

NOVA[®]
biomedical

CERTIFICATE OF COMPLETION

This is to certify that

Alexandru Grigoret

*has successfully completed Stat Profile Prime Plus Service and Application
Training.*

April 10-11, 2023

Date of Training

Huseyin Dibekkaya

Support Training Program Facilitator

International Regional Support Manager

Chisinau / Moldova

Location of Training

NOVA[®]
biomedical

CERTIFICATE OF COMPLETION

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Ion Negru

*has successfully completed Stat Profile Prime Plus Service and Application
Training.*

April 10-11, 2023

Date of Training

Chişinău / Moldova

Location of Training



Huseyin Dibekkaya

Support Training Program Facilitator

International Regional Support Manager

NOVA[®]
biomedical

CERTIFICATE OF COMPLETION

This is to certify that

Sergiu Sorocovici

*has successfully completed Stat Profile Prime Plus Service and Application
Training.*

April 10-11, 2023

Date of Training

Chişinău / Moldova

Location of Training



Huseyin Dibekkaya

**Support Training Program Facilitator
International Regional Support Manager**



CERTIFICATE OF COMPLETION

This is to certify that

Victor Meleca

has successfully completed Stat Profile Prime Plus Service and Application Training.

April 10-11, 2023

Date of Training

Chişinău / Moldova

Location of Training

A blue ink signature of Huseyin Dibekkaya, consisting of a stylized, cursive script.

Huseyin Dibekkaya

Support Training Program Facilitator
International Regional Support Manager

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Huseyin Dibekkaya

Support Training Program Facilitator

International Regional Support Manager



Product Service

Certificate

No. Q5 020747 0242 Rev. 00

Holder of Certificate: **Nova Biomedical Corporation**
200 Prospect Street
Waltham MA 02454
USA

Certification Mark:



Scope of Certificate: Design and Development, Production, Distribution, Installation, Servicing and Technical Support of In-Vitro Diagnostic Clinical Chemistry and Hematology (Co-Oximeter) Medical Devices including Near Patient / Point of Care Analyzers, Calibrators, Controls, Reagents, Sensors, Kits used in the Detection of Blood Analytes, Electrolytes, pH, Metabolites; Self Testing and Near Patient / Point of Care In-Vitro Diagnostic Devices for the Management of Diabetes Blood Glucose, Ketone, Cholesterol and Uric Acid, including Meters, Test Strips and Controls; Self Testing In-Vitro Diagnostic Medical Devices for the Determination of the percent Hemoglobin A1c (HbA1c), Total Cholesterol, High Density Lipoprotein (HDL) Cholesterol and Triglycerides in Whole Blood, and Albumin and Creatinine in Urine including Analyzers, Test Cartridges and Controls; Contract Manufacturing of Electronic Medical Devices; Contract Manufacturing of Disposable Medical Devices; and Distribution of Lancets

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 020747 0242 Rev. 00

Report No.: 72166286

Valid from: 2021-10-29
Valid until: 2024-10-28

Date, 2021-10-29

Christoph Dicks
Head of Certification/Notified Body

Certificate

No. Q5 020747 0242 Rev. 00

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies): Nova Biomedical Corporation
165 Lexington Road, Billerica MA 01821, USA

Production of Near Patient / Point of Care, and Self-Testing Meters
for the Management of Diabetes Blood Glucose, Ketone,
Cholesterol and Uric Acid.

Nova Biomedical Corporation
39 Manning Road, Billerica MA 01821, USA

Production of Near Patient / Point of Care, and Self-Testing Test
Strips for the Management of Diabetes Blood Glucose, Ketone,
Cholesterol and Uric Acid.
Distribution of Near Patient / Point of Care, and Self-Testing Test
Strips, Meters and Controls. Distribution of Lancets.

Nova Biomedical Corporation
200 Prospect Street, Waltham MA 02454, USA

Design and Development, Production, Distribution, Installation,
Servicing and Technical Support of In-Vitro Diagnostic Clinical
Chemistry and Hematology (Co-Oximeter) Medical Devices
including Near Patient / Point of Care Analyzers, Calibrators,
Controls, Reagents, Sensors, Kits used in the Detection of Blood
Analytes, Electrolytes, pH, Metabolites; Self Testing and Near
Patient / Point of Care In-Vitro Diagnostic Devices for the
Management of Diabetes Blood Glucose, Ketone, Cholesterol and
Uric Acid, including Meters, Test Strips and Controls; Self Testing
In-Vitro Diagnostic Medical Devices for the Determination of the
percent Hemoglobin A1c (HbA1c), Total Cholesterol, High Density
Lipoprotein (HDL) Cholesterol and Triglycerides in Whole Blood,
and Albumin and Creatinine in Urine including Analyzers, Test
Cartridges and Controls; Contract Manufacturing of Electronic
Medical Devices; Contract Manufacturing of Disposable Medical
Devices

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Huseyin Dibekkaya

Support Training Program Facilitator

International Regional Support Manager

Chisinau / Moldova

Location of Training

PRIME PLUS / VET SHELF-LIFE & WARRANTY INFORMATION

REV: 07/2021

Stat Profile® Prime Plus and Stat Profile Prime Plus VET



DESCRIPTION	WARRANTY	SHELF LIFE
Sensors Cards		
57820 Prime-Plus Sensor Card: w/ COOx (Standard)	14 Days/200 Samples*	12 Mos
57822 Prime-Plus Sensor Card: w/ COOx (High Volume)	14 Days/400 Samples*	12 Mos
58642 Prime-Plus Sensor Card: NO COOx (Standard)	14 Days/200 Samples*	12 Mos
58643 Prime-Plus Sensor Card: NO COOx (High Volume)	14 Days/400 Samples*	12 Mos
57821 Prime-Plus: Renal Micro Sensor Card	7 Days/200 Samples*	12 Mos
58577 Prime-Plus VET- Sensor Card: w/ COOx (High Volume)	14 Days/400 Samples*	12 Mos
58578 Prime-Plus VET- Sensor Card: NO COOx (High Volume)	14 Days/400 Samples*	12 Mos
58581 Prime-Plus VET- Renal Micro Sensor Card	7 Days/200 Samples*	12 Mos
58379 Prime-Plus Sensor Card- BLANK RENAL Sensor Card: (Clinical & VET)	Free of Defects	n/a
57823 Reference Sensor- Prime-Plus (w/ W/R Pump Tubing) (CLINICAL)	Free of Defects	18 Mos
59345 Reference Sensor- Prime-Plus (w/ W/R Pump Tubing) (VET)	Free of Defects	18 Mos
Calibrators		
57825 Stat Profile Prime Plus® Calibrator Cartridge 100 Sample	100 Samples or 35 Days	18 Mos
57826 Stat Profile Prime Plus® Calibrator Cartridge 200 Sample	200 Samples or 35 Days	18 Mos
57827 Stat Profile Prime Plus® Calibrator Cartridge 300 Sample	300 Samples or 35 Days	18 Mos
57828 Stat Profile Prime Plus® Calibrator Cartridge 400 Sample	400 Samples or 35 Days	18 Mos
57829 Stat Profile Prime Plus® Calibrator Cartridge 500 Sample	500 Samples or 35 Days	18 Mos
57831 Stat Profile Prime Plus® Calibrator Cartridge 100 Sample with Creat / BUN	100 Samples or 21 Days	18 Mos
57832 Stat Profile Prime Plus® Calibrator Cartridge 200 Sample with Creat / BUN	200 Samples or 21 Days	18 Mos
57833 Stat Profile Prime Plus® Calibrator Cartridge 300 Sample with Creat / BUN	300 Samples or 21 Days	18 Mos
57834 Stat Profile Prime Plus® Calibrator Cartridge 400 Sample with Creat / BUN	400 Samples or 21 Days	18 Mos
57835 Stat Profile Prime Plus® Calibrator Cartridge 500 Sample with Creat / BUN	500 Samples or 21 Days	18 Mos
58395 Stat Profile Prime Plus® VET Calibrator Cartridge 200 Sample	200 Samples or 35 Days	18 Mos
58396 Stat Profile Prime Plus® VET Calibrator Cartridge 500 Sample	500 Samples or 35 Days	18 Mos
58405 Stat Profile Prime Plus® VET Calibrator Cartridge 200 Sample with Creat / BUN	200 Samples or 21 Days	18 Mos
58404 Stat Profile Prime Plus® VET Calibrator Cartridge 500 Sample with Creat / BUN	500 Samples or 21 Days	18 Mos
AQC Packs		
57838 Stat Profile Prime Plus® Auto QC Cartridge 160 Sample	160 Samples or 32 Days	18 Mos
57839 Stat Profile Prime Plus® Auto QC Cartridge 320 Sample	320 Samples or 32 Days	18 Mos
57840 Stat Profile Prime Plus® Auto QC Cartridge 480 Sample	480 Samples or 32 Days	18 Mos
57841 Stat Profile Prime Plus® Auto QC Cartridge 105 Sample with Creat / BUN	105 Samples or 21 Days	18 Mos
57842 Stat Profile Prime Plus® Auto QC Cartridge 210 Sample with Creat / BUN	210 Samples or 21 Days	18 Mos
57843 Stat Profile Prime Plus® Auto QC Cartridge 315 Sample with Creat / BUN	315 Samples or 21 Days	18 Mos
58406 Stat Profile Prime Plus® VET Auto QC Cartridge 160 Sample	160 Samples or 32 Days	18 Mos
58407 Stat Profile Prime Plus® VET Auto QC Cartridge 480 Sample	480 Samples or 32 Days	18 Mos
58408 Stat Profile Prime Plus® VET Auto QC Cartridge 105 Sample with Creat / BUN	105 Samples or 21 Days	18 Mos
58409 Stat Profile Prime Plus® VET Auto QC Cartridge 315 Sample with Creat / BUN	315 Samples or 21 Days	18 Mos
57844 Stat Profile Prime Plus® Ampuled Controls BG, COOX Levels 1, 2, 3	Free of Defects	12 Mos
57845 Stat Profile Prime Plus® Ampuled Controls Chemistry Levels 4,5	Free of Defects	12 Mos

57812	Stat Profile Prime Plus® VET Ampuled Controls BG, COOX Levels 1, 2, 3	Free of Defects	12 Mos
57813	Stat Profile Prime Plus® VET Ampuled Controls Chemistry Levels 4,5	Free of Defects	12 Mos

Miscellaneous:

52669	Luer Station Safety Port (5/pack) (Prime/Prime-Plus)	Free of Defects
52582	Probe/S-Line Assy : Prime/Prime-Plus	Free of Defects
49200	Printer Paper (rolls: 5/pkg) (small-style)	Free of Defects

Electro-Mechanical Components & Assemblies

***Whichever comes first.**

NOTE: THE WARRANTED USE EXPRESSED ABOVE IS ONLY VALID IF IT OCCURS

PRIOR TO THE "USE BEFORE DATE" LISTED ON THE PACKAGE LABEL.