de norm EN ISO/IEC 17025:2017 te hebben verleend aan:

**Pfizer sa**  
**Boulevard de la Plaine 17**  
**1050 Ixelles**

De instelling heeft aangetoond bekwaamheid te bezitten voor de activiteiten uitgevoerd in de activiteitencentra zoals gespecificeerd in de accreditatiescope 653-TEST die integraal deel uitmaakt van dit certificaat.

De huidige versie van de accreditatiescope is beschikbaar op [www.belac.be](http://www.belac.be).

Dit certificaat blijft geldig onder voorwaarde dat de instelling blijft voldoen aan de accreditatievoorwaarden.

De Voorzitster van het Accreditatiebureau BELAC,

Maureen LOGGHE

**Versie** : **3**

**Geldigheidsduur** : **2022-12-12 - 2027-12-11**

*De originele versie van dit certificaat is in het Frans.*



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## Accreditation Certificate No. 653-TEST

In compliance with the provisions of the Royal Decree of 31 January 2006 setting up BELAC, the Accreditation Board hereby declares to have granted accreditation conform the requirements of the standard EN ISO/IEC 17025:2017 to:

**Pfizer sa**  
**Boulevard de la Plaine 17**  
**1050 Ixelles**

The body demonstrated the competence to perform the activities in the activity sites, as described in the scope of accreditation 653-TEST which is an integral part of the present certificate.

The current version of the scope of accreditation is available at [www.belac.be](http://www.belac.be).

This certificate remains valid as long as the body continues to meet the accreditation conditions.

The Chair of the Accreditation Board BELAC,

Maureen LOGGHE

**Version : 3**

**Validity period : 2022-12-12 - 2027-12-11**

*Original version of this certificate is in French.*



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## Akkreditierungszertifikat Nr. 653-TEST

Aufgrund der Bestimmungen des königlichen Erlasses vom 31. Januar 2006 zur Gründung von BELAC, bestätigt das Akkreditierungsbüro, gemäß den Vorschriften der Norm EN ISO/IEC 17025:2017, die folgende Stelle akkreditiert zu haben:

**Pfizer sa**  
**Boulevard de la Plaine 17**  
**1050 Ixelles**

Die Stelle hat ihre Kompetenz für die in den Aktivitätszentren durchgeführten Aktivitäten gemäß dem Geltungsbereich der Akkreditierung 653-TEST, der ein integraler Bestandteil des vorliegenden Zertifikats ist, nachgewiesen.

Die aktuelle Version des Geltungsbereichs der Akkreditierung ist unter [www.belac.be](http://www.belac.be) verfügbar.

Dieses Zertifikat bleibt unter der Bedingung gültig, dass die Stelle die Akkreditierungsanforderungen weiterhin erfüllt.

Die Vorsitzende des Akkreditierungsbüros BELAC,

Maureen LOGGHE

**Fassung** : **3**

**Gültigkeitsdauer** : **2022-12-12 - 2027-12-11**

*Die Originalfassung dieses Zertifikats ist in französischer Sprache.*



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Annexe au certificat d'accréditation  
Bijlage bij accreditatiecertificaat  
Annex to the accreditation certificate  
Beilage zur Akkreditierungszertifikat

# 653-TEST

EN ISO/IEC 17025:2017

Version / Versie / Version / Fassung	6
Validité / Geldigheidsperiode / Validity / Gültigkeitsdauer	2023-12-20 - 2027-12-11

## Maureen Logghe

La Présidente du Bureau d'Accréditation  
Voorzitster van het Accreditatiebureau  
Chair of the Accreditation Board  
Vorsitzende des Akkreditierungsbüro

L'accréditation est délivrée à / De accreditatie werd uitgereikt aan  
The accreditation is granted to / Die akkreditierung wurde erteilt für:

**Pfizer sa**  
**Boulevard de la Plaine 17**  
**1050 Ixelles**

Sites d'activités / Activiteitencentra / Sites of activities / Standorte mit aktivitäten:

Pfizer Clinical Research Unit Brussels (PCRU)	Route de Lennik 808 1070 Anderlecht
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Internal code	Test sample/ Product/ Matrix	Property determined/ Parameter determined/ Type of test	Standard specifications + Equipment or Techniques used
<b>CLINICAL TESTING</b>			
<b>HEMOSTASE / Procedure : BEL-BRLAB04-WI04 Sysmex CS-2500 Coagulation Analysis/Sysmex CS 2500</b>			
APTT	Plasma	Activated Partial Thromboplastin Time	Clotting time measurement after activation by phospholipids and calcium/Sysmex CS 2500
FIB	Plasma	Fibrinogen	Clotting time measurement after activation by thrombin/Sysmex CS 2500
PT/INR	Plasma	Prothrombine Time/International Normalized Ratio	Clotting time measurement after activation by thromboplastin and calcium/Sysmex CS 2500
D Dimer	Plasma	D-Dimer	Immunoturbidimetry/Sysmex CS 2500
<b>HEMATOLOGIE / Procedure : BEL-BRLAB04-WI03 Sysmex XN-1000 Hematology Analysis</b>			
RBC	Blood	Red Blood Cells	Impedance/Sysmex XN 1000
MCV	Blood	Mean Corpuscular Volume	Calculation/Sysmex XN 1000
PLT	Blood	Platelets	Impedance/Sysmex XN 1000
RETIC	Blood	Reticulocytes	Fluorescence Flow Cytometry/Sysmex XN 1000
MCHC	Blood	Mean Corpuscular Hemoglobin Concentration	Calculation/Sysmex XN 1000
WBC	Blood	White Blood Cells	Fluorescence Flow Cytometry/Sysmex XN 1000
BASO	Blood	Basophils	Fluorescence Flow Cytometry/Sysmex XN 1000
HGB	Blood	Hemoglobin	Photometry/Sysmex XN 1000
HCT	Blood	Hematocrit	Impedance/Sysmex XN 1000
LYMPH	Blood	Lymphocytes	Fluorescence Flow Cytometry/Sysmex XN 1000
MCH	Blood	Mean Corpuscular Hemoglobin	Calculation/Sysmex XN 1000
MONO	Blood	Monocytes	Fluorescence Flow Cytometry/Sysmex XN 1000
MPV	Blood	MPV	Calculation/Sysmex XN 1000
EO	Blood	Eosinophils	Fluorescence Flow Cytometry/Sysmex XN 1000
NEUT	Blood	Neutrophils	Fluorescence Flow Cytometry /Sysmex XN 1000

CHIMIE CLINIQUE / Procedure : BEL-BRLAB04-WI01 Cobas 6000 Chemistry and Immunology Analysis			
ALB	Serum	Albumin	Colorimetry(Vert de Bromocrésol)/Cobas 6000
ALP	Serum	Alkaline Phosphatase	Colorimetry (p-nitrophényl phosphate)/Cobas 6000
HCO3	Serum	Bicarbonate (CO2)	Enzymatic with phosphoenolpyruvate/Cobas 6000
BUN	Serum	Blood Urea Nitrogen	Kinetic Photometric (Urease/glutamatedeshydrogenase/ NADH)/Cobas 6000
CA	Serum	Calcium	Colorimetric Photometric/Cobas 6000
CL	Serum	Chloride	Indirect Potentiometric/Cobas 6000
U CL	Urine	Chloride	Indirect Potentiometric/Cobas 6000
CHOL	Serum	Cholesterol	Enzymatic Colorimetric/Cobas 6000
HDL	Serum	Cholesterol HDL	Enzymatic Colorimetric/Cobas 6000
LDL	Serum	Cholesterol LDL	Enzymatic Colorimetric/Cobas 6000
CK	Serum	Creatine Kinase	UV test /Cobas 6000
U CREA	Urine	Creatinine	Kinetic Colorimetric/Cobas 6000
CREA	Serum	Creatinine	Kinetic Colorimetric (Jaffé)/Cobas 6000
DBIL	Serum	Direct Bilirubin	Colorimetry (Diazoreaction)/Cobas 6000
GGT	Serum	Gamma Glutamyl Transferase	Enzymatic Colorimetric/Cobas 6000
GLUC	Plasma	Glucose	UV test Enzymatic (Hexokinase)/Cobas 6000
U GLUC	Urine	Glucose	UV test Enzymatic (Hexokinase)/Cobas 6000

AST	Serum	Aspartate aminotransferase	UV absorbance IFCC/Cobas 6000
ALT	Serum	Alanine aminotransferase	UV absorbance IFCC/Cobas 6000
MG	Serum	Magnesium	Colorometric/Cobas 6000
PHOS	Serum	Phosphorus	Photometric UV (phosphomolybdate)/Cobas 6000
U K	Urine	Potassium	Indirect Potentiometry Ion Selective Electrode/Cobas 6000
K	Serum	Potassium	Indirect Potentiometry Ion Selective Electrode/Cobas 6000
NA	Serum	Sodium	Indirect Potentiometry Ion Selective Electrode/Cobas 6000
U NA	Urine	Sodium	Indirect Potentiometry Ion Selective Electrode/Cobas 6000
TBIL	Serum	Total Bilirubin	Colorimetry Diazomethod/Cobas 6000
PT	Serum	Total Protein	Colorimetry Biuret method/Cobas 6000
U PRO	Urine	Total Protein	Turbidimetry/Cobas 6000
TRIG	Serum	Triglycerides	Enzymatic Colorimetry/Cobas 6000
UREA	Serum	Urea	Kinetic test (Urease et glutamate deshydrogenase)/Cobas 6000
URIC	Serum	Uric Acid	Enzymatic Colorimetry/Cobas 6000
CYS	Serum	Cystatine C	Immunoturbidimetry/Cobas 6000
U URIC	Urine	Uric Acid	Enzymatic Colorimetry/Cobas 6000
GLUC SERUM	Serum	Glucose	UV test Enzymatic (Hexokinase)/Cobas 6000
NEFA	Serum	Non-Esterified Fatty Acids	Colorimetry/Cobas 6000
HSCRIP	Serum	High Sensitive C-Reactive Protein	Immunoturbidimetry/Cobas 6000
Lipase	Serum	Lipase	Enzymatic colorimetric / Cobas 6000
Amylase	Serum	Amylase	Enzymatic colorimetric / Cobas 6000
LDH	Serum	Lactate Dehydrogenase	UV assay (Lactate to Pyruvate)/Cobas 6000
IgA	Serum/Plasma	Immunoglobulines A	Immunoturbidimetric assay/Cobas 6000
IgG	Serum/Plasma	Immunoglobulines G	Immunoturbidimetric assay/Cobas 6000
IgM	Serum/Plasma	Immunoglobulines M	Immunoturbidimetric assay/Cobas 6000



<b>SEROLOGIE / Procedure : BEL-BRLAB04-WI01 Cobas 6000 Chemistry and Immunology Analysis</b>			
HBSAG	Serum	HBs Antigen	Sandwich principle (Electrochemiluminescence immunoassay)/Cobas 6000
HBSAB	Serum	HBs Antibody	Sandwich principle (Electrochemiluminescence immunoassay)/Cobas 6000
HBCAB	Serum	HBc Antibody	Competition principle (Electrochemiluminescence immunoassay)/Cobas 6000
HCVAB	Serum	HCV Antibody	Sandwich principle (Electrochemiluminescence immunoassay)/Cobas 6000
HIV AG+AB	Serum	HIV Antigen-Antibody	Sandwich principle (Electrochemiluminescence immunoassay)/Cobas 6000
INSU	Serum	Insulin	Sandwich principle (Electrochemiluminescence immunoassay)/Cobas 6000
INSU	Plasma	Insulin	Sandwich principle (Electrochemiluminescence immunoassay)/Cobas 6000
FT3	Serum	Free T3	Competition principle (Electrochemiluminescence immunoassay)/Cobas 6000
FT4	Serum	Free T4	Competition principle (Electrochemiluminescence immunoassay)/Cobas 6000
T4 total	Serum	T4 total	Competition principle (Electrochemiluminescence immunoassay)/Cobas 6000
<b>ENDOCRINOLOGIE / Procedure BEL-BRLAB04-WI01 Cobas 6000 Chemistry and Immunology Analysis</b>			
FSH	Serum	FSH	Sandwich principle (Electrochemiluminescence immunoassay)/Cobas 6000
HCG	Serum	HCG	Sandwich principle (Electrochemiluminescence immunoassay)/Cobas 6000
TSH	Serum	TSH	Sandwich principle (Electrochemiluminescence immunoassay)/Cobas 6000
<b>TOXICOLOGIE / Procedure : BEL-BRLAB04-WI01 Cobas 6000 Chemistry and Immunology Analysis</b>			
U AMP	Urine	Amphetamines	KIMS (Kinetic Interaction of Microparticles in Solution)/Cobas 6000
U BARB	Urine	Barbiturates	KIMS (Kinetic Interaction of Microparticles in Solution)/Cobas 6000
U BENZ	Urine	Benzodiazepines	KIMS (Kinetic Interaction of Microparticles in Solution)/Cobas 6000
U CAN	Urine	Cannabis	KIMS (Kinetic Interaction of Microparticles in Solution)/Cobas 6000
U COC	Urine	Cocaine	KIMS (Kinetic Interaction of Microparticles in Solution)/Cobas 6000
U METH	Urine	Methadone	KIMS (Kinetic Interaction of Microparticles in Solution)/Cobas 6000
U OPI	Urine	Opiates	KIMS (Kinetic Interaction of Microparticles in Solution)/Cobas 6000
U COTININE	Urine	Cotinine	Enzymatic Colorimetric/Cobas 6000

<b>CHIMIE URINAIRE QUALITATIVE / Procedure : BEL-BRLAB04-WI02 Cobas u411 Urine Analysis</b>			
UA BILI	Urine	Bilirubin	Dipstick/Cobas U411
UA KETONE	Urine	Ketones	Dipstick/Cobas U411
UA ERYTH/HEMO	Urine	Erythrocytes	Dipstick/Cobas U411
UA GLUC	Urine	Glucose	Dipstick/Cobas U411
UA LEUK EST	Urine	Leucocytes	Dipstick/Cobas U411
UA NITRITE	Urine	Nitrites	Dipstick/Cobas U411
UA PH	Urine	pH	Dipstick/Cobas U411
UA PROT	Urine	Protéins	Dipstick/Cobas U411
UA SPEC GRAV	urine	Specific gravity	Dipstick/Cobas U411
UA UROBIL	Urine	Urobilinogen	Dipstick/Cobas U411
<b>CHIMIE URINAIRE QUANTITATIVE / Procedure : BEL-BRLAB04-WI06 Refractometer Operation and Maintenance at the Brussels PCRU</b>			
U SPEC GRAV	Urine	Specific gravity	Refractometer
<b>CHIMIE URINAIRE QUANTITATIVE / Procedure : BEL-BRLAB04-WI10 pH-Meter Digital Hand-held "Pocket pH Meter 4311-E10</b>			
U PH	Urine	pH	pH-Meter